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 TWO

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

VOL. I

DAY ONE

WEDNESDAY, FEBRUARY 15, 2012

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 February 15, 2012.

C O N T E N T S

February 15, 2012

TRANSCRIPT LEGEND

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In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (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.

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P R O C E E D I N G S

(12:08 p.m.)

WELCOME

DR. MIDDENDORF: Good afternoon. If the committee members will come to the table, appreciate it, we'll get started. I have a few administrative details that we need to take care of here at the beginning. I'd like to extend a warm welcome to the members of the public who are here in the room and also those who are on the phone. We very much appreciate your interest in these proceedings and look forward to your participation. For those who have signed up who would like to make comments, we do have public comments scheduled to begin at 3:45 this afternoon and then we'll have another public comment session tomorrow morning.

For those of you who are here in the room, I'll point out the emergency exit routes. If you look around the room, you'll notice that there are three doors that have exit signs above them. You need to ignore two of those exit signs. The exit sign back here behind me to the left is not an exit door. Please don't go out that way.

The double doors in the back far corner of this room are not exit doors. Please do not go out of those either. If, for some reason we need to evacuate the room, this door that's about three quarters of the way down here on my left is the door to go out. And the quickest way to get out is when you go through that door, turn to your right, go until you see two double glass doors on your left. Go through those double glass doors, immediately turn right, go down that hallway, and you'll see a door that says Fire Exit on it, and that's the way you get out of the building. So please, that would be the best way to do it.

For those of you on the phone, I suggest that you look around, figure out the evacuation route for your buildings. I need to point out that we do have copies of the agenda for this meeting. They are on the back table, and they're also available on the committee's website for anyone who is on the phone. You can download the agenda from our website.

We also have copies of the public comments that were received as of about 11 on February 13th. They have been offered, filed to the committee before the meeting, and they're here on the back table. If you don't want to haul around a lot of paper with you, these comments will be posted on NIOSH's docket, which is docket number 248 for this committee and that's also available through the committee's website.

We need to do a quick roll call, and so we'll go around the table first and I'd ask each of the members to identify themselves and state whether or not there have been any changes in their employment or interest that would affect their conflicts of interest, and then we'll go to the members on the phone.

This is going to be a little difficult because we only have two working microphones.

MS. MEJIA: Good afternoon. Guillermina Mejia, no changes.

DR. QUINT: Julia Quint, no changes.

DR. ROM: Bill Rom, no changes.

MS. FLYNN: Kimberly Flynn, no changes.

MS. HUGHES: Catherine McVay Hughes, no changes. I'll bring the mic over.

DR. TRASANDE: Leonardo Trasande, no changes.

DR. MARKOWITZ: Steven Markowitz, no changes.

MS. DABAS: Valerie Dabas, no changes.

MR. CASSIDY: Stephen Cassidy, no changes.

DR. NORTH: Carol North, no changes.

DR. TALASKA: Glenn Talaska, no changes.

DR. ALDRICH: Tom Aldrich, no changes.

DR. HARRISON: Bob Harrison, no changes.

DR. WARD: Liz Ward, no changes.

DR. MIDDENDORF: Okay, and -- oh, I'm sorry.

MS. SIDEL: I'm Susan Sidel, no changes.

DR. MIDDENDORF: Thank you, and on the phone?

DR. DEMENT: John Dement, no changes.

DR. WEAVER: And Virginia Weaver, no changes.

DR. MIDDENDORF: Okay, thank you all very much. To those of the members who are on the phone, please let me know when you leave and when you return so we can be certain that we continue to have a quorum.

Also, I want to remind everybody that there may be some topics which come up that present a conflict of interest for members. And when these topics come up, I'll ask each of the members to state that they are recusing themselves so we have that on the record. That's just the best way to handle that.

I also ask everybody to -- we have a couple of issues; one is the microphones. We only have two microphones available in this room.

Tomorrow we will be moving into conference rooms A and B, so we'll have more microphones in there. We're going to leave this microphone turned on so we don't have that problem with the lag time that we had before, and then we'll just pass it around. I just wanted to point that out.

One of the microphones will be up at the podium until we're done with presentations, or if presenters want to present from their table, they can do that and we'll just give them that one from the podium. I think that's all I need to handle right now, so I will turn this over to our chair, Dr. Ward.

DR. WARD: Good afternoon. The first speaker today will be Dr. John Howard. He will give us introductory remarks.

INTRODUCTORY REMARKS

DR. HOWARD: Can you hear me? Good afternoon. Welcome to the second meeting of the Scientific Technical Advisory Committee for the World Trade Center Health Program. It is with sadness that we begin our meeting. Today, not only noting the passing of responders and survivors since September 11th, 2001, but also the recent passing of **[identifying information redacted]**, Professor of Preventive Medicine at the Mount Sinai School of Medicine.

