This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held in New York City November 9-10, 2011, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

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

convenes

MEETING ONE

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

VOL. I

DAY ONE

WEDNESDAY, NOVEMBER 9, 2011

Jacob K. Javits Federal Building
26 Federal Plaza New York, NY

The verbatim transcript of the

Meeting of the Scientific/Technical Advisory

Committee held at the Jacob K. Javits Federal

Building, New York, New York, on November 9, 2011.

STEVEN RAY GREEN AND ASSOCIATES
NATIONALLY CERTIFIED COURT REPORTERS
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This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

C O N T E N T S

November 9, 2011

TRANSCRIPT LEGEND

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-- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

-- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

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

Committee Members

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Representative of Certified-Eligible WTC Survivors:
Kimberly Flynn,
Co-Founder, Director, 9/11 Environmental Action

Catherine McVay Hughes
Vice Chairman, Community Board 1 World Trade Center Redevelopment Committee, Lower Manhattan World Trade Center Redevelopment, New York City.

Susan Sidel, J.D.
Resident of New York City and volunteer WTC responder.

Industrial Hygienist:

John Dement, Ph.D.
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Epidemiologist:

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Mental Health Professional:

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Environmental Health Specialists:

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Designated Federal Official:
Paul J. Middendorf, Ph.D., CIH
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P R O C E E D I N G S

(8:40 a.m.)

DR. MIDDENDORF: If there are any other committee members, now would be a good time to come up to the table, and I think we should begin.

As this is the initial meeting of the World Trade Center Scientific/Technical Advisory Committee, it seems appropriate for us to take a few moments to remember those who were killed in the attacks on 9/11, and also those responders and survivors who have since died because of those attacks. So if we could just take a few minutes to reflect on their sacrifices, and do that in silence.

(Pause)

Thank you very much. I do have a few administrative details that I need to go over here at the beginning of the meeting. First off, I want to point out where the emergency exit routes are. If there is an emergency the evacuation route would be through either the door on this side or the open area on that side (indicating). Go out to the corridor immediately on the other side of the doors, make your way down to the left and then go through the glass double doors. And as soon as you go out through the glass double doors, walk to your left, go down to the end of that hall. That's where the fire exit door is. That's where the stairs are. So that's how we (telephone connection interference).

I should also make another announcement that no coffee or food is allowed here in the conference center. Water and soft drinks apparently are acceptable.

WELCOME

My first duty on behalf of the World Trace Center Health Program is to extend a very warm welcome to our newly-impaneled members. I think we're looking very much forward to hearing some very robust discussions, the many perspectives that each of you will bring to help develop recommendations that you will give to the program administrator.

So one of the first things I need to do is take a roll call, and what I'll ask each of you to do is to identify yourselves. And when you do that I also need you to identify whether or not any changes in your job status or any changes in your interest have occurred (electronic interference) -- any changes in your interest or changes in your job would have occurred since you filled out the OGE-450 that would impact your conflict of interest status.

So why don't we start with our Chair, Dr. Ward.

DR. WARD: No changes have occurred in my job status or interest.

DR. NORTH: I'm Carol North; no changes.

MR. CASSIDY: Steve Cassidy; no changes.

MS. HUGHES: Catherine McVay Hughes; no changes.

DR. HARRISON: Robert Harrison; no changes.

DR. ROM: Bill Rom; no changes.

UNIDENTIFIED: Status quo.

DR. QUINT: Julia Quint; no changes.

DR. TRASANDE: Leonardo Trasande; no changes.

DR. DEMENT: John Dement; no changes.

DR. WEAVER: Virginia Weaver; no changes.

MS. MEJIA: Guillermina Mejia; no changes.

DR. MARKOWITZ: Steven Markowitz; no changes.

MS. DABAS: Valerie Dabas; no changes.

MS. FLYNN: Kimberly Flynn; no changes.

DR. DEMENT: John Dement; no changes.

DR. MIDDENDORF: Okay. Dr. Talaska, are you on the line?

(No response)

DR. MIDDENDORF: Dr. Talaska is a member of the Committee. He will be participating at various times by telephone, but he's not present at the moment.

I also want to extend a warm welcome to the interested members of the

public, many of whom are here in the audience, and we also will have some folks on the phone.

I want to point out to you that there is time on our agenda later this afternoon and early tomorrow morning for members of the public to speak to the Committee if you would like to. If you're interested in presenting, you must sign up out at the registration table which is over in the corner. I also want to point out that there are a limited number of slots. They will be assigned on a first come-first served basis, and each public commenter will be given up to five minutes to present.

And also posted there is a copy of our redaction policy, and you need to read that before you sign up for making a presentation.

I also want to point out that there are copies of our agenda for the meeting on the back table, as are several other handouts. These handouts are available not just here, but they're available on the website for the World Trade Center Health Program, so you can get copies of those there as well if you happen to be on the phone.

If we have any written comments which are submitted while we're here, or afterward, if they're submitted to the addresses identified in the Federal Register notice, they will all be posted in the docket. Our docket number for this Committee is Docket No. 248. That's the NIOSH docket page, is where you would find those comments.

With that, I think it -- I'm done with my administrative things and I will turn it over to our Chair, Dr. Ward.

DR. WARD: I'd also like to add my warm welcome to the members of the Advisory Committee, the representatives of responders and survivors who will speak to us today, representatives of the Centers of Excellence who will speak later in the day, and really to everyone who has -- attending this meeting. I think there are many people in the group that have contributed a great deal to our recognition of the health conditions that are associated with the World Trade Center exposures and whose hard work and advocacy has led to passage of the Zadroga Bill. So I want to recognize your contributions.

This Advisory Committee will have several functions. One is to give formal responses to Dr. Howard's -- the questions that Dr. Howard poses to us as World Trade Center administrator. But I also think one of our most important functions is to have discussions here at the table where we're bringing together a huge amount of expertise in the clinical sciences and the epidemiology and public health, all of the sciences that

bear on the questions about the health conditions that we'll be discussing. And in a way, the sum of the knowledge of this group will be greater than the individual parts. So we are emphasizing really the discussion part of the function of the Committee, but at the same time our agenda today is packed with a lot of speakers and information. Today is really a day to -- for us to gain information, so we will have limited time for discussion today. If members of the panel want to ask a question or speak, please designate it by raising your name card on end, but we may at times have to move the discussion along in the interest of hearing everyone who's here to speak today.

So thank you very much, and we'll move on to Dr. Howard.

DR. MIDDENDORF: Before Dr. Howard begins, we're going to try to get rid of this buzz. We're going to call back to the phone folks, the conference line, and see if they can get rid of that for us.

INTRODUCTORY REMARKS

DR. HOWARD: Good morning, everybody, and -- here on the Committee and to those of you that came this morning. Thank you very much. To all the responders and survivors and other attendees, welcome to the inaugural meeting of the Scientific and Technical Advisory Committee. I want to thank each of you for --(telephone/electronic malfunction).

(Conversation with Dr. Middendorf and the operator in an effort to clear the line of electronic interference.)

DR. HOWARD: I'm going to try this again. The Committee has a very important role to play in the World Trade Center Health Program. The James Zadroga 9/11 Health and Compensation Act specifies three general areas of contributions from the Scientific and Technical Advisory Committee.

One, the Act requires the Administrator to seek advice from the Committee with regard to determining eligibility criteria for responder and survivor membership in the Program.

Second, the Act requires the Administrator to seek advice from the Advisory Committee with regard to identifying research needs for the Program.

Third, the Act provides the Administrator may consult with the Advisory Committee regarding whether a particular health condition should be added to the list of the World Trade Center health-related conditions.

I want to provide you this morning some brief updates on these three

roles of the Advisory Committee. With regard to eligibility criteria, no modification of the statutory eligibility criteria for responders or survivors is planned at this time. Work to determine the eligibility criteria for the Pentagon and the Shanksville, Pennsylvania responders has begun and is ongoing. Information is being gathered to develop a timeline of on-site response-related activities, and exposure information is being accumulated on airborne toxins and other hazards present during the Pentagon and Shanksville responses. And I've provided you with an information sheet on the progress of that project to date, and at a subsequent meeting we'll be reporting to you and seeking your advice on that particular project.

Second, research. A solicitation for research proposals was announced on April 23rd, 2011 for the award of research contracts in FY 2011 for up to three years with annual budgets of up to a half-million dollars. Four proposals received funding in July, 2011, and four additional proposals received funding in September for the second round of the same announcement, which is now closed. A brief description of each of those funded projects, all eight of those, has also been provided to you and is a handout in the back of the room. I encourage you to look at that.

A new announcement is currently being planned for FY-12 funding. The solicitation process for FY-12 funding research offered by the World Trade Center Health Program will be open to all qualified applicants, and will be competitively awarded based on scientific quality criteria. The objective is to support the best science in areas that will be most meaningful in terms of contributing to the scientific priorities of the program. And here's where the Committee comes in, in identifying, suggesting to the Administrator what are those priorities, where should research be funded and what are the best priorities for the program.

Thirdly, with regard to petitions -- with regard to petitions received to date requesting that a health condition be added to the list, the Administrator received a petition to add cancer to the list on September 8th, 2011. Pursuant to Section 33(12)(a)(6)(B)(i) of the Act, the Administrator requested advice from you, the Advisory Committee, on that petition. That petition and the letter to the Chair is also in your booklet.

Finally I just wanted to speak to you about the concept of advice. As the Committee considers any of the issues brought to it by the program, it's important to keep in mind that the Scientific/Technical Advisory

Committee was established by the Act to provide advice of a scientific or technical nature to the Administrator. Unlike the responder steering committee or the survivor steering committee with their broad representation across the community of interested parties, the Advisory Committee is not established as an advocacy committee.

Six members of the Advisory Committee, though, are representatives of the populations affected by the terrorist attacks of September 11, 2001, and have been seated on the Committee because of their diverse experiences with concerns of those populations of people rather than due to their specific scientific or technical expertise. The input of the affected population is an important part of any Committee deliberation as those views I think ensure that any discussion of science is grounded in the real world experience of the populations affected. Ultimately, though, articulating a scientific basis for any Advisory Committee recommendation to the Administrator will be of greatest value to the program.

So on behalf of the World Trade Center Health Program I welcome each of you to your service on the Committee. I thank you for the time and the effort that you will put into this important activity. We appreciate your time. We appreciate your interest and expertise. Thank you very much.

DR. WARD: Thank you. We'll now begin the panel of World Trade Center responders and survivors, and I think the first speaker is Jim Melius.

PANEL OF WTC RESPONDERS AND SURVIVORS

DR. MELIUS: That's why you're called the technical advisory committee. Anyway, I'd like to thank you for inviting me today, thank NIOSH for holding this meeting and for holding it in New York City where it's convenient for many of the people that are involved in this program. I'd like to also thank all of you members of the panel for your willingness to spend your time and efforts on this Committee. It's a very important committee and one that we do appreciate your willingness to do this.

I work for the Laborer's Union which represents construction laborers. Several thousand of those laborers worked in the rescue and recovery efforts at Ground Zero. But I also work with several other -- many other unions that -- really a very diverse group of people that -- represent a group -- very diverse group of people who worked in the rescue and recovery efforts at Ground Zero. And as you'll hear in one of the later

presentations, it really is very important to understand that this was a large group, many different people doing it -- very hard to really sort of pinpoint or characterize the people that were exposed, and that diversity I think is very important to your understanding of the program. Organized labor in New York has been very involved in this program right from the very beginning. We -- early on we worked to get funding to initialize the medical programs at Mt. Sinai and elsewhere. We lobbied hard and worked hard with our congressional delegation, particularly Congressmen Maloney and Nadler, to continue the funding for that, and we worked very hard over many years with many groups here in order to pass the legislation that established your Committee, among other things. We have a great deal -- feeling of ownership of this program. We've been very involved. For most of the time of the medical program I've chaired what's called the steering committee, which -- on the responder side, which for the responder medical program is a group that meets monthly of labor representatives and representatives from the medical programs to review and coordinate. On the program we've had a great deal of input and we expect to continue to have a great deal of input into that. As you may know, in the legislation the steering committee continues to meet on a monthly basis, and we continue to play that role.

Same on the side of the survivor community representatives, there's a similar program that started a little bit later but also has that level of involvement.

One thing I think that's important -- I chair a different committee sort of analogous to this that has to do with compensation for our nuclear workers in the United States. I chair that committee, been on it for almost ten years now, and one thing I think is very important, I urge you to do, is to, one, ensure transparency of your operations. I think that's very important for the credibility of your decision-making which -- and advice that you give. And secondly, that you provide ample time and opportunities for public input, meeting here, but also to the extent possible, to hold evening sessions, times that are convenient for working people and -- to attend. I think it's important not only for the input that you'll get, but also for the openness, and I think it will certainly help the credibility of the decisions and advice that you give to the Administrator.

One area that I just want to mention that I think is probably the most urgent issue to deal with -- I don't think we're expecting you to deal with

it today -- and that is the issue of new World Trade Center-related conditions. The listing that's in the legislation, been in place for a long time, it's conditions that were recognized relatively soon after 9/11 and one that I think is pretty well established in terms of follow-up studies. However, it's been over ten years now, and I think there's a great deal of concern, as well as I think now some evidence, that there are other, more latent, conditions appearing among this population, certainly a great deal of concern about cancer. And given that the funding for this program has been difficult to achieve, it has not always been very consistent over time, I don't think that NIOSH has had adequate funding to set up the kind of follow-up surveillance and follow-up studies that are needed to fully detect these new conditions on a very rigorous basis. And I would certainly urge you, in terms of your advice to the Administrator as well as your review of the research program and so forth, to ensure that this kind of function gets fully funded and fully evaluated. People are very anxious for answers, in particular with cancer, but with other latent conditions. And I think it's very important that this get done in as expeditious a way as possible. And that also that your advice to the Administrator in terms of adding additional conditions to the list of covered conditions also takes into account not only the science and surveillance that's underway and needs to be done, but also you give a great deal of thought of what's an appropriate way of making a decision on adding conditions. We do not want to wait until 30 or 50 years from now when all the mortality studies are done and we can look back and say Well, gee, there was an increase of -- whatever, some type of cancer; lung cancer, say -- so forth. And meanwhile, you know, hundreds, if not thousands, of our union members and people from the community have suffered and many of them may have died from this condition without compensation and without recognition of these conditions. And I think how to provide a fair and scientifically-based decision approach to address these, to add these -- evaluate and consider adding these conditions to the list of covered conditions I think is one of your most important functions and one that I think you need to work very closely with the Administrator on, and people in the program. So with that, let me stop here and let me introduce the next member of our panel -- there'll be two other speakers, one from the rescue workers' side and the other will be a person representing other workers that were involved in this. As you'll see, we overlap to a great degree. But next

person providing -- will speak will be Bill Romaka, who's the health and safety director for the Uniformed Firefighters' Association, which represents New York City firefighters. And Bill will come and speak now. Bill?

MR. ROMAKA: Good morning. I want to thank the Committee first for all your work and for coming together to try to help us make sense of everything that's going on regarding what's going on with the medical conditions of the responders and survivors.

The first slide I have up there is a PowerPoint presentation, just gives my -- who I am and the committees and the conferences that I've been attending to, and you all have that in front of you also. If I could just figure out how to work this -- I'm clicking on the right side. Now I'm clicking on the left side -- there it is.

The first responders -- I just want to -- these are the people with the most-documented exposures. That's what I wanted to present to you who, for the most part, we're representing today.

Okay, these are the related ailments that have been covered in the World Trade Center bill, the Zadroga bill. As you can see at the bottom, we've also seen a lot of auto-immune diseases and cancers, and those are the ones that haven't been covered yet but that we're trying to build the evidence for you to make an informed, scientific decision.

Continued problems, the biggest complaint of members in the World Trade Center medical monitoring and treatment program is that when a first responder is diagnosed with cancer in the program they are told they have to seek treatment elsewhere. Generally what happens after this is the co-pays, the deductibles, the loss of benefits contribute to the financial ruin of what was once a contributing first responder and their respective families. You've got to remember, it doesn't just affect the responder, it affects the families, too.

In the law enforcement responder cohort, frustration and concern have been expressed about the nature and extent of the data-gathering as it relates to police officers having cancer. Though the PBA has worked with Mt. Sinai to identify members who have been diagnosed with cancer to ensure the accuracy of their reporting, to their knowledge Mt. Sinai has not contacted NYPD to gain access to the NYPD database so they could then do a complete matching against the tumor registries, as does the FDNY. This action would ensure a greater level of accuracy.

For some time also the program did not accept reports of cancer. Even

now cancer is not a covered illness, which is itself a deterrent to report information about cancers. Many responders with cancer have informed the PBA that they do not wish to waste precious time by participating in a monitoring and treatment program that does not treat their disease. They spend enough time in medical offices. In addition, the PBA understands that 40 deceased officers may not be included in any study by Mt. Sinai, a decision that could skew the results.

And so science -- we're talking about the known exposure. Since 9/11 the FDNY has had almost 1,750 firefighters and fire officers retire due to pulmonary disabilities. During this time frame, based upon prior data and knowledge, the predicted retirements related to pulmonary disease was approximately 480.

Multiple myeloma -- in the Moline et al case series "Multiple Myeloma in World Trade Center Responders: A Case Series" reported in the American College of Occupational and Environmental Medicine in 2009, it shows that this disease is showing in much younger, less than 45 years old, exposed police officer first responders in numbers that were approximately four times the expected SEER cases in the general population.

In NIOSH'S first periodic review of science and medical evidence related to cancer in the World Trade Center program, the authors' point about cancers being prevalent in society was put forth. What we have is, according to the National Cancer Institute's SEER cancer statistics review, the median age of cancer patients at diagnosis for males was stated as 68 years old. In the recently published FDNY cancer study appearing in The Lancet, the mean age of first cancer diagnosis was 52.5 years.

Also in the fire department study big emphasis is made on biological plausibility and the likeliness of chronic inflammation. We have in front of you the wording that comes from the report. I hope that you can review it and understand it because it is very scientific in nature.

NIOSH and our government's history -- NIOSH has a history of covering cancer under its Special Exposure Cohort and Energy Employees Occupational Illness Compensation Act once provisions of eligibility have been met. Over eight years it has paid out $5 billion in benefits to 52,600 claimants. Its provision further states the following when it affects medical care: An employee who meets the statutory conditions of coverage is entitled to prospective medical care required to cure, give

relief, or reduce the degree and period of disability. Provider charges associated with the treatment of an accepted medical condition will be paid from the compensation fund and are subject to a fee schedule. Continuing on, the United States Department of Veteran Affairs assumes that certain diseases are related to qualifying military service. These are called presumptive diseases. VA has recognized certain cancers and other health problems as presumptive diseases related to exposure to Agent Orange or other herbicides during military service. Source document is attached and can be accessed.

Zadroga bill itself -- the mandate of the law to include periodic reviews of a link between cancer and exposure at the World Trade Center sites suggests that there was reason to believe that exposure to the toxins at the World Trade Center site may lead to increases in the cancer rates. According to the language of the statute, the program Administrator was required to review the scientific data regarding cancers no later than 180 days after the enactment of the legislation. This language speaks directly to the intent of Congress to have the basis for inclusion be on biological plausibility of a casual connection rather than on an exhaustive scientific process which would be completed when few, if any, responders would be alive to avail themselves of the treatment component of the law.

It also should be emphasized that this is very much a unique event. Science analyzes documents and compares. Science loses some relevance when there is no similar comparison to make. The exposure on 9/11 involved a very unique synergism that may take decades to fully analyze and understand. Unfortunately there is no current comparison to help make sense of this data in a timely fashion that might actually help save lives.

Also it's important to know that New York State legislation and the Governor have recognized this uniqueness and approved a presumptive accident disability benefit for all New York State and City workers who were exposed at the World Trade Center sites and have documented exposures. This presumption already includes cancer.

On May 24th and 25th of 2006 at the World Trade Center Medical Experts Advisors Meeting the cancer experts told everyone that the first cancers to be seen would be the blood cancers and the leukemias. This has been borne out by the science and is available in the reports that have been made to date.

Biological plausibility based upon what the experts have predicted, what we are seeing, should be the relevant factors upon which policy is made. Documented exposures with early scientific evidence should support adding additional conditions.

And I think it's important that you get the human element about what we're talking about. Here is a picture of one of our firefighters who was at the World Trade Center site in 2001. On the right is a picture of him at a Washington press conference in 2009. He passed away last year, leaving behind a wife and four-year-old son.

Thank you very much for your attention.

I'd like to introduce Micki Siegel as our next speaker for the responders.

MS. SIEGEL DE HERNANDEZ: Good morning, members of the Committee, and I thank you for this opportunity to talk to you today. I'm the health and safety director for the Communications Workers of America. Our union represents a diverse group of workers. We had members who were killed on that day, both in the towers' collapse and also on the planes. We represent a group of workers like the Verizon workers, the Lucent workers, in the telecommunications industry. We represent traffic enforcement for the NYPD who were part of the response, nurses at NYU downtown, broadcast employees and technicians who brought the vision of what was happening after 9/11 to the rest of the world. And we also represent workers who were in the area and who have been affected by the contamination that was spread.

So I'm going to be presenting to you a photo essay of sorts, with some comment about who we refer to as the other responders. Bill focused on the FDNY and the traditional first responder population, and we -- this is a large group that was part of the response afterward. So I'm going to pick up on that and certainly echo the concerns that Bill has raised, and we'll continue that.

I want to mention to you that we start off every steering committee meeting for the World Trade Center health program in a similar way that this meeting started. There are reports made of responders who have died since the month before, and we've never had a meeting where that there wasn't something to report, unfortunately. So this is not just academic for us. This is something that we live with every single day. The reports are often of firefighters, sometimes police, but of other unions as well who have already lost members to World Trade Center-related diseases, and it reminds us of why we're here and why we will

continue to advocate for proper health care.

So as Jim mentioned, the responder population was very, very diverse. Public and private sector actually heavily dominated by public sector because of the -- of New York City workers, protective services, police and other -- the construction trades. There were government responders at every level, telecom, utility workers, broadcast employees, relief organizations, volunteers, cleanup workers, medical personnel, mental health counselors, clergy -- and people were mostly from this area, but came from around the country, as you know, and also came from other parts of the world. So these are not mutually exclusive categories, but just to let you know how many different types of people that were there.

This was also a heavily unionized work force. I apologize for violating the rules of PowerPoint that say you should only use three or four bullets for a slide, but this is just to make the point about how many organizations were involved. And this is just a partial listing, does not go into all the local unions.

So let me talk first just a little bit about the exposures and what we refer to when we talk about exposures.

So as you all know, and you've probably seen these pictures of the dust cloud from the towers' collapse. That cloud is just a snapshot in time, continued to move through the community and obviously well beyond the boundaries of what became the Ground Zero site. We actually don't know what the boundaries are. That has never been established by any scientific assessment.

This is what the streets of the city looked like after some of that dust had settled and continued to coat everything. It was blown into buildings and continued to be moved around in the outside community. I put this picture in -- I actually took this from the top of the Verizon Building, which was at the north side of the site, but this was taken approximately a month to six weeks after the collapse, and you can still see the heavy layering of dust, which I think is reflective of how much the dust was -- was disturbed by the activities that were going on and continued to circulate around. It didn't end with the dust cloud, I guess is what I'm saying.

What's also very familiar is that any of those people who were caught in the dust cloud who were either escaping, who were responders, had an intense and overwhelming acute exposure. There's -- there's no arguing

with that fact. The gentleman in the center is a member of the operating engineers who happened to be working that day. There were others there on that first day, as well as the rescue organizations, and you can see the firefighters helping him in the back.

So the dusts were one type of exposures, and then there were fires that burned for many months afterwards. This was (telephone connection interference).

Okay, so this shows you the smoke that continued to burn, and again, this smoke (telephone connection interference) continued to spread in the community. This is one of the iron workers, and you can see the atmosphere that was surrounding that site and (telephone/electronic interference). So there were exposures from the dust, there were exposures from the smoke, and then there were also -- there was so much work going on on-site, and individual work operations created their own hazards.

This is a picture of an iron worker. He's doing something called lancing, that is a high-heat torch that can cut through rock and also releases a variety of metal fumes. It's just one example of one particular operation that affects not only that particular worker, but others surrounding them.

We're all familiar with the Pile and work on the Pile, and you can see from the next few pictures just the range of groups that are there. In the foreground are MTA employees. That's TWU Local 100. There's police, fire, and lots of construction.

There's another example of a morning meeting, getting set through -- to start some day's work.

And again I just want to draw your attention to the general atmosphere that was there. Again, this was taken from above looking down on the site from the Verizon Building.

There were lots of vehicles on site that also, for some of them, created additional hazards and -- diesel exhausts, different agencies and different companies were using them. As we -- as I go through the next few pictures I'd like you to also pay attention to the respirators, or lack thereof, that various workers are using because that -- that was an issue. It was certainly not consistent. It was certainly not something that all workers wore all the time, and there was quite a variety. So we have a dust -- there's a dust mask here which is not a respirator and -- but that's what was given out to many folks. Other vehicles here you can see in

working this crane, half-face respirator -- but again, it's not being used. Remember, the backdrop of all of this was that the government agencies were saying from the very beginning not necessarily that it was safe on site, but it was below levels of concern, did not meet regulatory levels. So the message was it's really not that bad. Right? There's really not that much to worry about.

Obviously there are lots of hazardous work that went on site. These are iron workers. This is a track worker for the MTA. This is a 24/7 operation, so these were not 9:00 to 5:00 jobs. People worked 12 hours, 14 hours, 16 hours, seven days a week.

So that's the Pile, and people understand what the Pile is. But then we talk -- we refer to what is adjacent to the Pile, and there are questions that are asked in the medical program when patients come in, 'Did you work adjacent to the Pile, or off the Pile?' And I think that there are some misnomers that once you got right off the Pile that there were -- it was -- they were safe areas, free of contaminants.

So I want to show you just a few other examples of what we mean by or what could be present adjacent to and off the Pile. So right adjacent to the Pile was the Verizon Building. It was heavily damaged. World Trade Center 7 collapsed against it. This is the east side of the building. You can see the stream of water coming -- the fire service was stationed there to help put out that additional fire that burned, and it caused a lot of damage as well as contamination.

Subway system was damaged in the area, some stations completely destroyed, and you have MTA workers who then had to go into these locations to perform cleanup operations. And again, here we have a dust mask that really doesn't protect against much. The subway.

Work was done on the street and in the general area. These are splicers. Again, if you look at the picture carefully, there's one guy wearing a dust mask, one guy wearing a half-face respirator, one guy wearing nothing. It was a voluntary respiratory program because, again, everything was, okay.

There were also lots of interior spaces, and interior spaces have gotten no play in the terms that they've been completely ignored as far as the contamination inside of them. And if you can imagine the contaminants that were outside, in interior spaces they are confined spaces, so as work was conducted people had extreme exposures in some situations.

So there were manholes around the site and around the neighborhood,

so for both Verizon, Con Ed, the electric utilities -- this one was covered just because of falling glass from the buildings above.

This is a picture of the concourse. Those are MTA workers. As I mentioned before, damage to the subway tunnels, and you can see the dust just caked along the walls. This is some interior damage I -- just because they are our members, I happen to have pictures of what some of that damage might look like, but there were many other damaged buildings where many other workers worked, and you can just see the degree of dust that was in those spaces.

This is the cable vault. The reason -- there was a lot of service lost, was because of what happened to that cable vault at the Verizon Building. That's not what it normally looks like. It's a vast area. You can't really see the extent of it, but this is where the hole was broken on the sidewalk into the vault.

This is Engine 10/Ladder 10, the fire house, and you can see the damage to that building. And again, many, many buildings. These are just a few examples. Basements in the area where lots of workers go. To be honest with you, we still have concerns to this day about cleanup that may or may not have been conducted in certain locations. And I bring that up because in terms of exposures and chronic exposures and when they could happen, we don't know when they ended. What -- we know when the site activities ended, but we really don't know when exposures may have ended for other workers continuing their jobs.

There was a lot of cleanup done in the buildings by either unionized laborers of Local 78, by SCIU 32 BJ building personnel. And then there were also day laborers who were hired by contractors and subcontractors to go into buildings, without training, usually without protection, to clean those buildings. This is a picture -- the guy -- second person from the left, **[identifying information redacted]**, has done a lot of advocacy work since that time. He told me that he worked at least ten buildings in six months. Only two of them provided respiratory protection. He cleaned the duct work of the HVAC system, so you can imagine what was brought in after the collapse and what his exposures were like. And the reason he is such an advocate is because he's very, very ill. So another group of responders that has gotten short shrift in all of this.

There were also off-site -- other off sites. The Staten Island landfill operations, here's some NYPD detectives sorting through -- 'cause

remember, this was also about recovering remains. It was not just about a big cleanup and getting rid of debris. We had barge operations and so you had trucks driven by Teamsters transporting that through the neighborhoods to off-load to bring to the Staten Island landfill. There were other work locations like places where the vehicles were brought that were contaminated, where they needed to be maintained and worked on by mechanics. You have the Office of the Medical Examiner who had temporary morgues on-site and also off-site, so many, many different locations, and the exposure scenarios are vast.

So to conclude, a few recommendations to you as a Committee. One, you really should consider a much more thorough discussion about exposures in a future meeting, and please solicit information from a variety of sources, including unions and others who have data that's not public data that sort of brings some of these issues to mind. The exposures are important because they speak directly to the development of disease.

When you are evaluating cancer and other diseases you need to look at a variety of evidence related to causation, as Bill mentioned, biologic plausibility. You cannot rely solely on published epidemiological studies, although there have -- fire department has a seminal study that came out recently. But that will always be after the fact, after workers have died. And as I -- as everybody has said, we have concerns about ongoing health issues.

We recommend increased efforts for continued and more rigorous disease surveillance than is currently happening.

And also we hope the Committee can advocate for continued outreach for many diverse groups who still have not been reached as part of medical need and to bring into this program.

So thank you for the following folks for photos that they contributed, and that's the end of my presentation. Thank you.

Oh, one more thing. I'm going to pass out to the Committee a packet that has been provided by District Council 37. They are the largest municipal union here in New York City and represent a huge number of job titles, and there's a video in here which talks about some of their members who were involved in the response. And I think it -- it's fascinating in the sense that there are job titles you would never ever have thought of that participated. So thank you DC-37 and I'll get that out to all of you.

DR. WARD: Thank you, and we'd like to invite the speakers back to the table for questions and comments.
DR. MIDDENDORF: And while you're coming to the table, I apologize for the static, Micki, during your presentation.
MS. SIEGEL DE HERNANDEZ: That's okay.
DR. MIDDENDORF: We're working with the conference line folks to see if we can get rid of that.
DR. WARD: Questions or comments for the panel?
DR. HARRISON: Is this on? There we go -- thank you. My name is Bob Harrison. I want to thank all three of you for wonderful presentations, particularly -- I'm from California and seeing the photos and the situations that the workers were in were really eye-opening to me, so I want to thank you particularly for sharing those.
I wondered if anyone would speak to your suggestion about using biological plausibility in addition to or separate from the epidemiological evidence for cancer. Particularly if you could speak about the type of exposures that occurred and what we know about the chemical constituents and the biological mechanisms.
MS. SIEGEL DE HERNANDEZ: I think we probably all have comments about this, and this is what I think needs much -- much more discussion in the future. The World Trade Center contaminants, both the smoke and the dust -- very complex, hundreds -- hundreds of materials. There have been estimates that -- reaching a thousand. And some of those components are carcinogens, known carcinogens, and there are others that, you know, have other kinds of health effects. It was a very caustic -- it was of a very caustic nature.
Bill mentioned synergism. There is nobody that knows what the effect of all of those components put together -- what that will be. And the method of assessment that was conducted in terms of exposures, the sort of one chemical at a time or one contaminant at a time, based upon some -- some known contaminants like asbestos, to make a decision about the whole mixture, we feel is a really inappropriate method. So I think there's enough evidence to look at some individual components that we do know about, but I think that we really have to also -- that the Committee really needs to understand and -- what some of the limits are about what we know about that mixture as a whole.
MR. ROMAKA: So in other words, we're advocating for biological plausibility based upon what early scientific evidence shows, 'cause if

you go with epidemiology by itself, it's based on the SEER principle. The last two letters of the SEER principle means end result. So we're not going to be able to help anybody by talking about after everybody's dead and gone, so we'd appreciate that -- is an open mind to using the science based upon what experts have said and what the biological plausibility is, just one-sided.

DR. MELIUS: Well, it's a long discussion, but just briefly, I think -- at least I think of it as one -- you know, what are the individual components and the exposures, the known carcinogens. Secondly, beyond that, you have this -- the inflammatory response and diseases that resulted from it, what does that say about the possible development -- development of cancer. And then third I think what's a fair and appropriate way of assessing that, you know, without waiting 50 years till mortality studies are done 'cause we're talking about people that need medical care in the short term and -- do that. And frankly, our country doesn't do that very well in the programs we have established so far. I mean the nuclear worker program -- we're actually compensating people from the Manhattan Project, which is World War II, so I mean it's sort of in some ways pretty absurd. I'm glad we're doing it finally, but it's -- but we need some way -- and I think, you know, what's the way of -- sort of the overall weight of the evidence that provides a fair evaluation and there's some plausibility in science to it, but at the same time, you know, maybe not have quite as strict a criteria that we would have for saying, you know, pure causality or something in terms of a regulatory sense or some other -- other venues. So it's putting those together, but it is a longer discussion but I think it's a very important one to have.

DR. WARD: Then we'll go down the row of raised name cards.

MS. SIEGEL DE HERNANDEZ: May I just add one more comment, just to finish that? One of the things that's striking in talking to members who have cancer is that they're often -- have more than one cancer, they have other diseases. And when we look at epidemiological studies and it's sort of rate by a particular cancer, it's not looking at the whole picture and sort of this issue of multiple diseases.

MR. CASSIDY: Yeah, I'd like to thank all of you for your presentation, and I thought what was powerful was -- I mean time heals all wounds and ten years later a lot of people have forgotten. Those -- those images that you showed us again kind of have drifted from people's recollections. But I do want to remind everyone that a lot of first responders and

others who were affected by this pointed to something that's happened throughout the country and happened here in New York about five years ago where second-hand smoke was banned in restaurants and public parks because second-hand smoke kills from cigarettes. So I just want to remind everyone if you take a look at those pictures, anyone who would trade places -- I'll sit in any bar anywhere while the waitress and somebody else is smoking cigarettes, but I don't want to go back to that Pile. And I think common sense has to play a role in this, and I want to thank you for pointing that out.

DR. WARD: Ms. Flynn?

MS. FLYNN: Many people here may not know that you were the labor liaison to the EPA World Trade Center Expert Technical Review Panel, and so you know a great deal about the flaws and inadequacies of the environmental measurements taken, on the Pile and well beyond the Pile. So in light of that knowledge, what is your thinking about how to approach exposure characterization and exposure assessment?

MS. SIEGEL DE HERNANDEZ: I try not to let people know about that ill-fated panel, Kimberly, so thanks for outing me. Again, this is a -- it's a much more complicated answer to that. I mean I think part of the discussion that we need to have about exposures is an understanding of what is not known, what data is not available, what data that was collected cannot give the answers that everybody is looking for, and -- but what can we look at in terms of figuring out exposures. So it's more complicated than what you say -- what you were asking about. I just think that in general, in the community, there was some sampling that was done on-site. As I said, it was one contaminant type sampling, and compared to occupational exposures -- occupational standards that are not health standards. So that was part of the problem.

Out -- once you left that Pile, virtually nothing was done, or very little was done that was applicable and that helps explain disease that people are experiencing. And to me, the biggest flaw in what happened after 9/11 was, as people were trying to assess -- what little was done to assess -- once people started getting sick, and that happened early on -- right? The fire department was reporting on World Trade Center cough in the beginning of October, within a couple of weeks. Once people started experiencing disease that -- then -- something wasn't jiving, something wasn't matching between 'it's safe based upon this measurement' and 'people should be okay, no long-term health effects

expected.' Well, that didn't completely answer it, I'm sorry.

DR. WARD: So Paul just reminded me that we are running short on time, so we'll take your comment and we'll take the three tent cards that were up initially, and then unfortunately we'll have to move on.

MR. ROMAKA: Well, I just want to make the point that -- okay, are we saying that -- you're down in here, you have this exposure, are we saying that it's not going to cause cancer? Are we saying that it was healthy for you? Are we saying that it's possible that it's going to cause cancer? Where is that line that the Committee or that people are looking for? We know that it wasn't healthy for you when you look at Washington -- they went around in space suits to clean that up. New York City, that never happened. I think that you just have to understand the difference between the two and where do you want that line to be drawn.

DR. MARKOWITZ: Just a couple of quick questions. Micki, you said that you thought there hadn't been adequate outreach to certain groups, and that may or may not relate to eligibility. I was wondering what you had in mind.

The second question is both you and Jim mentioned the need for more rigorous or more extensive disease surveillance. Again, if you had further thoughts, that would be of interest.

MS. SIEGEL DE HERNANDEZ: I think there are a lot of groups that still haven't been reached. Certainly with the change in some of the eligibility requirements and the extension of the time frames there are even members of our own unions who weren't previously eligible for the program who are now eligible. So I just think that it's something -- new people come into the program all the time. You'll hear that from the medical programs. And there are many, many reasons for that. Outreach is one part. We certainly have not reached out across the country. I haven't even spoken about national responders or some of our members who moved out of this area. So there are constantly new groups that we discover.

One thing that I didn't mention early on -- you just reminded me, Steve -- is we don't know how many responders were there. Nobody tracked that. Employers -- many employers did not track that. City agen-- the city doesn't know who was actually sent down there. So we don't have that answer. There are estimates about how many people were involved. We don't know. We don't know that denominator, as people call it, so continued outreach is still needed.

I'm going to pass the mic to Jim for the surveillance piece.

DR. MELIUS: That's actually part of it. But in terms of surveillance, I think there needs to be more resources put to case finding and follow-up. I mean we have to understand that in New York -- as well as I think many other states, but in New York the -- there's less and less reporting going to the cancer registry. It's less complete -- probably it was 20 years ago, lot more people being treated as outpatients now. And I don't believe there's reporting and I think there's actually some good evidence of that from some of the surveillance that the centers have done already. It's a significant problem. So case finding and follow-up I think is important.

Secondly, I think there's also -- as Micki said, there are no lists, and one of the major problems we have is that nobody knows who was there. Fire department I think has some records, police have some records. Most other city agencies did not keep records -- do that. Many private -- there were volunteers. It's very, very -- very complicated, but there are some. And I think looking at some of those -- our union, for example, kept records 'cause people worked for contractors, and for their pension and insurance benefits there's reporting back, so we have fairly good lists of people that worked there. And I think those are -- not all those people participate in the medical programs or the registry. And in fact, many do not, and I think follow-up of those lists is also another -- another possibility where we need more resources for surveillance.

It's -- when you talk about sort of resource versus sur-- I mean there's limited resources and this is going to be I think a very 'what do you focus on' 'cause there's so many issues that need to be addressed and would -- but I think on the surveillance side it just -- resources -- and Micki has a follow-up.

MS. SIEGEL DE HERNANDEZ: Specifically with the issue about -- related to cancer surveillance, I think there's an assumption that all the answers lie in the programs if we only analyze the data. You know, I know that many of our members who have cancer are not in the program, because everybod-- everybody knows it doesn't provide health care and they spend -- their lives revolve around their cancer treatment. And so there are a lot of cases that are not being captured, at least on the health program side. That also speaks to continued outreach and looking at other ways to try and understand really the extent of disease -- not just cancer, but other kinds of diseases that the program is just not covering.

MS. MEJIA: Guillermina Mejia here. I just have a brief question. Maybe you can -- can you give us a brief account of how the current covered conditions were identified so that we have a little background information?

DR. MELIUS: You probably could turn to the person next to you, he was as much part of -- **[identifying information redacted]**-- but I think it's fair to say they were -- and people in the audience here and everyone else on the panel can -- I mean they were identified essentially clinically. It's what -- if people were providing monitoring, there were people that were sick within the -- from the responder program and **[identifying information redacted]** was seeing similar problems in the -- within the community -- that. And at the time that the -- funding for this program, for the treatment part of the program, came in late 2006, really 2007 when it was implemented. And before the time that was being implemented, there was internal discussions within the programs and it's just what -- basically they determined what did they know clinically, what did they have evidence from from what had been published to date. I think obviously post-traumatic stress, the resp-- I mean I think they were all relatively straightforward, and all of them were subsequently I think confirmed from the follow-up studies that have been done. I don't think -- but it was based mostly on sort of clinical impression. But again, we're talking, within the responder program, over 30,000 people that had received treatment as of a year ago, it's probably more now, so it's a very large number out of a relatively limited population, so I think it's pretty straightforward.

DR. WEAVER: Mr. Romaka mentioned the presumptive accident disability benefit for New York State and City employees, and noted that it includes cancer. I'm interested to know which employees are covered, whether it includes fire and police department, and whether it covers all cancers or specific cancers. Thank you.

MR. ROMAKA: Right now the way it's written for the most part people have to first of all identify and get certified that they were there, that they had an exposure. They have to get signed off by their agency that this is what happened. It covers all cancers, but there is a different degree, depending on each individual pension system, as to what cancer constitutes a presumptive disability because a presumptive disability for running into fires is different than a presumptive disability for being a police officer or being another worker. And the Workers Compensation

system is for volunteers who weren't there also, so everybody who registered with -- from the State, it wasn't just firemen, police officers, it was everybody who registered with the State. It's up to the individual pension plans as to how they feel that it should be treated, what -- what constitutes a disability.

I'd just like to add something -- a little bit off the point, was the big problem that we have when we compare the cancers and stuff. We compare it to the New York State Tumor Registry, and that's two or three years behind all the time, which is a big problem for us when we're seeing increased cancers now. We had four firefighters diagnosed with non-Hodgkin's lymphoma within a three-week period and all with leukemia. That's not going to show up until five years from now. They're all problems when you look at just the science end of it.

DR. WARD: I think we'll have to forego all other questions, but if you have one last comment, we can take that and --

MS. SIEGEL DE HERNANDEZ: My one comment about the presumptive disability law is you should also know that it's not something that was just provided. It was something that the unions had to fight for and it was in recognition that, for many of these diseases that we are seeing our members have, couldn't wait again. Couldn't wait 20 years before it was proven a hundred -- you know, 100 percent scientific certainty, that the only way to treat people fairly and give them compensation was to presume that if they had those exposures, if they participated in the response, that these were the conditions that they should be compensated for.

MR. ROMAKA: And there is a committee that's -- looks at that bill each year to see what needs to be adjusted or fixed so that the right thing is done for the intent of the bill. That was made by government officials also, so it wasn't just labor going up there saying 'do this.' It was agreed to by all the interested parties.

DR. WARD: I think we unfortunately need to move on. Thank you all very much.

MR. ROMAKA: Thank you very much.

(Pause)

SURVIVORS

MR. SPENCER: While we're waiting I'll just say that we have two folks who are going to be presenting from -- one from Florida and one from California, and hopefully technology will not fail us.

Ready to start? Okay. So on behalf of the Survivors Steering Committee I want to thank the Scientific/Technical Advisory Committee for the invitation to make this presentation. We hope it will help the Committee gain a better grasp of the health problems affecting the survivor community. We have a PowerPoint up so folks can follow along. I'm Rob Spencer, the labor co-chair of the Survivors Steering Committee. I work for a City workers' union called the Organization of Staff Analysts. Our community co-chair, Kimberly Flynn, is a member of the STAC.