For over 40 years, **[identifying information redacted]** treated, counseled, and fought for thousands of patients who were ill because of hazardous exposures in their workplace. As Co-director of the World Trade Center Worker and Volunteer Medical Screening Program at Mount Sinai, he was an early and prominent figure fighting for a long-term health program to identify and treat individuals who worked or volunteered at the former World Trade Center site.

For all of his tireless work on behalf of the World Trade Center Health Program during its earliest and most difficult time, we honor him and his service to his patients, to the City of New York, his country, and to all of us. Please join me in a moment of silence to honor the recent passing of responders, survivors, and **[identifying information redacted]**.

(pause)

I have four items for you today before we begin the meeting. The first item is the teleconference meeting on January 24th. I apologize for the technical problems which caused the cancellation of the 24th January teleconference meeting of the committee. We are taking steps to ensure there will be no repeat of the technical problems if the

committee should want to hold another teleconference meeting in the future.

Second, during this meeting, you will hear a report regarding scientific findings and support for establishing the statutorily required criteria for Pentagon and Shanksville responders. Commander Robert McCleery of the NIOSH Division of Surveillance, Hazard Evaluations and Field Studies in Cincinnati, Ohio has provided a report which you have already received and today will make a presentation regarding his research on the potential eligibility criteria for these groups of responders.

I want to thank you in advance for your consultation on this important issue. Please note that no formal written communication from the committee on eligibility criteria is required. The meeting transcript will suffice.

Third, I also appreciate the committee's continuing consultative thoughts on research needs for the World Trade Center Health Program. Your thoughts to date have been extremely helpful. And in addition to the formal research funding announcement from the NIOSH Office of Extramural Programs, the committee's views about important knowledge gaps and research needs will be placed on the World Trade Center Health Program's website for potential researchers to review.

Again, thank you in advance for your consultation on this important issue. Please also note that no formal written communication from the committee on research needs is required. The meeting transcript will suffice.

Fourth, as you continue your discussion of Petition 001 to add cancer or types of cancer to the list of World Trade Center-related health conditions, please keep in mind that the Zadroga Act in Section 3312(a)(6)(C) notes that the advisory committee must submit their recommendation on the petition to the administrator within 60 days or by a date specified by the administrator, not to exceed 180 days from the date of the administrator's request.

A request for a recommendation on Petition 001 was made to the committee on October 5th, 2011. The maximum 180-day period for the committee's consideration of Petition 001 ends on April 2nd, 2012. I had asked the committee to provide its recommendation by March 2nd, 2012, in order to provide enough time for the committee chair to prepare the committee's advice to the administrator.

However, since the opportunity for the committee to meet on January

24th, 2012, was cancelled, I would consider modifying the due date for the committee's recommendation. If the committee believes that more time is necessary to reach a recommendation, I would ask you to discuss that issue at this date and for the chair to send a written request to me for more time by the close of this meeting on 16 February.

Any additional discussion on Petition 001 after 16 February, 2012, must occur in another public meeting, so please keep in mind scheduling issues when determining whether additional time would be beneficial to the committee. In any case, the April 2nd due date for a recommendation is a statutory requirement; and therefore, no extension beyond April 2nd can be approved.

I thank you again for your service. I wish you a successful meeting.

RESEARCH NEEDS

DR. WARD: Okay. So, Rob McCleery has not dialed into the call yet, so we're going to go on and discuss research needs and then go to Rob when he dials in.

So, I hadn't really planned a lot of discussion around the research needs since I think you've all seen the letter that we prepared. But I didn't know if there were any topics that any of you wanted to discuss regarding the research needs or the conflict of interest.

Oh, sorry, he's just gotten on the line, so we'll proceed as planned with Rob McCleery's publication -- I mean presentation.

PENTAGON AND SHANKSVILLE, PA ELIGIBILITY

MR. MCCLEERY: I apologize for that. I didn't have this particular number, so I, again, I apologize. So, good afternoon everyone. Again, my name is Robert McCleery. I'm an industrial hygienist at NIOSH here in Cincinnati, Ohio. I appreciate the opportunity to speak with you this afternoon concerning the Pentagon and Shanksville, Pennsylvania responses to the terrorist-related aircraft crashes of September 11th, 2001.

Next slide, please. As it pertains to the Pentagon and Shanksville sites, the World Trade Center Health Program administrator is required, conditioned to other responsibilities to 1) determine the end dates of cleanup at both sites and 2) determine eligibility criteria relating to an increased risk of developing a World Trade Center-related health condition resulting from exposure to airborne toxins, other hazards, or adverse conditions resulting from the 9/11 terrorist attacks.

In the following slides, I will provide information that addresses both of

these required determinations for the four responding groups listed in the Zadroga Act for the Pentagon and Shanksville sites: fire department employees, police department employees, recovery or cleanup workers and contractors, as well as volunteers.