The Survivors Steering Committee was created to play an advisory role on the administration of the Survivor Health Program and to represent and gain input from the community of affected non-responder stakeholders. It's the successor to the Community Advisory Committee of the World Trade Center Environmental Health Center, which is the Clinical Center of Excellence, serving non-responders. On the slide, by the way, is some of the groups that have been current or former members of the -- either the Community Advisory Committee or the Survivors Steering Committee.

Before we begin, the Steering Committee would like to raise one procedural matter, that of an imbalance on the Scientific/Technical Advisory Committee in the number of representatives of affected communities. We have requested that the Administrator add an additional representative of the survivor community to the panel, and that this addition occur prior to the second meeting of the body. The Survivors Steering Committee has recommended a well-qualified individual for that role, and we hope that that recommendation will be given serious consideration that it deserves.

Our goal here is to provide a brief overview of the non-responder populations affected by 9/11, their 9/11 exposures, and their health experiences. This morning you'll hear from individuals who were students, residents, and area workers on 9/11. And you can see, this is the morning of, and there is a slightly different version of the dust cloud approaching Chambers Street than Micki had in her presentation, but it gives you some sense of its sort of mode of force and how far it traveled how quickly.

The collapse and burning of the World Trade Center caused an unprecedented environmental disaster. Toxic dust and smoke permeated densely populated urban area. So you can see in these slides some of the people who were directly affected on the day by the initial

collapse cloud. And here you just see some of the residual effects in stores, on streets. I'm not sure I want that fruit and vegetable stand's produce.

Fires then -- in addition to the effects of the initial collapse cloud, the fires at the site persisted for many months. And you can see in these photographs -- these were taken anywhere from a few days to several months after 9/11. You can see that there's -- the persistent fires created smoke clouds that hung -- a plume that sort of shifted with the wind direction and hung over lower Manhattan neighborhoods and persisted.

And how did this deal with -- how did interiors look after this event. Well, this is an example of some buildings that border the World Trade Center site. These are apartments.

Throughout the Ground Zero cleanup, World Trade Center dust and contaminants entered buildings through multiple routes. Many of the residents of the affected areas were not evacuated, but remained in their homes throughout. Some area workers were brought back to the locations as soon as two days after the attacks, and I know that anecdotally from members of my own union.

On September 18th EPA Administrator Christine Todd Whitman through my people declared the air was safe, which put the health of tens of thousands of people at risk. Residents, students and area workers who had evacuated returned to the area and were exposed to World Trade Center smoke and dust, indoors and out.

The White House Council on Environmental Quality, influencing EPA risk communications, transformed statements of caution and concern to ones that downplayed health risk. Revealed by the EPA Inspector General's report in 2003, these altered communications misrepresented or concealed information that might have helped protect thousands from the contaminated air.

On the tenth anniversary of 9/11 ProPublica, working from documents obtained by the New York Committee on Occupational Safety and Health, revealed just how far this went -- and I think this quote is particularly interesting: 'In one instance, a warning that people should not report to work on a busy thoroughfare in the financial district -- Water Street -- was rewritten and workers were urged to return to their offices as soon as the financial district opened on September 17th.'

The same day, the New York City Department of Health issued an

advisory: 'How should I clean the dust in my apartment when I move back in? The best way to remove dust is to use a wet rag or a wet mop.' The advice for pregnant women, which is on the slide, or young children and area workers was sort of equally questionable. In fact, and this is an important point, there has been no comprehensive and scientifically-valid assessment of indoor contamination ever done.

After a lengthy struggle the EPA announced the Test & Clean Program on May 2002 for residences only in Manhattan south of Canal Street, purely on a voluntary basis. Workplaces were excluded, buildings were not treated as systems, and tests in HVAC systems in inaccessible areas that were most likely to harbor contamination were not conducted. Efforts by advocates to improve the program and expand the boundary above Canal Street and into Brooklyn were rejected.

The August 2003 EPA Inspector General's report criticized the cleanup as flawed and inadequate, and called on the agency to re-examine the remaining risks to residents, students and area workers in lower Manhattan and in Brooklyn. After another lengthy struggle the EPA created the World Trade Center Expert Technical Review Panel -- that was the panel that Micki was mentioning -- to examine the first Test & Clean Program and to develop a new program to address the remaining health risks to survivors.

After months of meetings the EPA unveiled the second program, which was essentially the same as the first. It was deemed unacceptable by a majority of the experts on its own panel, and all of the labor and community representatives. The Government Accountability Office conducted a review -- when you look at this slide you'll see the number of little bullet points in the right-hand column there are little things that they -- advice that they did not take, and those are pretty significant, including testing workplaces and so forth.

By 2004 the New York City Department of Health had opened the World Trade Center Health Registry. There was no input from affected community or labor stakeholders into the design of the registry and the wave one survey. Criticisms included arbitrary boundaries not based on any reasonable exposure criteria; exclusion of affected neighborhoods, including Chinatown and the lower east side; exclusion of area workers who were not present below Chambers Street on 9/11; carving out the entire population of the borough of Manhattan Community College; failure of the wave one survey to assess survivors' exposure to indoor

dusts; failure of the wave one survey to assess unmet health needs. These omissions and failures of public health policy and exposure assessment resulted in illness and the demand from affected communities, initially led by Beyond Ground Zero Network, for appropriate and needed 9/11 health care for survivors. The World Trade Center Environmental Health Center is the outgrowth of those demands, met by responsive public health professionals and the New York City health and hospitals cooperation.

The individuals who will present after me this morning will offer snapshots of the 9/11 survivor experience. We'll hear in order from Mariama James, who's sitting here; Jo Polett, who's here; Gail Benzman, who is on the phone; Lillian Bermudez, who is at the far end of the table; and Lila Nordstrom, who is also on the phone.

So first up is Mariama James.

MS. JAMES: My name is Mariama James. I live in Southbridge Towers with my family. That's on Gold Street -- my building's on Gold Street. I'm also a member of Community Board One, formerly of the World Trade Center Redevelopment Committee, presently on the Youth and Education and Financial District Committees.

On the morning of September 11th I was eight months pregnant with my third child. I did my usual commute from Gold Street to Queens, Long Island City Queens, that's two trains and a bus through the -- once I reached -- I was very early that day so I went to hang out in the engineering department, and through their floor-to-ceiling bay windows I was able to see the first plane hit. I immediately called my children's school and contacted them, urging them to close the school and let the children get home. I was only thinking of traffic at that point.

But by the time the second plane hit I could no longer reach them and weren't sure if they were -- whether -- if they were okay. Stayed at work as long as I could in hopes of speaking to them, and once that seemed futile I began pretty much a walk from Queens back to lower Manhattan. When I arrived home I was covered in dust from head to toe. My father, who had been successful in picking up my children from the Village, walking from Gold Street to Bleecker Street in SoHo and back, was also covered in dust, as were all three (sic) of my children.

At Southbridge Towers, the entire complex, we had no power, no water, no phones. At daybreak when the sun came out we were able to see that our home was covered in the same thick dust that was everywhere

else in the surrounding areas. Neighbors said that the building was engulfed in the collapse cloud.

Soon we were told the dust was safe to remove ourselves. At eight and a half months pregnant I got down on my hands and knees and ripped up my children's carpet -- the padding, the wood, entirety. I cleaned the rest of my house as well. My father was there to help with me as well, and he vacuumed with a non-HEPA vac. We used our wet rags and wiped up what we could.

Not long after 9/11 the City Health Department put out an advisory to residents that stated, in addition to cleaning with wet rag and mop and throwing away any spoiled food, pregnant women and young children do not need to take additional precautions. And I think there was just a quote in Rob's presentation a moment ago with specific regard to pregnant women not needing to do anything in particular.

My daughter was born on October 23rd. She was diagnosed with asthma and sinusitis, things of that nature, by the time she was ten months old. And my other children, none of whom had health problems before 9/11, developed the same conditions -- which are now considered classic World Trade Center illnesses.

For years all three of my kids took daily treatments of Zyrtec, Allegra, Singulair, Asthmanex, Albuterol, Rhinocort, Qvar and Advair for allergy, sinusitis and asthma-related symptoms and were eventually also prescribed Prevacid for GERD that the doctors said was caused by post-nasal drip from the sinusitis problems.

There was no program to treat children who were sick from 9/11. I had to be -- which is myself -- to find a pediatric pulmonologist. For many years she required them to come in once a month, and then later, as they became better, three times a month (sic).

We still keep steroids and nebulizer meds on hand in my house, in the event that any children -- any of the three children should reach their what they call red level of asthma action plans. They miss school often. At five my daughter knew how to load the nebulizer and administer treatment to herself.

In 2002 when my son's teacher and I realized that he was having difficulty processing instructions, we had him tested and he has since been diagnosed with learning disabilities. His sisters later followed in being diagnosed with the same.

Our health care costs went through the roof, averaging around $820 a

month because of $50 co-pays for each med and $50 co-pays for each doctor visit. And as a result, I by myself could not afford to go to the doctor, so I've only recently begun to seek treatment.

All three of my children still have persistent asthma, sinusitis and GERD, for which they are now being treated at the EHC. And the last, and I guess most important at this point, point I'd like to make is that children are in many ways the most vulnerable population exposed to 9/11 dust and smoke, yet they are the least studied. It is absolutely critical that NIOSH fund the pediatric study proposed by Drs. Leo Trasande and Liz Fiorino which will test hundreds of downtown children for World Trade Center exposures and related symptoms. Years ago we called for a program to screen the area's children and we didn't get one. We must have this study. Without it we have no clear picture of the effects of 9/11 on the physical health of downtown children.

MR. SPENCER: And next up is Jo Polett.

MS. POLETT: My name is Jo Polett. I'm a patient at the WTC EHC and I live at 105 Duane Street, a 52-story rental high rise located seven blocks north of the World Trade Center site. Constructed in 1990, the building has no asbestos-containing material and no interior source of lead.

On 9/11 dust from the collapsing towers entered our building through windows, the louvers of heating and air conditioning units, and the building-wide ventilation system. In the months following the attacks smoke-borne contaminants from the fires that burned at the site polluted the air and continued to enter our homes.

On the morning of 9/11 I watched the towers burn and collapse through the living room window of my south-facing apartment. I spent a week with friends in Brooklyn and returned to my apartment once power and water had been restored to the building.

Respiratory symptoms were common among my neighbors, but we were assured by federal and city officials that our symptoms would be short-term, with no lasting consequences, so we tried to ignore them. As the symptoms of some intensified, it became hard to do that. I had no history of respiratory problems, I was not caught in the dust cloud and, because my windows were closed when the dust cloud hit the building, when I returned home I saw barely any dust.

Yet by the end of October respiratory symptoms that had begun to occur intermittently following my return became persistent and increased in severity. On November 20th I consulted an occupational physician and

was advised to vacate my apartment until it was professionally cleaned. A FEMA inspector declared it uninhabitable and I was relocated to a hotel on the upper east side.

I spent the next two and a half years working with my fellow tenants to get our building properly cleaned. Our efforts met with little success. By the end of November we'd learned that, even if tenants who could afford to do so had their apartments professionally cleaned, if the ventilation system was circulating contaminated air the cleaned apartments would be re-contaminated. On December 3rd of 2001 we brought in a certified industrial hygienist who sampled the supply air diffuser or hallway vent on the tenth floor. The sample was collected by micro-vac and analyzed by TEM for asbestos. The sample tested positive for asbestos at a level of 550,000 asbestos structures per square centimeter. Expected background for buildings such as ours, constructed without ACM, is usually below 1,000 structures per square centimeter, though some studies show that in a poorly-maintained building in an urban area the level can be as high as 10,000 structures per square centimeter. 105 Duane is a well-maintained building, but in either case the sampling result in asbestos level between 500 and 50 times expected background shows that the ventilation system was contaminated with asbestos from the World Trade Center. In either case, the presence of additional constituents of the collapse dust and smoke.

There is a supply air diffuser on every floor of the building. Outside air is drawn into the ventilation system through an intake vent at the base of the building, and is then vented into the hallways through the supply air diffusers. That air enters apartments through entry doors and is circulated out of apartments through exhaust vents located in kitchens and bathrooms. Sampling in July 2002 of the entry doorframe of a fifth floor apartment yielded a result of 123,000 structures -- asbestos structures per square centimeter, indicating that the ventilation system was circulating asbestos and other WTC contaminants through hallways and into apartments.

Sampling of the FAMCO unit of the living room heating and air conditioning unit in that apartment yielded a result of 37,000 asbestos structures per square centimeter. That unit had not been turned on since 9/11. Identical sampling in an identical unit that had been turned on since 9/11 showed a level of 16,700 asbestos structures per square centimeter. That sampling was collected in my apartment in January of

2002.

In addition to findings of trace amounts of asbestos in the kitchen and bathroom exhaust vents, the sampling report also noted the presence of World Trade Center dust and debris still visible on an exterior window ledge.

In addition to independent sampling results, my building has EPA sampling results that also confirm WTC contamination. My apartment was one of the 222 residence (sic) in lower Manhattan that EPA sampled for heavy metals and dioxin during the first test and clean program that launched in May of 2002.

The wipe sample result for lead on my bedroom floor, taken in May of 2003, was 127 micrograms per square foot. It was five times of EPA's health-based benchmark for lead. The result for antimony was 1090 micrograms per square foot. EPA's health-based benchmark for antimony was 627 micrograms per square foot.

The eight residences in my building sampled for heavy metals and dioxins more than a year after the collapse, four exceeded EPA's health-based benchmark for lead.

Though EPA and the New York City Department of Health responded to the inconveniently high number of positive lead results in lower Manhattan by attributing them to interior lead paint in older buildings, there was no interior source of lead at 105 Duane Street. And it is, and was at the time, a known fact that there was lead in World Trade Center dust.

Thank you, and please keep in mind that the sampling results I've cited came from a building that did not appear to be significantly impacted by World Trade Center dust, yet harbored contaminants in sufficient quantities to cause lasting health effects.

MR. SPENCER: Next up will be Gail Benzman, who's going to speak to us hopefully over the phone from Florida. Gail?

MS. BENZMAN (via telephone): Thank you. Good morning, ladies and gentlemen. My name is Gail Benzman and I am a survivor of 9/11, even though I was not physically in the area at the time of the attack.

On 9/11 I had taken the day off to work on the primary election. I was lucky. I watched the planes hit from Queens. If not, I would have been at a meeting within a block of the collapse of the towers.

On 9/11 I was employed by the New York City Comptroller's Office located at Chambers and Center Streets. That night the mayor issued an

order that all non-essential city personnel were not to report to work. On September 18th EPA Administrator Christine Todd Whitman announced that the air had been tested and was safe. I received an order to report to work on September 20th.

As I rode the subway to work that morning, at each station as the train doors opened, the smell of smoke became more intense. At the City Hall stop the platform was black with smoke. We all had to cover our faces as the tears rolled down our cheeks and we ran up the stairs. In the street was more smoke and the smell of burning debris and chemicals. Dust and debris were continually being blown through the air and hosed off the buildings, coating everyone and everything, as well as being blown through the open windows of the buildings and circulated by the ceiling fans.

Every morning, after we staggered through the smoke and fumes, before we could begin to work we had to clean our desks, papers, walls and rugs. My reaction to the smoke and dust particles was almost immediate. I had problems breathing and my chest hurt.

On September 25th I spoke with the deputy comptroller about the medical reactions I was having -- constant coughing, swollen glands, sore throat, pain in my sinuses, headaches and constant pressure in my chest, as well as nosebleeds. He informed me that the EPA had tested the air and that there was nothing wrong. If I felt sick, I should go home.

October 17th was my first of many 9/11-related doctor visits. The list of medications prescribed continued to grow -- V-Pack, Claritin, Brobin (ph), Flonase, Albuterol, Dioxin, Codeine, et cetera -- as did my absences and time spent in bed. The comptroller's environmental policy person arranged for an appointment for me at Mt. Sinai's Occupational and Environmental Health Clinic.

On November 8th I was informed that I had reactive airway disease and asthma, a respiratory disease I never had prior to 9/11. Additionally I have been diagnosed with chronic sinusitis and GERD.

All the while the federal and city agencies continued to say that there was nothing wrong with the air, in every statement and at all public hearings. Yet doctors, residents and workers testified to new and worsening illness.

I had been advised to think about applying for disability, but I had bills to pay, including a mortgage, and I would no longer be able to continue to contribute the time and money I needed to my pension. Dr. Levin

suggested I file for Workers Comp. Most attorneys would not accept my case since I had not worked on the Pile. Finally a small firm accepted my case in July 2002. After numerous hearings I was notified by the Workers Comp that I had won my case. My office was reimbursed for my absences and the sick time was credited back to me. I was also informed that I was afforded lifetime medical. But in 2007 my case manager disappeared. Messages left by her were never answered, nor was anyone else ever assigned to my case. Workers Comp stopped paying my drugs. Since 2007 I have been paying for all medications that my insurance has not paid for.

To avoid further exposure, I retired when I finally could and left New York. I moved to Florida on January 23rd, 2010. I still have the same medical problems -- reactive airway disease, chest pains, acute sinitis (ph), reflux, and problems with my voice, although I do not suffer as many attacks. Doctors in Florida do not have much experience in treating individuals with 9/11 health problems, even though there are over 1700 of us now living in Florida. After all these years I've learned which medications work for me and which don't.

I have been to New York City only three times since I moved. Every time I go I have had an attack of asthma, shortness of breath, chest pains and sinusitis. My most recent attack -- my most recent visit required me to be in a lower Manhattan building, and I suffered one of my worst attacks in a long time.

Since I was not at work below Chambers Street on 9/11 I was not eligible for the World Trade Center Health Registry. Although I now live in Florida, I recently had my first thorough examination at Bellevue's EHC. Thank you for listening.

MR. SPENCER: Thank you, Gail. Next is Lillian Bermudez.

MS. BERMUDEZ: Hi, my name is Lillian Bermudez -- I get emotional. I live in Delancey Street above Canal Street. I work for the New York City Police Department. I am a senior police administrative aide, and I have four children, which two -- **[identifying information redacted]**, who was 12, and **[identifying information redacted]**, who was 9 at the time of the 9/11.

A few days -- a few days after the 9/11 the fumes and constant -- constantly coming through my windows, my kids were complaining about the smell, and the towers were still burning. I could smell it, too, and it was very intense and I wondered if it was dangerous. But of course they said that the air was clean.

Neither of my kids had any health problems before 9/11. So by the end of October 2001 my son, who's been home from school for two days coughing and sneezing, and I thought it was a cold -- I thought he was suffering from a cold. He had complaint of his chest hurt and I thought that he was -- it was because of the cold that his chest was hurting a lot. On the third day, on a Sunday, when I saw that he wasn't getting better I decided to take him to the doctor at the Bellevue ER. When he was at the triage nurse he check-- they checked his oxygen blood level and asked for Mitch to be taken in right away. As soon as they took him in they put him in a bed, they started putting IV on him and giving him oxygen. And I asked them 'What's going on? What's wrong with him?' They told me that he was having an asthma attack. And I was shocked, because he never had asthma before. That's the first time I hear about it.

The next thing I knew, they're sending him straight to ICU where the doctor was struggling to get Mitch breathing under control. I stayed there with my son on the ICU for three days until he was better. The day after he was admitted the doctor told me that if I waited one more day and he would have died.

A social worker came to the ICU and started asking me questions, whether there was dust, pets, smoking in the apartment. We don't smoke, we didn't have pets at the time, and if -- and the -- in the apartment -- you know, and the apartment was always kept clean, no matter what. My kids had seen a pediatrician every year and both been healthy. They were never -- I was never told that any of my children, you know, had asthma at the time.

Because of the dust and fumes from 9/11 I have -- my daughter -- no, before the fume from 9/11 she's -- they said that the air was clean and it was not clean. Oh, God, I don't know where I'm at. I am so...

(Pause)

Yeah, after -- I mean after the social worker was drilling me, that's how I felt, I just kept paying attention to my son who was having problem breathing and the doctors could not get it under control. I said that the dust -- the dust fumes from 9/11 was not good. She kept telling me yes, they said it was clean, that it was nothing wrong with it. She kept resisting -- and I kept -- I got too upset, you know, I don't want to discuss it anymore, and I went over to my son.

Mitch came out of ICU after three days, but he was kept in the hospital

for five more days so they could keep giving him aburals, steroids and oxygen. He was given a diagnose of asthma and medicine, and we went home.

By 2002 my daughter **[identifying information redacted]** was sick, and when I brought her to the ER she was diagnosed with sinusitis. The ER doctor gave her a pump, but every time she got a cold it would get worse -- the sinusitis would get worse. Eventually she was diagnosed with asthma also.

Even though Mitch stayed on the medicine from the ER doctors, he continued to have severe asthma attacks, and I would take him to the ER. He was admitted to the hospital at least four more times.

In 2007 I met Dr. Joan Wright-- Re-- oh, God -- and she told me to take **[identifying information redacted]** and **[identifying information redacted]** to Bellevue World Trade Center Clinic to get tested. They got the right kind of medicine, and since then my kids have been doing great. Now they can live like kids again.

If my kids have any more asthma or sinus problems, the doctor there are there for them. They know my children's history from 9/11, and they know what to look for and how to get them well because where my children live, they didn't qualif-- and because where we live, they didn't qualify for the health registry, either.

And I just want to say one thing that -- I am not taking anything away from the first responders. I am so glad and thank God that they were there for us to be there to help out, but we as to living in the residency have problems also.

MR. SPENCER: Thank you, Lillian. Last up, from California, is Lila Nordstrom.

MS. NORDSTROM (via telephone): Hi. Can you guys hear me?

DR. WARD: Yes.

MS. NORDSTROM: Oh, great. Okay, good. So I was a Stuyvesant student on September 11th in 2001. Our school was just three blocks from the World Trade Center and on the day of the attacks we were held inside the building until about 10:30, just before the north tower fell -- I think it fell at 10:38 -- so a lot of us ran from the collapsing building the moment we exited, but a lot of us did not get out of the school until well after that time and exited into a scene full of dust and debris.

Stuyvesant High School was in the dust cloud and it was used as a command center for several weeks after the attacks. But it was not

cleaned adequately prior to our re-occupying it. The vents were not cleaned. There was no fabric or drapery replaced. It had a very cursory like mopping, essentially.

We returned back to Stuyvesant on October 9th, 2001. It was only three weeks after the attacks. The area was essentially a war zone. We had to go through National Guard checkpoints to get into school, and there were still fires burning at Ground Zero which burned for at least a month after our return. Smoke and ash were blowing into the school daily, and by the end of each school day the smell of smoke was really suffocating. I'm a life-long asthmatic and up until that point my asthma had been well controlled, but I started having breathing problems immediately, as soon as we returned to Stuyvesant. Coughs and nosebleeds and respiratory problems became really common in the Stuyvesant community.

To make matters worse, hundreds of trucks carrying the dust and debris from the Pile at Ground Zero passed by our school every day on their way to the barge, which was moored just outside of our building. The barge was facing a community college as well, and a large apartment complex. Their -- the trucks dumped their loads next to our air intake system, and environmental testing at the barge on several days showed that levels of particulate matter were higher there than they were at Ground Zero, so -- and that was right outside Stuyvesant's doors.

Stuyvesant students were minors at the time of the attacks, and we had no ability to advocate for ourselves and really no choice but to trust that the Board of Education had made the right decision to send us back. But the parent association at Stuyvesant eventually discovered that the City had really failed to disclose a lot of relevant facts about the environment in and around Stuyvesant, and they now maintain a website where a lot of their failed attempts to get the City to do further testing and cleaning are archived, and that's a good resource for finding out what -- you know, what information was available at the time and what wasn't.

Stuyvesant alumni from that year are right now in an age group with really high numbers of uninsured people, and we're already facing discrimination based on 9/11-related pre-existing conditions on the open insurance market. That's really problematic for us 'cause we are heavily dispersed nationwide at this point. We live in a lot of different states and not all of them offer the protections that New York State does in terms of pre-existing conditions when you're buying private insurance.

At the moment acid reflux and coughs and respiratory problems are very widespread with the Stuyvesant population. There are anecdotal reports of cancers and autoimmune disorders that are growing, but there was no comprehensive study ever done of the health impacts on Stuyvesant alumni, so we don't have exact data.

As -- I've -- I have four cancers and two autoimmune disorders were reported -- have been reported to me by former classmates in the last five years, but that certainly doesn't account for the variety that -- you know, that could be out there.

I just wanted to finish by reading a statement by my classmate from that year, Amit Friedlander. In 2006 he was diagnosed with Hodgkin's lymphoma. He said: 'All through college, which was 2002 through 2006, I frequently came down with severe flu and cold-like symptoms for a week at a time, and people often told me that I looked sickly and like a drug addict. I just figured I was tired and sick and looked worn out because I was working hard. Shortly after graduating from college a physical therapist noticed a lump in my chest, and the lump was diagnosed by doctors as Hodgkin's lymphoma. I found out that many 9/11 responders were being diagnosed with Hodgkin's and other blood cancers. And while I wasn't one of the heroes working in the rubble at the World Trade Center, I had significant exposure to Ground Zero dust, smoke and debris. It is also worth noting that every day there were numerous truckloads of World Trade Center debris going past the Stuyvesant High School building and being unloaded onto a barge right outside the school through late spring of 2002.'

Thanks.

MR. SPENCER: Thank you, Lila. So in closing I'd like to thank Mariama, Jo, Gail, Lillian and Lila, and also my co-chair -- my community co-chair, Kimberly Flynn, for their hard work in putting together this presentation. We hope the Committee has found it somewhat helpful. Thank you.

DR. WARD: And we'd like to take at least as many as three questions for the panel. We are running a little late so we'll have to limit it to three.

DR. DEMENT: Seems like a recurring theme in all the presentations -- at least most of them -- is the issues for young children, in particular present in the vicinity and certainly outside of some of the zones that were designated. I'd like to hear more discussion about what is going on with regard to looking at children, and maybe some comments about what should be done.

MS. POLETT: I mean, we'd just say that parents with affected children couldn't wait for the WTC EHC pediatric program, so they're -- they took them to doctors, you know, all over the city. And that's such a concern because they're dispersed, there's -- the large numbers of them are not being tracked. There are very few children in the World Trade Center Health Registry. I think it's what, 2,000 or --

MR. SPENCER: Three.

MS. POLETT: -- 3,000, so we're really concerned that there'll be no way to scope out emergent illnesses. If you remember back to the data in my building -- I mean obviously I'm not concerned about the asbestos long latency period, not a problem. I am really, really worried about the children who are living in my building now.

MR. SPENCER: One other interesting fact is that it's become -- first of all, there were several different pediatric populations. There were those who were in sort of high school that have now aged out into an adult population and they're part of the -- could be part of the EHC directly. There are people who were, you know, much younger children who are still being -- could be treated at the pediatric program. But one of the things we found that was very difficult with is reaching out and finding the people in the community, because in -- for example, the Department of Education has not exactly been forthcoming about facilitating outreach to parents or to, you know, anyone who was connected to this population at the time. And it's only, you know, recently that there's been any modest movement in this direction -- just pointing that out.

MS. JAMES: I would just first repeat again that the study needs to be funded for pediatrics, Dr. Trasande's study, Dr. Loosfemio's (ph) study. But also to say that I think that from the top there needs to be some encouragement to pediatric physicians. Not all of them take World Trade Center-related illnesses seriously, even to this date after they've been recognized. There needs to be something from the Department of Health, something from the national medical boards to these doctors to not basically laugh it off if you receive a patient -- a pediatric patient that's complaining of multiple respiratory and sinus diseases -- conditions.

MR. SPENCER: And the last thing I'd say on that is that often parents seem resistant to identifying, believe it or not, medical problems as being tied to 9/11. And one -- my community co-chair, who sits on your Committee, would probably tell you she's run a pediatric outreach

project on behalf of the EHC and sometimes getting people to sort of accept the idea that these post-9/11 onset illnesses are actually tied to that. For some reason there's more of a stigma in some of these communities to that than there would be that they just -- it just developed, you know. I don't quite understand it, but there it is.

MS. POLETT: And the other problem that -- parents who brought their children back or remained in their homes have a really hard time with that, so as I think Rob said, there's resistance. But the other problem is they're handicapped by the misinformation they have received. So a parent whose child was not caught in the dust cloud or didn't occupy or reoccupy an apartment with heavy dust or visible dust just assumes that, you know, whatever is going on with their child -- the asthma, the sinusitis, the learning delays -- must have some other cause.

MS. BERMUDEZ: I just want to say that the only reason why I found out about my kids being affected with the 9/11 was because one day I went to my -- to their doctor and she told me they were having a meeting about the 9/11. And me, I always thought that there was something wrong with -- with the air and all -- you know, all that stuff, and she told me about this meeting -- I forgot the council person that was supposed to be there, and I met some of the Committee people there, and I just sat in the back and I just listened to what they were saying. But if it wasn't for that meeting I would have never known that my kids was affected with 9/11. I just thought it was just -- they were sick. You know, a cold at the first, but then when they started getting worse and I realized he was getting worse, and then I had started putting two together and I said well, they were talking about that the air was clean, and all of a sudden, you know, all these things are happening and then it was talking about no, the air is not clean. And I spoke to some of the Committee members and they kept telling me well, keep coming to the meetings and we'll get more information about what's going on. But if it wasn't for that meeting, I would have been one of those parents that would have known nothing about what was going on, what was going on with my children. I mean all of a sudden they come out with asthma; from where, from what? And like I say, we were not informed at all about anything about the 9/11. And I have a -- and I met a couple of parents and I told them about it. 'Oh, no, I couldn't believe that; that couldn't happen.' I say 'Yes, I think you should start getting' -- you know, getting more information and go on the internet, there's a lot of

information about 9/11. And because of that, more parents are being aware, but there are a lot of parents out there that are not aware and the children are sick and not getting the right treatment that they should get.

MS. FLYNN: Can you hear me? Yeah. There was no official public health guidance for parents of young children until 2009. That is the time in which the New York City Department of Health issued its guidelines for children and adolescents exposed to the World Trade Center disaster. And there was no funded pediatric program for children suffering from 9/11-related mental or physical health effects until 2008.

MS. HUGHES: I want to thank all of you for sharing your stories with you, and as a fellow mom, I really want to thank the parents and it's been a really hard struggle for the last ten years to get to where we are. And it'll be interesting to see what this Committee will be able to address, and we can't forget about the children, too. Thanks. Thanks a lot.

DR. WARD: I think we will move on to taking a short break for 15 minutes. I thank all the members who spoke very much. I think it was a very enlightening session. Thank you.

(Recess 10:37 a.m. to 11:00 a.m.)

DR. WARD: If everyone could take their seats.

(Pause)

DR. MIDDENDORF: Just a note to the record as we reconvene that all the previous members are currently at the table except for Dr. Rom. When he returns we'll put a note to the record that he has returned.

And I'll also ask if Dr. Talaska's on the phone?

(No response)

Not hearing, I'm assuming that he has not joined us as yet.

Before we get on with the rest of our program I do want to remind folks that, if you aren't aware, that today at 2:00 o'clock the federal government will be conducting the first nationwide test of the Emergency Alert System. The test will last up to three and a half minutes. During this period the regularly-scheduled radio, television, cable and satellite shows will be interrupted as the system is being tested. So we're informing you that this event will be just a test and not a real emergency alert. My understanding is that there may be sirens and things like that going off as well, so it is not a real emergency. We will -- if it's too loud, we'll wait for it to be over and done with. If we

can, we'll work through it. So I just want to make sure everybody is aware of that.

And a note to the record that Dr. Rom has now returned.

DR. WARD: Then we'll begin with Dr. Mark Farfel.

TREATMENT PROGRAMS AND HEALTH REGISTRY:

WTC HEALTH REGISTRY

DR. FARFEL: Are the slides cued up? So thank you for the opportunity to speak for about 15 minutes about the World Trade Center Health Registry. It's been mentioned a number of times this morning already. As I look around I see a number of you are very familiar with registry activities and research through service on the registry's advisory committees, the science, labor and community, and some of you have gotten recent updates on registry research at the October WTC seminar that Steve Markowitz helped organize. But I know that others may not be as familiar, so what I'm going to do this morning is just briefly present on registry background and some of the past findings, but really focus on ongoing research and planned research. I think that would be of interest to the Committee.

Let's begin with our registry aims. We have three, and the first is expanding knowledge about long-term health effects of 9/11 and gaps in health care. And in a nutshell, we -- this basically entails three approaches to the research. One is we do periodic health surveys of our enrollees; two, we do in-depth studies, some collaboratively with external researchers, and we also do matching to other health registries such as the National Death Index. The registry also responds to health needs and concerns of enrollees and others who were exposed. It was mentioned earlier the pediatric physician guidelines, there was also the adult guidelines, came out of this specific aim of the registry. And we now also have a treatment referral project that I'm going to mention a little bit later that's part of the core registry function under aim two. Lastly, we expend quite a bit of effort maintaining updated contact information, or an updated registry, so that we can reach people for the first two aims, and also so we can serve as a resource for external researchers doing 9/11-related research.

So briefly on the history of the registry, the Health Registry was actually conceived shortly after 9/11, and the registry was established at the

health department in partnership with ATSDR in 2000 (sic). We're currently funded by NIOSH and that came in the more recent years.

The first registry survey was in 2003 and 2004, and at that time we had 71,000 exposed persons enrolled in the registry, and including the 3,000 children that were mentioned earlier. And they took a 30-minute telephone interview which gathered information about physical and mental health symptoms and conditions, new or worsening conditions, and 9/11 exposures.

The second registry survey was 2006-2008, and nearly 70 percent of the adult enrollees responded to that survey, and we had just over half of the parent proxies who responded for their children who were in the registry also responded to that survey. So the goals there were to assess the course of symptoms and conditions that had been reported on wave one. We did get some exposure clarifications, including asking questions about the intensity of the dust cloud exposure, and we asked about any new emerging conditions.

The wave three survey, which is the 10-year follow-up, the 2011-2012 survey, is currently underway. We did launch in July to the adults and most recently to the parents of children still enrolled. And our goals there are to assess the course of conditions, emerging conditions, unmet health care needs there.

So very briefly, the registry had four eligibility groups that were individuals who were highly likely to have been exposed, have had high exposures to the 9/11 event or the aftermath. And the largest group by far, the building occupants and passersby of Chambers Street on 9/11, and that includes occupants of damaged and destroyed buildings and about 4,000 occupants of the twin towers; followed by rescue/recovery workers and volunteers at the site, and that includes several thousand of NYPD, FDNY, Department of Sanitation employees, as well as about 5,000 people who reported they were there as volunteers. The third group is the residents south of Canal Street, 14,665; followed by children and staff in schools south of Canal Street.

Now the numbers do add up to more than 71,000 because about one in four of the enrollees were actually -- fell into more than one of the eligibility groups. So the registry has about 17 percent of the estimated 400,000 people who are eligible across the four eligibility groups. And of course exposed persons did not need to be ill to be eligible for enrollment in the registry.

Just wanted to say a word about recruitment briefly. We have two main groups, the first that we call list-identified, which comprises about 30 percent of the enrollees. These are people who are recruited from lists of names that were culled from employers and organizations, or residents through publicly-available directories, so there are a large number of lists with a large number of potential enrollees, and they were reached out to by the survey vendor and assessed for potential eligibility.

So this group, since it was recruited from lists, is less likely to be subject to selection bias compared to the remainder of the enrollees that we call the so-called self-identified.

These are people who responded to the extensive media outreach and awareness campaigns -- subway and bus ads and so forth, letters sent to parents -- and pre-registered or contacted a toll-free number. And then those inbound calls were handled and people were interviewed.

So we do take into account recruitment source and registry analyses, and when we do look at list-identified enrollees separately we do find similar trends in findings.

Now this attack truly was an attack on the United States, and this map reflects that the registry has enrollees from all 50 states. We actually have responders from all 50 states as well. The majority -- we also have enrollees from 18 countries. The majority of the enrollees resided in New York City on 9/11. We had about -- close to 90 percent in the New York City metropolitan area. And then we have enrollees -- large numbers of enrollees in states like California, Pennsylvania and Florida.

A few strengths of the registry to point out at this point is that we do have published estimates of the numbers of exposed persons, and it was addressed earlier this morning that these are just estimates, but we do have them. The registry, as I mentioned earlier, is a vehicle for external researchers to conduct their own WTC research, or in collaboration with the registry. We have about ten external collaborations to date with local researchers affiliated with local universities, including Columbia, NYU, Cornell. We also have collaborations with international researchers from the United Kingdom. And the topics really range quite widely, from looking at evacuation procedures and understanding behavioral aspects and structural aspects of building evacuation to understanding the transmission of PTSD from first responder parents to their children.

And I think first and foremost, you know, we do have the diverse groups of enrollees that we follow, with quite a number of subgroups in there that I've alluded to. And each of these main registry groupings that I just presented has experienced a large burden of both physical and mental health symptoms and conditions.

And I just wanted to show a couple of slides of some of the more common conditions. I want to begin with PTSD. I have one slide, and then one slide on new asthma after 9/11. So we call this probable PTSD because the -- our surveys, which were self-report surveys, actually screened for PTSD using the PCL checklist, which was a 17-item checklist grounded in the events of 9/11, so that's why we refer to it as probable.

So by the point of the second wave of our survey in '06-'07, about one in four of our enrollees had new-onset PTSD that had no prior history of PTSD; about ten percent had late-onset PTSD at wave two; and about ten percent had reported PTSD or screened positive at both waves one and wave two. Most of those individual enrollees who had the chronic or the late-onset PTSD reported poor mental health in the past month, it was 13 days or more poor mental health, and no mental health care in the past year. And I think that last finding really highlights the importance of ongoing mental health services following a disaster and the importance of understanding the barriers to care.

And when we looked across rescue recovery groups there was a range of prevalences of PTSD from seven to 24 percent. It was lowest in the police and it was highest in workers who were least likely to have had any prior disaster experience or training, such as sanitation, construction, and the spontaneous volunteers.

Now what you see next under the risk factors are some 9/11-related risk factors and others for probable PTSD, so the 9/11 is being caught in the dust cloud, witnessing horror, being injured on 9/11; also heavy dust in the home and the workplace, which has been mentioned earlier today; for rescue/recovery workers, early arrival, longer duration of rescue/recovery work; and then event-related loss of job or spouse and low social support. So the ones I've highlighted in gold-colored font are also risk factors for new-onset asthma after 9/11. And for rescue and recovery workers, delay in deploying a mask or respirator after 9/11 was also associated with new-onset asthma.

So let's turn to asthma, and this is the annualized incidence of new asthma post-9/11 in persons who had no history. And the asthma rates

were significantly elevated after 9/11. They were highest in the first 16 months. The rate in 2001, which was about three percent, was six-fold higher than the general U.S. population rate. And then you can see it declined starting in 2003 to less than one percent. And there was an increase in 2006 which we think is just attributable to the fact that we were asking about asthma again in the wave two survey, some recall. The fact that so many of the people who were diagnosed after 2003 had actually reported symptoms of wheezing before 2003, we suspect some of the late diagnosed asthma may actually be 9/11 event-related asthma that was just -- had a late diagnosis.

By 2006/7 12 percent of rescue/recovery workers and eight percent of other enrollees had new-onset asthma, first time. And there was a similar pattern in annualized incidents of asthma among the children enrollees in the registry.

I wanted to talk about some recent findings. Some of these were actually presented at the October WTC research seminar, but I wanted to mention some of these. The first was a result of a collaboration between the registry and NYU Bellevue. It was a nested case controlled study of residents and area worker enrollees which were -- sort of tended to be more of under-studied populations post-9/11. And the oscillometry and PFT testing showed lower airway disease among residents and area workers that were associated with persistent symptoms at waves one and wave two and exposure.

And we also, in the second finding reported here, we looked at 9,300 rescue/recovery workers who had worked on the Pile, and those that reported wearing a respirator were less likely to report symptoms and -- respiratory symptoms and conditions than those that reported no or lower levels of rescue -- of respiratory protection. Predictors of adequate respiratory protection we found were working in the construction, utility or remediation trade, having had prior respiratory training. And it came up earlier that there was mixed degree of respiratory protection on 9/11, and we actually found in this study that 50 percent reported no respiratory protection at all on 9/11.

And the third -- the third recent finding is risk factors associated with heart disease, and we reported dust exposure and the psychological trauma was associated with an elevated risk of non-fatal heart disease two to six years after 9/11, and that PTSD was independently associated with heart disease.

Then the last bullet, we also found, looking at about 37,000 adults, that persistent symptoms of GERD, gastroesophageal reflux disease, were common. It was actually reported by 13 percent, and that those symptoms were associated with 9/11 exposures, independent of both asthma and PTSD, 'cause it's known that you can have elevated GERD symptoms when you have asthma/PTSD, so it was important to look at that independently.

Other recent findings was -- here's one case of a less common physical effect. It was a nested case-controlled study led by Dr. Jim Cone, who's here, on sarcoidosis after 9/11, and that was found to be associated with rescue/recovery work on the Pile, and there were 43 biopsy-confirmed cases. It was actually one of the largest studies of sarcoidosis out there.

Back to the volunteers, I mentioned we have 5,000 volunteers in the registry, and the study here compared the lay volunteers or people that spontaneously arrived at the site, and compared their health to the volunteers who reported they were affiliated with organizations like the Red Cross. And we found that the lay volunteers arrived earliest and were at greatest risk for post-9/11 first time asthma/PTSD compared to the affiliated volunteers.

Last one on this slide is a paper that was recently published in the special Lancet volume where we reported the initial results of the registry's ongoing mortality study. The overall mortality reported was below population rates, but we did report elevated all cause and cardiovascular mortality among the intensely exposed survivors relative to those who were less intensely exposed. And by intensely exposed in that analysis were individuals that had more than one injury on 9/11 and residents who did not evacuate from the home, as well as school children who were present in their school in lower Manhattan on 9/11.

Wanted to now begin to talk about some of the ongoing research that we have at the registry, and fortunately we obtained consent from enrollees to do matching to other health registries -- that we obtained in 2003/4 at the time of enrollment. So we have three sets of matching activities that are ongoing. The second one I'll mention first because that -- that I've mentioned we published the initial study, but the matching to vital records and the National Death Index to ask the question 'Is there evidence of excess mortality among enrollees; and if so, are they related to 9/11 exposures?' That's ongoing, initial findings published. The top is -- refers to matching to state cancer registries, and

we matched to eleven that comprise about 90 percent of enrollees, and we have a similar research question that we're asking, but in this case with regard to cancer.

The last item is matching to New York State hospital discharge data, and we're looking to that as an important tool to validate, again, registry self-reported -- of outcomes, for example, heart disease. And the good news is the first installment has just arrived. We haven't received all the data requested, but now we're, you know, in a position -- hopefully in 2012 -- to actually -- to begin working on that.

We have a lot of analyses underway. I just wanted to list some of those to give you an idea what to expect in the future. **[identifying information redacted]**, who's the founding PI of the registry, presented at the WTC seminar in October on unmet health care needs. And I think it's going to help us understand better which groups have perceived unmet health care needs. The registry also has done focus groups with survivors to talk about their perceptions of health care and access, so I think those two together will help us understand better how to conduct outreach to different populations that are affected by 9/11. The referral evaluation will also give us a handle on how many people who scheduled visits actually kept them, and to help us understand if health status has improved.

We're also looking at injury on 9/11 and asking the question about long-term health impacts. We're asking questions about the relationship between 9/11 exposures and heavy or binge drinking among enrollees. We're asking the question about pediatric asthma, so we're looking at the wave two and we'll be looking at wave three asthma data in children. We also have almost 300 pairs of parent-child enrollee data, and so we're looking at -- similar to what was done by external researchers -- is parental PTSD related to stress symptoms and behavioral problems in children.

And then of course the whole wave three survey that we're going to complete in March gives us an opportunity to look at the continued course of symptoms and conditions previously reported in asking about new or emerging conditions.

Just a little bit more about the initial cancer study that's underway now. The methods are to compare incident cancer observed cases with expected cancer cases. The population for the initial cancer study are our enrollees, who are New York State residents on 9/11. The source of

the cancer data will be linkage with state cancer registries through 2008. We'll be looking at the first primary invasive cancer or borderline bladder. And the comparison population will be New York State reference population rates, and the person years calculation will be based on the time of enrollment into the registry to the time of cancer diagnosis, death, or the end of 2008, whichever is earlier. The timeline -- I can tell you we're working hard to have a paper submitted early in 2012 as possible, and we're also -- of course it's hard to tell when there may actually be a publication, but we're also hoping that's as early as possible in 2012 because I know this Committee would find that information helpful.

Just want to talk a little bit more now about wave three, 'cause it is our ten-year follow-up. We launched in July and by 9/11, the tenth anniversary, all 67,000 adults in the registry were sent a survey. And like wave two, we have three modes. We're offering the web, paper and telephone. And we're offering the surveys in Spanish, Chinese and English. We have -- we're approaching the 30,000 milestone, 30,000 completed surveys. The response rate is 44 percent. And it's interesting that among those who responded to the wave two survey we have over 50 percent of the surveys back. So that's a high-responding group, which will give us a third point in time for large numbers of enrollees.

And as was the case in wave two, the rescue/recovery workers are responding the best so far, and we've started building outreach in lower Manhattan with the help of our community advisors, and we do plan to do door-to-door outreach to try to boost the response of some of the other groups, and local media outreach as well.

Now the child survey was launched November 1, and we now have 1,200 children who are below the age of 18. And actually at this point, ten years post 9/11, all of the children are adolescents ten years and above. So we had a separate survey booklet for the parent and one for the adolescents. And for the first time we're offering a web-based survey both to parents and children. We thought that might engender a better response than we had last time. And we're offering the paper in three languages.

And I just wanted to briefly mention some of the new content for the child survey. We have well-being on the adolescent survey. We have school functioning, school engagement. We're asking questions for the first time about illicit drug use and use of prescription drugs. And for

the parents we're getting more information on their own physical and mental health status.

I thought you might be interested in just a tad more detail on the content of the adult survey, so we're getting updates on wave two items, physical and mental health symptoms including asthma and heart disease. On the mental health side we're again having a PCL checklist for probable PTSD, the K-6 scale for severe psychological distress and diagnosed mental health conditions. We're getting more information on health status and quality of life and functioning, social support, life events and alcohol use. And then we're also asking again about use of the WTC programs and unmet needs.

What we've added new to the wave three survey is more questions to get at GERD rather than GERD symptoms. We're asking about sleep apnea and other respiratory conditions. We're asking more about medications and hospitalizations for health conditions as an indicator of severity. We've added asthma control both to the pediatric and the adult survey. We have for the first time scales for depression and anxiety assessment. We're getting for the first time a history of trauma 'cause we need to take that into account in understanding PTSD and depression. And we're getting information on health insurance coverage.

But the survey length, since we're no longer asking about exposure issues, we've actually managed to still retain about a 20-minute length survey.

I had mentioned earlier we have a treatment referral program, and it's interesting and worrisome that, despite multiple rounds of outreach by the registry and certainly quite a bit of outreach by the clinical programs, that we have large numbers of enrollees who are just not well-informed about the WTC clinical programs. And so our treatment referral program started through a subcontract to HHC's Environmental Health Center, a World Trade Center of Excellence. So what we were trying to do is encourage the eligible survivor enrollees to seek care at the Bellevue Clinic at no cost to enrollees. And so our initial focus was of course the residents and area workers who were in New York City, and we focused on those who had unmet health care needs, as well as either physical symptoms and/or probable PTSD, and we got guidance from Joan Reibman about which symptoms, you know, to put in that cluster. And we did personalized outreach, which was different from what we

had done in the past. We had personalized letters and telephone calls, and we have staff who are trained as nurses and we have a pharmacist, someone who's -- has a pharmacy background leading the unit. And we've reached out to more than 9,000 enrollees to date, including a large number of people with PTSD symptoms. And the good news is that about 1,000 enrollees have actually made their first appointment at the EHC center. And what's good news in there is that some of those enrollees are enrollees with PTSD. So it seems like we're learning some new things about how to do successful outreach to these populations, particularly people who have the avoidance characteristic of PTSD.

And now of course the program's referring our enrollees to the WTC Health Program, and we're planning to include survivors outside the New York City area. And we believe that the registry is an untapped source for WTC Health Program outreach to that population, as well as rescue and recovery workers.

So let me just conclude on some next steps and priorities. We are going to complete the wave three survey by March of 2012. This would actually be a much more compressed time frame than we've had in past surveys. We plan to submit manuscripts based on ongoing research, including the initial cancer study and analyses of wave two and three data. We're going to share findings with the public, enrollees and policy makers. We do post-publications on the website. And in order to keep all this going, we're going to need to apply for continuation funding from NIOSH. We are currently funded under a three-year cooperative agreement and we're anticipating that early in 2012 we'll be writing that continuation application.

Thank you.

WTC ENVIRONMENTAL HEALTH CENTER/
HEALTH AND HOSPITALS CORPORATION

DR. WARD: Dr. Joan Reibman.

DR. REIBMAN: Good morning. It's my pleasure to be here, and many of you I know and many of you I don't know. And I would like to do today is sort of, as the only clinical center for the non-responders or the survivors, I sort of have a heavy load to lift because I have a large diverse population to talk about and so I'm going to take a few liberties. But and I also apologize for not giving you a handout.

Let me start by first giving you a little definition that I think you're hearing throughout the day that is a little confusing. What you've heard

is Health and Hospitals Corporation. That's the corporation that oversees the public hospital system in New York City. There are a number of hospitals, one of which is Bellevue Hospital, which you've heard about today, too. Many of those hospitals have academic associations. And so for example, Bellevue Hospital's associated with NYU, which is why you're hearing NYU Bellevue so much.

What I'd like to do today if I can figure out how to do this and I do right -- is that what it is? Yeah. I apologize for showing this slide again. I do it for a purpose. One, to remind you that, again, we think of lower Manhattan as a financial area, but it actually -- as you've heard today from so many people -- is a large residential area and also has a huge working population. These -- the data of the number of people who were down there around 9/11 comes from the World Trade Center Registry. Again, I show that to you because it strikes terror in the heart of the government when they look at these numbers of potentially 60,000 residents, 300,000 area workers and 15,000 students who might have been exposed. And when people start thinking about whether these people are sick, it raises enormous concern.

What I'd like to do today is a little bit -- talk about the problems with disaster exposure science and the community at risk, the background history of the World Trade Center Environmental Health Center Program, the clinical findings that we have, and certainly touch on unanswered questions.

I don't need to go into this audience about the basic tenets of environmental human exposure science, except to say that when we think about that, what you've been hearing today from responders, from community members, is that in fact those tenets are very difficult to do when you're talking about what we're really talking about today, which is environmental disaster exposure science. And that's because the systems are in disarray, politics and economics complicate questions of potential health risk, exposure assessment may not be feasible, and disease assessment systems may not be available. And so therefore you're hearing, ten years later, many of the problems because of these issues.

The first question for the community was did World Trade Center dust or fume exposure pose a health risk to the community, was really a difficult question to ask. Again, you've heard today about risk denied by the EPA, about warnings that -- about procedures that were told to the

community and that local workers returned soon after the event, and that the concept of potential health risk to the surrounding community was only accepted after prolonged delay. And it took many, many people working to get that word out that in fact there might be a description -- a problem.

You've heard people ask about what were the exposures, and I'm not going to go into them except to show you that most of the details about the potential exposures came from academic institutions, as well as other sites, and the key things were that there were huge numbers of small and large particles that -- as you've heard, the dust was very alkaline but that there were many, many other components. And as you're going to hear as people start talking about biologic plausibility, that there were huge other chemical constituents with potential health risks.

So how does one do exposure assessment for community members? And clearly for us it's been complicated by the wide variety of exposure possibilities -- the variable amount of time in the area that people had, whether they were there on 9/11, whether they were evacuated, whether they did not evacuate, whether they returned episodically to clean. And there were no studies done immediately after the event to assess exposure history -- assess exposure, meaning we had to rely a lot on recall, which all of you know is limited.

So again, you've seen these pictures, but I show them to you to remind you about exposure and what it means to us when we talk about acute exposures, we talk about dust cloud exposure and -- and in our clinic we say 'Oh, another dust cloud person.' These were people who were heavily coated in the dust. But it's not so simple because some of them had heavy coating, some had less -- were less coated. Some were there when the debris fell down before the clouds -- before the buildings collapsed. And there was also extensive dust in the afternoon.

We talk about chronic exposures, which are much more difficult to assess, including outdoor exposures -- and this is a picture of the workers returning on 9/11 -- on 9/17 when you can see that the streets were still heavily coated in World Trade Center dust. We talk about chronic exposures to indoor -- and these are pictures of people's apartments, these were their furnishings. And we talk about the fact that some residents were evacuated, many others were not. But we do know that the chemical composition indoor was similar to that outdoor.

And then we talk about gases and fumes.

But how do we put that all together for an exposure assessment? Well, it's been very, very difficult. Most of the time we just talk dust cloud; it's the simplest way to look at it. I take this picture from a publication that's in press in a collaboration we did with the World Trade Center Registry by **[identifying information redacted]** (ph) where she tried to look at acute and chronic exposures and do them by a principal components analysis, putting all of them in the mix. And what she basically concluded is that both acute and chronic exposures independent –- were independent risks for persistent lower respiratory symptoms in the residential and working community, suggesting that what we're saying by just saying acute exposures is inadequate, but we don't really have a handle yet on how to look at chronic exposures as well.

What do we do about disease assessment in the community? Well, it's been very difficult. Most of the -- really the -- we were alerted as an academic community to this really by the October 11th Pace University community forum when many of us were asked to be on a panel, and most of us had no answers. On that panel were also members of the FDNY, also organized labor, also Mt. Sinai representatives, and many community members were in the audience, all of whom were wearing dangling masks and coughing and saying should we be concerned or should we not, and we really had no answers at that time.

So we set out with the New York State Department of Health to do a residents' respiratory health study in October 2001. We obtained funding by the CDC, and this was a cross-sectional study of a control and exposed population. We did an exposed population surrounding Ground Zero. The control population was -- not on this picture -- in upper Manhattan. And we designed, implemented and completed the study 16 months after 9/11. It was a very difficult study. There were no -- mailing systems were not working. We had to go and do this by hand on site. We were lent really a lot of effort by the community. We were lent sites to do lung function testing, et cetera. We over-sampled the exposed community because at that point we were the first ones out there to really be looking at the exposed community, and we thought that this would be perhaps used for later studies later on.

And basically simply what we showed was, not surprisingly, that there was an increase in respiratory symptoms -- whether it was cough, wheezing, chest tightness, shortness of breath -- in this population a

year and a half after the event, and that these symptoms remained a year and a half after the event; that in fact one could also document that these symptoms were not just being reported, but they were associated with unplanned medical visits, with new use of fast-relief medicines -- Albuterol -- and with controller medication in the exposed population compared to the control population. And furthermore that the risk of developing these symptoms, whether they were new upper respiratory or new lower respiratory or persistent upper or persistent lower, was associated with the persistence of dust or odors in the home.

And so these were some of the early studies to document that in fact there was a civilian or community or non-responder or survivor population, as they're now called, that was also at risk for adverse health effects from exposure to the World Trade Center dust and fumes. And my pointer's not working, but as you heard from Mark, many of these studies have now been done and confirmed and supported by the number of World Trade Center Health Registry studies that have been done.

We then began a clinical program, first as an unfunded pilot project with community groups -- actually Beyond Ground Zero Network and other groups that are sitting in this room -- because people came and said can you treat us, and we actually didn't want to because we weren't funded and we didn't have a place to treat anybody, but we put people in our asthma program and began a small pilot program. We were eventually funded by the American Red Cross Liberty Disaster Relief Fund in 2005 to just do a treatment program, and in 2006 we obtained funding from the City of New York for a treatment program, and in 2008 we had our first federal funding from CDC/NIOSH.

These fundings were to do treatment. That is, we were never funded to do a screening of non-symptomatic individuals. We were always funded to do treatment for self-referred individuals with presumed World Trade Center-related illness. We worked with community members to define geographic exposure boundaries. We worked to define what kind of symptoms, and we tried to stay inclusive because we didn't know what to expect. We were initially not funded to do isolated mental health but only physical. Subsequently, with City funding, could we treat people who also had mental health symptoms.

Our target populations were the non-rescue and responder workers -- although, because of our initial funding, we had a small population of

rescue and recovery workers. But really our target population was residents, local workers, students -- and because of who we are, we also had a large number of cleanup workers.

And so we developed -- really working in parallel to the responder programs -- a multi-disciplinary treatment program providing medical, mental health and social services. And to date we have recruited nearly 6,000 individuals into this program, starting in September 2005 to September 2008.

Just briefly, because our population differs again from what you've been hearing about, these are early population of almost 2,000, the differences are we are -- have a large number of women in our clinic. This is very different from the responder populations. We have a very mixed race ethnicity, which -- a large Hispanic population. And consistently about 40 percent of our populationsay that they were in the dust cloud on 9/11.

Again, I don't have a pointer so it's hard to show this, but basically what I'm showing here is that when we ask our population what are their symptoms, whether they are a resident, a cleanup worker, a local worker, the symptoms are those we have been hearing about over and over -- cough, lower respiratory symptoms, cough, wheeze, dyspnea, chest tightness, et cetera. So the populations, regardless of whom they are, are having the same symptoms.

One of the areas we became interested in was what really were these illnesses. This is one very -- one simple case, a 37-year-old gentleman, previously healthy, not in the dust cloud, developed shortness of breath, came into our program, had wheezing, had spirometry shown in the little picture on the right -- that was classic for asthma. And so he's no problem for us. We say he has asthma and we can treat him. We know how to treat him. We feel very comfortable.

However, not everybody presented that way. And in fact, if you look at our lung function distribution similar to the responder, what you find is that in fact most people -- if you look at spirometry pattern, most of them have normal spirometry. Only a small number have an obstructed pattern consistent with asthma. Many of them have a reduced vital capacity; that is, a slightly reduced lung volume. And a small number have both an obstructed and a low vital capacity.

So we weren't sure what that meant and how to explain that, and there are a number of things one can ask about, including are these patients,

like an asthmatic, just have retained their lung function but they're hyper-responsive, or are we not detecting the abnormalities in the lung, do we need more sensitive assays? Or are they not even lung symptoms, that people have cardiac disease or mental health? And all of those questions remain of interest.

What I wanted to show you today is -- and this is reinforced by the fact that if you look in the firefighters -- and David will talk to you more and more about this -- and if you look at them in one point of time, they have normal lung function. If you look at them longitudinally you can see that in fact there's a decline in their lung function. But we didn't have that opportunity. We didn't have the early lung function in these patients. So we were just looking initially at one point and now, later on, longitudinally.

So we tried to ask are there other techniques we can use that might in fact be simple, because we couldn't do methacholines on everybody, but might be simple to identify are there other ways we can look for abnormal lung function. And as you heard Mark talk about, we did a collaborative study with the World Trade Center Registry looking at a technique called impulse oscillometry, which is non-invasive, which can be interpreted in a number of ways, one of which is to say that it might suggest that there's abnormalities within the distal airways that might not be detected by spirometry -- and I have a typo there, but that was this morning. Basically what we showed with the registry is that if you look in the shaded boxes, that's one of the measurements of impulse oscillometry in which you can see consistently across BMI -- we put BMI in because obesity is known to interfere with measurements -- but consistently across these groups that the patients who had symptoms, compared to those who did not have symptoms, in white, that the patients who had symptoms, in gray, consistently had higher oscillometry measurements, even if they had normal spirometry.

So that suggested to us that this might be a way to start to tease out some of the mechanisms or some of the reasons why people had these symptoms, even if they had normal spirometry.

We have done this consistently in our population in the clinic as well, but we didn't have a control population. So working with the registry allowed us to have a control population and that was very beneficial to us. And what you can see here is that the first box on the left is an asymptomatic group, and this is the measurement -- their oscillometry

measurement. And the other gr-- the other boxes are -- all are clinic patients with symptoms, and what you can see is that they have, regardless of their spirometry pattern, they tend to have higher oscillometry measurements, even if they -- and even if they have normal spirometry.

So this suggests to us that perhaps this is a tool that we can use, in conjunction with everything else, to try to figure out what are some of the causes of some of the respiratory symptoms in this population, and we think that that's helpful.

One of the other things we have done in this program is to look at pathologic findings, because we felt we didn't fully understand the disease. And so we did a case series of 12 patients who had clinically-indicated open lung biopsies. This is not an easy thing to do. We don't do this regularly. We don't like to do it. These were patients who either had abnormal CAT scans that we couldn't interpret or had very severe lung function findings. We ran these findings through four pathologists and none of -- only one patient could they come to a conclusion with a firm diagnosis. Most of what they felt they could do was describe what they were finding, which was a little bit of patchy fibrosis or scarring in the lung; a little bit of bronchiolitis or small airways abnormalities, that is inflammation around the small airways. Surprisingly, they described emphysematous changes -- that is loss of alveoli -- in all of the patients. And also uniformly they identified intracellular birefringing particles under polarized light microscopy.

So here is one of these patients, and what you can see is the CAT scan on the upper left. Panel A is the -- is a high reso-- cut through a high resolution CAT scan. It's basically pretty normal. Panel B is an expiratory film in what you can see is some areas which are dark. That's air trapping; in other words, the air is not being cleared out of the lung. Panel C is one of the biopsies in which you can see there is -- it looks a little lacier than it should be, but then there's some little areas of blue which are areas of inflammation. Panel C (sic), there's an arrow pointing to something that's a little difficult to see, but it's a particle within a cell. And if you look in Panel E, there's something that glows out, and that's the particle that's in the cell.

Now most things don't glow. Certain things do glow, and what we did do is send this to be analyzed by scanning electron microscopy, and what was -- been described in these patients is that in the patients there is

silica, aluminum silicates, titanium, talc, and a variety of metals which are unusual in human beings, including steel, copper and chromium.

So that suggested to us again evidence that these were in fact inhalational injuries that could most likely be due to World Trade Center exposures.

And what we also know now is that what we are seeing is a diversity of respiratory illnesses that include upper airway, include nasal, sinus, cough, irritant asthma is what we call the asthma now, airway damage including bronchiectasis, sarcoidosis as you heard, and a variety of interstitial lung diseases in a small population, and that these depend on the dose and clearly individuals' susceptibility that we don't understand in these populations because we know that not everybody is susceptible to all of these.

Finally -- two other things -- finally, one of the things we have been doing is looking longitudinally at our population at lung function. And surprisingly, what we have in our early data that we had submitted is that in fact overall what we are seeing in a population sent to us for treatment is that there is improvement in lung function in this group as a whole; that the improvement differs depending on the entering pattern of lung function -- that is, whether they started out normal and in fact they get better, even more normal, which suggests that the normal was a statistical normal; that the low vital capacity group improves; that the obstructive group improves their obstruction; and the group who have both obstruction and restriction in fact improve. So that's very helpful to us.

Except as you see here, very quickly, if you look at the group as a percent of predicted where they should be, shown in the red bar, the white is their initial, the shaded are their follow-up, what you can see is that the normals are normal, they get a little better, they stay normal. The low vital capacity improves but does not reach normal. The obstructed -- they improve their forced vital capacity on the left, that's their volumes, but they don't improve their flow to normal. And the low vital capacity again improve. The low vital capacity obstructed group improve, but don't improve to normal.

So what we are saying here is that although we are seeing improvement in those who started with abnormal patterns, they are not reaching back to normal over time.

One other thing -- we looked at this, again looking at longitudinal lung

function, now grouping our population as a potential exposure category -- resident, local worker, rescue/recovery, cleanup. And what you can see in yellow is that surprisingly, although the local workers improved their forced vital capacity a little bit, it didn't reach significance, and they didn't improve their flow to an extent that reached significance -- suggesting that there's something about the local worker population that's a little bit different, that they're not responding as well, and we don't really understand why that is.

We have also -- because our patients were enrolled for physical conditions, not for mental health, but underwent mental health screening, again using the PCL, we looked at who's at risk for probable PTSD in these patients. And several things came out that were interesting. One that, because we had such a large population of women, that women were at higher risk. Low income clearly puts someone at risk, as shown in red. And also shown in red being in a dust cloud puts someone at risk. And having respiratory symptoms, both upper and lower, puts someone at risk. And we use a dyspnea score, which is a score of degree of shortness of breath. And the greater the dyspnea score someone had also puts someone at risk for having potential PTSD.

Finally, you've heard a lot about children, and we have a pediatric program which we have had a lot of difficulty recruiting children into, for a number of reasons that -- some of which are known, some of which are unknown to us. What I'm showing here is data I should not be presenting because it's very, very, very, very, very preliminary, but just because it's interesting. But if we look at our first 80-some-odd children in whom we have full data, because our datasets are not closed yet, then in fact we see a lot of -- a lot of girls. We see a diverse race ethnicity, again with a 20-some-odd percent Hispanic population. We see that almost 40 percent of these children were caught in the dust cloud; that about 20 percent say they had a heavy volume of dust in their clothing or hair. Many of them had dust in their home, and 60 percent of them were in school in southern Manhattan on 9/11, suggesting that in fact this may -- this is an important group to start looking at. These are -- anyone who was 18 or younger on 9/11.

If we start looking at lung function -- and again, lung function -- we have to use different parameters for kids -- that in a population who came to us, about 20 percent said they had a new asthma diagnosis. The mean

latency was at -- of that was about three years. And that if you just look very simply, what's -- as a simple exposure -- again, dust cloud, 'cause it's the simplest exposure measurement you can do -- then in fact dust cloud was a risk for an abnormal ratio of FEV-1 to FVC, that is flow, and also for an obstructive pattern, suggesting again that we need to look at these children much more carefully; that there are issues that we haven't teased out in them.

There are many, many unanswered questions in the survivor population. There are a huge number of medical questions. I didn't even touch on cancer risk because our population is a self-referred population. We can describe what we're seeing. We can't give rates for population rates. There are lots of questions still in terms of the lung disease, what's the long-term progression, what are the types, how should we be treating these diseases, are there autoimmune or connective tissue disorders, are there neurological sequelae including headaches, peripheral neuropathies; who's vulnerable, who's not vulnerable, what are the populations that are at risk? We don't know the answer to those. Huge number of mental health questions -- who's at risk for persistent PTSD, what are the long-term outcomes of PTSD, how should we be treating PTSD in civilian populations, particularly when they're associated with complex mental health issues, multiple comorbid conditions and huge socioeconomic stresses, and is there a risk for cognitive defects in people who have persistent PTSD? And as you've heard, we have a huge number of unanswered questions in the children -- what are their lung risks, are they developmental, are there endocrinologic risks, and what are their mental health issues?

And I'm stopping there, and I thank you very much.

FIRE DEPARTMENT OF NEW YORK
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DR. WARD: Now we'll hear from Dr. Prezant.

DR. PREZANT: Thank you for inviting me here today. I'm going to take a little different tact in my presentation. I'm going to try to -- of course the temptation is to give you an overview of our program, and there are certain things that I will touch on that are overview in nature. But I'd like to concentrate on providing you with three specific issues.

One, understanding the unique exposure and the unique fact that our cohort is not self-referred and therefore is the only cohort that can do

true incidence and prevalence analysis.

The next thing I'd like to concentrate on is showing you how that exposure has impacted on health outcomes, including cancer.

And then finally, I'd like to make some brief comments about where I think future research should go.

You've already heard about the immense dust exposure and the tragedy on that day. The New York City Fire Department has approximately 16,000 rescue workers and recovery workers that were exposed to the dust. This 16,000 group is comprised of New York City firefighters and officers, New York City Fire Department EMS workers and their officers, as well as selected pre-9/11 retirees that came in to help us with our rescue/recovery effort.

We've heard about the dust exposure, that the dust cloud is the largest exposure, and I'll show you momentarily that we had 1,600 -- ten percent to 15 percent of this workforce -- that was there during the dust cloud.

We've heard that the dust is alkaline in nature, and that much larger particles than would be expected by physical science research actually penetrated into the lower airways.

And important when we think about biologic plausibility, that there was asbestos, silica, fibrous glass, volatile organic carbons, PCBs, dioxins, et cetera, that have all been shown to be components of this dust.

Now if everybody was in the space suit that someone else referred to earlier today, there would have been no respiratory exposures, and probably no systemic exposures. But as shown, that was not the case.

Firefighters had the best respirator on the planet Earth, a self-contained breathing apparatus. However, it lasts for only approximately 15 minutes. Thereafter, normally in a fire we bring either new firefighters in or, rarely, we bring new bottles in to the firefighters that are there.

Given the fact that this was an attack on New York City, we were unable to do that. And then we were unable to get them P-100 respirators for approximately a week or more. And after that, the nature of this work is so hazardous that these type of P-100 respirators that you see here really are not conducive to communication, they're not conducive to comfort, they're not conducive to outdoor rescue/recovery work, all right, in difficult conditions.

We know that large particles did get down into the lower airways. We have many collaborative studies going on at the fire department. One of

them is with NYU. And here was a firefighter who developed acute respiratory distress after having worked down at the World Trade Center site for 20 of the first 27 days, and became severely hypoxic, was taken to the emergency room at Bellevue, was intubated and was bronchoscopically lavaged. And as we published with NYU, there were uncoated asbestos fibers, degraded fibrous glass, and fly ash particles, which are large elements of pulverized concrete, down in the lower airways and alveoli. This is stuff that normally, in a low-density exposure, would be confined to the nostrils and sinuses. But in this type of exposure overwhelmed our normal respiratory protective mechanisms and penetrated down below. This is an isolated firefighter who was extremely ill, all right.

However, we found the same thing, or similar issues, on ambulatory, mildly symptomatic firefighters which we published with an Israeli collaboration in 2004. These are 39 firefighters who had induced sputum -- they did not get lavaged, they did not require intubation, they were walking, healthy firefighters. They had their sputum induced. They coughed up this sputum. It was analyzed for dust particles, and in their dust particles were very similar to World Trade Center dust, and there was an exposure gradient -- which I'll get to in a moment. Every one of our studies, with rare exceptions, has demonstrated an exposure gradient based on arrival time.

Understanding that there was dramatic exposures, that there was symptoms occurring from day one that were unusual for any type of a fire, we started the first long-term medical monitoring and treatment program, starting monitoring on October 5th of 2001.

(telephonic/electronic interference) ...our previous disasters, and we also knew that our cohort, our patients, our members would be asking repeatedly about late-emerging diseases. And therefore we immediately set up to take in information about things like cancer and autoimmune diseases.

Typically in an environmental disaster -- I'm sorry let me restart that. Typically in an occupational exposure we count the number of days exposed as an occupational worker. We're able to say you were in a particular area of the factory or the sandblasting area or the quarry, and therefore your exposure -- as long as you weren't wearing respiratory protection -- was the same each one of these days. Count up the days, count up the hours, and you're able to get a very nice exposure gradient

that really is based on duration. And if you have specific air contaminant information, you can even express it more than just hours, days, years. You can even express it on the basis of the number of particles or the amount of that chemical or asbestos fiber that has been inhaled over time.

That is not the case in an environmental disaster. If we were still looking for modeling data based on the various different amounts of chemicals and dust that were out there and what the air quality demonstrated day one, day five, day 15, people are in different areas, some are crawling into crevices, most of our firefighters were in fact crawling into crevices -- they're being exposed to air that was really more typical of day one. So any type of complicated modeling will never answer an exposure response gradient for this workforce.

Rather, we found that initial arrival time is the best exposure response gradient. Day one in the morning, you're exposed to the dust cloud and the collapse. And from a mental health perspective, you're also exposed to the most severe, life-threatening conditions, as well as the loss of your coworkers. On subsequent days -- day one, day two and the beginning of day three -- there's still immense dust cloud exposures to everyone, no matter what they're doing.

The night of day three there were rains, but that does not eliminate the dust exposure. The dust exposure persisted for all the reasons that you were -- that you heard about earlier this morning, including persistent fires. But for firefighters and certain other workers, even day three, day 14, day 20, they're actually crawling into crevices and having exposures that might be similar to day one, though in a much more isolated fashion.

Therefore, we found that doing this type of gradient -- day one, day two, day three through 14, and after day 14 -- was our best predictor of disease, and our best predictor of both physical health and mental health disease. Duration is a mild predictor, and most of our workforce -- the median amount of months that our workforce spent down there was four months. And we do have, for some of our outcomes, duration being a useful predictor. Because all of our workers were down there -- you can see from this graph, way over 80 percent of our workforce was down there in the first week, we are not able to do exposure gradients based on the use, or lack of use, of a respirator because they did not have a respirator in that first week.

This will take too much time to go through, but I just want to mention to you that we have a variety of medical questionnaires that we update. Our questionnaires have been used by the other groups as well, as we have benefited from their questionnaires. These are both mental health and physical health questionnaires that utilize the same PCL-17, depression scores, et cetera. We do spirometry and many of the other tests. And then these move on to treatment referrals as needed.

All of this data is processed and is available for analysis, and has been the basis of every sentinel study produced after the World Trade Center exposure via collaborations with Albert Einstein College of Medicine, Montefiore Medical Center, NYU, and to a lesser extent, Robert Wood Johnson. This is a critical thing that we are able to analyze this data. Why? Because arguably we were the most exposed workforce. But very clearly, we're the only workforce that knows the denominator of those people that were exposed. We have pre-9/11 data on every one of our workers, so we can have an objective comparison. We know the exact number of people that were down there so that we can -- this is not a self-selected group. And by analyzing this data, internally and with outside collaborators, we are able to provide analyses and information in a very rapid approach and then seek corroboration through the other data Centers of Excellence.

But it is also important because our individual members, when they come in they ask two questions, repeatedly. And that's why this data is useful on a micro level as well as a macro level. Our members come into our program because they know they can get outstanding medical care. The first question they ask, 'cause they're humans, 'How am I doing?' The second question they ask is 'How are my buddies doing?' And because of that we've been able to work with their representatives, the various different unions, to make it clear that research is not a four-letter word. Rather, it is the only way that we can provide people with credible answers, and then adapt our treatment protocols to meet their needs.

And the proof of this is the fact that this is the most successful labor-management health and safety initiative ever. We have provided 15,375 baseline medicals to a little less than 16,000 people that were exposed. This is over 98 percent compliance. We have over 95 percent compliance with our second exam, over 90 percent compliance with our third exam. We have already over 82 percent compliance with our

fourth exam, and that was just started in 2008. Give us another year and that will be above 90 percent as well. Longitudinal dropout is minimal in this workgroup, and we achieve this without spending one dime on health care advertisement. This has allowed us to be the sentinel group for first demonstrating the World Trade Center cough syndrome in September 2002, and demonstrating the exposure response gradient that I've already discussed based on arrival time; that the World Trade Center cough syndrome is obstructive airways disease, chronic bronchitis and asthma, along with sinusitis and GERD.

We've published on several occasions both cross-sectional and longitudinal analysis of how their symptoms have gone over time. They started with cough and sore throat as their main symptom, and as you can see, those are the -- at around 60 percent on year one. If we had looked at this on week one, they would have been over 95 percent.

By year eight, and this is true even in year ten, the cough and sore throat have dropped down to less than 20 percent. But the other symptoms -- dyspnea, wheeze, sinusitis and GERD -- remain in the 35 to 45 percent range.

We looked at lung function because we have pre-9/11 lung function when we were able to demonstrate very rapidly that there was a tremendous drop in lung function in the first six to 12 months. We then followed that up with a seven-year study, began demonstrating minimal longitudinal dropout, with the median length of time being over six years in both our firefighters, our EMS people. And even if we break this down by active and retirees, we see the same thing. In total we analyzed nearly 62,000 spirometries. This was done in collaboration with Montefiore Medical Center and Albert Einstein College of Medicine, and there were -- and there were over 2,000 people in this group that were present during the early arrival time of this 13,000 people that were studied.

Here's our findings. The dotted lines represent extrapolated values for this group over time. They don't come from the published literature but rather from the pre-9/11 data themselves in this group. They were dropping at approximately 30 milliliters per year, which is normal for a male population. Those are the dotted lines. The blue line is what actually happened in our firefighters after 9/11 over the next seven years. There was an initial drop of approximately 350 milliliters, and that drop demonstrated an arrival response time gradient, which I'll

show you in the next slide. Thereafter, as a majority, they did not recover. Their lung function remained persistently low, without recovery. This is in contrast to what you'd see if there were normal smoke inhalation, which we have over 30 years' experience dealing with, and typically within two months lung function returns to the dotted line after normal smoke inhalation.

We see the same in the red line, which is our EMS workers. It starts lower because they have a lower health requirement for joining the workforce, and it starts lower because there are more females. In our firefighter workforce it's about 96 percent male. In our EMS workforce it's about 60 percent male. The red line, though, despite the fact that this is both males and females in EMS, despite the fact that they have a little less exposure in terms of their work tasks, demonstrates again a dramatic decline in lung function -- a little over 300 milliliters in the first six months -- and once again a persistent abnormality in that decline in lung function.

People have said oh, this must be because everybody's a cigarette smoker. The reality is that in the New York City Fire Department there are less cigarette smokers than there are in New York City. New York City on 9/11 had over 20 percent of its population smoking. The fire department had about 17 percent. And shortly thereafter we initiated a very aggressive tobacco cessation program, dropping tobacco to about seven percent in the fire side, and this was published in CHEST in 2004, the tobacco cessation effort.

But here you can see the fact that tobacco is not the major issue. The blue line this time represents never smokers. The red line this time represents ever smokers. You can see that although at each time point lung function is lower in the ever smokers, and that is a statistically significant effect, in reality the drop in lung function is predominantly in nearly all due to World Trade Center dust, and only minuscule impact of cigarette smoking. You can see this because the red line is only slightly lower than the blue line.

The exposure response gradient is demonstrated in this group because if you look at that first drop in lung function in the six to 12 months, in this study averaging 372 milliliters, you can see that there was the greatest lung function in those people called here early, which are people that were there in the morning of 9/11, slightly less reduction in lung function in those people who arrived in the next day, and slightly less

reduction in lung function -- but still substantial -- in those people that arrived for the first time at a later time point.

Now this resulted in many people becoming ill. This is not just a reduction in lung function, as I can show you -- as I've showed you already. There's a large amount of asthma, sinusitis, GERD-like symptoms. And in your main presentation, which I have had to excerpt some of the slides and not show you, this is also corroborated by diagnostic data, both internally at FDNY and by self-reported diagnostic data from their own physicians.

But we were very interested in looking at whether these drops in lung functions and these symptoms were due to obstructive airways disease or due to restrictive airways disease. Dr. Reibman presented some oscillometry data demonstrating that it was obstructive airways disease, for the most part, in her group. We approached this in a slightly different area -- again collaborating with Einstein and NYU on this issue. We looked at 1,720 people that were referred for in-depth pulmonary function testing. This would be bronchodilator response, lung volumes, diffusion capacity. And we found on the Y axis is the drop in lung function after 9/11. If you are less than one, you dropped lung function after 9/11. On the X axis on Panel A is a bronchodilator response, and this shows that the greater your drop in lung function after 9/11, the more likely you are to have a bronchodilator response; i.e., the more likely this is to be obstructive airways disease rather than interstitial lung disease. Likewise on Panel B, the greater your drop in lung function, the more likely you are to be hyper-inflated, to have big lungs. This again is consistent with obstructive airways disease rather than interstitial lung disease.

We looked at bronchodilator response correlated with lung volumes, again demonstrating more likely to be obstructive airways disease than interstitial lung disease. We looked at chest CAT scans, again demonstrating in nearly every case that this was air trapping rather than interstitial pulmonary fibrosis. And we looked at methacholine challenge testing, again suggesting obstructive airways disease more likely than interstitial lung disease.

When we put all of these findings together in that study we could find that there was some evidence for obstructive airways disease in about 60 percent of this group. Well, that raises the point, the question, well, does that mean that 40 percent had interstitial lung disease, 'cause that

is a substantial amount. And that is not the case. For the 40 percent we had no interstitial lung disease or obstructive lung disease. Time will tell what they have. In only 1.7 percent did we have evidence for interstitial lung disease, so it is very clear that interstitial lung disease is incredibly rare after World Trade Center dust exposure.

We do have a few cases of pulmonary fibrosis, two of which have required lung transplantation. We have 27 cases so far of post-9/11 sarcoidosis, and we demonstrated that sarcoidosis was the more likely disease that -- if you're looking at interstitial, though very unusual. There was a blip of sarcoidosis in the first year, and then a continued slight increase, and this was published early on in CHEST 2007.

Sarcoidosis is slightly different than we had in pre-9/11. Our rates are higher than pre-9/11. Again, by having pre-9/11 data we are able to show objectively change in population rates for our cohort. But in addition to the increased incidence, the disease itself is presenting differently. It's much more extrapulmonary, much more involving rheumatologic problems, and that these problems have required substantially different medications. The vast majority of people pre-9/11 did not require any medication for their sarcoid. Post-9/11 31 percent have required steroids, and nearly all of the rheumatologic cases -- here it's shown as three bone cases, but we now have almost ten cases. Almost all of them have required either Methotrexate or more expensive medications like Humira or Enbrel.

The other groups have talked about post-traumatic stress disorder. About 12 percent of our workforce had probable PTSD in the first year. About seven percent have it now on year nine. However, what this slide shows is based on arrival time. And what you can see in the blue line at the top of your graph is the incidence cross-sectionally of PTSD in those who arrived in the morning during the collapse. And here we have early on about 20 percent of our group having PTSD and nine years later about 12 percent. While in the other groups it is far lower. In fact, this 20 to 24 percent of PTSD in year one is almost as high as survivors in other studies -- survivors of the actual collapse or of other disasters, like in Oklahoma.

This has resulted, both the lung and PTSD issues, in over 1,700 retirees, 1,400 due to lung/World Trade Center disability, for a projected pension cost of $826 million through 2008.

And this prompted both the large number of respiratory problems, the

mental health issues, the exposure, the questions from our cohort -- 'Will I be coming down with cancer?' -- has prompted us to be the first to come out with this early assessment of cancer outcomes in firefighters. Our subsequent studies will concentrate on EMS, but our first study concentrated on our firefighters.

The study period was 1/1/96 to 12/30/2008, and we started off requiring that everybody be active on 1/1/96 so that we could have them all be similar on that date -- active, not retired. Because we would be comparing to U.S. data, we concentrated on white, black and Hispanic males. We required that they be working at FDNY for more than 18 months, because if you've only been there for a year it's likely that you're a different type of person and also that you've had very limited smoke exposure. And by starting on 1/1/96 we had nearly everyone exposed, but we had a small number of people who were unexposed. We also required that they be less than age 60 on 9/11 because even though cancer is a disease of the elderly, we would wind up with very few people above age 60 on 9/11 and therefore would not have good data for comparison.

There's been a lot talked or mentioned about matching. We have consent forms to match to every registry. But unique to us is that we have the Social Security number for our entire workforce, and our IRB has allowed us to match -- for the entire workforce, both pre- and post-9/11 -- so that we are capable of matching to people who were hired in 1980 and were never at the World Trade Center because our IRB has -- working with us, has appreciated our demonstration that there would be no negative impact to matching even without consent. And the IRBs in the tumor registries that we have matched to have agreed with that. So therefore we are matching against our entire cohort, 100 percent Social Security numbers, 100 percent of the cohort, whether they were there or not there.

However, as also mentioned, with more and more hematologic illnesses being diagnosed as outpatients, these are not being reported to tumor registries. If they're diagnosed as outpatients in a hospital they are being. But if they're diagnosed as outpatients in a private office, although there are state requirements that they be sent to the tumor registry, they are frequently not. So we have also endeavored to make certain that we can supplement cases with those who are self-reported, but only after confirmation with pathologic data. And we keep these

separate, so when we compare to the U.S. SEER data, we're only using those data from tumor registries so that we're comparing like to like. But when we compare exposed to non-exposed firefighters, we use both tumor and self-reported cases. But again, only self-reported cases that have pathologic confirmation.

And we have these two comparison groups, external to the U.S. population and internal compared to unexposed firefighters. Our internal comparisons will get better over time because we will have more unexposed firefighters over time as we supplement this with -- with newer firefighters.

It's very important when you do these comparisons to not only correct for age group, gender and race, but to also correct for calendar year, because this way you're able to correct for both decreases and increases in cancers that are occurring normally due to other issues in the population. For example, there's been a decrease in certain cancers, but recently there have been reports both in the U.S. and in the world of increases in thyroid, prostate and melanoma cancers.

We look at observed cases divided by expected cases, and we can also look at this as a ratio found in the exposed to unexposed. This has been quite controversial, but we've had multiple inquiries about this and, after discussing this, we always are able to come to a conclusion that this, after answering questions, is a reasonable statistical design.

One of the biggest issues with our data, and with any data on cancer that will come from any of the groups, is the impact of surveillance bias on increasing the number of cancers that we report. And this is a very reasonable concern because our members are now in a monitoring exam and therefore may -- we may find more cancers than would be in the general population. We may find even more cancers in our unexposed group because our unexposed group may not be as likely to participate in monitoring, though we disagree with that and because we have very good rates in our unexposed group as well. But to address these concerns we removed the -- we did one analysis with all these cancers there, and then we did a second analysis which we call the corrected analysis where we removed any cancer that we could have diagnosed in an asymptomatic worker due to our monitoring exam. What we found here is -- this was published in Lancet 9/3/2011 -- we found that in our exposed group, with 61,000 person-years, we had 263 cancers of all types, and we would have expected in the general U.S. population 238.

This creates a ten percent increase. But if we look at this as exposed divided by unexposed, the increase is a 32 percent increase.

Now that's before correcting for surveillance bias. If we correct for surveillance bias by removing the cancers, if we remove the cancers by just postponing their diagnosis two years, essentially removing almost every one of those cancers, we get -- instead of a 32 percent increase, we get a 21 percent increase. And if we removed every one of them we would get only a 19 percent increase in the likelihood of developing cancer.

Now we lose statistical significance when we do that. You can see that the odds ratios drop below one. And when we look at individual sites we do not have statistical significance, especially after we correct. But we have trends that again argue, as talked about this morning, for the possibility that there will be an increased cancer signal in the blood-borne cancers, the ones that you would have expected to have occurred earlier. We believe that after another year or two of additional data these will rise to statistical significance based on extrapolating what we currently have.

Now yes, some of these lose statistical significance. I'm now back to talking about all cancers, not just the individual sites. Yes, when we adjust these analyses for surveillance bias or for early versus late diagnosis, it is absolutely true that some of these point estimates lose statistical significance. However, five of the eight analyses still had statistical significance. And every single one of them, as shown on this figure, is to the right of an odds -- of a points estimate of one point zero. And statisticians, both our own as well as those on the World Trade Center Cancer Expert Panel that we convened, said that this was the most important finding. Not whether a single analysis has statistical significance, but whether every one of your analyses has a point estimate above the level one, and every one of ours does.

We believe that this reflects the potential of a biologic plausibility, though clearly more study needs to be done studying additional populations. We are already in progress with nearly finishing our EMS population and studying all of these groups for longer amounts of time.

I again say to you that we need to be very careful, especially in this area, in looking at whether other centers are able to demonstrate the same. It is easy for other centers to demonstrate the same when it came to things like obstructive airways disease, World Trade Center cough

syndrome, because the numbers are so huge. In terms of cancers, the numbers are small. This is not an epidemic. And therefore knowing the entire population is critical in obtaining excellent data.