Next slide. At the Pentagon, fire department personnel arrived on scene very shortly after the aircraft crashed. Personnel within the Arlington County Fire Department served as the incident commanders during the fire rescue phase of the response.

Numerous other fire departments responded to the incident by backfilling other fire stations or responding directly to the Pentagon. This was set into action by mutual aid agreements previously established between these fire departments.

On September 21st, Arlington County Fire Department transferred control of the site to the FBI. The site now entered into the crime scene phase of the response. At this time, one firefighter company, a technical rescue team, and paramedics remained at the site until the FBI turned it over to the Department of the Defense on September 26th or 28th.

The literature differs as to the date of transfer of this command. From September 26th or the 28th, the available literature does not provide any information as to what period of time fire department personnel were on site until the end of the demolition and cleanup phase of the incident on November 19th, 2001.

Next slide. The police departments. The lead law enforcement agencies on site included the Arlington County Fire Department, with jurisdiction of areas surrounding the Pentagon, Defense Protective Services, federal law enforcement agencies within the Pentagon, with jurisdiction of the Pentagon, and the FBI.

Many other police departments respond -- responded either at the Pentagon or by backfilling police stations, by way of the Northern Virginia Law Enforcement Mutual Aid Agreement or the Northern Virginia Sheriffs Mutual Aid Agreement.

The available literature indicates that the Pentagon response had a police department presence until the FBI turned the site over to DOD on September 26th or 28th, 2001. The literature suggests that while the Pentagon site was under DOD control, services typically provided by police departments were handled by military police or Defense Protective Service personnel.

However, the literature does not provide additional information as to what period of time police department personnel were on site until the end of the demolition cleanup phase of the incident on November 19th, 2001.

Next slide. The Pentagon response and initial cleanup of areas of the Pentagon surrounding the incident site as employees began returning to work on September 12th, 2001. The demolition cleanup of the incident site itself was delayed until after a memorial service recognizing the one-month anniversary of the 9/11 attack on October 11th, 2001.

The demolition and cleanup activity of the most severely impacted area began on October 18th, 2001, and concluded on November 19th, 2001.

Next slide, the volunteers. The information in the literature does not provide a comprehensive list of all of the volunteers onsite for the time frames of participation of those that did respond. Literature indicates that there were many volunteers that played a role in the response, with specific mention of the Red Cross and Salvation Army.

It is reasonable to conclude at least some volunteers were onsite through the FBI relinquishing the site to DOD on September 26th or 28th, 2001. The literature does not provide additional information pertaining to volunteers remaining onsite through the demolition and cleanup phase of the response.

Next slide. So the available information concerning the Pentagon response does have limitation. The information has uncertainties as to when each of the responding groups faced increased-risk activity at the Pentagon site.

Next slide. For the Pentagon response to the September 11th terrorist-related aircraft crash, the recommended concluding date is November 19th, 2001. To ensure that each of the groups that did respond are provided adequate opportunity for medical monitoring and treatment benefits, the World Trade Center Health Program eligibility is recommended for the period covering September 11th, 2001 through November 19th, 2001.

The available literature indicates that documented air and wipe sample monitoring conducted through September 28th, 2001, did not reveal any exposures of concern. However, no information is available on exposures during the demolition of areas directly affected by the aircraft crash.

The next few slides will cover the Shanksville, Pennsylvania response.

Next slide, please. At the Shanksville site, fire department personnel arrived onsite shortly after the aircraft crashed. The FBI controlled the site from the onset of the response. Most of the fire department personnel left the site after the FBI turned the site over to the Somerset County coroner on September 24th, 2001.

There was a limited fire department presence until the conclusion of the final sweep of the crash site which took place on September 29th and 30th, 2001. The available information does not indicate whether fire department personnel were onsite during the site restoration activity from October 1st through October 3rd of 2001.

Next slide, Shanksville Police Department. Law enforcement personnel were also on site quickly after the aircraft crashed. Like the fire department, most police department personnel left the site after the FBI relinquished the site to the county coroner. Police department presence was limited at the Shanksville site until the conclusion of the final sweep of the crash site for aircraft parts and potential human remains on September 29th and 30th, 2001.

The available information does not indicate whether police department personnel were on site during the site restoration activities from October 1st through the 3rd of 2001. The literature does suggest that law enforcement personnel remained at the Shanksville site for a number of years to provide security.

Next slide. For the recovery or cleanup contractors, the literature indicates that environmental restoration contractors restored the site as close as possible to the original appearance as they could from October 1st through the 3rd, 2001.

This included backhoeing the crater with soil, adding topsoil to the crater area as well as the forested area near the site and seeding the area with flowers and grasses.

Next slide, volunteers. The available information does not provide a comprehensive list of all of the volunteers onsite or the time frames of participation of those that did respond. The Red Cross and Salvation (sic) are cited as responding to the Shanksville site. Like fire and police personnel, most of these volunteers left the site on September 24th, 2001 and had limited presence until the final sweep of the site on September 29th and 30th.

The available information does not indicate whether volunteers were on site during the October 1st through the 3rd site restoration activity. As

with the Pentagon, the Shanksville site has limitations in the information and that information has uncertainties as to when each of the responding groups ceased increased risk activity at the Shanksville site.

Next slide. The Shanksville response to the September 11th terrorist-related aircraft crash, the recommended concluding date is October 3rd, 2001. And to ensure that those who did respond were provided adequate opportunity for medical monitoring and treatment benefits, the World Trade Center Health Program eligibility recommended for the period covering September 11th, 2001 through October 3rd, 2001. Environmental monitoring at the site indicated that surface soil, subsurface soil, and groundwater did not exceed Pennsylvania Department of Environmental Protection health standards. Remediation was not required at the site. No indication that surface water contamination was attributable to the crash.

Next slide. The following is proposed eligibility criteria for the Pentagon responder: being a member of the fire or police department, whether fire or emergency, active or retired or worked for a recovery or cleanup contractor or was a volunteer who performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site for terrorist-related aircraft crashes of September 11th, 2001 for at least one day during the period beginning September 11th, 2001, ending on November 19th, 2001.

Next slide. The following is the proposed eligibility criteria for the Shanksville responder: member of a fire or police department whether fire or emergency, active or retired or worked for a recovery or cleanup contractor or was a volunteer who performed rescue, recovery, demolition, debris cleanup or other related services at the Shanksville, Pennsylvania site for the terrorist-related aircraft crash of September 11th, 2001, for at least one day during the period beginning September 11th, 2001, and ending on October 3rd, 2001.

This concludes my presentation for this afternoon.

DR. WARD: Are there questions for Rob? So, does anyone on the committee want to ask any questions or make any comments about Rob's presentation?

DR. HARRISON: Thank you very much for all the comments. I think it's very reasonable.

DR. WARD: I agree. Is that the general sense of the committee, that it's

reasonable? Okay, well, we'll record that for the record.

RESEARCH NEEDS

So, now we'll go back to the research needs and where we were on that was I was asking if anyone had any questions or felt the need for more discussion on the research recommendations or the document that was circulated regarding principles for handling conflict of interest within this committee.

PETITION ON CANCER

Okay, hearing none, we'll move on, and I guess our next topic is the petition on cancer. For those on the phone, I am going to be moving to the podium so that I can present some slides I prepared, and that will take -- that transition will take just a minute. It will be another minute because Paul is conferring on something. Are we okay to proceed?

Well, I think as most of the committee members know but possibly some members of the public may not, we had hoped to discuss -- is this on? Is that better?

DR. MIDDENDORF: Would you prefer to use this one or that one?

DR. WARD: Maybe we should use the other one, and probably we should turn this one off. Thank you. I do have a small voice, so this will be very helpful.

As most of you know, when we had to -- when we weren't able to have our last meeting by teleconference, one -- the plans for how we were going to address the petition on cancer was one of the things that we were going to discuss as a committee, so in the absence of having that meeting, I really thought hard about how we could approach this topic in a way that we could really have meaningful discussion at this meeting despite that circumstance.

And as you all know, we received a letter from Dr. Howard subsequent to a letter he received from several congressmen asking us to review the available information on cancer outcomes associated with exposure resulting from the September 11th terrorist attacks and provide advice on whether to add cancer or a certain type of cancer to the list of World Trade Center-related conditions.

And as we discussed that at our last meeting, I think we realized that there were a number of very complex and difficult questions embedded in that -- in that request. And one of them was basically whether, based on what people were exposed to at the World Trade Center, do we believe it's possible, probable, or not that the exposures could cause

cancer.

And it's -- whatever our recommendation is, we would need to provide a scientific rationale. Now there's a second topic. There's at least one other really complex topic that came up at our last meeting, which was what are the criteria for having a health condition?

And so my idea was to focus today's presentations and discussion on the first question: Do we believe it's unlikely, possible, probable, et cetera, that exposure to the dust may cause cancer, and then depending on where the committee stands at the end of the day, we'll decide how best to use our time tomorrow.

And I think it's important. My boss says -- at the American Cancer Society -- says this all of the time, so I guess he's implanted it in my head. I think when we talk about the scientific rationale, it's really going to be important to talk about what we know, what we don't know, and what we believe, because I think that, you know, we'll all -- in all the presentations today, one recurring theme will be we wish we had more data; we wish we understood the exposures better; we wish we knew more.