Finally -- I'll close very rapidly, and I appreciate your patience with me in addressing the final issue I wanted to mention, is where are we now in terms of research? The Zadroga Act, as you know, has provided specific funding for research. This increased funding will allow us to do more than just case studies and cross-sectional analyses. It was meant to allow us to continue these analyses and to continue our longitudinal analyses. It was meant to stress collaboration that is already ongoing, but to expand it further. It was meant to add basic science studies, which we could not do before, and fund those. And it was to be all determined on the basis of peer review.

The problems that require immediate solutions may or may not be addressed by this. For example, can disease surveillance or new illnesses be done in this type of methods when you don't yet know what the illnesses are? Can time-critical research be done, even though it has not yet been funded? And can peer review be done effectively?

The problems with these issues do have solutions. So can disease surveillance be done, can time-critical research be done? I believe it absolutely can be done, if we continue to fund the data centers and the World Trade Center Registry to do analytic work. The data centers are in touch with the clinical centers. They're in touch with the workers. And they should be the ones that do the analytic clinical and epidemiologic research 'cause they can do it most rapidly and most efficiently.

This could be funded through specific research awards through the data centers for trends analyses and disease surveillance. It could also be done through a project program grant and awards that have been used in the past by NIH to expand upon this proven research process. All the information you're seeing has been provided by the registry or these data centers. We should be expanding on that process, not abandoning it.

In addition, we could also use another process called the Career Investigator Award to fund both proven researchers as well as junior researchers to continue in this effort. And we should use isolated small awards, the RO1 award process, only to look at mechanistic research, to look at hypothesis-driven, mechanistic research, and then when they find that, it could be corroborated in a larger scale by the data centers.

The awards need to be based on peer review. But we have found that there's a potential problem in the way peer review was done during the BAA process which Dr. Howard talked about briefly this morning in that there were eight awards given. All of these awards are certainly excellent awards and it is not my duty to demon-- you know, to look backwards at that. However, the process can be improved.

What happened was there was peer grading, but the grades were not looked at in a study section to then compare grades to normal those -- normalize those grades for graders that might have a more strenuous grading process than others, and to prioritize it based on the needs of the program or the program administrator. Those things are typically done using an NIH study section. They do not require any budget, any large-scale budget because it can be done by a conference call, and is a critical part of any peer grading process and should be added to this process at the next available option. Peer grading should continue, but a study section should be added.

On my last slide, just to summarize everything into lessons learned, we now know that pre-disaster health baselines, including pulmonary function and mental health screening, should be a requirement. We should protect workers by training and educating them before the disaster. There should be strict enforcement of worker protection laws at a disaster site, especially after the initial rescue effort. All workers should be registered electronically with electronic ID cards so that we know their exposure, their times of exposures and their durations. We should consider restricting workers to minimum number of hours possible during hazardous work environments. And we should continue to integrate these programs to have monitoring, treatment and research together, and also in a collaborative fashion.

I thank you for your patience.

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STONY BROOK CLINICAL CENTER OF EXCELLENCE

DR. WARD: Next speaker is Dr. Luft.

DR. LUFT: We'll all take a deep breath -- a lot of material, lot of data. I feel a little bit at a loss where just at this point to present what we do. Let me introduce myself. My name is Ben Luft of the -- director of the Long Island World Trade Center Medical Monitoring Program. I'm not an occupational medicine person. I'm actually a molecular biologist who

came to work on the World Trade Center after 9/11. Actually I spend most of my time in genetics and making vaccines, some of which are in human trials in Europe.

But after 9/11 we began to -- we saw the need that there was -- that 9/11 occurred and as an institution at Stony Brook we were preparing to take care of the responders, people who had -- actually survivors. We thought there would be a great deal of people who would be coming out to Stony Brook who were casualties, and unfortunately there were very few and none came out to Stony Brook.

Immediately thereafter what we did is we decided to start a program to take care of the responders. You know, we visited the World Trade Center site. We saw the disaster there; it was really quite dramatic. And our approach at that time was that, being -- just from the point of view of providing care is that we saw that the actual toxicity there was really very complex. It was a combination of both physical -- I mean we've heard a tremendous amount about the dust and the caustic nature of the odor and the burning material, and I think that, in a lot of ways, as scientists we can kind of grasp that very quickly and that inhaling that will cause a tremendous amount of injury.

But at the same time we knew that there was going to be a tremendous amount of psychic trauma, and that psychic trauma was, you know, from this continuous danger that these people were under, both to their life, their -- being -- not only were they seeing their colleagues killed, but they were be-- seeing them dismembered. You know, they were finding body parts and they were -- and this was not just occurring over a very short period of time. You know, usually when we think about being in an event, it usually occurs -- you know, you're in a car accident. It occurs in ten to 15 seconds and it's all over. Here people were under continuous psychic trauma for a prolonged period of time. And even as an internist, it became evident to us that we were going to be dealing with a very complex set of injuries.

And I think -- I wanted to emphasize that because that's really how our program developed, and a lot of the research that we've been doing has evolved from that.

So if you look at the -- if you go to the first slide, you look at the geography of what we deal with. We're in Nassau and Suffolk Counties. We're responsible for about 1,200 square miles of suburban area. We wanted to set up two clinical centers, one in Nassau County and the

other in Suffolk County. And we recently -- establishing a center in Brooklyn, and these were Centers of Excellence that were supposed to take care of both the medical and the psychic injury.

We have a fairly large cohort size, around 6,000 patients, and we have an extraordinarily high patient retention rate. About 84 percent of our patients come back to us from year to year. You know, that's basically our monitoring program when we -- we have our patients -- we have a very stable cohort that we're able to study. And a very large percentage of our patients take on treatment, and I think that that's also a very important thing. If you look at what our -- the number of patients who come in for monitoring and the percentage of their illnesses that we identify, whether it's pulmonary or mental health or -- or gastrointestinal, that a very high percentage of those patients accept care. So we actually are almost -- it's almost identical, you know, the ones -- cases we identify, the same -- almost the same percentage of patients go on to treatment, which is very -- very important.

In our population we have two groups, of course. We have the traditional responders, and I think it's very important to realize that. You know, when you hear about the fire department or the police department, those are very traditional type of responders, and about 50 percent of our patients are the non-traditional responders. And when you look at the disease rates among the traditional responders and the non-traditional responders, it can be very different. I think that that really, you know, states the importance of what was talked about when we talk about the survivor program, the fire department and the responders, that each of these groups have very unique populations, and that the diseases may be quite different from population to population, how the disease actually manifests itself.

And that was really very important to us 'cause I'm talking to you as -- from the point of view of a clinician, of a clinical scientist trying to do research as to how diseases -- how syndromes -- how patients are responding syndromically.

You can see that if you look at it on a pie chart of what the diseases are, it's very similar to what you find amongst the different populations in our treatment program. The largest number of patients have upper airway, that's in the blue, about 28 percent have upper airway disease; 29 percent have lower airway; and mental health disease we find in about 30 percent of patients.

Well, as I said to you initially, because we began our program as a treatment program what we began to do is we wanted -- and because we had noted that these patients were exposed to a very complex injury, we wanted to set up a unique model for therapy. And the model that we set up was a -- what we call a collaborative care treatment model, which basically allowed us to treat both the medical -- the mental health and the medical disease concomitantly. Actually our internists were initially trained in some basic psychiatric -- and began to perform certain psychiatric care, and they were teamed up with a social worker who provided care with both -- who are psychiatric social workers. And so when the patients were seen, they were seen by these -- this grou-- these two individuals who were able to provide care for both of these things concomitantly. And we felt that this was an important way to be able to treat these -- this particular patient population, not really having a lot of data. But this was our conviction, our -- we were convinced that this was an appropriate way for treating this particular disease syndrome.

And so what we were able to show was that by doing this that this was cost-effective. When we began to look at the cost per patient actually it was quite reasonable and it was -- compared to other centers. It was comprehensive. It decreased the obstacles to care, the barriers to care. The patients were much more accepting of mental health care, as well as their physical health care. It increased adherence to regimens, they would be coming back often, you know, to being seen for treatment. There was no stigma that was associated with being treated by mental health versus physical disease because basically you were being treated in the same way. And I think an important part was, like I said, it really overcame a lot of barriers to treatment, the personal barriers, personal prejudices, providers lack of ability (sic). You know, there was a question as to how many -- whether you could get to a psychiatrist or a psychologist. This allowed us to be able to treat them very promptly. Various financial barriers -- sometimes they wanted to keep, you know, their mental health treatment secret. We were able to take care of that. And geographic barriers as well, they were able to come and do really one -- one shop stopping -- one stop shopping, as is familiar in the medical parlance.

So this was really a very effective way of being able to take care of these patients. And I think that that was really what was responsible for our

high retention level and our high, you know, adherence to treatment was this particular model.

We really didn't have a scientific basis for this, and so we began to do a study where we wanted to really prove that this was really an effective manner. And so we did a study which I think -- which is going to be published within the next month in Psychological Medicine, and you have that -- the actual manuscript attached to that. But we looked at about 20,000 patient responders who were followed in our World Trade Center medical monitoring and treatment program, and we wanted to see whether post-traumatic stress -- how that was related to various medical conditions. And for this particular paper what we did is we only did it in response to respiratory disease.

So in this population we looked at 8,508 police and 12,333 non-traditional responders who were examined at the various World Trade Center health programs. And what we were able to show was that PTSD and respiratory symptoms were correlated with one another, and that PTSD statistically mediated the association of the World Trade Center exposures with respiratory symptoms.

I think this is a very important piece of information. Although this was a study that was only done cross-sectionally, it did indicate, by using a variety of statistical models, that PTSD itself, the psychological condition, may actually mediate between exposure and a physical manifestation of disease.

Now this has, I think, very important ramifications when you think about what the compensation fund -- how they deal with mental health -- actually mental health is really pushed aside, but this may indicate that the mental health condition plays a very important or almost pivotal role as to how a physical condition will manifest itself.

It also has -- very important in terms of biological model. As I said before, my interest is in molecular biology and genetics and genomics. But there are some data that is -- that exists currently that patients who have PTSD, that they can have alterations in their lymphocyte function and that perhaps those inter-- and -- and actual infection disease manifestations, actually -- and there was a very nice paper that was published in the proceedings of the National Academy of Science. And so I think that this is an important piece of information, that the link between PTSD and respiratory symptoms is notable, it supports our integrated medical and psychiatric treatment of pa-- responders, and it

con-- gives rise to being able to develop a hypothesis to kind of look at the biological linkage between the mental health and the physical health. I think that this is an important area that we -- we want to continue to explore.

As I said, when we did this initial study we did this as -- in a cross-sectional population, and so there's a lot of provisos when you do things cross-sectionally. It's much better to do it longitudinally. It prob-- it real-- it can nail down things. And so we actually applied for one of the grants that was -- and we actually were funded -- where we looked at the burden of mental and physical morbidity. And we worked with a psychiatr-- a psychiatric epidemiologist, **[identifying information redacted]**, who has extensive experience in disaster psychiatry and mental health, and we're now currently doing that.

And what we want to do now is we want to identify the mechanisms responsible for the co-morbidity. Psychiatrically we're going to be looking for PTSD, anxiety, and depression, and I think instead of being able to do the PCL, which is a checklist and they're probable, we're doing a SCID analysis on 5,000 responders.

But not only that, we're going to begin to look at -- at other issues, such as quality of life. This hasn't really been systematically ascertained, because what our prejudice or what our -- is that when patients have that combination of a mental health disorder such as PTSD and a physical disorder that they are much less functional than a patient that has either one of those things alone; and that it's not just additive, but that this combination actually has a synergistic impact in terms of their quality of life and other indicators of well-being.

So this is, as I said, part of this project we're going to be looking at 5,000 responders. We're going to be doing SCID analysis on each of these responders. We're going to be looking for various other parameters such as quality of life parameters. And the other part of it is we're going to continue to do our longitudinal analysis looking at the second and third wave data that has recently become available.

The other thing that we'd like to do is we'd like to -- since we think that our site, you know, had this collaborative model, it'll also give us an opportunity to compare the outcomes at our site at the Islandia site, which had this partic-- our -- our particular strategy for the care of patients with other sites that had a different strategy, more traditional strategies for care, and perhaps give us some insight into how we should

be taking care of responders or individuals who are exposed to these very complex set of mental health and physical traumas.

The other aspect that we've become very interested in has been looking at other types of interventions. Now how do we -- you know, one of the things that we've been very interested in is that -- you know, we're now ten years post to the event, and it's remarkable the number of patients that are still sick. You know, you would think that, you know, they had this initial injury, it was an environmental injury, it might have had some impact on their lung function where they lost 300 milliliters of lung function and now it seems to be leveling out. But there's a tremendous amount of continued illness and poor well-being. Patients continue to have a large number of somatic and mental health complaints. And so we want to look at various interventions that we can do to be able to reverse that.

And one of the areas that we had noticed was that patients who had PTSD, that they had a higher incidence of smoking as well, and perhaps respiratory disea-- and respiratory problems as well. And so we wanted to -- we developed an interventional study looking at patients who have this combination of PTSD, respiratory problems and smoking, and we developed a program to -- an intensive program for smoking cessation and seeing how that would impact these various parameters; do they feel better once you do that, do they improve in terms of their mental health, do they improve in terms of their quality of life and physical functioning? And so we're going to be doing this in a randomized clinical trial to look at the effect of enhanced treatment versus standard treatment on abstinence from tobacco.

So that -- you know, we feel that the development of a powerful new intervention for a difficult group of patients to treat may be a way that we can really impact the quality of life and the actual diseases in this patient population.

Lastly, I wanted to mention another project that we are doing at our site, and that's our World Trade Center Oral History Project. This is a project that we began about -- over two years ago, maybe two to three years ago, I'm not sure -- but we were featured on "60 Minutes" on 9/11; they did a half-hour program on our oral history project. And the oral history project was basically that, although there was a tremendous amount of emphasis on the physical and mental health issues that we were dealing with in terms of the responders, we felt that these -- it really didn't deal

with what was the impact of -- to them in terms of their life, you know, and how they responded in a very qualitative type of manner. You know, what-- why they responded, what motivated them, how they sustained themselves, what sacrifices they made, how they were able to overcome -- you know, where did they get their sense of resilience. And we thought that that was really a very important piece of information, of qualitative information to -- for the responders.

Certainly it's not a scientific study in the traditional terms, but certainly in a very humanistic way, it is. And so we bas-- we've now interviewed about 150 responders. We document their perspective of the disaster. We focus on their personal stories from their perspective, the responder's perspective. We highlight their motivations, their values, their struggles, their resiliency. And we expand our knowledge beyond the medical effects. This has become a very important resource, as I mentioned. You know, "60 Minutes" has utilized it, PBS had a documentary of our program which also was shown on 9/11. And it's been very useful in terms of recruitment and retention, you know, among patient populations. We've developed library curriculums and educational programs for schools. And the Library of Congress is now -- has agreed to provide us with a permanent home for this project in their institution, to maintain it in perpetuity, all of these interviews, and we really -- we think it's really going to be a very important piece of information and also an important legacy to this program as to who we took care of and why we took care of it and why it was so important to do so, and how we should do so in the future.

So I've attached a copy -- I didn't want to go into a tremendous amount of detail since I knew that there was going to be a lot of data that was there. I attached a copy of our manuscript which goes into this mediational model, and I think you'll find it very useful and informative. But I do think that it's important that we start to look at our data, that we start to develop hypotheses and no longer just deal with -- and then begin to test it, you know, in an experimental manner.

And I think I'm going to end here since the hour is late and I'm sure everyone's tired.

DR. WARD: Speakers back to the table for a short period of questions or comments from the panel -- yes, Steve -- oh, Valerie.

MS. DABAS: Hi, my question was for Mark Farfel. You identified that a lot of the cohorts that you identified in the monitoring program with

your -- came from employers. Were you able to access the NYPD database for World Trade Center responders?
DR. FARFEL: I don't have the exact number, two or three thousand NYPD. Are you asking me how we were able to outreach, at least through the enrollment process?
MS. DABAS: On your fifth slide you had the list of identified as 30 percent of enrollees that you received the list and names from the employers and their volunteer organization, and I was wondering if NYPD was one of the ones that you received?
DR. FARFEL: Oh, no, they -- I think the NYPD are almost exclusively self-identified.
MS. DABAS: Okay.
DR. CONE: And from the roll call.
DR. FARFEL: Oh, that's Dr. Jim Cone from the registry. Did everybody hear his answer? He was saying that there was outreach through roll calls at police stations.
MS. DABAS: I have a follow-up question to that. The outreach through roll calls, once those people came in, they were directly -- did NYPD then provide a list, or was that once they were -- the registry was announced at roll call, those people then identified themselves?
DR. CONE: The people identified themselves once they were approached individually or as a group in the roll call. They also did the same thing in the fire stations. We didn't receive lists, but we did go to individual police stations and attend roll calls to personally recruit police officers. We signed up over 4,000. We also went to firehouses throughout the city and did personal recruitment of the firefighters.
MS. DABAS: Thank you.
DR. MARKOWITZ: My question's for Mark, and also David. And I ask this as -- I'm not authorized by this Committee to ask this, but -- we haven't had a chance to discuss it yet, but by March 2nd or thereabouts we need to produce I think a recommendation guidance to NIOSH about cancer. And Mark, we heard from you that you hope by early January to have a manuscript ready for submission, peer review; and David, you're working on EMS and cancer. My concern is that any manuscripts you might have won't necessarily be ready by a March 2nd date for us to review. So the question I have is whether, when you complete your analyses and they're ready for submission, whether you'd be willing and able to share those with us so that, if NIOSH -- if it's in accordance with what NIOSH

wishes, we can look at those data and consider those in our recommendation to NIOSH. I understand under the Act, NIOSH can only use peer-reviewed publications. Nonetheless, it's not clear whether we're -- we have that similar restriction or not.

DR. FARFEL: First I just wanted to say we're working as hard as possible to have something submitted as early as possible in 2012, and so there actually is a potential trajectory, given the importance of this topic, that we may actually have a manuscript that's in press or been accepted by the March date that you gave. And so I think -- let's -- let's cross that bridge when we come to it and see what the trajectory is, and we can certainly update the Committee and NIOSH on the progress on that submission. I think it's important, though, to have the peer review aspect to the findings, and that's certainly something that -- that's been the case of every registry publication. So I think let's just recognize that there is a trajectory that may work; and if not, then we need to communicate about the timelines that we are on.

DR. PREZANT: I have to defer of course to Dr. Farfel on what the registry can do, but I find it impossible that the registry, or anyone else, will be able to get you anything within your timeline. I know the work it has taken us to get the firefighter study to be completed. We will show the same level of attention and caution in doing the EMS data. I also know that this month is November and therefore, knowing both the analytic process as well as the process that goes on at the Department of Health, it is impossible for you to see any of our studies by March. I mean I -- I just find that to be an expectation that would be setting you up for failure.

DR. ROM: I'd like to address a question to David. For making cancer and respiratory health effects assessments, I think it'd really be important to know what's happening to the 1,700 folks who get disability retirements, whether you're able to follow them up for both of these diseases and examine them and what have you.

DR. PREZANT: Our data includes the 1,700 that have been retired. Our data, when we publish, if you look at any of our publications, you know, after 2004, have always demonstrated both cross-sectional and longitudinal data. The longitudinal data of course always has less people in it than the cross-sectional data. Cross-sectional data can be the entire cohort. The longitudinal data suffers because people have had to come for multiple, specific time points in the exam, but we have not lost the

1,700 that have retired with disability. In fact, they are very much in our cohort and they -- and even -- and here's the point that I was trying to make: For future respiratory studies, mental health studies, et cetera, we have to keep them, and we are. But for cancer or mortality studies we only have to keep them in terms of getting data that supplements the registry's because we match with 100 percent of our cohort.

DR. MARKOWITZ: The Chair has permitted me to ask a short question, so maybe you could produce a short answer. This is for David and Joan. Do you believe that persistent inflammation underlies the permanent reduction in pulmonary function that you've seen? I raise that because Bill and Micki this morning made a strong plea on biological plausibility in consideration of outcomes, and so I'm heading in that direction.

DR. REIBMAN: I think we know very little about the biology of what's going on in these lung diseases. I think that -- let me back up a little bit. And first I want to second something that David said about research in that I think the intent of the BAAs and the research in the Zadroga Act was to allow us to enhance our understanding and in fact ask questions just like you're asking, which is what are the underlying mechanisms, is there ongoing inflammation, should we be treating and pushing anti-inflammatory treatments in these patients or is that futile. And I don't think we know the answer to those.

I think that the other, analytic questions I think that are equally -- or not equally, but are also important, such as the continuing analyses, longitudinal analyses, et cetera, should be ongoing even without the support of the BAAs.

So to get back to your question, which is do I think that there is ongoing inflammation, I think the interesting thing, for example, in the biopsies show that there's in fact very little inflammation that we can see. And in fact, if you look at the airways themselves, they don't look like asthma airways. They don't have the mucous hyperplasia. They don't have basement membrane thickening. They don't have what's classically seen in asthma, and the inflammation may not -- is not the same. But that's that subgroup.

So what about the others who have the asthma-like syndrome? And I don't think we can answer that. I think we're starting to get some of the biologic background on them, but I don't think that's clear.

I think the other way to answer that would have been a clinical intervention, but we don't have that either.

DR. PREZANT: So to me, this is the value of having a study section that's looking at the various different grants that are submitted, because one of the highest priorities should be whether chronic inflammation is ongoing. We at the fire department, in collaboration with NYU, have now had accepted for publication three papers looking at mediators of inflammation. One actually was with Einstein Montefiore that's already been published on alpha-1 anti-trypsin. Another two were with NYU looking at inflammatory biomarkers and then another one looking at metabolic syndrome biomarkers. And these are all preliminary studies 'cause they're done on small numbers of patients, and they also are done with blood that's drawn within the first year and not years later. But clearly those studies demonstrate that there is an inflammatory mechanism, at least to the initiation of this process, or to the persistence of this process one year later.

In addition, in the study that I did show you on particulates in induced sputum, we saw a very big increase in MMP9, another mediator of lung disease. So I think by having prioritizations both in terms of the RFPs, the BAAs, the award announcements, but also in terms of the study section itself, hopefully these additional studies can move forward.

DR. WARD: We should probably brea-- did you want to make a response to that question or -- no. Okay.

I think we should probably break for lunch. As you know, we are behind schedule so we're only going to take 45 minutes and -- so what time will we see everyone back? We'll see everyone back at 1:50. Thank you all for your great presentations.

(Recess taken from 1:05 p.m. to 2:08 p.m.)

DR. WARD: Let's begin the afternoon proceedings. I would like to ask the speakers to try to limit their presentations to 15 minutes. We won't cut you off at 15 minutes, but we will give you a warning that it's reached 15 minutes so that you can draw your presentation to a close. And we'll get started with Dr. Crowley.

DR. MIDDENDORF: Ms. Hughes has returned.

MOUNT SINAI SCHOOL OF MEDICINE

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DR. CROWLEY: Good afternoon. So I'm going to be speaking on behalf of the World Trade Center Health Program at Mt. Sinai. **[identifying information redacted]** was going to be here today but unfortunately he

had a previous engagement at -- in Japan, so I'll do my best to cover.

(Pause for technical problems)

THE COURT REPORTER: If you could start over, I'd appreciate it -- so I can get her name.

DR. WARD: Yeah, but we are still getting a pretty big hum up here.

THE COURT REPORTER: Still?

DR. WARD: Okay. Yeah. So we're ready to start over, and if you wouldn't mind giving your name again --

DR. CROWLEY: No problem.

DR. WARD: -- and start from the very beginning.

DR. CROWLEY: Okay. My name is Laura Crowley and I'm from Mt. Sinai. I work with both the data coordination center and the clinical center, and I'm going to do my best to describe the World Trade Center Health Program. Dr. Michael Crane could not be here today.

I don't see it moving forward, unless I'm doing something wrong -- thank you.

Okay. So just as a basic introduction, it's always good to review the exposures. I know everyone's seen this list umpteen times, but I feel like it's important to (inaudible) -- I think I keep coming in and out so I apologize; I'm not sure why.

So people have sustained a variety of exposures -- smoke, dust, particulate matter, a variety of toxins, asbestos, concrete, glass fibers, polycyclic aromatic hydrocarbons and polychlorinated furans and dioxins, to name a few. I think it's important to reiterate this list because a lot of what this expo-- this exposure drives what we're facing today. And the common effects to date that we know of are respiratory and mental health consequences. However, we're here today to also investigate the long-term consequences and exposures of late-emerging diseases.

Okay, so I'll do my best -- I'll talk really loud.

Okay, so the population -- they're divided into two categories, the traditional responders and the non-traditional responders. We heard from Dr. Prezant this morning about the traditional responders, being the firefighters and paramedics. We're going to speak about the cohort that involves non-traditional, along with law enforcement officers.

The non-traditional responders included construction workers, the laborers, the telecommunication workers, gas and electric workers, transit workers, public sector workers and volunteers.

Just a slide to describe our program. We've been deemed the Clinical Centers of Excellence. We have six centers and a data center. Our job is to provide comprehensive clinical periodic monitoring exams for all eligible responders, and treatment for those with any World Trade Center-related conditions. We're also tasked with the job of disseminating information about World Trade Center health effects to our responders, the public, and all health care providers. And we do this by collecting standardized clinical information to identify any physical and mental health consequences. In addition to that, we analyze that data and conduct a disease surveillance in our data center.

The cohort -- this number's dated -- outdated, but it's over 28,000, with the majority of those being male at 86 percent. The median age tends to be about 38, with 57 percent whites, 11 percent black, one percent Asian, three percent other. We do have a population that's unknown, depending upon if the person answers the question or not, and 31 percent Hispanic; 83 percent are in a union. And the work status, about 81 percent are employees, 11 percent are volunteer, and eight percent both.

Here's just a bar graph of the description of the cohort in terms of occupation, and at the bottom you can see that a majority of our responders did come from the protective services, or military, with it being over 12,000; and construction, almost 6,000; we had 1,700 in electrical or telecommunication; transportation was 1,000; 4,000 in other occupations; and about a handful, 477, in unemployed or retired.

This slide's a little busy, but I think it's helpful. It's helpful when you look at it on the paper that you have in front of you. Basically it trends the visits in numbers over the years, and the really pretty key number is the bottom number that shows that there's been about 78,000 total screening and monitoring program exams since the beginning of the program, which is pretty amazing.

Publications -- I have about 19 slides' worth of publications. I'm on a time limit so I'm going to move as quickly as possible and not go into the details for each publication. This was published in the American Journal of Industrial Medicine. It reviewed the health effects of the World Trade Center site workers and the lessons learned. This -- it was published by Dr. Levin and colleagues. And just a note -- I'm going to hit the highlights of the science to date. There's many other published articles out there which many of my colleagues sitting around me have worked

on today, and I'll start with this one. But this one really highlighted the importance of advising our colleagues in the health care profession to advise our health care professionals of the importance of seeing patients that had been exposed and how to evaluate them clinically; how we were going to capture all of those folks who were exposed; whether or not there was going to be a registry; how we were going to distribute respiratory protection; that we needed rapid mobilization of health care services; and make sure we communicate effectively with our public health agency regarding exposure hazards.

Another paper published in 2004 in the MMWR reported a similar message about the importance of provision of medical care for responders and respiratory protection.

2004, Dr. Landrigan and Dr. Leroy published on the health and environmental consequences of the World Trade Center disaster with the purpose being to examine the dust elements, and found that it contained much of what I spoke about in the beginning of the presentation. And the pH of the dust was highly alkaline, which attributes to much of the damage that is seen in many of our responders to date. This particular study looked at firefighters, cleanup, community, pregnant women, and the health effects in those populations and found that they were seeing a high level of bronchial hyper-reactivity, persisting cough, and elevations in the level of -- you know, frequently many of their patients were reporting asthma as well.

In 2006 Dr. Herbert, Dr. Moline and Dr. Landrigan and Dr. Levin reported on a five-year assessment of our program, and they looked at over 9,000 patients and found that exposure was definitely related to an increase in respiratory and pulmonary symptoms, and this persisted -- at the time persisted up to two and a half years after the attack, and we know that it's persisted much longer because we're all sitting around this table today.

This was a paper -- small study -- published in JOEM in 2007, looked at air trapping and reviewed the symptoms, much of the respiratory symptoms we see in our patients, and looked at it from a radiographic perspective. It was performed by Dr. Mendelson and Dr. de la Hoz, and revealed that air trapping explained a lot of these PFT -- these pulmonary function and breathing test abnormalities that we're seeing in our population.

Again another small study by Dr. de la Hoz in the American Journal of

Industrial Medicine, and it looked at a finding of vocal cord dysfunction. So we're seeing a variety of respiratory ailments, and this was one of them. These patients presented with respiratory complaints and were found on spirometry to have abnormalities consistent with vocal cord dysfunction.

2008 -- this was a comprehensive review. It was done in the Mount Sinai Journal of Medicine and really discussed -- you know, even under circumstances where the program had limited resources and in spite of all the challenges, what they were able to accomplish. But also it discussed, you know, in the absence of a prior model, we were able to come up with a program and see quite a few people in the midst of this disaster.

2008, Dr. Stellman and colleagues published Environmental Health Perspectives: The psychological impact on World Trade Center disaster workers, and found that 11 percent were reporting symptoms consistent with post-traumatic stress disorder; eight percent depression; five percent panic; and 62 percent had sustained a substantial stress reaction, really showing that psychological distress and psychopathology was exceeding what we found in population norms.

2008, Dr. de la Hoz presented a paper in the Journal of Occupational and Environmental Medicine on reflux symptoms and disorders, pulmonary disease in our workers. And it was a small subset, 42 responders. Looked at spirometry and upper endoscopy and 24-hour pH, and found that there was a spectrum of reflux disorders and spirometry, which was suggestive of air trapping. And he associated reflux findings and pulmonary disease in our cohort.

Again, all of this is consistent with, you know, much of the diseases we're covering and treating our patients for to date. All of this literature drives much of the diseases and what we're treating to date.

CHEST, this was a publication by Dr. Skloot and colleagues about the longitudinal assessment of spirometry, and it revealed elevated rates of spirometry was found on both -- if a patient ever returned for an exam, we saw abnormal rates of spirometry in both first and second exam, and that the most common finding was a reduced forced vital capacity. This finding's a bit different than what we see in the firefighter cohort, but again, it just highlights the fact that we're seeing spirometry abnormalities in our cohort.

This was published in The Psychiatrist, and it was -- it focused on iron

workers, and it was published in 2009 and revealed, again, that we're seeing PTSD, panic attacks, depression in this cohort. And Dr. Stellman's study highlighted that this was consistent with what we were seeing across the cohort.

Dr. Moline's here today so she'll probably go into more detail about this, but this is a case series of multiple myeloma, and she reviewed, along with our colleagues, eight cases that were observed and found that four of these -- the expected rate was 6.8, and we found eight. Four of these were younger than 45, and this is what was noted to be unusual. We did not expect that.

I think -- this is a study about snoring and obstructive sleep apnea. Dr. Udasin, who's sitting next to me, will be talking a little bit about the work they've done. Bottom line is we've now deemed sleep apnea -- in the right setting, with the right World Trade Center-related conditions, deemed to be a -- now a World Trade Center condition. Due to the inflammation in the upper airway, some of our patients are presenting with sleep apnea and it is now a covered condition.

Dr. Moline also was involved in this study. This is a study published by Dr. Wu. It was a study that was a case report of seven responders, and they looked in detail at the histopathology and found that they were seeing interstitial lung disease and described those patterns that they were seeing. Also did a mineralogic analysis and found aluminum, magnesium, asbestos, calcium. And in addition, an abnormal fi-- what was -- not abnormal; all of this was abnormal. But they found an unexpected finding of carbon nanotubes. So interstitial lung diseases is also one of our World Trade Center-related conditions as well.

Dr. Dalton and Dr. Ken Altman, separately, conducted studies on chemosensory loss, and basically found the prevalence of significant chemosensory impairment in our group, which certainly could be problematic for some people in certain occupations.

This is a study I was involved in with my colleagues. We looked at -- similar to what the fire department had done, we looked at how many cases of sarcoidosis we were seeing. Sarcoidosis is a granulomatous pulmonary disease, interstitial lung disease, and we found that we had 38 cases and went on to look at the incidence rates. When we compared them to background rates, our incidence rates were elevated, and we also found peaks of incidence rates similar to what the fire department found in the first and second year -- we found it in year three and year

four. He had found it -- Dr. Prezant's team had found it earlier, but we were finding peaks earlier on.

This is Dr. Altman's study.

Lastly, this is a study that was published for the 10-year anniversary in The Lancet. It was conducted by Dr. Wisnivesky and Dr. Landrigan and colleagues, and looked at the persistence of many of these illnesses in the World Trade Center recovery workers to date. And unfortunately, we continue to see elevated levels of asthma, sinusitis and gastro-reflux disease, and this paper highlighted -- highlighted that.

Okay. So future scientific projects. I'm going to describe the three projects that are funded to date by NIOSH. We received funding after applying for -- submitting our projects. This is the first one, cancer among the World Trade Center responders, and then enhanced surveillance, exposure assessment and cancer-specific rates. This -- this study -- to be fair, this -- we've been doing this already, and we've been conducting surveillance for cancer. It's been an ongoing -- prior to this funding. We've been validating, identifying cases through exams, through a phone bank, collecting for any physicians that tell us that there's a case of cancer, and reaching out to patients to get detailed medical records. We've matched our population with the cancer registries in New York, in New Jersey, and Pennsylvania and Connecticut, and currently we're waiting for a match from Florida and North Carolina. Our group is working on expected rates and observed rates, as is, you know, the rest of the folks who described their studies this morning and hope to, in the near future, be able to discuss those in more detail and have a publication.

This -- what's outlined here is a continuation of that work that we've been doing. And basically it outlines -- we know that there's a latency between exposure and cancer development for most human carcinogens. We need to follow up this cohort, and our goals will be to continue to identify and validate all cancer cases in World Trade Center responders, link exposure to cancer risk in these World Trade Center responders, and identify the risk of cancer.

DR. MIDDENDORF: Dr. Crowley, you're at 16 minutes.

DR. CROWLEY: Thank you. I'll be speedy. This is a study -- Dr. McLaughlin is the PI on this study. It's pulmonary function abnormalities, diastolic dysfunction in World Trade Center exposure. Basically a whole litany of tests will be reviewed with the purpose to

determine if there's a risk of cardiopulmonary disease in our folks who were exposed.

And Dr. Adriana Feder is the PI on this project, trajectories of psychological risk and resilience in World Trade Center responders, with the purpose to examine the extent of resilience, recovery and chronicity over the eight years, and identify risk factors for these patients. And hopefully all of these studies will guide prevention efforts and preparedness planning for disaster responders.

These are the goals of our program, many of which are obvious, but it's really -- we want to identify, treat diseases in early stages. We want to report on trends of certain diseases over time, continue surveillance of diseases with long latency.

I would like to reiterate what Dr. Prezant and Dr. Reibman highlighted this morning regarding the importance of the data center being able to continue to do disease surveillance. It's something we were tasked -- hopefully we'll continue to be tasked to do 'cause it's a very important job; and obviously educate responders to seek care if they developed any of these illnesses.

In conclusion, I just think it's important to reflect on how many people have been screened and monitored -- over 30,000 since July 2002 -- and we've treated over 15,000. So you know, we hope to continue to be able to help our responders.

And that's it.

DR. MIDDENDORF: Just a note to the record that Dr. Rom has returned.

DR. WARD: We'd like to take a few questions for Dr. Crowley since both of our first two speakers may have to leave before the panel session would occur at the end of this -- at the end of this section.

DR. DEMENT: The cancer study -- it looks like it's just underway, so obviously no projected time frame for the -- for your cancer study being completed?

DR. CROWLEY: Actually I would say it's more than underway. I think -- you know, we've been approved for formal funding, you know, as of the -- you know, now. But we've been doing it for quite a while, so hopefully in the very near future we will have a publication. It's hard to give a firm date.

DR. DEMENT: I understand. Also your comment about continued ability to do surveillance -- continue your work, basically. Is that -- I mean do you have a -- what, a five-year contract now?

DR. CROWLEY: Correct.
DR. DEMENT: Okay.
MS. FLYNN: I also want to follow up on the question about data analysis. Just looking at the presentations from FDNY, from you and from Dr. Reibman, it's very clear that having a robust data analysis is absolutely -- it's the cornerstone of the knowledge base. So is there any question of your ability to continue with that work in the future?
DR. CROWLEY: I mean I think right now we just want to be able to continue to do it. We want to be able to continue to do disease surveillance. I think Dr. Prezant's point this morning in terms of the logistics behind, you know, applying for each individual project -- I would have to agree with him about the logistics of. I think, you know, the data center is set up to do disease surveillance and we'd like to continue to do so.
DR. QUINT: I was wondering if you had any plans to do biomonitoring of any of the cohort at some point? There's some of the toxicants that people had exposure to that are persistent and could be compared to NHANES and I'm wondering if there's any possibility of that in -- sometime in the future.
DR. CROWLEY: Yeah, I mean we actually put in a whole host of proposals to -- for -- we submitted a bunch for funding, and hope that around the corner there'll be another opportunity for that because ideas like that, and others, we hope to be able to explore.
DR. WARD: On to the next presentation.

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY CLINICAL CENTER OF EXCELLENCE

DR. UDASIN: So I'm going to be giving you the advantages of being a small clinic, and so I don't want to repeat what the large clinics have done, but with being a small clinic --

(Pause)

The advantages of being a small clinic are that we get to know our patients really well. We don't have -- maybe we don't have to worry about doing some of the other things that some of the other clinics -- the data center -- has to do. But now I'm going to say something about our individual cases that may make the Committee understand how difficult some of the surveillance is between the time frame of when we actually see patients with illnesses and when they actually are able to be

confirmed, so to speak.

But this picture, to start my presentation, is the Elizabeth fire trucks on the Staten Island Ferry leaving to go to New Jersey -- leaving to go to New York, rather, from New Jersey. The Elizabeth Fire Company sent all 200 of its firefighters to work alongside the firefighters in Staten Island, and so I honor them by putting this presentation up. And this is actually Deputy Chief Workus, who gave us the most -- the best picture of any of our responders. And for those people who don't see World Trade patients on a day-to-day basis, you can see the chief's respirator is around his neck. You can see the World Trade Center debris all over his body. I actually used this picture when I testified before the Energy and Commerce Committee because I thought this was the best picture of any of our responders. And again, we are the only, outside of FDNY cohort, that sees a lot of firefighters. We see the Elizabeth people, we see other fire companies in New Jersey.

And just to make things a little bit more interesting about Elizabeth, this is the same fire company that 30 years ago fought the chemical control fire, which Dr. Melius was involved with in NIOSH way back when. And so I have original records on many of the same patients that Dr. Melius saw way back 30 years ago.

So we've seen more than 1,700 unique patients. As a 'boots on the ground' kind of person, since we've been seeing them since January of 2003, I've seen almost all of them for at least one of their visits. Eighty percent of the patients that we see in New Jersey are offered some kind of treatment. That's a little bit higher -- of course, some of the treatments that we offer are things like nasal saline irrigation and are not expensive treatment, but we are pretty aggressive about preventive health.

The next line is a typo that I fixed after I made my 25 copies. What I wanted to say is that most of our patients are civil servants, if you will. Most of them have health insurance, and that should say under-insured. I thought I changed it -- it says 'uninsured' but it should say 'under-insured' there, with -- especially with respect to mental health. Nobody's got good coverage for mental health, and that's one of the things that I'm grateful that our provider -- that our program actually lets us refer to people that are actually good at mental health, not the people that your prescription -- that your insurance plan allows you to see.

Different than the other clinics, our three major counties that we see are Middlesex, Monmouth and Staten Island, but we see all over New Jersey, we see Pennsylvania -- we basically go along 287 for those people who know the northeast. We see a lot of people in upstate New York who know that you can zip down the highway 'cause if you drive through New Jersey most people go at about 95 miles an hour on the highways in New Jersey. So our cohort's a little bit more spread out than the other people.

Similar numbers except for the fire numbers, but I'm going to also say that we see the Port Authority Police, they're our biggest group, and I'm hoping that when I go to the airport that they're going to get me through the lines 'cause that's where I'm going after this, and they promised me I don't really have to get there four hours before the Israel flight 'cause they're going to get me to the front of the line.

The Port Authority Police lost 37 of their members out of a small department of 1,800 people. That means virtually everyone that was in the Port Authority Police knew somebody that died, and knew them really well. The Port Authority Police are -- many of them were physically there, 'cause many were stationed downtown, right around here. If they weren't stationed there they were stationed at a lot of the other airports. The only place that the Port Authority Police are stationed that's not a terrorist target is Staten Island. And they will make jokes about that, but every place else they go is a terrorist target. We've seen a huge number of mental health issues that we take care of in our Port Authority Police, as well as physical health issues.

We see a lot of New York City police officers who live in Staten Island, New Jersey state troopers, the various county and municipal sheriffs, and as I said, we looked -- we had an enormous group of people called 'other.' And for those of you who know New Jersey, we have lots of hazardous waste workers in New Jersey, but we also have lots of OSHA inspectors who live and work in New Jersey. We've seen a huge number of OSHA inspectors in our population.

Similar numbers to everyone, high numbers of upper airway conditions, lots of GI, lots of mental health, lots of lower airway. I had a student presen-- a student working for me this summer and, interesting, while upper airway is the highest number, the highest number of prescriptions filled is actually GI, and that's maybe a bit surprising that we do this. And we actually have put in some funding to look at our medication use

and how it correlates with exposure and illness. And I guess we're still working on it because it didn't get funded yet, but we're still working on it. But we are -- this is old. This is before the CSC people came along. But we've been tracking our prescribing patterns pretty carefully -- our most used prescriptions and our most expensive prescriptions -- and you can see the psych meds are all on the most expensive prescriptions. That Seroquel and Abilify and Cymbalta, all that stuff costs a small fortune. But I want to call everybody's attention to the fact that number one, Nexium, is one of the highest -- is our highest prescription that we write. I want you to notice that number 13 is Omeprazole. There's really no evidence-based reason why the Nexium should work better than the Omeprazole, but yet it does seem to work better in practice. And I actually think that that probably correlates well with the mental health components because when people see the advertising and they see the purple pill, maybe they're more likely to get better. I'm not real sure about that, but why the heck am I using so much more Nexium than Omeprazole? I'm just giving you this as my hypothesis here.

But the other thing is you see that there are three proton -- four proton pump inhibitors on that list, and gastro-esophageal reflux was not originally a covered condition. And it became a covered condition and it's huge. And in a couple of slides I'm going to tell you some reasons why I think it might be different in many of our responders.

So highlighting what we've seen and done in New Jersey, and I've been on many of the papers that Laura just presented, and we had another one about symptoms and spirometry that didn't make the hot 19 that was on there, but that Dr. Enright worked on with us as well.

But what I was really proud of was our sleep apnea paper. Dr. Marroccoli and I were the two clinicians in our group, and we were very, very conscious of who we were referring to Dr. Sunderram in the sleep lab to see who we were referring. We were not merely referring people with sleep apnea. We were referring people with sleep apnea who had aerodigestive illnesses, and Dr. Sunderram was the one that noticed -- and all the rest of the people here are the ones that helped us analyze the data. But basically we found that in our population the sleep apnea did not correlate with their body mass index, and this was of course contrary to popular belief, that being like a big fat slob is what made you have sleep apnea. And indeed in our population we do feel strongly that there are other inflammatory mechanisms. And we are also going to be

looking to, number one, expand this study; and number two, look at the mental health issues and sleep apnea. We were in the process of improving that study as well.