EPIDEMIOLOGY AND OVERVIEW OF MECHANISMS OF CARCINOGENESIS

So what I'll be doing is just reviewing the epidemiologic studies that are completed and ongoing. I am going to talk about the potential carcinogens present in the World Trade Center dust, and then I am going to give a quick overview on mechanisms of carcinogenesis, really focusing on those issues that I think pertain most to our discussion today.

So with respect to the epidemiologic cohorts, we had several presentations on them at our last meeting and we also have access to published information on them. So I am just going to go through them very quickly.

Among the cohorts that are under study, there are -- there's studies going on of the Fire Department of New York, and I think these studies probably from an epidemiologic point of view are the most -- are going to be the most complete and informative because we know that they really have a well-defined population and a population that is, you know, highly exposed, a comparison group.

And they also have a separate set of EMS workers that has not been published on. They're also doing an employer-based medical screening program, which will provide additional information.

The second large cohort that can be studied is the New York -- is from the New York and New Jersey World Trade Center Clinical Consortium, and I think that will also be a very informative study. It will suffer from the limitation that it essentially was a self-referred group of people.

The third one, which I'm not sure is actually being studied for cancer or not. I'm sure someone in the room knows. It's the cohort that's been identified through the World Trade Center Environmental Health Center, and this population is unique because it includes some children.

And then there's the very large World Trade Center Health Registry that's being run by the New York Health Department. And that one is clearly the largest in terms of sample size. Probably the most severe limitation is that about 70 percent of the cohort is self-referred rather than identified from the list or records, and that group is being followed both by surveys and by linkage with cancer registries and mortality data.

So in the first publication of cancer incidence data from the firefighters cohort, the incidence ratio for all cancers combined was 1.10 compared to the general population. And depending on particular adjustments used, it was 1.19 to 1.32 in comparison to non-exposed firefighters.

There are also some excesses for particular cancer sites. The findings differed a little bit based on which adjustment was used, but basically, there were significantly elevated or borderline excesses observed for stomach, colon, melanoma, prostate, thyroid, and non-Hodgkin lymphoma compared to the general population rates.

And I think one thing that's important to note here, because it's been noted by others in the literature, is that there are a number of these cancers that no -- are likely to be detected by screening or by just access to medical care, and the paper did attempt to control for that bias in the analysis.

But with respect to other epidemiologic studies, in the first publication from the World Trade Center Health Registry study, there was no excess of all cancers combined or eight major organ systems reported. There have also been case reports suggesting the possible excess of multiple myeloma in the literature.

So I think one of the things that it's important to understand before we move on from the epidemiology studies is that epidemiologic studies in general have their strengths and their weaknesses. One of the strengths is that you're actually studying the events, not animal systems or models.

On the other hand, it's often very difficult in epidemiologic studies to accurately estimate exposure, and I think that applies even more so in these studies; although, I think there have been really good attempts to use surrogates of exposure, like in the firefighter cohort, kind of developing exposure classifications based on when people arrived at the site, for example.

So I think that the existing studies are doing the best job that they can, but ideally, you know, what you'd love is an exposure matrix for each person so that you knew, you know, this person was very highly exposed and they didn't work well. And that's probably not going to be present. And so, when you don't have good exposure information, you may not be able to see some of the things that you tend to look for when we look for causal association, so we may not see a strong dose response, because we don't have good exposure data. We may not see the trends that one might expect to see.

Another criteria for causality that's considered is consistency between studies, and again, I think, especially in this case, we may not see that level of consistency because we don't have one exposure. We have many exposures, and we have different populations and individuals who were exposed to different things, so I would not be surprised at all with the different studies that they show increased risk for cancer. They may see increases at different sites, so I think we have to be really cautious about especially making negative conclusions about the findings of these studies.

And the last -- well, the last one on this slide is even though many of these populations are sizable, they're still, in many cases, small enough or early enough in the follow-up period that there are not very many cases expected based on population rates.

So if we don't see an effect, we really need to be careful in interpreting that because it may be -- the studies may be too small to rule out small risks or risks for rarer cancers. One of the most important things, and I know it came up in our discussions last time, and I'm sure it will come up again today, is that, you know, I think when we all were trained in occupational health, those of us who were, we all thought, well, you know, usually solid tumors you're looking for at least 20 years between the onset of exposure and disease and hematologic cancers, the latency period is shorter.

And -- but I guess what I wanted to emphasize is the issue of latency

period is most relevant in epidemiologic studies early in the follow-up period when we have negative results and follow-up may be too short to see a positive effect.

It's not necessarily relevant in the sense of saying, well, this cancer can't be related to exposure because, you know, the exposure only occurred five years ago. I'll get more into that later, but I don't think you can make those kinds of assumptions based on what I'll present to you about the mechanisms of carcinogenesis.

So, if -- I think we got the -- I got the sense in the discussion last time, and this doesn't probably represent everyone's viewpoint, but I did get the sense from the discussion that many people felt that they could not make a decision on the cancer petition based on the epidemiologic data alone.

Obviously, the strongest study is the firefighter study, but I don't -- I didn't sense an overwhelming consensus that the findings of that study were so definitive that it would be the basis for a recommendation. So then the question was, what can we learn from looking at the exposure data, but I think we have to acknowledge at the outset that it's incredibly difficult to interpret the -- especially air sampling data from the World Trade Center study.

And one critical limitation was that there's almost no data from the first week after the attack. A lot of people said that last time, and I think, you know, I think we all understand that. I'm puzzled about some of the air data, because it really seems like the low air levels measured in some of the personal air sampling studies done on the workers seems really inconsistent with the extent of respiratory symptoms that we're seeing.

And so I don't know how to answer that question, but it's my belief that it's, you know, I don't see it fitting together well. So, one approach to looking at the cancer hazard which I thought we could take today is really to focus on the composition of the initial dust and smoke as reflected in the mass dust samples that were collected.

And those samples were collected and analyzed by more than one group so at least we have some -- we can look at consistency of their findings.

And the other benefit, I think, of looking at the dust and smoke is that there were a lot of populations exposed to that.

So, for example, we know that there were fires at the site, and we knew that -- we know that firefighters and police officers who were on the

site itself were exposed to combustion products from the fires, but just for the purposes of having a simpler discussion today and a discussion that kind of encompasses exposures to all of the groups, I thought we could first focus on the dust and smoke, recognizing that there's more -- there's more to the story that we'll have to get to later.

So, in poring through the literature and, you know, all of the exposure papers, I have to confess, I am not a chemist; I am not an industrial hygienist, and it's not easy to read these papers. But, you know, one of the things that I got out of it was really, you know, what went into the buildings is really what came out of the buildings.

So, if you look at, you know, there was a lot of light-weight concrete; there was asbestos; there was gypsum; there was drywall; lots of glass. There was glass fragments and man-made vitreous fibers from insulation. We know that there were polycyclic aromatic hydrocarbons measured in the bulk samples. We know that there were metals measured in the bulk samples.

And then, we also know that there were volatile organic compounds in the mix. Now those probably, looking at the dust, is not the best way to look at exposures to those, which is why I have them in blue, because we know they were there. In the dust, though, they may have been absorbed onto particles and fibers and other things, so they may be there, but it's probably not the best way to measure them.

So, what, I mean, what -- so, two of the reasons I focused on these particular exposures is one, that they were pretty substantial. So, for example, the asbestos was, you know, in a few of the bulk samples was from .8 to 3 percent of the total weight of the sample. So that's pretty significant. The other thing is a number of them are -- have been recognized as human carcinogens for which, based on epidemiologic data, so they are substances for which we have fairly strong epidemiologic data.

So that's why we're focusing on these particular exposures. It doesn't mean that there aren't other classes of exposures of concern, and you know, we're not talking today too much, at least in the presentations, about PCBs and furans and, you know, TCDDs, but again, you know, we have a limited amount of time, and I wanted to focus on the things where I thought there was the clearest data to talk about.

So, now shifting gears a little bit, and I want to thank both Julia and the National Cancer Institute for these slides. Julia pointed out to me that

there was a slide set on the National Cancer Institute website that we could use for this presentation because I think that a picture is worth a thousand words.

So all of the slides in blue come directly from that website and have not been modified. So basically, what is cancer? So, when a cell becomes cancerous, basically, it loses the ability to control its own growth and to organize itself appropriately in tissues. And this -- one of the key things in that process is the damage to the DNA of the cell.

So this is a slide that summarizes a number of different characteristics of cancer cells, and it's really, at least historically the way that cancer has been recognized is pathologists look under a microscope at the appearance of the cells from the tumor. So the cells will be different. They'll have larger nuclei. They will not organize themselves into neat structures the way they're supposed to.

So that's a real quick review of that, but you, typically, you know, for our classic carcinogens, both tobacco and asbestos, we see a 20-year latency period, and that's -- but what that means is in 20 years from the onset of exposure to the peak of disease in the population, so in this case, men started smoking in the United States soon after 1900, and we saw the peak in lung cancer in the 1970's.

So the -- so as I mentioned, the key, you know, the critical step in carcinogenesis is an interaction of exogenous or an endogenous substance with DNA within the cell, and that can be a chemical, it can be a virus, it can be radiation. So there is a component where there is an interaction with DNA.

And typically, what happens, and this is grossly oversimplified, but basically the DNA is the cell's mechanism that basically codes for the production of everything a cell needs to grow and sustain life. So, what happens is when there's a chemical damage, for example, that might change one of the -- and so, and the code is really in the three -- it's in three, you know, it's in three chunks.