Going to GI, though, we had an abstract that our GI fellows were working on, and this is about eosinophilic esophagitis, and this condition is not well-understood and symptoms are possibly inflammatory, possibly allergic, we're not 100 percent totally sure. But the people who get referred for this thing are the people with intractable heartburn. And I was discussing this last night with Dr. Harrison when we were preparing our presentations, the gastroenterologists have to be looking for this pattern with the rings when you do this. And maybe because we're a medical school and we had the fellows on the teaching scopes, we saw a lot of these, because the pathology diagnosis is based upon seeing the eosinophils in the high-power fields. But the reason why I'm bringing this up and we presented this abstract is we're still seeing this. This is responding to steroids. This was our cohort.

The cohort of people that they reviewed -- and this was, again, a Fellows presentation -- but what was interesting was that three of the 45 patients that were referred to these Fellows that they were involved with the care of had eosinophilic esophagitis. Most of these people were on inhaled steroids. And so I bring this up as an emerging illness because I'm still seeing this thing. We're seeing -- we can't get our patients off of PPIs. I'm suspecting in the field of gastroenterology that you will be seeing other emerging illnesses. I think this is an emerging illness. It's very -- it's hard to report because my understanding is you actually have to be looking for this to find it. On the other hand, for many of our GERD patients that are really hard to treat, many of them might have it. Interestingly, a lot of our patients who have this are police officers. Again, though, we're a small clinic. We have an awful lot of police officers, so I'm not sure how to interpret that, but I wanted the Committee to see that.

Now the other thing I want to say is a little bit about our cancer cases. I have a medical student who, when we see a cancer case, he pulls out everything that he can find with what did they do, where did they live, what other exposures did they have, what's their job. And some of these cases are on the road to being confirmed, some of them are already confirmed. But I'm just giving you this as a small clinic -- raw numbers, not something that's going to be published in a paper because of course

we're part of the consortium, but just something more to think about. So we've seen four cases of multiple myeloma. Two were reported. I was one of the co-authors with Dr. Moline on the multiple myeloma study. The 68-year-old and one of the men in his 50s was included in that study. They were in the table, not the 40-year-olds. But interestingly, we've seen two other people in their 50s with multiple myeloma since that study. And so I suspect that the other clinics might be seeing multiple myeloma at some point and we may be able to report on it.

We've seen five cases where I've seen the pathology of non-Hodgkin's lymphoma. Four of them were in law enforcement, one of them spoke very eloquently on CNN, and we have another case that I'm waiting for the pathology to be confirmed. And you know, for all the talk about, you know, when can you get a cancer study, so I've seen the patient, comes into my office, tells me about his non-Hodgkin's lymphoma, so I first have to find the pathology. Then I have to get the pathology over to the nurse who works for Laura, and then that person has to then match it up with all the things she has to match it up for. So it's, you know, not as easy as when the patients are all contained in one place.

Two cases of CLL, one case of AML. The myelofibrosis case is kind of interesting 'cause that patient had absolutely no other exposure other than his exposure at World Trade. And of course it's only one case, but having trained under **[identifying information redacted]**, I look at that diagnosis and I think you have to have benzene to have myelofibrosis. So anyway --

DR. MIDDENDORF: Dr. Udasin, you're at 16 minutes.

DR. UDASIN: Oh, gee -- head and neck cancer, we are seeing a surprising number of head and neck cancers -- and I'm nearly finished -- and some of our other cancers we're reporting on. And that's basically what I have to say here -- and 16 minutes, that's not too bad. So I thank you for your indulgence and I hope you're going to continue to want to fund surveillance and the other patient-related activities that we do.

DR. WARD: Thank you. (Electronic interference) presenter. Dr. Harrison? We have to stop at 3:15 to allow for the public comments to take place at the predicted time, and then we'll continue this session afterwards.

DR. D. HARRISON: (Off microphone) of the clinical program at NYU Medical Center at Bellevue. Just -- I will start by giving a quick overview of what we're seeing in our patients, similar to what's been shown for the other clinical centers. We are the smallest clinic in the group, and we have a total cohort registered and monitoring of over 2,200. And of these we refer about 30 percent of our patients to treatment. We have right now 630 patients who are referred for treatment.

Most of our patients are English-speaking, the mean age is about 48, and again, most are male. Just to go over the cohort -- you can see most of our patients are white or Caucasian, 65 percent, with 9.6 percent black, four percent Asian, and the rest 'other.' Most of our patients, 89 percent, are employed, six percent retired, four percent unemployed, and one percent disabled. Of these, over 87 percent -- I mean around 87 percent are insured, with 13 percent uninsured. Most of our patients, like most of the other centers, are -- where you see a lot of -- 46 percent is law enforcement, 11 percent are in construction, and 15 percent 'other', and the rest break down into those groups that you could see.

Again, one of the most common referrals for treatment are for mental health disorders, and this represents the range of mental health disorders that we are seeing in our center. Like most centers we see a high rate of PTSD, followed by social stressors, and also for the expected depression, generalized anxiety and panic disorder.

Most of our patients are referred for lower airway symptoms, and followed by upper airway, GI and also sarcoidosis -- a small number for sarcoidosis and interstitial lung disease.

This is a breakdown of the types of cancers. Apparently -- these are patients within our treatment program. The numbers are much higher if we look at our total cohort, but not all the cancer patients are referred for treatment. So again we are seeing a lot of lung cancer patients, followed by thyroid, others which includes multiple myeloma, prostate cancers and breast cancer.

So since mental health disorders are one of the most common reasons for referral to treatment, we decided to look at -- to do a systematic review of treating post-traumatic stress disorder in first responders. This study was mainly done by Dr. Haugen and Dr. Evces, the two psychologists in our clinical center. For the purpose of this review they defined first responders as paid professionals and volunteers responding to emergencies, usually have high levels of work demands, routine

exposures to both physical and psychological stressors, and unique exposure recognized in revision to PTSD in upcoming DSM-V -- that is experiencing repeated or extreme exposure to adverse details of the event. For example, in 9/11 workers collecting body parts.

As expected, there was a lot of mental health disorders found within these -- in the review papers of first responders. This includes depression, somatic or psychosomatic complaints, chronic fatigue, difficulty with alcohol, and post-traumatic stress disorder, which was the focus of this review. Most of the studies that are done on PTSD in first responders are really small-scale studies. There's no national representative large-scale studies, and within the literature there's a report of variable rates, range from seven to 19 percent in police officers and four to six percent in volunteer disaster workers responding to a disaster.

To estimate the prevalence of PTSD in first responders we looked for comparison to the military population because we thought that population might more closely represent our group. Specifically we looked at the National Viet Nam Veterans Readjustment Survey which was done in 1990, and looked at -- and it was a good survey because it was nationally representative and was done years post-exposure. From that paper the inciden-- the prevalence of PTSD was estimated -- full PTSD was estimated to be around 15 percent, and partial PTSD at 11 percent.

To get a further estimate on the prevalence of PTSD we looked at -- from the Bureau of Labor and Statistics in 2008 there was one thousand -- 1.5 million patients that were registered as first responders. So to get the estimate of full or partial PTSD we multiplied that by the -- the estimates from the veterans study. And then we concluded that about 390,000 of first responders nationally -- that there are about 390,000 first responders nationally with full or partial PTSD. Of course this could be -- the numbers could be higher because this does not include non-traditional first responders like volunteers.

So we -- they conduct a literature review of status of treatment outcome studies for PTSD in first responders, looking at studies that involve psychosocial treatment, pharmacological treatment, and combined psychosocial and pharmacological treatments. Inclusion criteria for the study, the papers had to address psychological or pharmacological intervention. Subjects were first responders. Subjects had primary

diagnosis of PTSD based on DSM -- or ICD-9 criteria. PTSD diagnosis or symptom status was the chief study outcome. The psychosocial treatment studies compared two active treatment groups or one active treatment group to a non-specific control or wait list group. Pharmacological treatment studies compared drug treatment to placebo or active comparator.

So in total, a total of 845 articles were reviewed. Of these, 21 were excluded because they were not in English, and 84 -- 824 patients were considered for the study. 807 were excluded for various reasons (telephone/electronic interference) treatment study, some were not first responders, or the PTSD was not a primary outcome. So they were left with 17 articles for the review. Of these, only two articles were randomized control trials.

(NOTE: Electronic interference was present throughout this presentation, with the sound of dial tones and telephones dialing.)

So one of the -- this first article was done by Difede et al in 2007 at Cornell University, and involved a randomized control clinical treatment trial for World Trade Center attack-related PTSD in disaster workers. And they looked at -- they randomized the participants to two different treatment groups, what they called cognitive behavioral therapy or what's referred to as 'treatment as usual' therapy, which is essentially referring the participants back to their occupational physician or to their primary care physician to address the PTSD needs.

They also used two measurements to measure PTSD. One was the CAPS, which is the gold standard and is clinician-administered. The other was the PCL, which is a self-administered and is what we use in the treatment program. And as you can see, there was -- when you compare pre- and post-treatment data, the mean scores for pre- and post-treatment, the drop in symptoms were higher for the CAPS compared to the PCL. However, if you include -- there was a high dropout rate in the patients that were treated with cognitive behavioral therapy, so if you include them in the intend to treat samples, the drop was not that significant.

Another randomized control study that was done looked at the use of brief eclectic psychotherapy for police officers with post-traumatic stress disorder. These were Dutch police officers, and they randomized -- 22 patients were randomized, either to brief eclectic psychotherapy or they were -- this was compared to -- a wait list was used for a comparison

that included 20 patients. And what was interesting to note was that after four sessions there was no significant difference between the two groups. But post-test and follow-up studies showed that 96 percent of the patients that were in the brief eclectic therapy had no PTSD and those 35 percent on the wait list had no PTSD. And that was true also for other PTSD symptoms.

What's interesting, too, at the bottom of the slide, is when you look at resumption of police work, that 86 percent of the patients at the end of therapy that were treated with -- that were treated with brief eclectic psychotherapy, 86 percent returned to work as compared with 60 percent that were on the wait list.

In summary, around 400,000 first responders with PTSD symptoms, a review of 845 articles, two randomized control of psychosocial treatment, there was no randomized control trials of pharmacotherapy or combined treatment. CBT and brief eclectic psychotherapy was evaluated, effect size was large, and based on studies identified treatment guidelines used our questionnaire. Barriers to treatment research for first responders due to status which -- we know the people on active duty are associated with lower levels of treatment, referral and engagement. Stigma concerns, meaning negative evaluation by peers or leadership. Changes in job status, meaning that they're afraid that they might get reduced. Changes in job duties or reduced pay. And also it seems that first responder organizations are unaffiliated with academic institutions, unlike the Veterans Administration health systems.

So recommendations for future treatments in PTSD is to begin with treatment with the strongest preliminary evidence for efficacy with first responders as the CBT and BEP. Psychosocial and pharmacological treatments identified in non-random control trials should be tested in random control trials. And psychosocial and pharmacological treatments represented in current treatment guidelines for PTSD need to be studied, especially for those evaluated with active duty military personnel subjects with many similarities to first responders. Also we need to focus on non-law enforcement, as a majority of studies are focused on law enforcement -- majority of current studies focus on law enforcement. And we need to assess duty status as a potential moderator during and post-treatment. Duty status has been known to be associated with exposure to traumatic stressors, which may complicate treatment, attenuate outcomes.

So the next common symptoms that we're seeing in the treatment pro-- problems that we're seeing in the treatment program is respiratory disorders. And as you all know from the previous presentations that respiratory symptoms are common among World Trade Center responders. Cough, dyspnea, wheezing are common respiratory complaints, and there are essentially two groups: World Trade Center responders with symptoms and abnormal spirometry, and World Trade Center responders with symptoms and normal spirometry.

It was reported by Dr. Herbert from Mt. Sinai using the clinical center consortium in 2006 that over 9,000 World Trade Center responders, 72 percent have normal spirometry results despite respiratory symptoms.

A study that was done at NYU evaluated 174 patients with respiratory symptoms and normal spirometry. This was done by Dr. Berger et al from the pulmonary department at NYU, and they looked at impedance oscillometry, which -- without going into details about, it's a way -- it's a simpler test to do -- some think it's a simpler test to do than pulmonary function test, and it's good for measuring distal airway disease. And they also looked at the use of oscillometry to look at resistance and reactions in these patients, which are measurements used to determine distal airway disease. They also looked at what's called frequency dependency of compliance, and frequency dependency of compliance simply is usually in normal people with no symptoms and normal pulmonary function, when you increase your respiratory rate there should be no change in the compliance. For people with distal airway disease, increase in respiratory rate may cause a decrease in lung -- distal air-- in compliance with distal airways. And this testing was repeated after bronchodilation.

DR. MIDDENDORF: Dr. Harrison, you're at 15 minutes.

DR. D. HARRISON: Okay. I'm almost done. So despite normal spirometry, mean resistance and reactions were elevated, resistance and reactions normalized after bronchodilators, and so they determined that there was a need to look at these alternative ways of measuring lung disease in patients with World Trade Center-related symptoms.

On the flip side, this was a study that was done by Dr. Udasin, who just spoke, on respiratory symptoms associated with lower spirometry results during the first examinations of World Trade Center responders. They looked at over 18,000 responders with dyspnea, wheezing and cough, and they found that the mean FEV-1 and FVCs were lower for

participants who reported persistent respiratory symptoms. Responders reporting respiratory symptoms also had larger bronchodilator response. The conclusion was that responders reporting chronic persistent cough, wheezing or dyspnea at first medical examination were more likely to have lower lung function and bronchodilator responsive compared to those without symptoms.

Conclusions therefore that, similar to most people with occupational environmental exposures, World Trade Center responders present medical conditions which may have diverse etiologies. These include not just respiratory and mental health conditions, but other disorders such as GERD and sleep apnea. The New York population allows for the study of multiple diagnostic and treatment modalities that can be applied to responders in future disasters.

Thank you.

DR. WARD: I have seven minutes until public comment, so are there any questions for Dr. Harrison?

(No response)

Well, I think -- it seems like we shouldn't start the next presentation, so we should --

DR. MOLINE: Oh, feel free to interrupt. It's not a problem. I mean I can truncate my talk. My talk's sort of split into two, so I'm happy to start so you don't have to sit and waste some time while we're waiting for public comment, and then I can just continue after. I don't mind. It's -- whatever you prefer.

DR. WARD: Okay, let's just take a very short stretch break and be ready for public comments.

(Recess taken from 3:08 p.m. to 3:15 p.m.)

DR. MIDDENDORF: We do need to come back to the table so we can get into the public comment period.

(Pause)

DR. WARD: Okay, third call for Committee members to come back to the table and -- because we'd like to start our public comment period.

(Pause)

DR. MIDDENDORF: We need to move on. Okay, we're going to begin, and a note to the record that each of the Committee members is here at the table except for Dr. Trasande. And let me ask -- Dr. Talaska, are you on the line?

(No response)

And not hearing anything, apparently he's not on the line at this point.

PUBLIC COMMENTS

So we do need to get into our public comment period. Each of our public commenters has signed up earlier today on a first come, first served basis, and each of them will have up to five minutes to present. It's often surprising how quickly five minutes can go, particularly when you're talking about a subject that you're very passionate about. So what'll happen is at four minutes I will politely say -- let you know that you have one minute left, and we will also be using these cards so that when you start I'll hold up the five minutes, when it gets to one minute left I'll hold up the yellow card letting you know there's one minute. And when your time is up, I'll bring up the red card and I will have to rudely interrupt you. I apologize for that up front, but it is part of our requirements.

So I should also point out that you do have the option of submitting written comments to the docket for this Committee. The docket is number 248 and the information on submitting the comments is on the NIOSH docket web page and it's also in the Federal Register notice for the meeting.

And the other thing I want to point out is the -- we do have a redaction policy for public comments, and that was also published in the Federal Register notice and was at the table where you signed up.

So with that, I'll turn it over to Dr. Ward.

DR. WARD: **[identifying information redacted]**? And you can come to the microphone at the table where the speakers have...

(Off microphone discussion, not audible due to electronic interference.)

DR. WARD: Okay. Alec Sanchez?

MR. SANCHEZ: Good afternoon. My name is Alec Sanchez. I am a 9/11 responder, cleanup worker. I would like to start out my testimony by very much offering a moment of prayer for a renowned leader to the 9/11 community. Right this minute he's in the hospital, New York (Indiscernible) Hospital, he suffered a stroke -- **[identifying information redacted]**, President of Unsung Heroes, Helping Heroes, and one of our own.

(Pause)

I would like to recognize members of the STAC committee. Mr. Chego (ph) and I have had the honor to work with some of the familiar faces in

this Committee -- Steve Cassidy, Madame Mejia, Madame McVay Hughes, Madame Flynn, Madame Fidel (ph), thank you for your commitment to the 9/11 community and to your service to our country.

My name is Alec Sanchez, once again. I am a 9/11 cleanup worker. On September 11th I had a very close encounter with terror. I was standing a very short distance from this building, and I witness the gate to Hell open. On September 12th I get a call -- phone call from my supervisor. Prior to performing cleanup here at Ground Zero, I did janitorial work for New York University. On September 12th I get a call and my supervisor, Major Oliver, tells me 'Alec, get your team ready; we're performing cleanup work at Ground Zero.'

I had two great news in 2001. I became a father for the first time. And as a New Yorker, being able to be part of the recovery of my city, it was like winning the lottery.

9/11 changed the world. And it's very much evident, just coming into this building here today, how security has changed so much since 9/11. On 9/11 we encountered contamination never seen at this level -- not in Hiroshima, Nagasaki or Kuwait. Sadly a registry was never put in place. New York City, unlike D.C., was despair of the action taken at the Pentagon where FBI tasked EPA for rescue, recovery and cleanup to wear the personal protective equipment. Here in New York City we encountered a very casual sentiment to 9/11 contamination -- the air is safe to breathe. Ten years later impunity for those elected officials whose job is to serve and protect, more than a thousand have died since 9/11 -- 1,020, to be exact. There is no doubt in my mind that we will surpass the number of 2,751 who lost their lives -- those innocent soul who lost their lives on 9/11.

These last eight years **[identifying information redacted]** and I continue to be on the front line on behalf of a community afflicted by the maladies of 9/11 exposure. Through advocacy and political activism, **[identifying information redacted]** and I have established a relationship with the orphans, the widows, the mothers, the fathers -- like James Zadroga, Sr., a dear friend, who today is raising his 10-year-old granddaughter due to 9/11 exposure.

As a cleanup worker we were never trained or licensed to perform our duties. Also we must note no training in emergency management.

Today we have noted numerous of findings. Nearly 70 percent of those exposed to 9/11 contamination have respiratory ailments, gastric

disease, post-traumatic stress disorder also being recognized. Clinical studies have shown pregnant women who were exposed had a very low birth weight with their newborns. The Lancet study recently I know all of you are very familiar with.

Being in the front line nearly a decade provides a whole lot of insight, seeing those who were exposed to 9/11 contamination deteriorate right before our very own eyes. Example: Jack McNamara; we were sitting in Senator Lieberman's office, and two months after that --

DR. MIDDENDORF: One minute, Mr. Sanchez.

MR. SANCHEZ: Excuse me?

DR. MIDDENDORF: One minute left.

MR. SANCHEZ: Two months prior to that we were sitting in Senator Lieberman's office and then two months after that I reached to **[identifying information redacted]** and asked him, 'Who is that gentleman?' He said 'That's Jack McNamara', who very much deteriorated before our very own eyes.

Let me speed it up so I can conclude. We cover all the bases today. What I haven't heard today is the economic aspect to all of this. Under the Zadroga Act the crazy provisions in the Zadroga Act provided by a political establishment, the Republicans, who have turned their backs on 9/11 responders since day one. Every society honors and reveres those who go to the front line. We have been --

DR. MIDDENDORF: Mr. Sanchez, hold on just a second. Your five minutes is up, but before you leave, since we have nobody else on our list that is going to make any public comments, let me throw it to the Committee -- would you like to hear another five minutes from Mr. Sanchez?

MR. SANCHEZ: Thank you so much.

DR. MIDDENDORF: It's unanimous.

MR. SANCHEZ: We have had a Republican establishment that have turned their backs on 9/11 responders, as I mentioned. Every society honors and reveres those men and women who go to the front line. One of the crazy provisions implemented by the Republican Party to the Zadroga Act is $2.8 billion being spread throughout five years -- $800 million is the first five years, the remaining $2 billion on the sixth year. If we recognize these cancers -- there's not enough money in place as it is, but if we recognize these cancers, then -- and we will recognize these cancers, by the way, because we will continue -- our resolve continues to

be the same. We will fight to the very end for those who helped lift a city, an economy and a nation.

And one of the most proudest thing I ever done in my life is serve at Ground Zero and watching these men and women very much vanish right before my very own eyes, and the children -- I mean I am a single father of an amazing 10-year-old. I wish I can say -- he is our youngest advocate. Jack started advocating along my side since he's five. But I witnessed numerous of diaper change on the bus on the way to D.C. and back. We must continue to strive forward. We are a better country than this.

J. Edgar Hoover provided food for millions of Russians. Ronald Reagan gave amnesty to undocumented and put an end to the Cold War. John F. Kennedy put a man in the moon. We are better than this. We need to take care of our own.

John Feal, President of the Feal Good Foundation, an officer and a gentleman also, tells me there's a code in the military, you never leave yours behind. We have spent so much money in Afghanistan and Iraq, $360 billion to be exact, we couldn't come up with $10.7 billion to help those who helped lift our city and our nation. This is not the country I want my 10-year-old to grow in.

We shall never forget, and may God bless the United States of America. Thank you.

DR. WARD: ... the video that was submitted earlier, or do we have another public...

(Discussion with off-microphone speaker)

DR. WARD: Oh, right. Well, I thought the video was part of the public comment period. That's my confusion.

(Discussion with off-microphone speaker)

DR. WARD: Okay, so we'll go to Dr. Moline then. Dr. Moline?

LONG ISLAND JEWISH MEDICAL CENTER
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DR. MOLINE: Standing between you and Executive Session, I will make my comments as 15-minute-worthy as possible, I hope. It's a pleasure to be before all of you, to be in front of many of my former teachers, some of my former trainees, some colleagues, and many people whose names and papers I've read for many, many years. It's a pleasure to be here presenting.

I'm going to be talking about some aspects of the Queens World Trade Center Clinical Center of Excellence, which was started by Dr. Markowitz; and the Center for Biology of Natural Systems at Queens College, and as of July 2011 became a partnership with Long Island Jewish Medical Center and is now the Queens World Trade Center Clinical Center of Excellence at Long Island Jewish Medical Center Queens College. And if I could have my slides, please?

The advantage of going last is that I don't have to give you a lot of background or give you much more, and I'll just give you some numbers on the cohorts and means, and then I'd like to talk to you about a research project that's been funded while we're getting the slides up.

And so there have been about 3,200 folks registered in Queens. Of that, there are 2,885 in the total cohort and about 1,700 who are actively involved in monitoring. If you can see our -- a map of where most of our responders live. Of note, Queens is the borough with the largest number of World Trade Center responders so it's critical that there be a clinical center within the borough of Queens.

And as of the end of September we had 443 unique patients in active treatment. These are people who have been seen within the past 12 months, with about 350 in physical health and 200 in mental health, and many of those obviously are in both, which brings us up to our number.

Total number of exams is nearly 6,000 that have been done since the inception of the Queens Clinic in 2002. There have been 2,700 treatment visits, and almost 5,000 mental health visits. And social work benefits have been -- benefits, evaluations and advice have been given to over 900 individuals.

Like many of the others, our patient distribution is mixed. Law enforcement makes up the bulk of patients that are seen in our clinical center. We also have construction, transportation, many unemployed, retired, and in a variety of different trades.

As Dr. Crowley mentioned earlier, we worried about multiple myeloma and my -- to talk a little bit about cancers, and the reason that this was -- we felt it was important to publish this paper was not that the rate was so much higher in the aggregate -- because the expected rate, given the population size, was 6.8; we saw eight that we counted at the time that we were collecting the data -- but that there were four people that were under the age of 45. And for those of us who have been involved looking at sentinel health events in our occupational medicine careers, things

strike out. And sometimes very small numbers are what makes the case, whether it's three cases of hemangiosarcoma in one plant leading to the connection between vinyl chloride and that rare cancer, but it was very striking. Multiple myeloma is not a disease of the young. It's a disease -- it's actually the second most common hematologic malignancy, but it's when you're 70, not when you're 40. And we had four folks under the age of 45, and it just seemed unusual so we wanted to alert folks of this. All of them happened to be in law enforcement, which I think is just a chance finding of our cohort, and this was based on -- by way of history, I was involved with the Mt. Sinai Medical Center and was the director there until April 2010, so this was during my tenure at Mt. Sinai, and this was based on the clinical consortium.

But there were possible etiologies that we had (telephonic/electronic interference) multiple myeloma, whether it's with benzene exposure -- although usually it's a longer latency than the other hematologic malignancies that are associated with benzene, whether it's solvents or many of the other toxicants that were seen, or whether it's a cofactor of the mixed exposure that people were exposed to.

In the manuscript, or in the paper, we also described additionally cases where there were one and (telephonic/electronic interference) in the surveillance project that's being done by the data center at Mt. Sinai and has been reported on by other groups as well, whether it's multiple myeloma or other cancers.

I wanted to talk about a project that's been funded as part of one of the research projects with Alfredo Morabia and Steve Markowitz at Queens College, and this is the World Trade Center heart project which is looking at cardiovascular health impact, prediction of incident cardiovascular events among World Trade Center responders. And it's a cohort study looking at the Framingham health -- the risk factors, which are smoking, cholesterol, blood pressure, diabetes; and treatment, looking at the impact of exposure at Ground Zero and also depression. It's following up on much of the work that's being done looking at co-morbidities, whether it's at Stony Brook or at other centers, to see if there is something unique about the World Trade Center exposure, not just purely from an exposure basis.

So what is the evidence and significance? We know air pollution is a risk factor for cardiovascular morbidity and mortality. We know that PTSD is an important risk factor for cardiovascular morbidity and mortality. And

so the question is do they modify morbidity and mortality above and beyond the established risk factors for coronary artery disease or coronary heart disease, which is the most prevalent killer in the United States. There are -- the first objective is to see whether this cohort can use the Framingham health -- the Framingham score to accurately predict the cardiovascular risk for primary and subsequent cardiac events. If any of you are interested in what your heart risk score is, just Google Framingham health risk, plug in your various factors that it will ask you for, there are a variety of on-line tools, and it will give you a percentage and a percentage score. And actually in preventive cardiology this score is used to determine whether you should begin medications or at what levels, and also to give you some semblance of maybe what you should focus on in terms of modifiable risk factors. Leading to objective two, which is there a need for a special score for World Trade Center score for cardiac health; is there something that's a cofactor between the exposures, as well as the standard cardiac risk factors; and are World Trade Center responders at higher risk of cardiovascular disease than other New York residents who weren't exposed to the air pollution and the mental stress. So is there something unique about these folks that we might be able to add to? We plan to recruit about 6,000 people, very ambitiously, who will be undergoing their monitoring and exams both at Mt. Sinai and at the Queens program. We will be assessing the risk factors, looking at the PCL score for PTSD which has already been collected, and also looking at the dust exposure which has already been corrected -- collected, and it will be integrated into the usual clinical assessment so it will not require an additional visit. There will be a two-year follow-up. Power analysis has been done which, given the prevalence of heart disease and in an aging cohort, there is sufficient power to determine if there is an effect in terms of the primary or secondary events. And there will be annual contact to see if people have been hospitalized to determine -- and these are heart end points in terms of cardiovascular diseases, also looking at SPARCS data for ER visits and medical records. The investigator team includes Dr. Morabia and Dr. Markowitz, as well as colleagues from Mt. Sinai and the Mailman School of Public Health at Columbia.

One of the things I wanted to talk about was -- and it's something that came up when Dr. Udasin was speaking, the eosinophilic esophagitis

made me think -- you know, one of the true values of the World Trade Center and the research into it, and something I think we need to think about, is that we can learn a lot about some diseases that are idiopathic, or we thought -- or we classified as idiopathic, as a result of looking at the World Trade Center cohort, and maybe these diseases are not truly idiopathic. The more we're learning about sarcoidosis, for example, is that it's a dust-mediated disease now. And there are studies from all three of the major cohorts or the three groups, whether it's the fire department, whether it's the clinical consortium or the health registry, that have all shown elevated rates of sarcoidosis. I think research on the etiology to find out what it was would be very informative, and this is talking about looking at some of the mechanistic causes for sarcoidosis that could inform us to see are there other things besides beryllium which causes a sarcoidosis-like disease. Maybe there were other metals there. Beryllium doesn't seem to have been that big a factor, but maybe it's aluminum. Should we be looking -- and we know aluminum was there. Could it be other metals that are there? And think about using the information that we've gathered to fund research that will look into the etiology of sarcoidosis that would have far-reaching implications above and beyond just the World Trade Center responders.

Certainly it's important to think about continued cancer surveillance, and urging that all cases be considered as the studies and the surveillance is being done that we not exclude folks who are coming in to the monitoring examinations who come with a diagnosis of treatment of having a cancer. These are not standard epidemiologic studies where you exclude people who have pre-existing disease when they come in. In a standard epi study you would exclude them because that's -- you want people free of disease at the time they come in if you're doing a rigorously-conducted study. This was not how any of these programs were developed. They were developed as clinical screening, evaluations, and to not count folks who come in with diseases would be a travesty to what was meant, the spirit by which people came into these programs, and I think it's important that we think about that in looking at all the studies as we go forward.

And Mr. Sanchez also raised something -- we had actually put in a proposal, that was not funded in the latest round, looking at the socio and economic impact of the World Trade Center among responders. That's something that needs to be done beyond what has just happened

to folks clinically. We've published many, many papers on the health effects, haven't (telephonic/electronic interference) looked comprehensively at all the responders to see what the true impact of the World Trade Center has been in terms of economic loss, in terms of disability, in terms of changing careers. And this goes above and beyond those who have clinical disorders. But that's something that really should be funded, and I don't mean to sound self-serving because that's our proposal, to put it in there, but it's the type of information that is really critical for folks to get a full understanding of what impacts (telephonic/electronic interference) of disasters could be. And again, this does have implications beyond just the World Trade Center. But what happens when people respond, and what can be the long-term sequelae in terms of the overall impact on health, and that's something that should be addressed.

So I think I -- in conclusion -- I'm the only person who didn't get the Mr. Middendorf, you've had 15 minutes, so I'm happy to conclude and take any questions. Yes?

MS. HUGHES: On the second slide it said 25 had deceased. I was just curious, was there any trend among the people, the 25 who had deceased, in your group you were looking at?

DR. MOLINE: We don't have the full information on what they may have died of, and they may have called in. But we can certainly look into the cause of death, and I think that's something that's also important. New York State was collecting death information on all folks. Certainly these should be collected -- the causes of death.

MS. SIDEL: I just had a quick question. I was wondering when you were talking about seeing disease in somebody that's 45 and it's a disease that you usually see in somebody that's 70. Are you finding that with other diseases, that people are like sort of almost prematurely aging?

DR. MOLINE: Aside from the investigators prematurely aging?

MS. SIDEL: No, I mean --

DR. MOLINE: That's a joke. That was a --

MS. SIDEL: -- that's exactly -- right.

DR. MOLINE: -- I'm sorry. For many of us who have been doing this for ten years --

MS. SIDEL: I'm using that as a -- I'm using that as a lay person, but what I'm trying to say is that they're getting diseases that usually old people get.

DR. MOLINE: It's actually -- it's a really critical question, and that's one of the things that I think we have to be alert for, and there have been some concerns about things like follicular lymphoma, which is again a cancer that may not be so increased in number, but yet is something that we see later in life.

You know, the cohort is actually -- as time goes on with the monitoring program, people are getting younger, if that makes any sense. When we started it, the average age was 43. Now over time, the average age has gone down to 38. So people coming in actually -- the young-- the people who were there coming in over time, so it'll be important to see whether there are those trends in terms of diseases and rates. Apart from the lymphoma and the myeloma, I'm not aware of any, but it's certainly something that is critical to find.

MS. FLYNN: So thank you, Dr. Moline, and thank you for the multiple myeloma study which we read with great interest when it first came out, very important work. And as a lay person I would say yes, we do -- we detect the signal in that study, and you have mentioned two ways to proceed that sound like they should be on a list of how this Committee could approach the issue of emerging illnesses, especially cancers, in a forward-leading fashion so that we are able to sooner than later address the emerging need in the population of sick responders and survivors. And the two things that I caught were, one, to not just look at the issue of greater than expected frequency of disease, but to look at all kinds of other unusual, unexpected patterns. And the other thing you said was that people should not be excluded who enter the health program with a pre-existing diagnosis.

Are there any other ways that you can propose where we might lean forward and hope to capture an emerging need sooner than later?

DR. MOLINE: I mean it sounds so simplistic, but to approach everything with an open mind. I think if you had asked all of us eight or nine years ago if we would be expecting to see folks coming in with persistent health problems, we would have said no, it's going to go away fairly soon, or we're going to have it in ten percent of folks, not -- certainly not in 30 or -- 30 percent of individuals who remain affected, or to see drops in pulmonary function that never come back in otherwise healthy folks, as they saw in the fire department. I think that, you know, having the open mind and just being willing to accept that there are issues that we need to look at seriously.

One of the things that befuddles all of us, which is how to work with existing regulations and rules and data sequestration -- and there are very strong rules that protect individuals' privacy and we can't circumvent that by any means -- but to be able to utilize whatever resources we have, whether it's the registry that has been done by the police department, for example, and folks that may not have come in with cancer to any of the programs because, quite frankly, they're going to so many doctors they don't want to go for another examination. They're not counted, so they don't exist in any of the studies. And we have to figure out a way of looking at all folks that have been -- that have disease that is verifiable, and include them in a comprehensive review of who was there -- who we know was there -- and say 'What are we seeing across all?' I mean it's easier said than done, because the datasets are distinct, and they have to be distinct for a variety of reasons. But for some of these issues I think that it's important to go to different data sources -- again, verifiable, scientifically credible, whether it's working with the health -- the cancer registries in the region or whatever it might be -- but not to miss out on folks who haven't come into the programs because they've had many other reasons why they wouldn't want to come into a program for yet another examination.

DR. R. HARRISON: It strikes me that, in listening to the presentation that you made, as well as others, that there's been a tremendous amount of research that's -- has shed and potentially will shed even more light on disease patterns and mechanisms, potentially, of the disease in this cohort and that that's tremendous benefit. I mean and the publications are really, really impressive, and I think we really have learned from the research many things that will be valuable in the application to other occupational cohorts and environmental disasters in the future.

But there's a question that struck me that might be worthy of further attention and I wondered if I could get your reaction to it, and that is the question -- really the bigger question of has the program made a difference? Has the application of probably what is the largest medical monitoring and treatment program that I've been aware of certainly in my career made a difference in health outcomes, whether that be -- has it improved the management of occupational and environmental lung disease, has it improved compliance with medications, has it improved patient satisfaction with care, has it improved access to care? In learning about the resources that we spent over the last ten years, it

strikes me there could be a number of interesting findings or lessons to be taken away that I bet -- my hypothesis would be that on a number of fronts the answer would be yes. But not to know that or not to take away from this historical experience some additional lessons about -- you know, it just strikes me that, you know, when I hear the firefighter data that these firefighters have been coming in, you know, every year for eight years, that we see a number in the consortium people who have been coming in religiously every year, that's pretty extraordinary and I think has some lessons in terms of care in the American medical system that's different in this experience than in your general primary care setting. These folks have gotten a chance to talk to occupational and environmental health experts. So is there -- are there some questions that could be answered about that?

DR. MOLINE: I think they're great questions. I think it's something we could certainly add or amend to the application that we put in that wasn't funded that was looking at the overall impact, because they do go in line with how they have -- what the overall impact has been in terms of access, anecdotally. And from working at the Sinai cohort, and now in Queens, the access issue is -- for many folks this is their only source of medical care. It is certainly their only source of medical care for folks who understand occupational and environmental exposures. Countless folks were placed on antibiotics in 2011. There was probably a shortage of antibiotics in the fall of 2011 in New York City from the number of people who were placed on antibiotics for a cough, who didn't have an infection but they had reactive airways or the beginnings of the World Trade Center lung issues that we still see.

So access? Absolutely. Have we learned -- we've also learned that the treatment -- and if you were to apply the NHLBI asthma guidelines in terms of what's considered good treatment, we'd all be considered horrible clinicians because none of our patients are behaving, in those who have World Trade Center-related asthma, in a way that we would like in terms of being able to have them under good control, meaning needing a rescue inhaler less than once or twice a week. They require it far more often so it's a somewhat different disease. So have we learned something from that in terms of patient outcome and utilization? Yes. Could we look at the fill rates and see if that's made a difference in a program that has covered the costs? I mean certainly we can do that, and it's an important question to say 'If you give people access to these

medications and they do in fact take them' -- first of all, are they in fact taking them? Are they using them correctly? One of the elements of all of our treatment programs across the consortium has been the nursing education component and the sheer amount of time that people can spend with a patient, which is different from a primary care practice and the demands. So that has also been of value, and does that mediate the effect? I mean those are all important questions to ask, to look at how has this program made a difference. Certainly in terms of access, there's no question.

You know, we've had philanthropic donations that allowed people to even get to the clinic because they didn't have the economic resources for a subway trip, and have been able to provide subway tokens or -- they don't have tokens anymore; I'm dating myself -- but Metro cards for folks because they couldn't otherwise get to their treatment. And removing that barrier, and particularly for folks with mental health issues who need frequent visits, that has often been the difference between them go-- becoming compliant and not compliant. And I think those are critical issues to look at.

DR. R. HARRISON: I think that there ought to be some way to capture that, what you just said, either in qualitative or quantitative terms. I think that's really, really important because as we look back on this, funding a lot -- will bring a lot of money, a lot of resources into this, and I think there is a question -- you know, what -- is this a good thing to do, from a policy, from a care integration point of view. Are we picking up more people with hypertension and diabetes because of this? Are people losing more weight because they're coming in every year?

DR. MOLINE: Losing more weight? No. Are we picking up more diabetes? Yes.

DR. R. HARRISON: Yes, I mean I'm just -- yeah, I'm being facetious.

DR. MOLINE: But you know, one of the aspects is -- you know, are we turning this -- the programs are prohibited from doing any of the primary care treatment. What we can do is primary care health problem awareness, and increase people's awareness of -- and certainly we are identifying the newly hypertensives, the out-of-control hypertensives, the diabetics, folks with a litany of other medical conditions and trying to urge them to get the medical care and, as being in part of a program, show that the rates may be different is a question. I don't think we've been doing very well with the weight, though.

DR. WARD: Would you like to come back up to the table since we're having a more general discussion, and then I think the next tents were John and Julia.

DR. DEMENT: Thank you. My question has to do with sort of the process and -- of how you would take some of the leads. The sarcoid is an interesting observation. Sort of the current structure I think is something that needs to be looked at in a lot more detail. How would that occur in sort of the current framework for how the centers work with the care centers? I see it's not one of the research projects -- one of the eight funded research projects, so you know, your comment on how that would go about.

DR. MOLINE: The sarcoid question, you know, we've always -- it's been striking, and you know from Dr. Prezant's paper it appear-- the sarcoid was a different type of sarcoid than he described earlier among firefighters even in terms of the symptoms. How we would have to do that would be, with the way things are set up, is we'd have to apply and hope we'd get funding. Or we'd have to find a donor to help fund some of this research, and do it the way that you'd do in a standard way -- which is in many ways a shame that we're not able to easily leverage data that has been collected and say 'We have 75 percent of it, but we can't do the research without that last 25 percent.' And to say you can -- or we should be looking at issues, whether it's something about sarcoidosis and trying to identify other etiologies for it, or the factors that may have caused it. I think that the structure as it's set up now is challenging because there's this very clear partitioning between what a clinical center can do and what we would like to do. And many times there's not the financial resources, the staffing, to do anything except provide clinical care.

DR. QUINT: Hi, I have I think what is a simple question. I may have missed this, but is there a gender breakdown in the people who are a part of the folks who are being monitored? I don't know if I remember --

DR. MOLINE: It's 86 percent male, 14 percent female. It's been steady since 2002.

DR. QUINT: Okay. And have you seen any differences between the -- based on gender? I mean different problems or manifestation of problems in women versus men?

DR. MOLINE: No, we haven't -- I don't think anyone's looked at it specifically, but you know, anec-- when we think about who we've seen,

it hasn't -- there hasn't been anything that's popped out in terms of gender differences. It would be important to see the groups maybe differently.

DR. QUINT: Right. And the other question I had, I don't know how many of the people are -- have continued to work. I guess I'm interested in terms of the persistence of symptoms over these many years, whether or not there are other co-exposures, either community exposures where people live -- 'cause there could be high pollution which could exacerbate, you know, the in-- you know, the initial WTC impact. Or whether or not, you know, at work there are other exposures that could cause the, you know, symptoms to persist. You mentioned SES and I just think that that's a fascinating thing to look at, you know, not overall in terms of the questions that you raised about the impact of SES. But also we know that, for a number of toxicant exposures, there's a SES pattern, so I'm just -- was curious as to whether or not there's been any look at the data to see if there's any correlation between, you know, where people live or where they work and either severity of symptoms or if that could explain in some way the persistence of symptoms.

DR. MOLINE: There hasn't been any work that's been done yet. I think it's something that's critical to look at. And as part of the ongoing monitoring and examinations there are questions about what people's exposures continue to be, to see not only what was your exposure, what were you doing on September 10th, what did you do during the time interval that you were working at the World Trade Center site, but what trade are you in and what job are you in -- and we do have addresses and there certainly should -- could be some geo-coding of where people live and diseases and see if there is, and maybe that will be one of your recommendations, which is to also look at whether we are seeing patterns of environmental injustice that are mitigating some of the health effects. Or is that also a co-factor as socioeconomic status has declined as a result of the World Trade Center exposures. Again, those are critical things to look at to really assess the impact. Because if somebody's environment has changed because they can't work at what they did before, their salary's gone down and they're moving to an area that may -- as we know, many of the less-advantaged neighborhoods tend to have higher rates of pollution -- or local pollution.

DR. ROM: Jacquie and Denise. So we've heard an awful lot today about cough and dyspnea and wheeze, and then we've heard from Mark Farfel

about a real increase in new onset asthma, and asthma aggravation also seems to be a major disease outcome that we're seeing a lot of. And then David Prezant presented a 12-year decline of FEV-1 in one year, that he lost 375 mls in one year, and this -- that doesn't seem to be recovered. So this all looks like the monitory events leading to COPD, and what we may have is a gigantic cohort of invalids ten or 15, 20 years from now of people who are short of breath and have the effects of all this dust. And so should we be really focused on this disease pathway now to try to identify what may be causes and how do we intervene and should we start thinking about this, 'cause this may be a huge respiratory disease problem. And what we've seen is cardiovascular disease and stroke and diabetes and cancer, now COPD is an emerging huge global problem, and we may have a big problem or disaster in our back yard with emerging COPD, and I'd like your comments and thoughts about that.