So, CAA codes for a particular thing, and if you substitute one of its -- one of the chemicals, it changes the whole, that whole code. So, basically, three things can happen. You can change a single base. Those things are called bases, and the three together are (indiscernible).

You can change a base. You can put an addition in a base, or you can make a deletion from the base, but in any case, it basically messes up the code such that the gene is not effectively doing what it's supposed

to do.

And there's really three kinds of genes that are involved in the process of carcinogenesis. One type -- and you know, this is large categories. One type is oncogenes, and what oncogenes do is they -- when they're -- they accelerate cell growth and division. Tumor suppressor genes enable the cell to put a brake on that kind of uncontrolled growth and DNA repair genes allow the cell to repair errors or mutations in the DNA itself.

So what happens, if you're exposed to a carcinogen and you have a mutation and in any of those three types of critical genes, if the cell does not repair that mutation before it divides, that mutation is going to be passed on to the daughter cells.

So typically what we see in cancers is multiple mutations, and it's kind of, it's thought that these mutations occur over a period of time, so possibly, you know, when you're 25, you get a mutation in a tumor suppressor gene, and if that is maintained, then as those cells divide and proliferate, they accumulate additional mutations, and in that process, though, you're not just -- the changes in, the mutations in the genes is not the only thing going on to lead to cancer. Other things are going on that kind of promote the growth of those cells.

So for example, for breast cancer, estrogen promotes the growth of tumors in the breast because breast tissues are naturally sensitive to, you know, hormones, for example. So it's not only the genetic mutation or the interaction with the DNA. It's multiple things going on.

And so, we tend to divide the process of the carcinogenesis into four big buckets: initiation, which is basically, at least an initial mutagenic effect; promotion, which is, you know, encouraging those abnormal cells to grow; malignant transformation, which means that the cell has kind of passed beyond the point where it can revert back to a normal cell. It's accumulated enough damage that it's essentially destined never to go back to normal. And then ultimately that tumor gets larger and invades other tissues beyond where it arose and it can metastasize to other parts of the body.

So the reason I'm emphasizing the promotion and progression is, is that it's important in the context of the exposures we're discussing today because inflammation is one of many -- it's one of the important mechanisms of carcinogenesis. And inflammation actually can do a large number of different things, but basically inflammation is a normal

response to tissue damage that can result from infection, chemical irritation, and/or wounding.

However, when it becomes chronic and it becomes chronic in a number of known diseases, it can damage the body and lead to illness. So, for example, we've all heard of Crohn's disease, which is kind of an inflammatory condition of the bowel, cirrhosis of the liver, which is an inflammatory condition of the liver. Many of the diseases, especially the infectious diseases that result in inflammation also result in cancer. And inflammatory processes can also occur as a result of chronic chemical and mechanical inflammation, but it's important to know that inflammation in general can really lead to cancer in a multitude of ways. Its increasing cell proliferation and turnover is actually generating mutagenic substances from some of the reactions that release oxygen and nitrogen species, and it's also producing cytokines and growth factors and other biologically active chemicals that are influencing the microenvironment around the area where the potential tumor is developing.

With regard to mechanism, I guess the other things I wanted to mention are that -- one of the things we have to consider is that for many of the people in the exposure group, the duration of actual exposure is relatively short, but I think it's important to note that at least in some of the populations studied, inhaled fibers and dust can remain in the body for a very long time. And so, in fact, a short-term environmental exposure can lead to a long-term biological exposure, and we've seen that in some of the bronchial lavage studies.

The other thing is, you know, we've talked about this average latent period for solid tumors, but I think it's important to recognize that it all depends on what stage in the cancer process an exposure occurs. So, for example, we see this curve in the population when in relation to onset of smoking in the population at large, you know, and then the lung cancer epidemic following 20 or 30 years later.

But when a person stops smoking, their lung cancer risk goes down dramatically within three to five years. So, what, you know, one thing that's probably happening there is that essentially tobacco smoking contains practically every carcinogen known to man, and some of those substances actually are promoting or, you know, causing the tumor to progress, so they're both initiators and promoters.

And so you see this much more rapid effect in an individual that stops

smoking than you would expect from the long latency period for the initiation, and we've seen something similar recently in breast cancer and this is really interesting.

So, in 2002, the Women's Health Initiative published a study showing that use of postmenopausal hormone therapy was associated with an increased risk of breast cancer and the surveillance epidemiologists noted in that year's data that there had been a dramatic drop in breast cancer incidence virtually the same month that those studies came out. And at the time, you know, everybody was saying it can't be related to HRT, it's not biologically plausible that something could act that fast. Well, if, you know, there's pretty good consensus now. I don't think anyone disagrees that one of the major factors or the major factor in that abrupt decline is that, you know, on a population basis, a lot of women stopped taking HRT, and HRT was really promoting or causing tumors to progress in the women.