DR. MOLINE: Sure, and then I'll happily turn the mic over to Denise to answer this, but one of the things we -- I was privileged to participate in while I was at Mt. Sinai was working with Maryann McLaughlin on a law enforcement cardiac study, and we hope to be -- we've had several abstracts at national meetings and are working on the manuscripts now of 2,500 law enforcement officers and doing fairly extensive coronary artery risk factor and actual measurements. What we did find was there was a fair amount of diastolic dysfunction or right heart dysfunction, and so the question is is that pulmonary in that I think was the idea for the project that she is now looking at. And there are other factors 'cause is it the stress related to being in law enforcement that could be mitigating some of these effects. So -- or is it something pulmonary, because we know there are these pulmonary issues. I think it's a group that is in many ways invaluable for looking at can we -- we've identified -- we know they had a pulmonary insult. Some had symptoms that were manifest, some might not initially have manifest symptoms. Should we be doing interventional trials that are preventive, and I think that -- and thinking outside the box again for looking at creative ways of maybe intervening when there aren't symptoms -- that you know they've had the exposure -- and seeing over time if that will decrease it. We certainly have the power in the numbers of folks who had the exposures and who are being monitored and you've had sequential pulmonary function tests on many, many of these folks. So I mean I think it's a

critical issue. And again that's something that could inform medical treatment above and beyond just World Trade Center responders. So in terms of bang for the buck, to answer Dr. Harrison's point in part, is to what have we learned and we've spent a lot of money, and we -- but if we are able to further medical knowledge in general by looking at these very specifically-exposed folks, then the money is very well spent, not just in caring for these people who couldn't otherwise get care, but in understanding or helping others who have these similar disease processes that are occurring more and more.

DR. D. HARRISON: We certainly know that a lot of our patients continue to have a lot of respiratory symptoms. What we don't know, however -- and we know that, despite the traditional treatment of some of these symptoms, like cough, they're not responsive to the steroid inhalers or to even systemic Prednisone, so there is need to look into what the etiology of this disorder is. And we think that there's need for continued study whether to look at whether it's a irritant-induced pathway as well as early airway disease, and surely more studies need to be done in this area as to what the etiology is.

DR. WARD: Okay. So we'll thank you very much for your presentations and the discussion, and move on -- okay.

So the next thing on our agenda is we're going to view the DVD that was submitted by District Council 37, and Lee Clarke will give us a brief introduction on that.

MS. CLARKE: My name's Lee Clarke. I'm Director of Safety and Health for District Council 37. DC 37 represents 125,000 New York City -- primarily based in New York City -- government employees. Our job titles literally range from A through Z, we're fond to say -- we love saying that. But they are, they're architects, engineers, housekeeping aides, mortuary care technicians, clerical workers -- we represent them all. We literally had thousands of our members -- our union building actually is right there, and we were shut out for more than ten months. We had thousands and thousands of our members respond and who were right there when the Trade Center fell. The members of DC 37 pretty much characterize our sisters and brothers in the private sector as well. So when you're looking at this, you're looking also at the private sector workers.

It's important I think for this Committee today to go back a few minutes to the beginning of this morning where you started to -- you heard about

the population, their titles and what they do. And throughout the course of this very long day people turned into cohorts and numbers and letters and graphs and charts.

So with that, the minute -- the video isn't very long. It may freeze. Just hit the 'play' button again. And thank you to the Committee for taking the time to view this.

I don't know if you get the sound with it. I hope you get the sound with it. That's what you need, is the sound.

(Pause)

DR. MIDDENDORF: For some reason it doesn't seem to be... I don't know whether or not this DVD player will work or not. Yeah, it -- I'm more worried about the equipment than I am the DVD itself.

(Pause)

Howard, who is with GSA, is going to take the DVD and play it from the other room.

DR. WARD: Why don't we take a short break, about ten minutes?

(Recess taken from 4:11 p.m. to 4:19 p.m.)

DR. WARD: Committee members come back to the table. We'd like to start the video.

I've just been informed we need to conclude our meeting by 5:00 because the building requires us to leave, so we don't have unlimited time here.

(Pause)

(Whereupon, DVD was played.)

MS. CLARKE: The video was made in 2002, right before the upcoming holidays, and everybody in that video, all those workers, were at Ground Zero. Thank you.

COMMITTEE BUSINESS

DR. WARD: We're now at the last part of our agenda, which is set aside for Committee business. What time is it? Okay, it's about 4:30.

And so I guess the question is what -- I'd like Paul's advice on what would be the most immediate business that the Committee should cover today and what we should defer until tomorrow.

DR. MIDDENDORF: I think you might begin discussing what issues are before the Committee, and begin discussing how you might begin approaching those issues. And to do that, you might want to go back to Dr. Howard's presentation first thing this morning in which he laid out

what he believes are the issues before you.
DR. WARD: This is still a public session, so anyone who wants to is welcome to come -- I mean to stay.
So I think there were several issues that Dr. Howard talked about this morning. I guess we're going to discuss the Pennsylvania and the Pentagon issues tomorrow, right? So that's a specific -- we'll be getting an update, but we don't need to make a recommendation?
DR. MIDDENDORF: What Dr. Howard said is that there's nothing we can report on at this point so he's not coming to the Committee to ask you to address that. There is -- in your binder that you received there's an update to let you know where we are in that process.
DR. WARD: So there's two issues that I recall discussing was the issue of what research recommendations we would have for the next round of funding, and also the consideration of the petition with regard to including cancer, or some specified cancers, as specified diseases.
So in the half-hour remaining, perhaps we should tackle -- or begin discussion on the cancer issue, only because I think what we heard today was that there are two studies where the results are pending that -- but not -- but not completed and not available for our consideration that might, you know, really have great bearing on any recommendations we would make about cancer. So the question there is how can we go about making a judicious decision without the two pieces of evidence, 'cause I do think -- you know, as an epidemiologist I wish we had more defined cohorts, like the fire department cohort where we have our denominator and our numerator. But lacking that, I think the information that's coming from the study of the New York Health Registry and the Mt. Sinai cohort is very substantial and important to discussions about whether there is evidence, even preliminary evidence, for increased risk of multiple myeloma, non-Hodgkin's lymphoma, and other cancers.
So does anyone have comments about how we should proceed on that?
DR. ALDRICH: Let me just first say that I feel that's cause for part of our cancer study. So although I don't think that biases what I have to say, I just want to make sure you know that. It seems to me it's unlikely that there will be more information in the near term, even if we do wait for results from Sinai and the others because there's going to be ongoing concerns about surveillance bias and about the denominator issue. And I don't think we're going to have better evidence than we already have -- and for several years to come. I don't think we should delay making a

recommendation.

DR. TRASANDE: I'm thinking about this a lot because it seems to me perhaps the primal point the STAC ought to consider right away. I'm still struggling somewhat for almost a menu of options the STAC could recommend to the Administrator. I could see off-hand recommending inclusion, not inclusion, or some middle ground, and I'm still at a loss -- I mean I struggle with the notion, just to start with, of saying -- of recommen-- I'm looking, like most of us on this Committee, for more data and for more perspective. But at the same time I think we need to be proactive and precautionary; yet at the same time I think we want to wait for more evidence, at least from my perspective, before making a semi-definitive judgment. And so I'm wondering what specifically would be a middle -- if we were to simply say 'there's not evidence at this time' I think that could have a potential chilling effect for the communities that are looking for our perspective and our guidance. And I think that that would be also something that I think that Mr. Howard would not necessarily want us to leave him with that suggestion. So I guess I'm looking for some guidance on what -- and maybe this is a bit of reflection back, and I don't know if Paul wants to comment, or others want to comment, about what might be some guidance to the STAC of what would be helpful advice.

MR. CASSIDY: I tend to agree with you. It's complicated, but there are a lot of different studies that are out there. The one point that I would like to make about Dr. Prezant's study is that it's a seven-year study through July of 2008. When 9/11 happened, I remember specifically the stories being written six months, a year after, 'It's going to take ten years for cancers to show up.' So this is a seven-year study. As the president of the firefighters' union, I already know of several firefighters who are sick and dying, are not in Dr. Prezant's study because they got sick after 2008.

What I think, when I heard what Dr. Prezant said, when I heard what others say, you know, Dr. Prezant's study is about -- it's just about firefighters, but it's really -- I think it gets to the heart of the exposure. And so it documents -- you know, he went into great detail about the level of exposure -- firefighters who were there on day one, day two, day three. And I think it -- you know, I think that highlights something. I think we should discuss what that highlights.

But then I -- you know, I think that because if there's not a study of

police officers or construction workers who were working in the same area that that doesn't mean that you can't say 'well, one is transferable to the other'. I mean I think we have to have a discussion about what does one study say about others, and does it say something about people who were not working right there on the Pile but lived five blocks away. I think what's been documented today is that you could have severe exposure, you know, living ten blocks away if your building was contaminated and they were blowing contaminated dust through your building. How do we determine that?

So I don't think the level of exposure is necessarily -- although I think it largely revolves around how close you were to the site, for what period of time and when you were there. But I do think we need to talk about levels of exposure in some way. And then I think Dr. Prezant's study is really about levels of exposure. I know it's about firefighters, but I think -- I think, I believe, it's about levels of exposure.

And then I think can this Committee then look at that, because it seems to be the only documents that are -- the only study that's out there that has pre- and post-9/11. I mean you can't lose 12 years' lung capacity in the blink of an eye and think that it doesn't really mean anything. It means something. Now what does it mean? I don't know we should be discussing it. But I think Prezant's study is more than just about firefighters. I think it's about levels of exposure, and I think we should talk about whether or not we can come to some consensus about level of exposure. And that's my thoughts right now.

MS. SIDEL: I think we need to craft a compassionate solution, that we can't just leave people that are sick untreated while we get the correct data. And you know, you're scientists and so you have a certain methodology for doing this, but you know, I'm also aware that you have certain criterias for risk assessment and that's something that, you know, other studies like the National Academy of Science are looking at how those things are done. And so I think that there are so many different factors that to do anything definitive that isn't -- I think that we should somehow craft a compassionate solution, and I think that Dr. Prezant's study is really important. But I don't know -- I mean what else -- you know, how much better can it get? I mean to have all communities that are sick and to have that evidence? I mean it may take a long time, because from what I heard today, I think that a lot of the data has not been compiled because of funding in the past, so a lot of

the Centers of Excellence haven't had an opportunity to really compile data the way -- the way it needs to be compiled. That could take a long time, and I think that people shouldn't have to suffer because of a failure to fund something.

DR. WARD: Now let me just make a comment. Now what I heard today, specifically in relation to the two cancer incident studies, is that the data are for the most part compiled and they're in the process of completing the analyses, which would -- in my mind -- translate into a six to 12-month time frame for us to have the results. But it -- you know, I don't know if others interpreted the comments the same way. But I do want to hear from everyone who has their tent card up. I think, Steve, you might have been first.

DR. MARKOWITZ: That six to 12-month time frame is probably right, and I think we have to, you know, express our opinion, even if it's provisional, but before then.

I have a couple of miscellaneous thoughts. One is I'd like to -- not this afternoon, but I'd like to seriously discuss the fire department study, because it was positive in the sense of showing cancer effect. It was -- unusual set of results. It's what we have, and it was -- the quality was very good, so I think we need to talk about that directly because that's what we -- really what we have in terms of epidemiology.

Secondly, I think we have to talk at some point about what criteria we're going to -- we're using to make judgments. And you know, the law says -- and I'm puzzled about this -- 'substantially likely to be a significant factor in aggravating, contributing or causing', so is that any different from the way we normally think about causation? Because if it is different, then we should be explicit about that.

And finally, I think we have to -- again, I don't expect to be able to do this today or tomorrow, but -- take a very serious look at exposure and about biological plausibility, because there's more there probably than we have in terms of epidemiology. And if -- if -- it's relevant to the case. I mean it's highly relevant to the case and I think, again, we have to look at those things directly, as fully as we can, and see what we think about them.

DR. QUINT: Yes, I guess as a toxicologist I don't usually rely -- wait necessarily for epidemiological data, and I'm concerned about a couple of things. I mean I know the fire department study is pending, and we have a cancer study that needs to be discussed. But I think biological

plausibility is something that should be considered. It's what we go with for many toxicants, such as the soup that people were exposed to at 9/11. And I think that -- you know, we have cumulative impacts of many carcinogens here, and we have latency, you know, that -- it hasn't been long enough to say that the cancers, some of the cancers, would have developed from some of the chemical-- from some of the exposures. So I think having set the criteria for how we're going to make decisions is important, because I've heard a lot of emphasis placed on, you know, epidemiological studies. And often it's -- you know, if you have those studies, that's -- and they're well-conducted and we don't have confounders -- confounding, that's great. But in the absence of those data, then I think we have to look at what we know about these particular exposures and, you know, bring to the table the biological plausibility that cancer could develop, and we haven't seen cancers because either we don't have the power to see them -- I don't know if somebody's done a power calculation for some of these cancers, but you know, we certainly haven't -- it hasn't been long enough for some of them to have developed, it seems to me. So I think that that should be part of the decision-- part of what we consider when we make a recommendation, however we write it.

DR. ROM: I don't think we're there yet for cancer and that's very troubling. My concern with the FDNY paper is several-fold. One is, no particular cancer came out, and I would expect maybe lung or colon or some cancer site to be increased, and that didn't come across. It wasn't there. And we know that there were carcinogens in the mixture. There was a lot of asbestos. There was some benzene and there were polycyclic aromatic hydrocarbons, so we know that carcinogens were there. They may not have been very high, but the exposures were very intense to a lot of people. I don't want to say I'm against compassion, we all have compassion, but we are a scientific/technical advisory committee, and we're going to have critics out there of anything we say, and we have to be on solid footing to -- before we say anything so that the critics can be quelled. So a 1.2 -- or a 20 percent increase is not that impressive, I wouldn't -- everything below two is a little bit bothersome. I like to see threefold and fourfold. When you have eight multiple myelomas and 6.8 are expected, you know, I want to see 16 or 20 and then I feel a little bit more confident and I'll stick my foot out -- and my neck out. So I think we need more data. And it's nice that there are

some studies coming down the pike, but I would push NIOSH heavily that they are -- that the Administrator's in a pickle and we need more data. And there are research BAAs coming down the pike and we should start thinking about how these BAAs are going to generate data that's going to answer some of these critical questions. We need studies that address cancer and we need studies that address asthma, and we need some more of this science. And if there's just four of these funded when there's like eight or nine really good ideas and a bunch that are on cancer or biomarkers or monitoring or modeling, those might move up in the priority list.

MS. DABAS: I have to say that I think we should make some kind of decision when it comes to cancers. For one, I think the fire department has probably some of the best information that we're going to get because they have information on the responders prior to 9/11 and after 9/11. Mt. Sinai's study is not going to have the pre-9/11 information on their people that they are gathering on. I also know that Mt. Sinai has not done an exhaustive search for responders with cancer. One of the things that they are still doing, and I believe haven't even done to date, is to reach out to the NYPD to get the list of responders to cross-check that with the cancer registry. So I don't believe that their specific study is going to come out within the first quarter of the next year, which they've said that it would but have backed away from that timeline time and time again. And if we're going to wait for Mt. Sinai to get to that -- I also spoke to the WTC Registry, who also haven't contacted the NYPD to identify any members that were there so that they can also cross-check their study with the cancer registry. Mt. Sinai also had informed me on a separate occasion that they will not include the 49 police officers that have died of cancer to date, which -- because they would not be able to make a proper assessment of where they were at the World Trade Center and how long they were there for. I think that was going to greatly skew their numbers. So to date I think the fire department study might be our best study.

The multiple myeloma as well, Jacquie Moline did cite -- while she said the number of occurrences was not high, the age of the occurrences were. When you have people, six out of the 16 of the multiple myeloma cases were of men under 45 in a disease that shows up at 70, that I think is a number that we need to look at.

MS. MEJIA: Well, I don't even know where to start, but all I can say is

that I am not a statistician. I am not an epidemiologist. I am not a toxicologist. But I do know -- what I do know is that we have a lot of members and a lot of workers out there that have developed cancers since 9/11. Now the question I have is should all cancers be covered, and that's something that I think we need to, you know, discuss a little bit further because cancer is cancer, and so we need to determine whether we're going to cover one cancer versus another cancer, or are we going to cover the entire world of cancers. And so I do have that question out there.

MS. SIDEL: I already touched on what I was thinking, but one thing that I'm concerned about is this whole thing with creating zones and what day were you there, because you could go into your apartment and have -- and get a great big pile of dust in your face, and you could have a predisposition toward something, and it could have happened three months after the fact. But those toxins don't get less toxic -- I don't think, do they? I mean I think that they are what they are. And so no matter when you get them, you know, when they get into your system they're going to do the same thing. And every body -- and I mean body -- is different, and I think that -- I understand as scientists you want to find a commonality. I think it's really hard and it's unfair to a lot of -- I think that there's no way to not exclude people that need to be included.

DR. WARD: At this point there are many complex questions, and I think -- you know, what you said really kind of resonated with me because I think -- you know, when you look at the firefighters study and you look at the results, and there were excesses for specific cancers and there was a somewhat -- there was also an excess for cancer overall, but it was not large. And so you look at that and you say okay, if you wanted to be compassionate and cover some cancers, which one of those cancers would you feel that there was enough evidence, you know, to say was associated with the exposure? And I think from those results it would be very hard for most of us to say there's one. I mean I'm certainly concerned about the multiple myeloma because we've heard about it in more than one population. Some of the others, like thyroid and prostate, you know, it's -- it would be hard to single them out because again we know they are susceptible to early detection -- whether there's detection bias or not, those are cancers that are just very susceptible to being detected when people see a physician. So it's really -- even though I think it is a strong study, there's not a single pat-- there's not a single

cancer or a pattern that's kind of screaming that it's causally related to the exposure. And so I think that's the dilemma we face. Plus, of course, the very complicated issues of what -- you know, the different exposed populations and what constitutes high exposure and how do we best characterize exposure in all these diverse circumstances.

So we do have to close at 5:00 and I think -- does -- we can certainly mull these questions over tonight and come back in the morning refreshed, and hopefully come to some completion. I doubt that we'll come to a final conclusion, but hopefully we'll have some level of consensus on a plan for how to proceed and what criteria we should use, and kind of how to frame the discussion tomorrow so that we make the best use of our time together.

So I guess it's about time? Yeah. Well, thank you -- oh, yes?

DR. TRASANDE: I'm just looking for the Chair and Paul's guidance here with regard to whether -- with regard to what our agenda is for tom-- for the half-day tomorrow. Is our intent to focus on the cancer question? Are there other questions of import that we're -- I mean I'm just cognizant that we want to use our time efficiently as well and respond -- I recognize we have three core missions that Administer Howard outlined here, and I just -- I'm only asking that because I think we should try to think about it rather than mull that and have it be uncertain until the morning -- tomorrow morning.

DR. MIDDENDORF: What I would say is that you have a definite deadline on the cancer petition, so that's something that you must begin discussing tomorrow. You need to plan a way forward, how you're going to address that, and then come up with a recommendation by March 2nd that you can give to the program administrator.

I think the research issue is something that is on the table that maybe you want to start thinking about just process, how you might as a Committee begin addressing the issue as to how you might develop recommendations for Dr. Howard as the program administrator. But I would not get into any details at this point in time because of the potential for conflicts of interest. That's something we're going to need to deal with between now and when you start getting down to specifics.

DR. WARD: So I think it would make sense that when we reconvene that we first discuss the cancer question, but that we agree in advance that we'll have a certain amount of time set aside for the research question because I think it is important, after all we heard today, to really identify

some top areas that we'd like to see addressed in the research agenda, while all the discussion from today is fresh in our minds.

DR. MIDDENDORF: That's -- why don't we say 8:15, just to make sure the people can get through the door. Does that work for everybody, 8:15 in the morning? Great. Have a good evening.

DR. WARD: Thank you, everyone.

(Meeting adjourned at 4:59 p.m., to reconvene at 8:15 a.m., Thursday, November 10, 2011.)

CERTIFICATE OF COURT REPORTER

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COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of November 9, 2011; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither related to nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 6th day of December, 2011.

_____

STEVEN RAY GREEN, CCR, CVR-CM, PNSC

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PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes

MEETING ONE

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

VOL. II

DAY TWO

THURSDAY, NOVEMBER 10, 2011

Jacob K. Javits Federal Building
26 Federal Plaza New York, NY

The verbatim transcript of the

Meeting of the Scientific/Technical Advisory

Committee held at the Jacob K. Javits Federal

Building, New York, New York, on November 10, 2011.

This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

C O N T E N T S

November 10, 2011

TRANSCRIPT LEGEND

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P R O C E E D I N G S

(8:29 a.m.)

DR. MIDDENDORF: Good morning. Here we are for the second day of our meeting. The first thing we need to do are some of the administrative tasks again. I'd like for each of you to identify yourselves for the purposes of taking a roll call. So Dr. Ward, if you'd like to start.

DR. WARD: Elizabeth Ward.

DR. NORTH: Carol North.

MR. CASSIDY: Steve Cassidy.

MS. HUGHES: Catherine McVay Hughes.

DR. ROM: Bill Rom.

MS. SIDEL: Susan Sidel.

DR. QUINT: Julia Quint.

DR. WEAVER: Virginia Weaver.

MS. MEJIA: Guillermina Mejia.

DR. MARKOWITZ: Steven Markowitz.

MS. DABAS: Valerie Dabas.

MS. FLYNN: Kimberly Flynn.

DR. DEMENT: John Dement.

DR. WARD: So before we start the public comment period, I'd just like to give a very brief overview of how we think the agenda should be today. We'll have the public comment period and then we'll ask John and Emily to come to the table and give us an overview again of the options regarding how to respond to the petition regarding cancer, so everyone's clear in our mind what the options are for that. And also the Committee can ask any questions about -- that might have arisen yesterday regarding the criteria for a condition to be listed among the World Trade Center-related conditions, as well as any other procedural or legal questions that came to mind.

We'll then move on to reviewing some of the criteria that's used to determine carcinogenicity. Specifically we'll look through the Bradford-Hill criteria, which is in our notebook, and some of the material from IARC and NTP.

We'll then start a substantive discussion of the cancer question, and probably spend up to an hour and a half on that topic before we move on to discuss research.

And for the research component, what we'll do is we'll think about -- we'll really try first of all to identify all of the main ideas or topics for research that came up during the discussions yesterday, and then flesh those out a bit.

PUBLIC COMMENTS

So we'll move now immediately to the public comment period, and the first person is Micki Siegel de Hernandez.

DR. MIDDENDORF: If I can break in for just a second, I just want to check -- Dr. Talaska, are you on the phone line?

(No response)

There was no response. So for the public comment period, as it was yesterday, each of the public commenters is -- who will be speaking signed up earlier on a first come-first served basis. They will each be given up to five minutes to present. And I'll remind them that it's often surprising how quickly five minutes goes by, so as we're going through that -- well, at the beginning I will be holding up the five-minute green sign. When we get to one minute left I'll be holding up the yellow one-minute sign. And when time is up I'll hold up the red card to let you know that time is up, and I will have to rudely interrupt and, again, I will apologize for that but we have to follow those rules.

MS. SIEGEL DE HERNANDEZ: Okay, thank you very much. I wanted to take these few minutes to expand on one of the bullet points that we had in the PowerPoint presentation yesterday, and that is the bullet point relating to looking at all of the evidence that's available, not just an epidemiological study, in order to build a case around inclusion of cancer. And it looks like that's the way this Committee is going.

We think that there are enough pieces of the puzzle right now. Taken separately they don't make that case but, put together, we think that there is much stronger evidence. And I know that this Committee is in a very tough position right now, and we also know that waiting is not an option for all of the studies.

A few things that I want to mention. The studies that are pending from both Sinai and the registry, I think that there are also some limitations to what those studies can tell you, and they may not be the be-all and end-all that everybody is expecting. In June of 2010 New York City Department of Health and FDNY pulled together a group of cancer experts, statisticians, to look at analytic methods related to cancer --

analysis of cancer. One of the things that was very clear from the expert meeting, and John Dement was part of that group, was that in terms of cancer epidemiology each of these cohorts is actually a very small size. We're usually looking at much larger numbers. And so detecting an increase is very, very difficult.

And we also know that there are cases -- that there are reasons why we believe that cases are missing, including the matching to cancer registries which are two years behind, which are much better at detecting solid tumors but not as good as recording cases of hematologic cancers, which are the ones that we would expect -- and Jacquie Moline mentioned that yesterday. So this issue of the power of the cohorts is very important.

And while we look forward to those analyses, and they will be -- they will add to the knowledge, there will still be limits. And I think you also need to look at that when you look at the FDNY study.

What we do have is the FDNY study. Steve yesterday -- Steve Markowitz -- had suggested really taking a careful look at that, and I think that Steve Cassidy's comment about looking at it in a broad sense about what it says about exposure, not just about one particular population, and how that might apply is very important.

This issue of biologic plausibility, that really has not been explored at all, and a careful look at at least the toxicants that we know about and that there is some evidence -- historical evidence in terms of disease causation, I think that this Committee needs to take a careful look at that piece in the development of disease, as well as the issue of sentinel and unusual cases.

Jacquie Moline mentioned the multiple myeloma cases that were in an earlier age group that were kind of surprising. There were mention of some other cases of cancer that are just particularly rare cancers and, again, by themselves don't give you the answer. But put together into a bigger piece, they do.

So as you move forward -- and there may be more. I mean I think that this Committee will probably come up with more pieces of evidence that could be brought into the record to make this case.

I think this Committee -- you have a limited time frame in terms of meeting, but the Committee has other powers, I believe, in terms of soliciting information that may be helpful. So if there's information about exposures, about particular cases -- I'm not sure exactly the

procedures for that, but I think that that is possible, as well as subcommittees, sort of continuing work, between the regular Committee meetings.

So thank you. That's my comment.

DR. WARD: Our next commenter is Lee Clarke.

DR. MIDDENDORF: While Ms. Clarke is coming to the table, I'll just note to the record that Dr. Trasande has joined the Committee.

MS. CLARKE: Micki Siegel de Hernandez expressed my thoughts and I appreciate it. Thank you.

COMMITTEE BUSINESS

DR. WARD: Okay, so we're going to ask Emily to join us at the table and first for Emily to give us an overview of the options that we have for responding to the petition, or for making our recommendations to Dr. Howard of how to respond to the petition.

MS. HOWELL: Hello. I was asked to speak with you all about questions that had arisen yesterday regarding what your path forward at this time may be regarding submitting a recommendation to the program administrator on the petition request that you've received. I think under tab 8 you have a copy of the letter that Dr. Howard submitted to the -- to Dr. Ward, the Chair. In that letter he asks for the STAC to review the available information on cancer outcomes associated with exposures resulting from the September 11th, 2001 terrorist attacks and provide advice on whether to add cancer or a certain type of cancer to the list specified in the Zadroga Act. He provides you with the two reports, the first periodic review of cancer by NIOSH, as well as the FDNY contact that has come out -- I'm sorry, the FDNY study that has come out, and this letter was in response to a petition received from the Congressional delegation of New York State.

A recommendation from the board would typically take the form of an up or down yes or no vote. However, as a Committee you, in your recommendation letter, Dr. Howard has specifically asked you to give rationale and scientific basis for what you are recommending. So in this instance it's foreseeable that you could choose to say 'We don't see a basis for adding cancer at this time, given the two studies we have in front of us and the other information, and we are aware of future studies that will be coming out that we think will shed more light on this.' It's also possible that you not vote today. You have until March

2nd, and you may feel that more information will be coming forward between this time and that time. You could vote yes today, but you would need to give a rationale that the program administrator can rely upon in making his own determination. Because once he receives a recommendation from you all, he then has the option of moving forward with proposing a rule to add the condition or publishing a determination that it's not warranted at this time.

I also wanted to clarify that of course what you're voting on is a specific petition. So if for some reason, whether it's through -- regardless of how the Committee votes, but if this condition were not added at this time there's always the possibility, and we fully anticipate future petitions on a range of conditions to come forward. So if this particular petition does not result in an addition of perhaps all cancers, we could receive a petition tomorrow on another specific type of cancer or broadly cancer, or any number of other medical conditions and the Administrator would then have at his discretion sending you all a request to consider that petition.

So just to make it clear that this is not necessarily the only opportunity that you will have to discuss the condition. It's just the -- this would be your opportunity to discuss this specific petition. So I just wanted to make that clear.

DR. MIDDENDORF: And could I ask a quick question or make a point? I think it isn't just that Dr. Howard would need to have a petition. If there's evidence that comes out he could, of his own volition, come to the Committee --

MS. HOWELL: Yes --

DR. MIDDENDORF: -- and ask for it.

MS. HOWELL: -- that's also true. He can self-initiate consideration of an addition. And if he does that, he could also choose to submit that to you all.

One of the other things that came up during discussion yesterday was some reference to the language in the statute about the 'substantially likely to be a significant factor' and 'aggravating, causing, contributing to' test that's in the statute. We wanted to make sure that the board was aware that that language actually pertains to the individualized consideration and linkage between 9/11 exposure and an individual's condition to their being covered for treatment. When you all are looking at adding a condition to the covered list of conditions, that really doesn't

figure into your consideration. What you're looking at is whether or not a condition could be associated with the kind of exposures that you understand to have been present at 9/11. And then it's up to the individual physician to look at their patient's particular case and link the exposure to 9/11 with their diagnosis of that condition, which has been sent to the Administrator and the Administrator certifies that for treatment.

So you all, as a Committee, are welcome to discuss the kind of standard of evidence and burden of proof that you all would like to see used. But it's separate and not linked to the 'substantially likely to be a significant factor' test that's in the Zadroga Act for an individual's condition being linked to 9/11 for certification of treatment. So we just wanted to make that clear.

Are there any questions on that? I have -- yes, Dr. Markowitz?

DR. MARKOWITZ: To clarify that last point, you said that we would provide advice based on -- about a relationship between WTC exposures and a condition, if it could -- if it could be caused by WTC exposures. Which I interpret 'could' actually is meaning 'possible', not even probable or definite, but possible.

MS. HOWELL: I think it's up to the Committee --

DR. MARKOWITZ: Right, no, no, and then you said that we actually need to decide and define on the criteria we would use to make that decision.

MS. HOWELL: Yes.

DR. MARKOWITZ: So it's the latter instruction which pertains. Right?

MS. HOWELL: Yes.

(Pause)

DR. TRASANDE: I apologize, I wanted to be courteous in being acknowledged first. Thank you, that's extremely helpful.

I wanted to ask for some historical context. The World Trade Center Health Program is not the only program of its kind historically and legally. And I have to imagine there have been decision processes not unlike the one that we're undertaking that have been done before and there are perhaps criteria by which inclusions were made or not made. And while I find the Bradford-Hill reference in the first report extremely helpful, required reading, required context for thinking, and something that is routinely done in the epidemiologic literature, I think that relates very well to Dr. Markowitz's point that at some level I'm wondering to my-- the same question: What degree of causation, what degree of

linkage, epidemiologic data do we need to build upon to include such a condition in the historical context as well.

Thank you.

MS. HOWELL: I'm really not sure how to respond to that. I mean other programs that are compensation programs, whether they're providing financial compensation or health care, often do have standards, but oftentimes those standards are either statutory in nature or regulatory, so they've been set out and that's what a committee may have to rely on. Or there is no committee and that's what the program relies on, which in this case the program has a standard that it has applied in certifying individual conditions. However, in terms of the standard that the program Administrator will apply in determining whether or not to add a condition to the list, that has not been articulated in the statute, and also has not yet been articulated in the regulations. So while I understand, you know, how it might be helpful to have other examples, there are legal and policy bases for those examples that aren't applicable here, so I don't want to muddy the water by pulling in a lot of other examples of other causations that have been used when that hasn't been done in this case.

Now you're welcome as a Committee -- I know that yesterday there was some discussion about the standard that the New York State Workers Comp uses in their -- in making their presumptive determination. If you guys wanted to look at that as a committee, you could. Again, the reasons that they're choosing for a presumption might be very different and have a really different underlying rationale when you're talking about workers comp versus this kind of a health compensation program. So those are things that I think there's really not a shortcut to. That's the kind of discussion that, as a Committee, you may want to have. Or you may want -- you may have a very clear idea of some standards that are appropriate in the scientific or medical fields that you wish to apply, and then the program administrator will be struggling with those questions for himself about what the program standards to apply will be.

DR. TRASANDE: Thank you. I appreciate very much that this is a unique series of circumstances, but for all of us, who come from different backgrounds, I think that historical and legal context would help at least how I'm thinking about it. I would want to be somewhere in the range of historical context with regard to a judgment that a condition should be included or not included insofar as this Committee has a unique role in

potentially adding -- playing a role in adding a list to -- a condition to the list.

DR. ROM: Thank you, Leo. I think now I have three questions instead of just the one. The first is sarcoidosis. So there's the prescribed list of conditions in the Act, and I've heard that sarcoidosis has been added and I want to find out if it really has and what -- what the process was for that.

And then second of all, this list in the Zadroga Act lists conditions fairly broadly, like chronic respiratory disease. I mean that can cover a lot of possible conditions, and has that been clarified or do we clarify that.

And then the third thing is, NIOSH has had the nuclear workers program for years, and there are conditions that are compensated, like chronic beryllium disease and cancers, and can we get some information about that program that would inform us on how we recommend things, because that should have plowed this ground ahead of time. And it would be very helpful if John or someone could inform us about this.

MS. HOWELL: Okay, I will take -- let me see if I can remember all these questions. The second question was in regard to whose job it is to kind of define what the medical terms that are outlined in the Zadroga Act might cover since they are so broad.

That is within the sole discretion of the World Trade Center Program Administrator and his medical staff. So obviously that might be something that you all have opinions on, but -- and may want to discuss, but it's something that he would be in charge of, figuring out how broadly that's applied.

In terms of whether -- I think your first question as to whether anything's been added to the list. Nothing has been added to the list. Sarcoidosis has not been added to the list at this time. I am not aware of specific instances where it may have been determined to be a medically-associated condition that therefore has received coverage. That's something that would be specific to an individual patient and therefore would not be discussed in this forum. But nothing has been added to the list at this time because rule-making would be required for any addition to the list, even with an advisory committee recommendation, et cetera, and that's a pretty long process. So the list is as it stands in the Zadroga list.

Your third question about the Energy Employees Occupational Illness Compensation Program Act, or EEOICPA as we refer to it at NIOSH --

EEOICPA has its own burden of proof that's statutory, which is what I was kind of hinting at with Leo there -- or Dr. Trasande. And so -- I mean I can discuss what that burden is, but I have a hard time with you all using something that was established by statute as their basis that was not included in the Zadroga Act to try and figure things out. I just -- there's a hesitation there.

Now if you all discuss and decide that that's what you want to do as a Committee, that's one thing. But I just don't want for the absence of direction in the statute to then force you to look specifically at another one that was written for another purpose.

The standard of proof in the Energy Employees Occupational Illness Compensation Program Act is whether or not it's feasible to reconstruct an individual's dose, radiation dose, with sufficient accuracy. And there are standards that were then put into rule-making for what they have, which is a Special Exposure Cohort, and there's also dose reconstruction -- it's a different program.

There are two different -- two different ways in which somebody can be compensated. And this is a program -- for those of you who are unaware, EEOICPA is a program that compensates nuclear energy workers who were exposed -- or may have been exposed to radiation on the job in weapons work. And the first way that individuals can be compensated, and it is a financial compensation as opposed to health care program like ours, is through a dose reconstruction which goes through and looks at the actual dose received. And using a variety of estimation measures, figures out whether or not the person had over a 50 -- met over a 50 percent threshold for their dose. And there are certain speci-- there's a list of cancer that's included to that. Until recently it only excluded a few, such as chronic lymphocytic leukemia which is now potentially being added. And then where there was not enough information to reconstruct dose with sufficient accuracy, there was a second way that someone could receive compensation through something called a Special Exposure Cohort, and that is where they show that as a class this group of individuals' dose cannot be reconstructed with sufficient accuracy. There's a list of 22 specified conditions, cancers, that are covered for that. You mentioned beryllium or silicosis, those are under parts of the Act that are not under NIOSH's purview. They're run by the Department of Labor and NIOSH is not involved in those medical determinations generally.

So that's a very brief background on that. Again, like I said, those standards were established by that statute and the regulations from it, and so it's a very different system than this one is.

DR. WEAVER: So I guess I'm less concerned about legal differences in some of these other compensation systems, but given the complexity of having to grapple with the cancer issue as our very first charge, I'm looking for any boilerplate that we could come up with. And I'm not sure if I'm allowed to ask something this specific, but Dr. Melius is in the room and he has worked for a number of years on the atomic energy issue, and I'm wondering if it would be possible for him to give us any of the medical background or the scientific background that could have been involved that ultimately resulted in the legal acts following it.

MS. HOWELL: I mean I think what you're describing is someone giving you legislative history on another act -- I mean because -- I mean, you know, if the Committee wishes to hear from Dr. Melius and he wishes to share, I'm just -- again, I'm struggling with the direct usefulness of something when it was a statutory provision that was put in place by Congress.

DR. WARD: I have a thought on that which is just a comment, it's not a decision by the Chair, but from what I understand, with the Department of Energy Act it was -- there was a huge amount of epidemiologic data available on which to -- you know, to work from in terms of --

MS. HOWELL: They had 50 years' worth of data.

DR. WARD: -- dose reconstruction and lots of data on radiation-associated cancers. So I don't know how helpful -- how specifically helpful discussing that particular program would be. I think the one that's probably a little bit more relevant to our situation is the -- if there's a background on how the comp decision was made, because even though it's not a precedent, there was a line of reasoning that -- that was -- that led to that decision and might be helpful -- I know we have several members of the working group here on the panel and in the room, so that I think might be more helpful to the Committee than talking about the Department of Energy workers. But let's hear Guillia's comment and then we can decide what we want to do.

MS. MEJIA: I believe that the presumption on cancer for Workers Comp -- there is no presumption in terms of the Workers Compensation. The presumption comes in on the pension aspect of it, so I just wanted to clear that up.

Maybe you could clear this up for me, too. And I'm simplifying it. If we were to include cancer, recommend that cancers be a covered condition, the treatment is still left up to the program administrator? Is that...

MS. HOWELL: An individual -- although cancer would be a covered condition, or a specified cancer -- and I do want to clarify as well that it is within the Committee's purview to split the cancers; you know, to say there's a specific type of cancer which you believe at this time you have enough evidence to say should be -- to recommend it being added to the list, but maybe not other cancers. I don't think I made that clear before. But once cancer, or a cancer, is added to the list, an individual member of the World Trade Center Health Program would go to their physician. The physician would examine them, diagnose them as having cancer and document their World Trade Center exposures, and then the physician would have to put together a determination that linked their World Trade Center exposures with the cancer using the substantially likely standard that the program has in place. That determination is then sent to the program administrator. The program administrator applies his own application of the substantially likely test to certify that condition for treatment.

But in terms of what treatment is received, the program has protocols for treatment that are established in consultation with the data centers. And so the actual -- you know, what kind of treatment is best for that patient is kind of a separate question. But in order for a specific individual to receive treatment for cancer, they have to have received a determination from their physician that's been certified by the program administrator.

So anyone who is eligible for the program who has cancer is not necessarily going to receive treatment. They first have to take this additional step of having that condition certified as being substantially likely related to their 9/11 exposure.

Is that helpful?

DR. DEMENT: With regard, I guess, to the parallel with the DOE process, I'm not so sure that it's actually that much different, if you look at the Special Exposure Cohort side of it. And I think the criteria there -- and maybe Jim could speak to this -- is the inability to reconstruct a dose. I think clearly we have inability to reconstruct a dose here.

The other thing is that after you meet that threshold, the list of cancers are presumed to be compensable basically through an administrative

process. And so I think there is a reasonable parallel here to some of it. And I think certainly we have, in the list of exposures, materials that -- if you look even at the IARC criteria for causality -- would drop into that category. So I'm not sure it's inappropriate to think about that process.

DR. WARD: Thanks for that comment. I stand corrected, and I do think that would be an important thing to discuss, just as -- again, looking for precedents, 'cause I think many members of the Committee feel that we don't have -- you know, the framework for this situation is fairly unique, and I don't think -- while I think it's worthwhile discussing the IARC processes and NTP processes, it's just not a parallel situation, and so that might be one of the more parallel situations that would provide more precedence.

DR. MIDDENDORF: I just want to get back to Bill's question about sarcoidosis. I understand that's an interstitial lung disease. Is that correct? Okay. So it has the potential to be covered because interstitial lung disease is specifically listed as a covered condition.

DR. WARD: So -- so is -- I mean let's go through the questions and then we can see if there's someone in the room who perhaps could give us a little bit more background on the specialized cohorts in the DOE process. Tom?

DR. ALDRICH: Did you want to know about the New York State -- the cancer was included from the very beginning as a -- one of the conditions that provided presumption of eligibility for pension, and that's all. There's no treatment component of the New York State program, and there is Workers Compensation, which has -- as been mentioned, does not include cancer as one of the presumptive conditions.

DR. WARD: So that means that if you were exposed at the World Trade Center, you're considered eligible for a pension if you get cancer, but if you were not exposed, you're not -- cancer is -- you're not el-- you --

DR. ALDRICH: If you're not exposed, you don't have the presumption, which doesn't necessarily mean that you don't get a pension. But it means that you're going to have to go through additional hoops to qualify for a pension.

DR. WARD: Okay.

MS. MEJIA: But I do -- if you don't mind, I do have to -- it's a matter of determining whether it's an accidental disability or a regular pension, and that's where the difference comes in, so...

MR. CASSIDY: I was involved in actually negotiating this with then-

Governor Pataki. The way the bill works, and I think it was signed in 2004 or 2005. The way the bill works is for workers who have proven, have been certified to have been at the site working for 40 hours, documented by their employer, they are -- they are registered under the World Trade Center Presumptive Bill. If they get sick and -- then it is presumed that that illness is related to their work at the World Trade Center site. But you have to be documented by your employer. You have to qualify. They required you to be there for 40 hours, so that's the exposure component of it. If you get ill, it is for pension purposes only. It is presumed that it is related to that. There is a process that you go through in your individual agency; therefore whatever pension plan you're covered under -- I do this all the time with firefighters. So it's not a guarantee, but that's the process. You have to have qualified. You have to have had worked 40 hours at the site to qualify. And then if you get sick, you get to apply before your pension fund and that pension board will then take that into consideration and make a decision. So you can actually get your pension upgraded -- you can be retired, get sick, file for an upgrade of a disability pension under the World Trade Center Presumptive Bill, and you were covered based on being part of the covered group that spent 40 hours down at the World Trade Center site. I think I could have done better if I had another cup of coffee, and I apologize.

DR. WARD: That was great. I have one follow-up question. So who maintains the list of people who have qualified?

MR. CASSIDY: It is now shut, so you -- there was a time frame that was extended for a few years. Anyone who had -- obviously the site closed. It's only covered from 9/11 through June of 2002, you had to work 40 hours during that time period, and you had to get certified by your employer. The bill didn't get passed till 2004 or '05 -- I think it was '04 -- and subsequently you had I think two years to get your paperwork in and get certified through your employer. Once that was done, once the deadline was cut, nobody else has added to that list. You were either qualified or not qualified. If you get sick in the future or you were already -- been sick and covered under the presumptive bill, so be it. But it's a limited group. It's not an expanding group.

DR. WARD: And how many people are in that, do you know?

MR. CASSIDY: I don't know the answer to that, but we certainly can find that out.

DR. WARD: The reason I'm following up on this is, when we get to research recommendations later, I think one of the things that's really important to think about doing is ways to recreate denominators. Not -- you know, I think all of the information that's coming from the treatment programs is important and all of the information that's coming from the voluntary programs is important, but really, you know, the most impor-- the most meaningful epidemiologic data is generated when you start with a defined population and follow it. So I think, you know, one of the things we may be recommending as a Committee is that we look for opportunities to define cohorts of people in the past and so that we can get clear enumerators and denominators for future studies, and that sounds like such an opportunity. Yes?

MS. DABAS: (Off mic) ...there within the first 48 hours, you would also -- so if you didn't meet 40 hours but you were at the site within the first 48 hours, you are also presumed -- covered under the presumption.

MS. MEJIA: I just want to clarify that this only covers public sector workers. It does not cover private sector workers at all. And there is a registration that does occur, so it's not automatic. The worker still has to go through the system. There's still a lot of papers that have to be filed. There's a lot of notices -- records that have to be reviewed. So it's really the extension that -- right now it's true it was closed, but we're looking at opening the extension for additional people to be covered under this, but -- so...

DR. MARKOWITZ: I suggest that actually we're going to need to carry on this conversation about criteria that we want to use into the future, because -- in part because of the DOE precedent, in part because of Agent Or-- treatment of Agent Orange and veterans of various wars, so we need some mechanism actually for continuing this so we don't deci-- you know, this is a crucial decision, what set of criteria -- accepting Emily's instruction that there's no prescription here as a particular set of criteria we need to use, but the utility also of looking at precedents in terms -- just in terms of considering the universe of criteria to be used, whether it's NTP, IARC, IOM, DOE, et cetera. So I think we're going to have to put this into some sort of committee that we can carry on and -- the conversation.

DR. ALDRICH: To make a few points that I think are relevant to ways that we can start to make a decision, the first point is that, you know, a cancer diagnosis is tragic, no matter whether it's World Trade Center-

related or not World Trade Center-related. And the purpose of the World Trade Center Health Program is to deal with the World Trade Center-related conditions, and so it is important to know if there's a major increase in cancer. A minor increase, tragic for the individual, is not something that the Committee should be tremendously concerned with because -- well, I -- that's the one point I wanted to make.

I think we have to acknowledge that the state of our knowledge is just not good enough, and is not going to be good enough in the next several years, to make a determination if there's a major increase in cancer as a result of the World Trade Center, and which cancers those are. We're just not going to have that information. It's been only -- well, the data from the fire department is only seven years. The data from the registry and Mt. Sinai is only going to be about eight years. And that's -- given the latency of most cancers, that's just not going to be enough. We have to wait five, ten more years to really know the answers to the questions that we want to know.

Another sort of related point is that there's been a lot of discussion about multiple myeloma and whether or not it could be World Trade Center-related, and the data are only anecdotal. The data come from a study that showed a small increase in persons under 45 years of age, and a small decrease in persons over 45 years of age. Is that decrease over 45 years of age supposed to tell us that the World Trade Center exposure was protective for older people? Of course not. And so we shouldn't make too much of a very small increase under 45 years of age in a cohort that has serious concern about selection bias.

And so I think our consideration should be only -- or should be, from an epidemiologic point of view, based on data where we can have some understanding of selection bias, denominators and things along those lines. We have to be concerned with other issues like biological plausibility and exposures, and that's very important.

The final point that I wanted to make is that -- well, I think it's sort of related to what we've already talked about. There's perhaps a 20 to 30 percent increase in total cancers from the one epidemiologic study that doesn't have selection bias nor a problem with denominators. And among those, the best estimate of odds ratios greater than two were for pancreas, kidney, thyroid and close to two for non-Hodgkin's lymphoma. But all of those odds ratios -- the confidence intervals crossed one, so we still don't know whether those things are related.

I think our final decision for now ought to be in some -- should not be irrevocable. Either we should decide that some cancers or all cancers should be covered but that can be revisited in the future if it turns out that there's no substantial increase, or we should decide that they're not coverable at the present time but that decision should be revisitable in the future.

DR. WARD: So let me just ask -- one other comment 'cause I think inherently these decisions can be revisited in the future. In other words, we can respond to this specific petition -- let's say we said 'No, we don't think there's enough evidence to cover cancer' in response to this petition. Then the issue can be raised again at any time by another petition, or by decision of the World Trade Center Administrator. Is that -- that's correct, right? So certainly we're not being asked to make a decision that's irrevocable.

DR. ALDRICH: But I think we should explicitly acknowledge that we're not going to be able to make a fully informed decision and that we should plan on revisiting, not just wait for another petition.

MS. HOWELL: You can't revisit the issue at your own initiative. I mean there is a deadline associated -- there's a statutory deadline associated with the request you've received from the Administrator. However, Dr. Ward is correct that, you know, at any time the same condition could be put forth to you through a petition, by a request from the Administrator either through a petition or at his own initiative, so it is likely that the issue would not be over. But I just want to clarify that the Committee, at its own initiative, can't take something back up after that -- you know, after it's voted and/or the time has elapsed.

DR. ALDRICH: But surely we could present as the sense of the Committee that this would need to be addressed.

MS. HOWELL: Certainly. And you know, I think we're all aware that this is a very thorny issue. I think the program knows that, the Administrator knows that, and the sense is that this is not going to be the end of it. I think they've been waiting over here for a while.

DR. WARD: Susan?

MS. SIDEL: And my question is, each time we see a cancer where there are people going to an oncologist, does it get started with their occupational medicine doctor and then they go -- I mean I don't understand what the process is and what -- how the cancer committee is involved in this.

MS. HOWELL: That's probably a question for someone from the program.

MS. DABAS: (Off mic) ... you guys because I work with a lot of people that have been diagnosed with cancer. Most people are going to their oncologist, and the reason being is that back in 2004 and early on many of these physicians were saying that it was improbable for them to develop cancers. So one of the -- when people say that, one of the things that happens is we get a lot of people that are going to physicians and these physicians are not looking for these things. So a lot of people felt that -- from what I've been hearing, that a lot of their conditions were overlooked and not properly addressed at the beginning. I have always advised members when I speak to them to go to another physician if they feel like their conditions have not been properly addressed.

So from there, the way our program -- the way we've been working with Mt. Sinai is we get a call saying that they've been diagnosed with cancer. I send them a HIPAA release form to try to get them into the program at Mt. Sinai. The hurdle that we've come upon now is that Mt. Sinai's cancer study is saying that they are not going to include you in the study if you are not part of the treatment and monitoring program. Now they have to get certified in order to get into the monitoring and treatment program, which can take six to eight weeks, and then Mt. Sinai will then consider them for the cancer study once they have first filled out a HIPAA form, and then there's a second form that they must fill out in order to get into the study. So there is about now -- to date, if you've been diagnosed and you call me, I would say the lag to get into the cancer study at Mt. Sinai is possibly three months, the earliest.

DR. TRASANDE: Thank you. I'm going to wear my pediatrician hat with these questions, which is going to probably develop another dust storm, if you will, about this issue.

My understand -- these are questions directed to you, so -- is there any history with regard to pediatric exposure setting or pediatric disease monitoring and/or inclusion program? And then my second question is, is a decision of an included condition applicable to all age groups or all subgroups of populations? There's been a little murmur through this discussion about talking about subpopulations with cancer, but my read of the statute is that if you include cancer, you include all cancer. Thank you.

MS. HOWELL: Okay, so the first question as to pediatric groups, I'm aware of financial compensation programs that are largely -- I'm not sure that they're solely directed at pediatric exposures or patients. I'm thinking of the vaccine compensation program. However, that is largely for pediatric patients and that is again a financial program. I would have to look further to see if there were any programs that made health care available to pediatric patients. And again, the standards used in that program may be different.

The second question, you're correct. In terms of adding a condition to the list, it's not a ratified list. It's not -- if a condition is added to the list, it's a condition that would be covered for responders and survivors, or adults and children, for people within the World Trade Center disaster area, people who are eligible within the physical geographic bounds of the program, so it's not something where the Committee needs to look at that there's certain people -- the place where that comes into -- plays a role is going to be in the individual physicians' determination and the World Trade Center Program Administrator's certification of that condition, that there is a link between the exposure and the condition.

DR. TRASANDE: Brief follow up in that regard in that I know from old work history, having worked a little bit on the Vaccine Injury and Compensation Program, that the specificity of adding a condition to the so-called vaccine table is very regimented, much more so than what we're dealing with here. There's a condition that is added, but it relates to -- it asks specific questions regarding the nature of the condition, timing with regard to vaccine, particularly associated symptoms, fever level, things like that, for example. So we're -- I agree, we're in a very different situation, but that clarification is still nonetheless very helpful. Thank you.

DR. WARD: Four tents up, and I would suggest we go through your comments, and then I think it might be helpful if we asked Dr. Melius to give us a description of the Department of Energy program, if he's willing to do that. Okay, great.

So let's go through the comments, and I'm not sure who -- I think -- who was next? Okay, Guilla?

MS. MEJIA: I just wanted to know whether we can make a recommendation that we actually need additional time to look at this matter? I mean we are under a time constraint. We have to -- I believe we have to have a recommendation by March. Why can't we just make a

recommendation that we need additional time to look at, you know, whatever literature might come out?

NOTE: Extreme electronic interference with dial tones, sounds of dialing, et cetera throughout the following comments.

DR. MARKOWITZ: I just wanted to comment on Tom's remark that major versus minor increase and relates to actually something Bill said yesterday, that -- you know, let's talk when we have a three-fold increase in cancer, not a 20 percent increase in cancer. I think it really relates to the criteria that are used for deciding. We could decide, absent any epidemiology, that it's reasonable to conclude that cancer is likely among WTC-exposed workers. That wouldn't be a crazy decision. In fact, if you look at National Toxicology Program criteria, they're reasonably anticipated to be a carcinogen; all you need is animal evidence. If you look at IARC, they're -- probable carcinogen; all you need is animal evidence and maybe -- maybe a little bit of limited -- what they call limited human evidence. So we don't necessarily need epidemiology. This is really -- so this is why I'm suggesting that we need to take a careful look at the range of possible criteria and then deliberately decide how we want to approach that.

DR. WARD: Julia?

DR. QUINT: My comment was very similar. You know, I said yesterday it seems to be a heavy reliance on epidemiological data. And you know, we have the latency, you know, as an issue, and these studies are hard to do.

I just had a question since, if we do list cancer -- and in response to Leo's question that survivors, children, all of these folks would -- I mean all of these W-- exposed people would be a part of that, and we -- talking about getting denominator data, which I think would be helpful, are those studies being planned, or -- you know, I don't underst-- I know about the firefighter study. There has been some reference to a Mt. Sinai cancer study. But I'm not sure if the survivors -- who's involved in -- what these studies are. Because if we revisit this, if we make a decision and we can revisit it, it should be based on some possibility of getting more data or -- or something. And I'm not sure where we are in that spectrum so I -- you know -- if we're even able to get studies done.

DR. WARD: I think that the two epidemiologic studies that we heard about yesterday, one was being done by the New York City Health Department, and that registry included residents of lower Manhattan.

No? People are shaking their heads. Right, right, okay.
Well, anyway, but just to -- I mean all of these studies will have limitations, but just to address the question so we have that one study and then we have a study that's being done by Mt. Sinai, which is...
UNIDENTIFIED: (Off microphone) (Inaudible)
DR. WARD: Yeah, so what we'll -- what we'll do when we turn to the research -- and so I think if we reviewed the slides that were presented yesterday we'll -- you know, we can -- I think the nature of those studies was explained, but I think when we get to the research part of the discussion there may be a recommendation for additional epidemiologic studies or epidemiologic studies done differently than those that are currently being done. But as far as I know, there's at least those two, which have large population sizes -- relatively large -- and which are attempting to link with the National Death Index and the cancer registries to ascertain cancer incidence.
DR. MARKOWITZ: (Off mic) ... next study of the FDNY, which is going to be smaller than the firefighter study, but similarly conducted -- although I'm not sure they have pre-9/11 data, but in any case, that's the third.
DR. WARD: But I do think it would be help-- that one of the things that would be helpful for us would -- as homework is to really come up with a summary of all of the existing -- all of the ongoing epidemiologic studies -- you know, who's -- you know, what population is included, its strengths and limitations. I think that's something that the Committee will be looking at in the future as well. So -- yes?
MR. CASSIDY: So I'd like to comment a little bit on what Dr. Aldrich said and what Dr. Markowitz said, and to kind of summarize what I think we know for sure. Right? The fire department did a study. It's a seven-year study. By all accounts, most experts don't expect it -- would not expect to see a significant cancer spike for 10, 15 years, maybe longer. So we could say, until we have the numbers, come back and see us in ten years. We could take the approach, which I think is reasonable and common sense, to look at those statistics -- 32 percent, or 23 percent, depending on how you look at it -- and factor in the one thing that we know for certain, which is shocking, that New York City firefighters lost 12 years' lung capacity in the blink of an eye. Now that's a documented fact. That cannot be dismissed.
So if we're going to say that we know that's amazing and startling, but we're here to talk about cancers and we don't really have the numbers

for cancers, we're just going to have to wait. But I think common sense would say to anybody that those numbers are so startling that you can't possibly think that you could do that kind of permanent damage to your lungs through this, you know, unbelievable exposure -- which hopefully is a once in a lifetime thing -- that there is no comparison to, and say the cancers aren't really where they need to be for us to say yes now. I hope we're not there. I hope we take a much more common sense approach and look at it and say 'Of course cancers are likely to come.' Of course they are plausible to say we're going to have a spike in probably a wide range of cancers. I mean the blood-bornes seem to be jumping out more than any others right now. And I'm not a scientist, but I do know that the damage that was done to people who were there, with the severe exposure, is unmistakable. And I hope we take a common sense approach and do not dismiss the 12 years' lung capacity which was lost on New York City firefighters. And I would say anybody who was there for an extended period of time probably has similar results, so I don't want this -- I don't want everybody to think that I'm saying firefighters and firefighters only. But I will say the 12 years on average -- think about that. There are firefighters who were there for 400, 500, 600 hours. They didn't lose 12 years' lung capacity; they lost 18 years' lung capacity.

Now if you lost 18 years' lung capacity and you get sick, but we're going to say 'We don't really have the data to say that your cancer is related to your exposure', I say that's crazy, and I think that a plausible response, a common sense response, is to say 'Of course it is linked to this horrific event.' And I hope we consider that when we decide where we're going.

DR. WARD: So Jim, can -- is -- come up to the microphone?

DR. MELIUS: I will try to be brief. This is EEOICPA-like. I think Emily actually gave a fair amount of good background, and Emily and I have talked about this a lot in public meetings. I serve on the advisory board that deals with that.

Legislatively the DOE workers, the EEOICPA Act, deals with cancer, and it bases -- as it has been mentioned, though a dose reconstruction process. That dose reconstruction process uses a methodology that was developed by the National Cancer Institute, essentially a -- sort of a life table approach for calculating your risk of developing cancer based on what your past exposures to radiation were. And the data that -- the epidemiological data that went into that approach, calculation was

based on the people in Japan -- Hiroshima/Nagasaki, the lifetime follow-up study that was done there -- plus the uranium miners study that was done by NIOSH and NCI over many years and follow-up of those workers. And it then, for an individual, can make a calculation that, based on a certain radiation exposure, you will have a certain risk of developing cancer. And the criteria that is used for the -- determining whether or not you get compensated in that process is a -- that the calculation that's done through this what's called IREP model is greater than 50 percent chance that you will develop cancer. So roughly a two-fold risk.

However, the IREP model as applied through this legislation takes into account the error in making that estimate, both the error in terms of the epidemiology estimate of risk which, despite all we know about radiation -- I mean it's probably studied as much as anything in terms of cancer, epidemiologically, when it comes down to estimating individual risk, the error is quite large. And on top of that, it also takes into account the error in the dose reconstruction, the dose estimation. So essentially the greater uncertainty there is about your -- what your dose -- actual dose was that was calculated based on your work history at these atomic facilities, which is nuclear bomb facilities, which is very complicated exposures, they -- is also quite large.

So it ends up being a -- won't say -- don't know if generous is the right term, but it is -- certainly does not require that you have -- demonstrate that you have a very -- a significantly high risk epidemiologically of developing cancer. In fact, you can -- the actual studies that have been done of Department of Energy workers would probably not document the same degree of risk that has been provided through the compensation program.

Now there are problems doing those studies, and basically because of past dose records, size of populations, all the usual caveats on that, and of doing epidemiological studies, but the fundamental model that's used here is one that does not require the worker show that they were -- would have been at very high risk -- you know, really far below a two-fold risk of developing cancer, you know, as measured through some sort of an epidemiological study.

This was adopted from legislation and methodology was being used for atomic -- military veterans, people -- veterans that were involved in some of the atomic testing, where there's a presumption that if you were -- worked or were stationed within a certain distance of the above-

ground testing that you would be compensated for certain cancers if you developed certain cancers. Again, this was post facto -- after the -- many years after the testing was done. And if you were -- actually had other forms of cancer or if you were a little further distance away where you were stationed, then there was a dose reconstruction process that was established, in some ways more simple to do than what NIOSH now has to do in terms of providing and estimating dose -- exposures now in this program 'cause these DOE facilities are so complicated.

There's also a provision that was put into the legislation that -- so-called Special Exposure Cohort, which is in instances where NIOSH found that they were unable to reconstruct dose for a particular group of workers, those workers were then automatically compensated if they had worked essentially at least one year at the facility and had a list of 22 cancers that were sort of broadly defined as radiogenic. There was a list developed within NIH many years earlier, but radiogenic is sort of a slippery term for this -- you know, and what's radiogenic changes over time and -- depends on your perspective, what you're looking at and so forth. So -- but that's provided.

To give you some, again, perspective of the people that have received cancer compensation through this program, I recently looked at the data, about a third of them received it through dose reconstruction, about two-thirds have received compensation through the SEC process. I think it's roughly 15,000 and 30,000 or 18 and 36, something like that, that have received compensation there. But it's -- again, I think the differences to keep in mind, it's based on radiation which is certainly obviously a known and proven, you know, carcinogen -- do that. It's a relatively -- not a very strict criteria in terms of proving that your cancer is related to your work or you're at great risk -- greater risk -- significant risk because of your exposures at that facility. There simply isn't enough data to be able to do that, even though these DOE facilities actually have been -- many of them have been fairly well studied, but the amount of information it takes to develop one of these tables and make, you know, somewhat accurate predictions of cancer risk is quite large, so it's just not possible to do with it -- and the system works.

The committee I now chair, been on for ten years, we spend a lot of time trying to figure out when you cannot do dose reconstruction, which is also quite common.

For other parts of the program there are some other diseases that are

covered. The criteria are in some cases specified in that, and then there's a basic sort of compen-- Workers Compensation for other diseases that these former nuclear facility workers have that then the requirement is substantial likelihood that their disease is related, and it gets quite compli-- you are -- you can be sort of doubly compensated through this.

But that's sort of EEOICPA light -- do that. I think there's some good background information on the NIOSH web site under -- that would explain some of that. As I said, the legislative history is they took the criteria from I think legislation -- sort of adopted it from what was already going on for atomic veterans, but essentially upgraded. And then the Special Exposure Cohort was added because it was, you know, documented that DOE's records were extremely poor in terms of even keeping track of what materials went to what sites. While the legislation was under consideration they suddenly discovered three of the major sites had handled significant amounts of plutonium and nobody had bothered to tell anybody about it, so...

Any questions? Anything I misstated or -- clarify, Emily?

DR. ROM: Could you recall whether multiple myeloma was part of that list of 22 radiogenic cancers?

DR. MELIUS: I believe it is, yeah.

DR. ROM: Do you remember any others on that list?

DR. MELIUS: Oh, it's the, you know, lung, leukemias, the -- that it -- it goes fairly down the list -- I mean it's broad categories of cancer on that. The list is on the NIOSH web site under the -- it's called the DCAS program, Division of Compensation and Analysis or -- is that right, John?

DR. MIDDENDORF: I just want to make sure that they understand, the list of cancers are listed in the statute that are covered. Is that correct?

DR. MELIUS: Correct, it's a -- it's a --

DR. MIDDENDORF: And it's based on a lot of scientific data which has a fairly high degree of scientific certainty. Is that an accurate statement?

DR. MELIUS: Well, it's based on radiation epidemiology. The criteria for the list is not what risk you -- what risk needed to be found in epidemiological studies of radiation is not clear, and you -- if you look up -- if you look at various review articles on radiogenic cancers, various lists, they vary quite a lot. It depends on sort of which kind of exposure you're looking at and what criteria, so -- so they adopted something that the NIH had used and was -- it had been used, I believe, in one of the

atomic veteran compensation programs.
DR. MIDDENDORF: And just a last point, I think what you were saying is that whether or not an individual is compensated is based on their individual exposures.
DR. MELIUS: Or the fact that one can't reconstruct their exposure, it's one or the other. It is different in that and is certainly different in it is based on a, you know, carcinogen that's -- you know, substantial amount of other evidence for, but it's not based on epidemiological studies of those particular workers. The criteria's not that they have to meet, you know -- you know, a study at Hanford doesn't have to show a two-fold risk of lung cancer to demon-- for those people to get compensated. It's based on their exposures.
DR. MIDDENDORF: And I was just trying to make the distinction that what this Committee needs to deal with is whether or not to make it -- something a covered condition, which is similar to the list that was in the statute for the EEOICPA. That's what they're --
DR. MELIUS: Yeah, yeah -- no, I -- yeah, fine. Any other -- yes?
MS. FLYNN: I actually have a Zadroga-related question. I know that you were involved, as other people in the room were, in the crafting of the Zadroga bill, and I guess I would -- I would hazard this statement that in fact it is the intent of the statute, out of a recognition of the unprecedented nature of the exposures and also the lack of comprehensive environmental measurements, to provide for great flexibility, that the statute recognizes that we are on uncharted territory. And I'm not saying that we should not entertain any useful precedents. I think we should. But I also think we have to recognize that we are on some new ground here and that the -- and that in many ways it sounds like this Committee is being asked to structure these deliberations in recognition of the unprecedented nature of exposures and resulting illnesses. And I'm wondering, Dr. Melius, if you could reflect on that.
DR. MELIUS: Only I think it's been stated already -- I mean it is a unique situation and the criteria for -- I think the statute was developed in a way that it was expected that there would very well be additional conditions that would be added as time went by because -- just simply latency and follow-up of these people and the natures -- unknown nature of their exposures and effects, and so it was left open and it is -- it is something -- you know, it was not -- there was no model that would -- legislatively that would -- was an exact fit for this.

I would urge you, having been through this process at the other end with the DOE program, it is important what Emily and John have told you. It is -- I think it is important when you make a decision to include your rationale for that decision because that's important in carrying this forward through the process and in the decision that the Administrator has to make. So some careful thought to how you're approaching it is also important -- and important to document.

MS. FLYNN: Thank you.

DR. MELIUS: Thank you.

DR. WARD: So I think at this point it would make sense to take our short morning break, and then reconvene. We do need to get on to some of the other items on the agenda, but first we need to make a plan for how we're going to proceed on the cancer petition when we get back from break.

(Recess taken from 9:55 a.m. to 10:08 a.m.)

DR. MIDDENDORF: As I was just -- it was just pointed out to me that -- and I've noticed it, I just haven't said anything about it, is that there's about a one-second lag time between when you turn the microphone on and when it actually starts picking things up. So if you'd either turn it on early or, you know, just wait a second or two before you actually start speaking so that our reporter can take down what you're saying.

Okay, for purposes of the roll, just a note to the record that all the Committee members are at the table. Dr. Talaska, did you happen to join us on the phone?

(No response)

I guess not. Okay.

DR. WARD: So in this phase of the meeting we will be trying to wrap up the cancer discussion and figure out what our next steps are. It is -- you know, there is a provision for us to follow the formal procedure of someone making a motion, the motion being seconded and voting. So it may be appropriate to do that in the course of this discussion.

I can summarize what my sense of -- from the Committee discussions is and -- I mean my sense is that most people who've spoken do not feel comfortable making a recommendation to include cancer or to not include cancer in the -- among the covered conditions based on the evidence that we have in front of us and based on our discussions today. So that my sense is we probably will want to have at least another meeting to discuss that issue, probably one in person where there can

really be good communication, in part because (a) it's a very difficult issue, it's a complicated issue. Our group is just forming. We're really still struggling to understand the exact nature of the Act and what our determination means in that context.

I also think, though, that we need as a Committee today to define what are the pieces of information or perspectives or data that we really would have -- would like to have in front of us when we come to that final determin-- our final recommendation so that we can have workgroups or individuals working on pulling that information together for us. We do have the oppor-- the possibility of forming workgroups that we can have -- you know, we can have workgroup telephone calls in between meetings, and we can have those open to the public and transcribed if we feel necessary.

So that's my general sense from the group, and I don't know if that is true for all of us or if people want to speak to that, but go ahead.

DR. ALDRICH: I think that, from my point of view, that's correct, that we're not quite ready to make a decision. But I think we have to say something. And we're going to have to have another meeting. I think we should -- you know, in advance of that next meeting, we should have some material to react to. And I think that there should be a group that gets together before the next meeting that comes up with position papers -- possibly two, maybe more, position papers expressing the different points of view. And then the Committee will have a chance to digest that in advance of the meeting. And rather than just start from scratch, we'll have some starting point.

MS. SIDEL: I just wanted to say that there's so -- you know, we all know what the carcinogens were that were at the World Trade Center site, and there's so much information about how so many of those cause cancer that I just don't understand why this is such a stretch to say that they caused cancer in some people and they caused certain cancers. I mean I'm not saying that everybody and every cancer should be covered, but there's -- you know, for example, NIOSH's own guide, chemical guide, what is it called, the chemical -- guide to chemical hazards. And you know, I have a copy and it's like Zagat's only it lists the chemical and then what -- you know, what -- what the health effect is of exposure to that chemical. So I just wanted to put that out there.

MS. DABAS: I actually wanted to see if we could go around the room and kind of just get where each person stands because I'm kind of -- I know

where some people stand, but -- on -- they've been vocal, but I'm not sure where everybody stands on how they -- what they would need to make this decision or whether they've already kind of come to a conclusion.

DR. WARD: Someone make a motion and second it, and then we could do that. Do -- well, maybe you can phrase -- frame the --

DR. ROM: I think Elizabeth phrased the motion best. I'll try to rephrase it.

I move that we have considered cancer as a listed condition and that we have not found enough evidence to either list it in favor or against, and that we need an additional round of information to our next meeting before deciding further.

DR. TRASANDE: Can I suggest a potential minor amendment to that in that I would just simply move that we have a subsequent discussion -- I'm just concerned that if we state there's no evidence either way at this time, that that -- I'm not -- just for a process protector, I'm not sure whether that's already information to the Administrator. I would actually rather have the time to have another meeting, and I was also going to further suggest that -- you know, in scientific conferences you can pre-release information for discussion among groups in a privileged fashion. And I'm wondering why the entities that are pursuing such research might not be willing to do that in this context. I think that that -- it could be tremendously important, and there is precedence for this.

DR. MARKOWITZ: So actually I don't see the need for a motion. We have till March 2nd. We haven't made any decisions. So I'm not sure that, you know, what we would accomplish by moving ahead on any sort of motion. I'm not sure that gets to Valerie's request to get us sort of a preliminary sense of where people sit.

DR. DEMENT: I think -- to address your question, I think we need a -- before we form committees to do this and that, I think we need a discussion of a criteria or what criteria will we use to make this decision. For example, if it's just going to be the epi studies, then we may as well go home because it's not there. I think the question is, given the list of exposures -- some of which are reviewed pretty well in the NIOSH document -- what of those exposures do we -- and what do we know about those exposures and the risk of cancer, and will we consider those exposures' biological plausibility in coming up with our final decision. So perhaps there are two committees, one to look at the epi data and

evaluate -- particularly the new study that came out. Maybe the other committee is the one to look at the issues of exposures and what data do we have and the plausibility that these will increase certain types of cancers but probably not all.

MS. DABAS: (Off mic) to make a motion and was actually piggyback offing -- piggybacking off the generalization that was made that it seems that there was a consensus, there was some reason to believe that people -- and I just -- there were some people I haven't heard what their take on this was, and I was interested in their opinion and not necessarily a vote on it.

DR. WARD: That's the -- you know, the three ways we can go in this decision would be to vote to include it as an eligible condition, to vote to not include it as an eligible condition, or to decide that we need further information and another meeting to make that determination. So maybe -- why don't we start off by maybe asking a raise of hands, how many people would support the notion that we should defer the decision and have another meeting to make this recommendation?

(Committee votes by show of hands.)

So that's a pretty large majority. But I really like the idea that we may want to approach -- I mean one approach that we might want to take is the position paper approach, because I think very clearly we have, you know, a difficult question here and the way you -- and so I think it would -- that would be very helpful to articulate all the reasons why, you know, one would argue that it should be less considered a World Trade Center-related condition and all the reasons why -- you know, all the evidence and rationale why we don't have sufficient evidence to do that at this point. That might be a helpful approach in this.

DR. MIDDENDORF: Just a note to the record that when Dr. Ward asked for people to raise their hands, 13 people raised their hands and two did not.

MR. CASSIDY: If we're going to look for position papers or additional information, we're going to come back and discuss it in the future, I think that it might be helpful if we have -- someone could do a review of other major exposures and how long it took for cancers to show up. I don't know -- there is no, obviously, similar event to the World Trade Center. There's nothing quite like it. So I don't mean to imply that we can find something that's similar and therefore do an A/B comparison. But maybe there are some large exposures that happened, and when did

cancers -- if cancers popped up, when did they pop up? Because if, as some experts have said, you're looking at 15 to 20 years and this Committee is going to make a decision strictly on numbers, then somebody already said it: We might as well go home.

But I think if we have some background that shows that previous disasters and/or serious exposures -- cancers came, but they didn't come for 15 to 20 years, then I think it gives us some leeway to be more flexible in terms of using the common sense that -- I think most people expect us to come out with some kind of approach that includes a common sense look at what we know now. And what we know now is really a seven-year study. It's not 2011, it's July of 2008. And the only real study that has pre- and post-9/11 is the fire department, and you can't dismiss the 12 years lung capacity, there's nothing quite like that.

So I think if we're going to come back, I think it's important if there's other -- if somebody can do some research for us that would present to us similar events -- there are no similar events -- disasters that resulted with cancers and how long it took for it to happen.

DR. DEMENT: You know, there aren't any similar events. The major events that occurred that are these rapid exposures, then follow-up, largely are radiation-related events. And there are a few others, but not to any great extent like this one. I'm not advocating that we use the epi. I think we use epi only to substantiate a positive. To go the other way and say there's no risk I think is not appropriate. And I think whatever review of the studies that would be done by a subcommittee needs to point out the limitations of the epidemiology in trying to make this decision. That's all.

MS. MEJIA: You know, there's a saying in the field of occupational safety and health that an injury to one is an injury to all. And we know that there are cancer cases out there, they've been diagnosed. We have members who have that diagnosis. They may not have made it on a chart or on a pie graph or been assigned a dot somewhere on an X/Y axis, you know what I mean, as -- so we can't ignore the fact that there are people out there that have the diagnosis.

So with that said, my question is how much weight can we put on the clinical observations that were made by -- at the -- you know, by the doctors that are treating these workers? Now clinical observations were the basis for establishing the original list of covered conditions, so why not -- you know, can we consider that as, you know, as a way to look at

this?

DR. DEMENT: I think the clinical observations are helpful for some conditions, and particularly those that we, a priori, know they're related to dust exposures. But when you come to cancers, the clinical observations may or may not be helpful. If it's a very rare cancer and we know the relationship with an exposure and you see the sentinel event, then I think it is, you know, very helpful. But simply observing lung cancers in a population over time doesn't tell you what the risk really is. It just simply says you have a numerator, but you don't know what you would expect in a normal population. So that's just the limits of epidemiology. It's not to dismiss the importance of these observations. So I think we have to back up and look at the exposures, are they biologically plausible with regard to these outcomes, and make some determination on how we're going to use that prior body of information. The Bradford-Hill criteria -- you know, we're not going to be able to apply that to our studies in any real meaningful way. I think it's going to be supportive information from the epi studies, but to use a negative is not the way to go.

DR. WEAVER: You know, I think the diversity reflected on this Committee is a really good thing because it illustrates the complexity of the exposure. It's -- we're very polarized. You know, we have the community members who very eloquently have stated that they've had -- you know, this massive exposure has occurred and cancers will result. And you know, I kind of think that's true.

But then we have the scientific view where we've sort of been entrenched in looking for P values of .05, and so I think maybe we should see where we can find middle ground, and Mr. Cassidy's comment about latency may be one such area. Because we could look at the exposure data to the extent that we have it, and that's challenging, too. You know, we have a huge range in who was exposed and where they were exposed and how they were exposed, and it was a disaster so there are no exposure data that were carefully taken like there would have been in a factory. It was mixtures. We don't know very much about mixtures. And we learned yesterday that it's controversial. There's a lot of concern about the exposure assessment and how adequate it was. And so I think that's kind of where we have to start.

But I think then moving forward and thinking carefully about latency and what kind of short-term cancers might we expect to see, and then

whether -- whether we move from being strictly scientific, even though that's our title, to addressing the fact that this is an incredibly unique exposure and people are caught, given our current health care system, in a situation where they may lose their jobs and they may not have health care to support their cancer care.

So you know, that's not strictly scientific and it doesn't have a P value of .05, but that's what I'm thinking.

DR. ROM: Well, I'm a scientist. For better or worse, I'm stuck with myself. There are things that would move me off the dime. And about case series reports for rare tumors or uncommon tumors, I could be moved on those kinds of things. Multiple myeloma, I'm not there yet with eight cases and 6.8 expected. But if those twos and twos and twos that are 16 are really cases, and there are 16 over there at Mt. Sinai, that's getting more impressive. And if that's published as a case series, then I think that's more compelling.

Non-Hodgkin's lymphoma is another one, and these are related to the polycyclics and benzene and the mixtures that were in the fires and in the aviation fuel and it's biologically plausible, so non-Hodg-- so multiple myeloma did not come up in the FDNY study. It was not significant, it was way down there. Non-Hodgkin's lymphoma was significant, and it almost made it when it was corrected for bias. But I think a case series on non-Hodgkin's lymphoma would also be compelling.

The other ones that came up in the firefighter study, thyroid came up -- you know, that's radiation-induced, and I have a hard time with that one. And melanoma came up, and it's the -- FDNY play basketball all the time, gets UV exposure, you know. And then the third one that came up was prostate, and prostate had 30 excess cases -- it was 90 observed over 60 expected, and that made the whole paper and that got them in The Lancet. It was all prostate, and prostate has nothing to do with anything other than you're a male and you're old, and that's the most difficult for an environmental exposure. So prostate, I have a hard time compensating those folks.

So we may have some sentinel cancers that might be doable, but I don't think we're there as of today to do that.

And the other thing is that there are tremendous opportunities here for research, 'cause this dust is really -- I don't know if toxic is the word, but it's caustic and it's got a lot of things in it and it's very inflammatory. It's a good inflammagen, if you will. And we know that inflammation and

cancer live right next to each other, and COPD lives as the third agent there, so there's opportunities for research on COPD and inflammation and cancer that you wouldn't believe.

One of the problems of this is that we can't do animal studies very well because this mixture is hard to reproduce. I mean we can take WTC dust and expose animals to that, but it was the fires and all these polycyclics and everything else, and that we can't do. And I'm not so sure just the WTC dust itself would be that convincing to cause cancer, so animal studies are kind of out.

So we're really left with human studies, and so we have a lot of opportunity to do human studies, but to really get at the answer we have to do pretty invasive things, like bronchial brushings and stuff like that. Maybe sputum would be something that you could do, but these invasive studies get you the samples that you can then study for inflammatory markers and mediators and gene expression and mutations and all of these things, and it opens up a very interesting door. But I'm getting a little bit -- I'm segueing into the next session on research.

So those are my thoughts.

DR. WARD: Is there anyone with their tent up wanting to speak? I just want to double check that nobody's -- okay. I don't know who's first. We'll have time for everyone, so why don't we just go in order around the table. Leo?

DR. TRASANDE: Thank you. I just wanted to make a couple of generic comments about pediatric cancer because that needs to be in the discussion. First of all, we'll never get a three-fold increase in the context of any population that one could study, so I think our threshold for including that category of cancer -- and I'm not arguing that should be our basis for deciding whether to include that condition, but I just wanted to voice that, that for all environmental cancer studies that I've seen for children, with the rare exception of some radiation, you're never going to get to a three-fold increased risk factors. I wanted to put that reality check in there because I keep hearing three-fold as a -- as a criterion, and I find that a little hard to accept.

So I'm going back to Dr. Dement's comment that we need to look at biological plausibility and the scope of exposures we best can characterize it as our guiding force here. So I'll leave it there for now. Thank you.

MS. FLYNN: Yeah, I mean I am coming from very much the same place as

Leo. I think that we need to look at bio plausibility, and I actually -- and of course we would also need to think separately about pediatric cancer -- bio plausibility in the context of pediatric cancers. And I'm wondering if this Committee should seek expertise -- you know, seek the most advanced thinking in making its bio plausibility arguments on the impact of synergies. So yes, I agree, we have PAHs, we have benzene, we have, you know, known bad actors. But we also have concentrations and combinations that haven't been seen before and I think that that could very much strengthen a bio plausibility argument.

MS. DABAS: My concern has been, one, I think Mt. Sinai has benefited and scientists will benefit from the ability to treat some of these ailments. And if we don't allow them to treat the cancers, it makes their research that much harder. When you have people -- the people that are studying in one institution at Mt. Sinai, and the people that are treating at Sloan-Kettering, who has not really been part of this discussion, there is a bridge that's just not there. So the information will always be muddled. And so if we keep asking for this information and this information and we don't build the bridge to get the information by looking at cancers and creating an avenue for the physicians that are studying these cancers to actually treat these cancers so they can learn more, then we're crea-- we are becoming part of the problem. We are kind of -- you know, Dr. Rom says he's a scientist. We're preventing scientists from doing what scientists do, and I think that we need to be careful that, in trying to prove something that seems to be, you know, 25 years from now before we can make a definite scientific proof and not provide the tools for science to do what it needs to do, then we're really going to hurt the process.

DR. MARKOWITZ: I am not terribly hopeful about the epidemiology that's -- we're going to get in the next year because those study designs are not as favorable as FDNY. The EMS study's going to be smaller, and even the fire department study clearly had some problems with statistical power and having enough people. And then there are problems with Sinai and DOH having to do with selection and et cetera. That's not to say that they won't be worth something, just that it's not necessarily such a hopeful situation in terms of clarifying it.

So then we're left with the rest of the case. And for me, the rest of the case -- I think about a hypothetical. If this were -- if we -- if Ground Zero were opened for ten years and there were benzene down there and

people -- we knew what the benzene level was, and then six years later somebody developed leukemia, we wouldn't be even thinking about epidemiology. We would say that yeah, the exposure was there, there's a known relationship, the disease occurred on time and we're good. And so the question is -- in my mind, is in nine months, which is how long it was open -- Ground Zero was open, is a short period of time for occupational studies. It was a long period of time for people down there, given the pictures of what we saw their exposure was like, but in our normal occupational epidemiology it's very sma-- it's very short.

So this hinges on are there data we can point to, not our feelings about it, but a scientific argument we can point to that acute or sub-acute exposures, relatively short-term exposures, can cause cancer, and can cause cancer in an accelerated time frame. And if we can find something that supports that, then I think that builds an argument. And if we can't, then we're stuck with this is a unique situation and -- which is acknowledged, but what do we say next when we say it's a unique situation? What can we say beyond that, that it's unique, we haven't seen it before, and therefore we conclude -- what?

MS. HUGHES: Hello? I agree with a lot of what you say, but I just want a point of clarification as someone who's lived downtown, one block from the World Trade Center, for the last 23 years. The exposure did not necessarily stop after nine months. A lot of this -- the chemicals dripped into the surrounding area. There's been construction and digging for the last ten years. Deutsche Bank was finally only down, not even the foundation, not even the complete foundation, and transferred so -- not even transferred, it was -- Port Authority was given access this January in 2011. And so the concrete -- even R. J. Lee with their $30 million toxicology study on contaminants, showed contaminants in the concrete. And so the surrounding area -- they had been digging it for the Vehicle Security Center so I don't think we need to be bounded by just the nine-month exposure. It might be nine months for -- depending on certain type of occupational exposure, but I believe it's a lot longer and even people in surrounding buildings that were not necessarily cleaned out in nine months.

For example, I don't know about the Verizon building, which is right there, or the World Financial Center. This -- only recently -- also about Fehrman (ph) Hall was there for years. You know, maybe it was finally completed two years ago, and you have all the debriding truck through

the community.
DR. MARKOWITZ: I overlooked that point, and I apologize. And I thought that Jo Polett did an excellent presentation yesterday portraying the continued -- the likelihood of continued exposure. Obviously it does not apply to the workers who ended in mid-June, but for the residents, sure.
MS. SIDEL: I just wanted to say something really quickly about the combination of chemicals that I just find -- nothing good is going to come from the combination of chemicals. So if it was like, you know, benzene and dioxins, I -- and they're pushed together, it's not going to be good. They're not going to cancel each other out, so it's just going to make it worse. And I mean I don't know how you prove that scientifically, or even why that's important because obviously it's just going to be more caustic. It's not going to be good. So when everyone keeps talking about the combination and we don't know how that affects people, it's going to be worse, that's going to be the effect. I mean I -- thank you.
DR. WARD: There's at least two large issues. I guess one is, you know, what can we infer from what we know about the material that was there and the extent of exposure to that material. And I think -- you know, a lot of the information that we have is basically a list of what was there, and there's some exposure concentrations, but it really -- I'm not sure what additional extrapolation or data you would need to kind of come up with a probabilistic statement about 'we believe that' -- I mean do -- what kind of chains of evidence would you need to say that, given the nature of this exposure, we believe it's not only possible but likely that this -- I mean I think already there's probably enough to say it's -- it could happen. So how do -- is there -- you know, is there someone who would like to volunteer to kind of either be on a workgroup or try to address the question of how much inference can be made about cancer from the composition and the exposure data that's available to date and bring that back to the Committee? Or --
DR. MARKOWITZ: You're asking -- you're asking about exposures, about taking a new look at exposures?
DR. WARD: Well, I mean we have data on exposures, and I think many people have said is it biologically plausible that these exposures could cause cancer. And I think for -- many people would say yes, it's biologically plausible. The question is how likely is it. I don't know if -- I mean I think one thing we need to do is frame the -- you know, we've

made assertions about what we know -- we've made assertions about we can -- what -- we can make inferences from the exposures, but I guess the question is to refine a little bit what inferences -- how to make those inferences and what those inferences are. So is it -- is it the fact that, you know, eight known carcinogens were present? Do we need more data to develop a rationale based on levels of exposure or concentration or -- you know, what is it that we need beyond what we have now to make more -- firmer conclusions about that? Leo?

DR. TRASANDE: Let me take a step back. How I'm thinking about this is maybe a bit different. There is a medical certification that follows from listing that needs to be performed before a condition would actually be, in practice, covered. So I'm -- to me, that takes some of the burden off of us insofar as we might add a condition to the list. There still is a step, a medical certification. I'm about to start filling these out myself in my own work, and they are serious -- from what I've read, they are very serious documents. Now if that represents a conflict, I'm laying it right on the table, just in terms of saying it. But anyway, so what I'm struck by, rather than going into a workgroup I think we -- I still -- I'm still struggling on what are our core criteria for inclusion first as a condition. And the only other point that I would like to make about epidemiologic evidence is there are some suggestive other studies that don't themselves look at outcome but look at biological markers, and especially -- I'm always struck by Dr. Ricky Preher's (ph) study on PAH DNA adducts in relation to World Trade Center proximity. Now that was not an occupationally exposed population. I'm not saying PAH DNA adducts jumps you down the line to cancer, but it's a marker of PAH exposure. So you know, I'm not answering the question that I posed to the group about criteria just yet, but I think what I'm also suggesting nonetheless is that if there's -- there's going to be very weak environmental monitoring data that we can work from, there's probably not a need to revisit the literature in full and come back with a consensus. There are a lot of review publications that have examined this, including the first report. But I -- and so I would urge us to think about what might be enough to push us over that -- push us off the dime, to use what Bill Rom said. And I'm already signaling that if you had decent biological plausibility in the context that we -- we can't identify a subpopulation that actually has an increased risk of cancer, it's not our job -- that if we can identify it within a subpopulation that we

think is highly exposed, that that may move us off the dime onto the list. And if there are other suggestive evidence of sufficient carcinogen exposure to potentially increase risk, then that might push me off -- off of that dime. So I don't know if -- I'm not being completely eloquent, but I think I'm starting to move -- try and move us towards a definition of what would lead to an inclusion of a condition.

Others should feel free to amplify, criticize and comment. Thanks.

DR. WARD: I mean, you know, one of the things that IARC considers is that when there's animal evidence of carcinogenicity but no human epidemiologic studies or weak epidemiologic studies, they look at mechanistic data and they specifically look at evidence that a mechanism that can -- you know, that whereby something causes cancer in animals or known to cause cancer is -- is present. So looking at the biomarker studies, DNA adducts for example, would be one of those indicators that would make the link between potential carcinogenicity based on what's in the mixture, and the fact that the population had exposure at a level that is increasing this marker, you know, that's related to cancer. So I think that is something that we should definitely look at more carefully, as well as consider in our research recommendations, is what biomarkers have been looked at and do they in any way contribute to how we evaluate the existing data.

Tom?

DR. ALDRICH: Well, I acknowledge the weakness of the epidemiologic data, and the issues of latency are a really big problem. But I don't think we should be too sanguine about the exposure data at all. I mean we are all exposed to asbestos. We are all exposed to benzene. It's a matter of dose, and we just do not know the doses that workers or residents or anybody received of any of these potential carcinogens. And so I just don't see that knowing a list of chemicals that were present is really all that helpful.

MS. SIDEL: I just want to say that I'm not sure why dose -- as a scientist, I can understand why that's an issue, but everybody is so different, everyone's body is different, so the way you respond to the same dose that I get could be totally different. And you know, I may have a genetic predisposition to something and this exposure triggers that predisposition. I just think people are too different and to say that one dose is going to affect everybody the same when there's just such a varied population there, I don't understand how that works and why

that's critical. We do know that there was -- we do know that there was a -- we have like all that information about the data of what was out in the neighborhoods, what was done on the Pile, you know, and what percentages. We have a lot of information about that stuff.

DR. TRASANDE: I was going to comment -- and maybe I'm in a middle place between the last two commentators, but I'll -- but try me here. I'm of the philosophy that if you're above -- environmental monitoring levels need to be above background. That drives me in a way that if they're in the range of background, that's -- that's important to me. And I think there are a number of studies that we have that suggest that for a number of key chemicals of concern for carcinogenicity, we do have evidence of levels above background. Now we also have biomonitoring data for dioxin and for perfluorinate, if my memory serves me correctly, in at least one population of biomonitoring evidence above background as well. And now that doesn't sway me for the whole population of WTC-related exposees, but I think it -- we don't have that -- the luxury of dividing up the population with regard to what's an eligible condition at this point. We either have to or -- or don't. And I think we have to act in that mode, and I think then from there it goes back to biological plausibility and some of the other arguments that we've had before. At least that's how I'm thinking about it. Now I may not be on base there.

DR. DEMENT: I think in some ways we're at the limits of what we can say about cancer risk related to dose. I'm yet to know a cancer where there's actually a threshold. Certainly we have background exposures and we have some risk. Take some examples that came from this exposure, asbestos and benzene. It's been controversial for years whether or not there's actually a level of exposure that you can have that you don't have some risk. The more studies we've had going on over the years, that level where you can actually demonstrate risk has gone down and down. And with benzene you go back to some of the models that look at the mechanistic process in terms of activation or deactivation of metabolic pathways, and there's still no evidence that benzene has a threshold for the -- especially for leukemia.

So I -- you know, I like the idea of exposures that are significant being related to potential cancer outcomes. If you ask me down the road do I think that we'll have excess cancers in this population demonstrated by epidemiology, yes, I do. To say, a priori, which ones there'll be is quite another question. I would probably guess we're going to probably see

some lung cancer excesses out of it down the road for sure.

DR. WEAVER: I just wanted to ask John if -- apparently you were on a cancer committee that met within the last year relating to World Trade Center? Can they bail us out at all with this?

DR. DEMENT: I think one of the studies you have before you actually came about -- at least a part of the discussion of the design for that and how it would go forward and some of the others that are already planned were -- that was the object of that discussion -- how would you characterize exposures, and maybe across the studies you can actually compare them a bit, and sort of the methods for linking up with some of the registries.

DR. WARD: So I mean it -- it sounds like, in terms of forming the workgroups, that we could have one or we could have two. And I would say that maybe we do think about framing it, because I think a lot of -- ultimately we're really going to be -- it is going to be an opinion, no matter what. I mean there isn't enough data to say, based on any external criteria that already exists, yes or no. But I think it's going to be an opinion, and I think what's -- so I think we would charge the Committee to really develop a case in favor -- what are all the arguments that could be made in favor of including cancer as one of the conditions, and what are all the arguments or the factors about the existing data that would make us hesitate to make that recommendation at this point, because I really think in the end it's going to be -- this recommendation is going to be built on opinions. And then I do think it's critical for us to try to identify what are the pieces -- the most critical pieces of data that could be used to make a more -- to have a more informed decision and to look at whether those studies are underway or they actually need to be initiated or recommended by the Committee.

Does that sound reasonable to folks? Does anyone have an opinion as to whether we should have two committees, one focused on exposures and toxicology and another focused on -- I would say epidemiology, biomarkers, with a little toxicology, because I think toxicology's relevant to both. Leo?

DR. TRASANDE: I don't know what others' thoughts are, but my sense is that this is a job for the Committee of the whole. I think segmenting -- I don't think this is something that the epidemiologists should go into one corner, the medical people should go into another corner, and the community advocates should go into another. I just think that's a

dangerous proposition. This is a tremendously significant decision for the group, and I think in the interest of enhancing transparency and having open dialogue like this that's been really helpful, I would prefer we go forward with this as an ongoing conversation. If that means teleconferences, if that means alternative modes of communication, so be it.

DR. WARD: I think that's a great point. I do think that we do need some people to commit to do some actual work, and so in that sense I was proposing workgroups, but you know, it's fine if the Committee wants to do that, as long as we have people who are tak-- you know, are willing to take on some defined tasks to prepare between the meetings for specific discussion topics.

DR. TRASANDE: I'm struggling a little bit with what work tasks. I mean I think we're at the point that -- you know, if we -- you know, one of the things that I prepared for this meeting, knowing that cancer was going to be a point of discussion, was the Administrator's first report, and I actually think that's a fairly thoughtful, fairly presented discussion of what we know to date. I just hesi-- I'm just not sure what the work products are going to be. I think we need to have more dialogue discussion about criteria and start to move towards a judgment call. I think that would be a more fruitful process. So my own opinion is we need dialogue, not reports on reports on reports. I respect that mode and at some point when we get to writing, I think we're going to want a companion opinion, maybe there's a small subgroup of people composed on this Committee who do the actual writing. That's just my perspective.

MR. CASSIDY: I think Leo's right. I think it needs to be the entire group. One thing I -- you know, we can't get away from is that there really is a failsafe built into this system. Right? So if we were to decide to include cancers, there is a failsafe. It's not like we then green-lighted this process where anybody who lives below Canal Street is in. We can't dismiss that because it's critically important to the process. I mean it's almost like when one of my kids comes to me and says is it okay if I go to the movies tonight, and I always say yeah, it's okay with me as long as you get your mother's approval. So in effect, you know, I've given like a half a green light. And there's some sense of reality to that because -- you like that, Leo? Good -- because that's the truth. I mean we're making a decision based on common sense.

If there was no failsafe, if -- if there was no failsafe, if no individual -- if

we were to grant cancer or add cancers and there was no failsafe, then I think it would be reasonable for a lot of people in this Committee to be skeptical about that decision. But because there is a failsafe, a real failsafe that requires a review and a confirmation by a physician, and an ultimate decision by the Administrator, I don't think that that is such a great leap that we are making, given the fact that we know what happened. We all watched it unfold on TV. It is a disaster of unknown proportions. And the exposure to thousands and thousands of people are documented, and some results -- although preliminary on cancers -- show an increase. The lung disabilities for firefighters is documented beyond belief. And I think when you factor all that in and you have a failsafe, I think that gives us leeway to make a decision to include it. But no matter what, I think that should be part of the discussion when we talk about where we're going.

DR. ALDRICH: Well, I generally agree that we should not be segmenting into an epi group and a toxicology group. I think what would be useful, though, is position papers taking -- I don't want to say extreme positions, but defined positions. And for me personally, I believe that the data at some day is going to show that there are increased cancers related to World Trade Center exposure. I have little doubt about that.

But I think that there are some -- that there's good reason to be cautious, and that is -- and there's very good reason to base our decisions on evidence. And furthermore, I think that it's not all or nothing. I think that it's extremely unlikely that a cancer that comes up in December of 2001 -- a lung cancer, let's say -- is related to World Trade Center. It's extremely unlikely and we should acknowledge that, along with the other things, that there's -- that the further out we get, the more the chances that a given cancer is related to World Trade Center exposure. The closer to the time of exposure, the less likely. And that has some importance for public policy, I think.

I don't know what's the right answer, but I think we should stake out some positions, even if they're a little bit more extreme than we really believe, just to take positions so that people can react to them.

DR. ROM: All of us have time constraints, so joining working groups is something that's almost impossible. But I do think there's a program administrator who does have a staff and could provide us with some information. And I would suggest two or three areas where we need more information.

First, we have these exposures, and there's a lot of measurements on benzene, polycyclics, asbestos and perhaps some other carcinogens, like dioxins, that could be brought together. And how much was in the building, like how much asbestos was there, and then all these measurements I've seen by the EPA -- generally they don't find anything. But I'd like to know what measurements have been made and have one piece of paper or a couple of pieces of paper that tells us what the exposures -- what the exposure data is.

And the second thing is -- so we'll have the FDNY study, the Mt. Sinai study and the registry study on cancer coming out in early '012, but I think it would be nice if somebody is going to capture that data and whatever else is out there and -- and have that for us at our next meeting.

And the third thing is there may be additional biomarker data that's out there that would be nice to have, that could help us make a case.

And I think staff helping us is not unusual for advisory committees, that that would be helpful, and we certainly would have the time to review documents, and to try to generate the documents ourselves would be more of a challenge.

DR. WARD: In the report that was generated by NIOSH there's a compendium of exposure data, but you're asking for another level of analysis, or an evaluation of each of the elements?

DR. ROM: (Off microphone) (Inaudible)

DR. WARD: Okay. So Steve, and then Leo.

DR. MARKOWITZ: I would propose a compromise. The request to us -- in the request to us, Dr. Howard wants us by March 2nd to include a description of our evidence, the quality of the data, description of the methods used to formulate the advice, so we're going to have to write something up and we might as well begin sooner rather than later. So we could have workgroups that are open to everybody and that achieves, you know, both purposes. And those workgroups could try to take -- consider positions perhaps more extreme than they might naturally move to as a way of getting out all the issues, and I would volunteer to be on one of the workgroups.

MS. FLYNN: I just want to respond, Bill, to what you were saying. We went through, many of us in this room, a nearly year-long process with the EPA's World Trade Center Expert Technical Review Panel --

UNIDENTIFIED: (Off microphone) (Inaudible)

MS. FLYNN: What?
UNIDENTIFIED: (Off microphone) (Inaudible)
MS. FLYNN: Yeah, yeah. So the data -- let's -- let me just state it this way. The data from indoor environments that the EPA gathered was widely discredited by the experts on the panel and by people in the community who got up, who had -- had done their own environmental auditing. The Stuyvesant Parent Association had hired a very well-known, highly accredited environmental auditor, and there also were a wide range of narrative accounts, eyewitness accounts by residents, about how the EPA's -- that the actual people entering buildings to do testing would not run fans and leaf blowers, would turn fans directly against the wall -- I mean it's -- the problems were legion, so I'm just going to -- you know, a very, very big red neon cautionary note on utilizing EPA data to draw conclusions about the exposures of residents, students and area workers.
DR. TRASANDE: Just thinking about the day and a half -- day and change so far, the one aspect of the World Trade Center disaster that we've not discussed in great depth, like what Bill said, is the environmental exposures themselves and what data we have for or against certain chemicals being above background, for instance. And there are experts in the area specifically who have thought about this in extremely great depth. There are some on this very FACA, as well. And that may help move our discussion in a facile way, in addition to what the Committee -- the Administrator's staff can provide. I think that would really be helpful. At least that's the area I think I'm hearing of greatest uncertainty perhaps about exposure.
I think from there we could probably move through the biological plausibility, and other components of the logical chain to cancer, more carefully.
DR. WARD: I think we are going to have to wrap this up or we won't be able to discuss research at all. I mean I hear a couple of people making the specific proposal that we -- I mean I think in general people agree that the main body of work will need to be done by the Committee as a whole, but there might be some preparatory work that could be done either by making requests to NIOSH staff for specific information or bringing in experts to advise us on specific topics. And I think the idea of dividing up into two groups just to maybe draft the arguments for and against has kind of resonated with a couple of people, so -- so if -- I

mean -- so if someone wants to make a motion to proceed in that way -- but I guess the -- essentially what we're saying is the group wants to continue to meet, possibly by telephone, to deliberate on this further. But -- and people are opposed to workgroups going off in isolation and doing a lot of work just off on their own, but that they are not opposed to having groups that would help prepare position statements for discussion by the group.

Is that correct, Steve?

DR. TRASANDE: May I ask a question and then possibly propose a motion?

As far as I know, we haven't defined a next meeting date, and presumably that meeting would have to happen by March 2, so I'm -- I'm a big fan of walking back from the date certain and potentially working out a strategy to get to a point where there's -- where we do our job. So I guess one proposal would be to actually suggest a potential meeting date and try to march backwards from there, but that's just a thought.

DR. WARD: I don't know if we'll be able to decide an actual date, but we could say that we'd probably plan an in-person meeting sometime in February -- I mean if we worked under that assumption. Yes?

MR. CASSIDY: I agree with Leo, we should work back, and I think sooner rather than later so -- you know, I do think there's a consensus that we all get in the same room. I don't like the idea of dividing into camps for or against because, to be honest, I want to hear the arguments of both sides and could change my opinion. And I don't want to think that I'm predetermined to be in a particular camp without hearing other people's arguments.

But having said that, I don't think we should wait till February. I think we should try to get a meeting in January, in case it doesn't go as well as we would hope. And March 2nd -- you know, if you're in February, you don't really have a time to get another one going. So I think we should try to get something early/mid-January which would give us time to get back late February to finalize something, assuming we're building a consensus. And if we're not building a consensus, we've probably got to get back in a room and try to figure out where we're going.

DR. MARKOWITZ: At least to clarify, make a motion that we do have two workgroups, one focusing more on the epidemiology and the toxicology as it approaches the epidemiology, and the other on the other side more on the exposure and then related toxicology; both workgroups be open

to all, and both workgroups consider the various sides of the arguments, and that the workgroups produce a preliminary write-up that would serve the purpose really just of furthering and focusing the discussion so that we can advance more quickly.

MS. FLYNN: I think I mostly agree, as long as working group conversations would -- everyone would be privy to those.

But before we move -- and I'm sorry to do this, but before we move in the direction of defining a working group around exposure, I'd actually like to ask Micki Siegel if you could just briefly give us an overview of what's available by way of exposure data, 'cause I think everybody needs -- I really do think this is very important.

DR. WARD: Right, but I do think -- we have a motion on the table --

MS. FLYNN: Okay, we have a motion on the table. We'll redefine the mission of the working group, the one that includes exposure data, after --

DR. WARD: No, and I also think it's important to understand that the group that addresses exposure data is going to look at the quality of data, look at the limitations of the data, and you know, people will have an opportunity to be -- to be represented and to share information. So -- so it -- but it's -- it's really just that that committee will focus on exposure data.

MS. FLYNN: I'm just not entirely sure that the people sitting around this table can -- because I'm not -- it's unlikely that the majority of people sitting around this table understand just how limited those data are.

DR. WARD: Well Paul, this is kind of a procedure question, so when we have these meetings they will be announced -- the telephone meetings of the workgroups, they would be announced in the Federal Register and open for public comment, and we also would have the option of asking specific individuals to come and speak to specific issues. And I think that could be recommended by some -- anyone on the STAC, that we -- if we -- so I think it's covered. Tom?

DR. ALDRICH: I don't think it's going to be helpful to have two separate approaches, because I think we're pretty much in agreement about the epi data, that -- well, we're in agreement that there's some value to it, but it's not going to be definitive. And so what our decision really hinges on is the toxicology. And so I think we should focus on that and just have a -- because if we have too many groups, we're just going to have -- it's going to impede our coming to a decision. I think we should have a

single discussion, clarify the toxicology, acknowledge the weaknesses in the data, try to determine if there are any data that are reliable, and present what we have and go from there.

MS. MEJIA: I really don't want anybody to leave this room thinking that there's a lot of exposure data out there because there really isn't. There's a big void there, and so let's not hang our hats on all this data that may not be there because there was -- there was no data captured, I think from day one. There wasn't any environmental monitoring done on day one. There was no personal monitoring done on day one. So let's not -- you know, don't walk out of here thinking that you're going to find a whole bunch of data out there that we haven't really tapped into.

DR. DEMENT: This is at least the third meeting that I've been to, maybe the fourth, where data on exposures has been discussed, and the same theme comes across every time, that they are limited. And frankly, I think the publications that are already out there summarizes what we're going to know. I think we could waste a lot of time trying to dig into these data, and the people who really know it very well, they've already done that and some of it summarized in the NIOSH report is in reference to the original publication. So I don't know where we're going to go beyond that.

DR. WARD: Given what you know and where you've been, do you have a recommendation on how to -- we should proceed to come up with this recommendation?

DR. DEMENT: I think we're overwhelmed by the exposure, both with regard to the initial magnitude of it and that which existed for a number of months, but also the complexity of it. Now there were like almost 300 different compounds that were -- and materials that were measured into the exposure, identified, and we can't -- there's no way possible for us to deal with that.

Now I think a sensible approach, at least in the way I see it, is pick the ones -- major ones which had a theme that went across most of the exposures, the ones for which there was reasonable exposure measurement data at least showing the exposures, and Paul LeRoy's papers have summarized a lot of that. And I think we have to base our decision on whether to include or not include cancer on those exposures.

DR. WARD: If we want to do that at our next meeting, we would really try to focus on those exposures and look at whatever limited quanti-- I

mean look at the cancer sites that have been associated with those exposures in prior studies, and look at the extent to which we have data on exposure levels.

DR. DEMENT: Exposure is a three-part scenario. Exposure levels, we don't have a lot of that. It's also where you were at the time. It's your duration of it -- frequency, duration and level, and we don't have a lot of personal exposures. The thing about occupational exposure measurement that you find typically is the general environment may or may not be very high. It's the environment that the individual's in. The breathing level samples, for example, closer to the source are typically much different from those that are far away. People generate their own micro-environments based on what they're doing.

So for us to hang a determination on some required exposure level I think is not doable.

What I was suggesting, though, there are certain compounds -- and I think NIOSH has listed a fair number of them in their report -- where there's some repeated measures. The levels certainly were above background in many cases, most cases, so you can -- I think with a fair degree of confidence -- say these are exposures that most people at the site would have had.

Then the next question is what do we know about those in the risk of cancer from NTP/IARC, largely.

DR. WARD: So that makes sense. I think what I was thinking of in terms of exposure is, and some of the things on the list are like vinyl chloride, for example, and I don't -- you know, you do need to get a sense of is this an important exposure in this setting or not, and I don't know if there's any data to know. But certainly we have benzene, we have asbestos, we have the silica-type compounds, we have -- there's actually a limit-- a pretty limited list of group ones, and then I guess we could go and include the 2-As and 2-Bs, and maybe start from that approach. Is that agreeable to everyone, so at least we have a direction that we're moving in, is look at those specific compounds that have substantial data on carcinogenicity?

DR. TRASANDE: Could I -- I don't know if we're still on a motion or not, so I'm a bit perplexed. But it might be good to continue this conversation on a call where we try to focus on a list of ten or so -- or something -- something that we can grab our hands onto and get some committee help with regard to giving us maybe some -- a synopsis with a

little bit more depth about exposure as we know it with regard to the World Trade Center, recognizing that we may only be able to do a binary above background/below background assessment as a Committee. And then, you know, I -- my instinct is that the rest of it from there is fairly judgmental. I mean it's based on -- you have IARC data, you have NTP, you have all these sources, and we have to just decide well, what class evidence are we going to accept as a basis for taking us to plausibility, at least at some level, from the standpoint of whether there was an exposure or not, recognizing that we can't even sub-segment the population, our task before us is quite straightforward.

(Interruption regarding conference connection)

What a pleasant interruption. So that's just my -- my suggestion is that we might move towards a conference call where we as a committee try to hone down. And then my suggestion would be to try to, after that conference call, start writing the -- start writing the document. It might be a very small subgroup of lead writers, but then it would always be done in an inclusive fashion towards actually -- and I think inherently it would include abstracted data from the staff reports about the exposure with regard to these key chemicals and the implications based on knowledge from IARC, NTP, et cetera. Those are just some thoughts that I have.

DR. WARD: Then I think where we stand with respect to the motion is Steve made a motion for the two committees, and I don't think it was formally seconded, and then there were -- other people put forth different motions, so -- can't do that? Okay.

MR. CASSIDY: (Off microphone) (Inaudible)

DR. WARD: Okay. So how do we correct this?

DR. MARKOWITZ: Why don't we have a restatement of the motion.

MR. CASSIDY: Let him restate his motion and then you see if there's a second, and then it's open for discussion.

DR. MARKOWITZ: I'm not going to restate the motion because -- I think the motion died. But I would like to say something else.

So we have these group one carcinogens. Everyone know-- everyone recognizes they're -- there are human carcinogens down there -- benzene, asbestos, PAHs, a couple of others. We know there was exposure. We believe there was exposure. We believe the epidemiology is not going to really help us yet. So what else do we need? And that's sort of a restatement of what Susan said. There's something else we

need, and otherwise we're not comfortable, but apparently there is some level of comfort that I've heard two scientists say here that they do believe in the future that cancer will -- could be produced from those exposures and it will have evidence thereof. So whatever else we need, then let's focus on that.

Now maybe that's just a restatement of what Leo said, but let's get there and hone in on that -- you know, either way. I'm not prejudging the decision. I'm just saying let's get there.

DR. DEMENT: If you were to ask me my opinion, that should we include cancer as something that would occur as a result of this exposure, my answer would be yes.

But back to ask the next level is which sites are going to be included or not, I think that's the more difficult question. Maybe it's not a question that we actually need to address, but it is an important question.

MR. CASSIDY: I just want to remind people, with reference to what Dr. Markowitz just said, that there were fires burning at the World Trade Center on St. Patrick's Day, and I was there, March 17th, 2002 -- March 17th, 2002, we were still putting out fires. So everybody knows that when you have fire, you have carcinogens in the air. The fact that stuff was still burning, you know, six months after the attack should say something about the level of exposure in the 22-acre site. And I think it speaks to -- you know, sometimes we can get bogged down in the technical data, the numbers, the benzenes. How in God's green Earth were things burning six months after? And the answer is: This is a once-in-a-lifetime event, and the exposures suffered by those who were there is, unfortunately, a once-in-a-lifetime event. And to think that cancers are not going to come out of it I just think are flat-out silly. They are. The early documentation indicates that. The fire department study on lungs is -- is definitive. All these bad things can happen to you. You cannot be in a site six months after an attack and still fires burning, and think maybe nothing's going to come from this. So I don't want us to get away from the common sense and facts that are maybe not scientific, but real.

DR. WARD: But it is incumbent on us, if we make this recommendation, to rigorously define the scientific rationale for that recommendation. And so I don't think we've laid the basis for doing that at this meeting. It could -- and I think what we're trying to do is struggle with how to approach this large body of evidence and, you know, apply it to making

this recommendation. Susan.

MS. SIDEL: This might be a situation where a lot of the legal community that's involved in this might be helpful because the writing recommendations for like say the victim's compensation fund or just briefs that they're doing, past briefs, **[identifying information redacted]**briefs, things that, you know, **[identifying information redacted]**wrote for Zadroga when he was representing him, there's a lot of -- you know, where they had to connect the dots to make a case, and that's essentially what you're saying here is that you're sort of making a case. And so what I sort of see is that we have the chemicals and now we're going to start -- you know, we have all this -- these things and we're just going to be connecting those dots. It's really like a brief, in a way. I mean it -- is that bad because it's not scientific? I mean but it is -- it's connecting the dots, putting it -- putting it together, sort of.

MS. DABAS: My question is, it goes back to Steve's question, which is what is it that is still missing that people need to -- for the science? What is it that is likely to be available within the next time that we meet that will make this case? And I pose that to the scientists. Like if -- if there is something that we feel that could be available or that will be available before March 2nd, I would -- I would love to know what it is because it doesn't seem that the fire department, Mt. Sinai or the WTC Registry will provide any information before then. It doesn't seem that there's anybody else that's going to provide any further scientific information until then. So I'm wondering if -- what -- what would we need? And if that information is even available.

DR. ROM: Valerie was looking at me. All right, I'll tell you what I want. For lung cancer, which is really possible 'cause this was an inhalation exposure and we have defined carcinogens that are great for making lung cancer, so the firefighters had nine lung cancers in seven years and they had 21 expected, and their SIR, this incident ratio, was .42, so you know, we have a long way to go.

I think lung cancer is not going to be seen to be increased for years. For at seven years, I don't think we're going to see much -- I don't -- ten years, 15 years, so it's going to be too long to wait. And the firefighters were the most heavily exposed for lung cancer.

I find the multiple myeloma and non-Hodgkin's lymphoma a little bit more likely and plausible 'cause they -- there's literature on them and I mentioned the numbers of cases. I'm not quite there yet. I'd like to see

some at least case series reports, which probably will be forthcoming in the not too distant future.

I don't think that we should list other kinds of cancers, like prostate or even thyroid or melanoma. You know, there's a biological plausibility for these cancers related to exposure, and I have a real problem with prostate and a pretty big problem with melanoma, and maybe a little less problem with thyroid. And then for other sites like breast or colon or -- or maybe larynx I could think of, but brain -- I mean these sites just aren't biologically connected. The dots don't connect. So -- and to go for all cancers, I think that's too much of a stretch. So that's where we are with the science.

MS. DABAS: I just want to comment in that you said that firefighters were the most exposed. I think a lot of the pictures show you that firefighters and police officers worked side by side on that day, so to differentiate between fire and police or fire and whoever was on that Pile is going to be a hard differentiation to make. That would be one of my things.

Second, there are about four or five cases making their way through the courts right now dealing with cancer, and I think it's important that the Committee kind of look at those cases as they come along. One of them that I'm familiar with is Mackery (ph) where somebody had a lung scan done two or three days prior to September 11th and it was a clear lung scan. And when they did it again in August 2002, their lung cancer showed. There might be some scientific reason for that, but that case is currently pending in the courts.

DR. ROM: Okay. I think the police would be an excellent cohort to study because, as you said, they were heavily exposed and I would make a research recommendation for someone to write a proposal to study all police in New York City and define the exposures and look at some of these outcomes.

As far as individual legal cases, there's -- you know, in the FDNY study there were nine lung cancers so, you know, there could be nine individual cases out there. I think that a surveillance program for lung cancer might be kind of interesting in some of this heavily-exposed cohort, like CT scans and maybe biomarkers, but that's a research study and I think that would be a compelling one to look at and possibly fund. I didn't write one, by the way.

DR. ALDRICH: One -- you know, I agree with much of what Bill said about

that not all cancers are likely to be consequent to World Trade Center exposures, but there are some that are. But there's also a time element, too. I mean notwithstanding the change in CTs between whenever it was and 2002, it's still quite unlikely that a lung cancer originating -- or discovered in 2002 started after 2001. So whatever recommendation we make should take that into account, that it's quite unlikely that a solid tumor in 2001 or 2002 was World Trade Center-related. Not impossible that a hematological malignancy was, and so there are important differences in that regard that make some sense to pay attention to from a public policy point of view.

DR. WARD: Any response to that?

DR. DEMENT: Yes. Yes.

DR. WARD: Okay.

DR. DEMENT: But I think that gets to the sort of the second level, that's the attribution of individuals -- a cancer to the exposure. I don't think we've been asked to do that. I think we're just -- we're being asked if this exposure, or these exposures, can cause cancer, are likely to cause cancer. The attribution comes at the next level when you have your cancer and you're with your doctor and you say 'I was exposed last year; can this be related to exposure?' You know, doctors say a lot of things, but hopefully an informed doctor would say 'Very unlikely.'

DR. WARD: Leo? And that'll be the last comment and then I'll make a proposal, we won't make it a motion, of how to proceed.

DR. TRASANDE: Just a quick comment that if we start -- and I agree philosophically with what Bill said, as well, except to say that there -- we also have to consider the fact that cancers get chemo and there's such a thing as secondary cancer to consider as an associated consequence, which is in the language of the Zadroga Act.

And the other thought that I had has since evaporated so I will defer.

DR. WARD: Well, I mean what I would propose is that we should set up a phone call sooner rather -- phone meeting sooner rather than later. We have not gotten to the research recommendations and I'd like to do that in a time frame that we can remember what we've discussed today.

I think we have gotten some suggestions about how to focus the discussion. One is to look at those specific carcinogens for which there is some data on exposure at the site and we can focus some discussion around that. We have a specific idea of maybe looking at particular cancers -- lung and NHL and multiple myeloma -- looking at those

specifically, and perhaps there may be some others -- obviously mesothelioma. You know, that there -- that if we're not ready to make the recommendation to include all cancers, there might be specific cancers for which we would be more inclined to make a recommendation.

So I think what we can do is we'll need to still do some work to develop the agenda for that meeting, and maybe we could do that through exchanging e-mails and so on, but --

DR. MIDDENDORF: I would point out that for you to have a meeting it takes at least one -- I'd have to have an agenda, or at least the matters to be discussed, at least one month ahead of time to be able to get it into the Federal Register in time.

DR. WARD: Okay.

DR. MIDDENDORF: So we have that kind of a lag time, and that doesn't include my time for developing the information or developing the Federal Register notice. So probably five to six weeks at least.

DR. WARD: Okay. So in the meantime is there -- is there a way that we could collect from the Committee, let's say their key -- the key things they captured from yesterday's discussion on research, or is it -- do we have to wait till the next meeting to get input from the Committee on -- or on their perspective on the discussion regarding cancer?

DR. MIDDENDORF: I think it might be helpful for us to delay the discussion of research, simply because it's one of those potential areas of conflict of interest and we need to review that more carefully in light of the individuals on the board -- on the Committee and make sure that we can appropriately and properly address the conflict of interest issues there.

DR. WARD: Okay.

DR. MARKOWITZ: Paul, what's the timetable for that?

DR. MIDDENDORF: The timetable? We'll clearly be -- I think we'll be able to handle that probably within the next month.

MS. FLYNN: And when are the next BAAs issued? I just want to make sure that we have this discussion about priorities before --

DR. MIDDENDORF: Yeah, I'm not sure --

MS. FLYNN: -- the process happens around funding research going forward. No date?

DR. MIDDENDORF: I'm not certain when that date would be. Nothing's been established yet, so it'll be a while.

DR. WARD: Okay, so is there anything that we should -- can do -- I'm sorry. Leo?
DR. TRASANDE: Can I make a motion that we sketch out an agenda for our next call now?
DR. WARD: Yes, excellent motion. I'm sorry.
DR. TRASANDE: Yeah, is that seconded?
(Motion seconded by multiple Committee members.)
DR. TRASANDE: Okay. Can I move we -- do we need a discussion -- this is Chair-- do we need a discussion about -- can we start to just -- I'll -- if I can, I'll just try to speed things up and suggest some items.
So I think clearly we need some staff input about a list of chemicals of exposure -- at least this is how I'm thinking, but maybe I'm an individual perspective on this panel, not the consensus. But if we could focus on a list of chemicals of concern, and focus on a list of -- that would fol-- so that would be one item.
Would -- we have a discussion of a more in-depth description of what we know to date about exposures and the aftermath of the World Trade Center disaster.
Then I think what we would probably have is an agenda item that would follow that, hopefully would be a discussion of the carcinogenicity of those elements.
And then a third would be potentially going where Bill was going, potentially looking at what types of cancer might be on a suggested list if indeed we are to proceed to make a suggestion to the Administrator of causation.
I would also like to further suggest that we move quickly to, once we get the conflicts issue sorted, to have a research-focused call fairly soon in tandem, recognizing a five- to six-week lag, so I'm probably attaching that to the motion, but I apologize for doing that if I'm out of order.
DR. MIDDENDORF: And I'll say that you need to have just one meeting, not two separate meetings. One phone call, which is a meeting, and then it needs to be an open meeting.
DR. TRASANDE: I'm just suggesting that we try to schedule the two consecutively, but not have one meeting and then schedule another meeting with a lag. I'm just sensing that we -- that would take us to March or...
DR. MIDDENDORF: What I'm saying is that we will have -- we should have one meeting in which we discuss both the research needs and these

other issues.
DR. TRASANDE: Thank you. That clarifies it.
MR. CASSIDY: If we have an approximate six-week lag time, then we really can only meet twice before March 2nd. Now that's the reality, right?
DR. MIDDENDORF: Well, what I could -- if you make decisions on the need to have two additional meetings, we could put that into one Federal Register notice.
MR. CASSIDY: I mean I'm just thinking out loud, but it seems to me that we -- we should strongly consider, before we leave today, agreeing that we need a physical meeting, face-to-face, sometime in February as a follow-up to this phone meeting, so that -- you know, maybe we won't need it, but we should plan on having it. Everybody's busy. We should get it on a calendar. We should leave here either knowing shortly that we're going to have a meeting scheduled in February, we're going to have a phone conference four to six weeks from now, and that those two events are going to be what we have left before March 2nd, and I think we should do both of those things.
MS. HUGHES: So many people already in New York, the conference call -- maybe there's a room where people who are in New York, to save you money, can be in the room, because somehow a conference call is not as effective as face-to-face dialogue, and money seems to be an issue.
DR. WARD: That's a great suggestion that we should go ahead and plan a face-to-face meeting in -- well, it's January or February, whatever is most feasible, in addition to a telephone meeting.
DR. MIDDENDORF: My suggestion would be that if you want to have a telephone meeting, we do that maybe in mid-January so you can get the Federal Register notice up and out. With the holidays coming up things tend to get slid a little bit. And then plan for something pos-- face-to-face possibly in mid-February.
DR. WARD: Yeah, I think -- I mean I think the Committee would prefer not to wait that long, because we want to be able to have some continuity of thought. Are the two of you commenting specifically on the meetings, the meeting schedule, or... Okay.
DR. WEAVER: Just in terms of moving the research agenda along, I'm wondering if it's allowed for us to e-mail our top three suggestions for research priorities so that those could be compiled. We could look for areas of commonality, and then conflicts could be addressed.

DR. ALDRICH: That's exactly my point.
DR. WARD: That sounds like a great idea to me. We'll have to see if it works with the FACA.
DR. MIDDENDORF: Okay, I think the answer to that is, in part, what we can do is you can identify areas of research and send it in an e-mail, but the information will need to be discussed publicly at an open meeting. Okay?
And the other thing is that individuals should not be putting things on their list, things in which they have the potential for possibly getting research grants so that they would potentially benefit directly.
DR. WARD: Does anybody else feel is it silly for Emily to have to whisper in Paul's ear, 'cause is there --
DR. MIDDENDORF: Yeah, this is the way she wants to do it so that's not a problem. The point Emily was making to me is that the e-mails all need to be one-way. It's not a dialogue. So if you set up your list, you should send it to Liz. Liz can compile the list and then that list will be discussed at the telephone meeting.
DR. WARD: So we have a proposal for the draft agenda for the telephone meeting, which is to discuss the exposures and the aftermath of 9/11, the list of chemicals of concern with respect to carcinogenicity, to discuss what types of cancer might be associated with those exposures and therefore on the suggested list, and then to move quickly to discuss the research.
Is there any other addition to the agenda or --
DR. MIDDENDORF: I do want to make the point that it's probably not appropriate for the Committee to assign tasks to the program, which is what it sounds like has been done -- or an attempt to do. That's not something that was in the Committee's purview, so we can't give the program required activities. So I guess what I'm saying is that if the information that's already been developed for the report of cancer, you can use that for -- to address your things about exposure, the things that you want to learn. You can go to the literature. But I don't know that we can go back to the program and say you need to do this for us for our next meeting.
DR. MARKOWITZ: Can we request assistance?
DR. MIDDENDORF: We can request, but we can't expect it. And Liz was putting it on the agenda as something that was going to be coming, so I don't think we can promise that.

DR. WARD: I'm not sure how we can do that based on the information that you have. I mean I wasn't even -- I mean you basically gave us a list with the IARC and NTP classifications, and you gave us summary data on exposure measures. And I do think -- and we have information on the sites of carcinogenicity from IARC, so I don't think that's an extensive preparation task that we're talking about.

DR. MIDDENDORF: So what, in addition to what's in the report on cancer, would the Committee be requesting?

DR. WARD: John, did you want to speak?

DR. DEMENT: Well, you have the classifications listed. And I think in addition, listing the sites where the cancers were found to be increased or suspected to be increased based on the available data would be helpful. It's certainly -- and I wouldn't say do it for this whole list. I think there's a smaller list of exposures that are actually discussed back in the paper and back in the document itself that would be appropriate to spend our time on. We can't deal with this whole list.

DR. MIDDENDORF: Okay. So if we were to extract those that were identified by IARC as categories one, 2-A and 2-B, and extract from the documentation of the IARC categorization the animal tests and epi tests that were done and identify what was found from those, is that what you're asking for?

DR. DEMENT: That's correct. I think we're looking for a little more direction. I started making my own list based on my recollections of some of the documents -- you know, sites that were found to be increased. I mean basically IARC has to make a decision, and the decision's generally based on either human data showing an increase or some animal data showing an increase, and so that's what we're looking for, those sites where the data show increase, either one, 2-A, 2-B.

DR. MIDDENDORF: We'll go ahead and put in that request to the program.

DR. WARD: Okay then, so is there -- yes?

DR. QUINT: I just want to point out, for the animal evidence the sites won't mean very much because it's not concordant necessarily with the human sites, so it -- that would only be relevant for the epi data -- the sites.

DR. WARD: Yeah, group ones, you typically don't have some specific sites, but --

DR. QUINT: Yes.

DR. WARD: -- the data will be limited, but I think the group ones will be the most informative.

DR. TRASANDE: Can I also suggest that perhaps, and recognizing that the hour's very late, that we might want to focus the program's attention on a certain sub-list of chemicals of concern? I mean I could rattle off a list of ones that come to my mind, but -- and I've mentioned some of them, but -- and that may not be helpful as what others might do. I think -- PHs, dioxins, perfluorinateds, particulates are some that jump out as of concern to me. That's not a complete list, that's just off the top of my head -- silica, asbestos, benzene -- thank you -- one three butadiene would be on my list as well. John, are you saying cesium? Diesel, sorry, diesel, thank you. Absolutely right. And we're doing this in extremely rapid fashion. I don't mean to push it that hard, but --

DR. WARD: Well, it is a good point because when I look at the -- I was thinking it would be pretty straightforward to look at the list and look for the ones and 2-As 'cause those will be the strongest ones, but then I noticed that diesel is not -- I mean I don't even see diesel on the list. Is it a 2 -- I don't remember if it's a 2-B, so I'm not sure -- so these were -- this list was based on things that were measured, but maybe some things -- I mean if diesel isn't specifically measured, it would not be on this list, so we may -- you know, we may have to look at the list and make sure that there are not things like that that aren't on it that need to be added.

DR. TRASANDE: I would also double check -- and we may need to do this informally -- that there aren't chemicals not on the list that were used as part of the cleanup or rescue or fire extinguishing efforts that aren't otherwise mentioned in here. I think the list is complete, but I'm putting a 'think' there for a reason.

DR. WARD: Okay. Yes, Susan?

MS. SIDEL: All of the oil that was burning from, you know, those -- I forget how many hundred thousands of gallons, but there was all this oil that was being stored in the basement for OEM. You know, there's all that -- okay, diesel, sorry. All right. I mean that was a big...

DR. WARD: So I think that's -- you know, I don't know if there's a mechanism for this, but if we're using the list that was put together earlier as our basis, I think we're adding diesel, including the stuff produced from burning diesel fuel. And I imagine it's okay for the Committee -- if they look at this list on the plane home and see

something missing, they can e-mail you and ask -- make that sugges-- or -- e-mail me and I'll make it to Paul to add.

MS. HUGHES: So in the World Trade Center, that's all, I just want to add plastics.

DR. WARD: Yeah. Susan?

MS. SIDEL: Yeah, because every floor of the World Trade Center site is basically an acre, and every acre had hundreds of computers, and think about the carpet on the floor, the boxing for the computers, so all that has to be included, too.

DR. WARD: So we're at 11:55. I think we've had some very productive discussions today and yesterday. I think we're worn out. So if anyone has any additional suggestions for the call-in agenda, send them to me. I'll convey them to Paul, Paul will work on setting up a time for the next telephone meeting and an in-person meeting, and we'll work on getting the agendas together and the Federal Register notices.

Okay, so we are going to need dates of availability from people. Paul, do you want to send out a poll with potential dates and then have people fill them in, or -- that might be the most efficient way.

DR. MIDDENDORF: Yeah, I just need to remind you that we need to look at availability of personnel to support the meeting. We have very limited support and they have other tasks as well, so that will be one of the considerations. And for the face-to-face meeting will be the availability of the location, so the sooner you can get me dates, the sooner I can make some decisions.

DR. WARD: So you want people to send you dates when they're absolutely not available or dates when they are available?

DR. MIDDENDORF: Probably not available.

DR. WARD: Okay, not available. Okay.

MR. CASSIDY: What time of day?

DR. WARD: Well, I think for the phone conference -- well, I guess that's -- it was brought up that maybe we should have the meeting -- the face-to-face meeting at a time when working people can attend, so we did have the idea of maybe starting let's say at 2:00 in the afternoon, going into the evening, and then continuing the next day, so that's a possibility. But a telephone meeting, I would assume it'll be probably at least three hours.

DR. MIDDENDORF: Yeah, we would probably start in the afternoon to accommodate our west coast folks so they don't have to get up at 5:00

o'clock in the morning.
DR. WARD: Okay, so -- yes.
MR. CASSIDY: What's -- this is a silly question. What's the -- for the face-to-face meeting, why would we start in the afternoon? Why wouldn't we start 8:00 o'clock in the morning?
DR. WARD: The idea would be to have part of the meeting off regular work hours. I guess the other option would be to do it on a Saturday, but I doubt that that's feasible if we want to hold it in the federal building with all the staff support, so that was the only idea is to allow some time for the public to be here when they're –-
MR. CASSIDY: When it's open to the public.
DR. WARD: Yeah, yeah.
MS. MEJIA: For the telephone meeting, are we precluded from meeting with some of the Committee members in one room to handle that telephone call? Can we do that?
DR. MIDDENDORF: Yes, you can do that.
DR. WARD: Thanks everyone. We'll bring the meeting to a close now, and I appreciate all of your participation and input, and I guess you are free to send me any suggestions via e-mail and I will convey them to Paul. Thank you.
(Meeting adjourned at 11:57 a.m.)

CERTIFICATE OF COURT REPORTER

STATE OF GEORGIA

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I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of November 10, 2011; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither related to nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 6th day of December, 2011.

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STEVEN RAY GREEN, CCR, CVR-CM, PNSC

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