And since that time we've actually seen a flattening out of rates. It's not continuing to go down, which further supports the hypothesis that it was that one time decline in HRT.

So, we'll be moving on. I have a few more things I'd like to present, but then we'll be moving on to the presentations that I asked people to prepare regarding specific exposures of concern. But before I wanted to go on, I wanted to mention that I think there is an opportunity to learn more about the potential health effects of the World Trade Center dust exposure that maybe we haven't explored as fully as we could.

So, one of the things I noticed in looking through the literature is that, you know, there was a lot of concrete in the buildings and concrete is a -- you know, two of the main components of concrete are cement dust and silica. Silica, as I mentioned, is an accepted lung carcinogen and it's also associated with autoimmune diseases and stage III lung disease. Pulverized concrete also contains a material called Portlandite, which is highly caustic and not shown in this slide, but I know many people in the room are aware of it. People who work with wet concrete often get skin sensitization because of hexavalent chromium in the cement mix. And many European countries actually regulate the content of hexavalent chromium in their cement, but the United States does not.

So -- but it appears, and again, this is very preliminary -- it appears that maybe the hexavalent chromium content of concrete once it's set would not be as high as the mesolithic form. But again, that is something of

concern.

But in fact, there have been a number of studies of cement dust exposure, many of them done, interestingly, in developing countries, but many of these studies, and again, some are small, but actually a few are, you know, large enough and well designed, at least on the surface. And many of the studies, not all, find increased respiratory symptoms among people who work in the production of cement, and they also demonstrate reduced lung function among people with long-term exposure.

What I found most interesting is that there was one study that actually found an increased risk of GERD-type symptoms among people exposed to cement dust. And by the way, all of these studies are on the FTP site under the folder that says cement.

Of even more concern is there have been some cohort case controlled studies that have suggested associations between cement-exposed populations -- and that could be either in the manufacture or in the construction industry -- in cancer of the lungs, stomach, colon, head and neck, pharynx and larynx.

So cement dust that has not been reviewed by IARC or NTP and the only kind of official review I could find of it on it popped up on the web, and it seems to have been done by the Health and Safety Executive of the UK, but the version of the document online is a little odd because it does not have a publication date. It has a number, but no date, but I think it was -- it looks like it was published in 2006.

And basically, their synthesis of the cancer literature at that time was that the epi data was not convincing, but that they felt that some of the associations that had been seen were biologically plausible in large part due to the known inflammatory responses associated with exposure to cement dust.

So one of the ways I thought -- I mean, I thought I had a pretty reasonable way to frame the discussion today and get into depth on some of the most important issues, but I think tomorrow, the agenda is wide open, and one of the things I thought that might help us frame an agenda would be to -- at the end of the presentations, we'll kind of poll the committee and ask each person to check one of these words and turn them in -- so, this is not a vote, it's just a poll.

And then what we'll do is we'll summarize the distribution of the results, just kind of arranged by the exercise. So, we'll summarize the

distribution of the results and that will help us know, do we have two really different viewpoints? Are some people really on the side of probable proof and are other people way off on unlikely, possible, or do we have, you know, a distribution centered at the middle?

And then we can really see, you know, how can we use our time tomorrow to, you know, to see if the group has a consensus or not or to figure out what issues are of most, we're most uncertain about. And again, we are all prepared to tabulate these result in such a way that you --

MS. HUGHES: I have a quick question. On the slides --

DR. MIDDENDORF: Wait a minute.

MS. HUGHES: Hi, I have a quick question. On the last slide, it says is the blank that exposure World Trade Center may cause cancer. Can we also use slash smoke, because not all of the exposure was dust --

DR. WARD: Yes.

MS. HUGHES: Because not all of the exposure was dust.

DR. WARD: Yes.

MS. HUGHES: Because then it would be more consistent with some of the other slides.

DR. WARD: Yes.

MS. HUGHES: Okay, great, thanks.

DR. WARD: We can make that -- yeah. So, anyway, I think this will be helpful in framing tomorrow's discussion and, you know, and these are various options that we could discuss tomorrow. There may be -- it may be that people feel that there's critical evidence that we didn't cover today that we should go into in more depth tomorrow.

It may be that there are clearly opposing positions that we should try to address tomorrow. If we're -- if there's apparently a high degree of consensus, then we can start talking about the rationale for the position.

If we are leaning towards saying probable, then we can discuss the issue of what sites do we think are probable, and then hopefully have whatever -- wherever we are, and certainly we can discuss the possibility of needing to have another conference call or meeting before we can make our recommendation.

So, with that, along with my presentation, are there any questions?

DR. MARKOWITZ: So just a couple of comments. One is I don't really favor taking a poll before we have the public comments. We have the

public comments at the end of today and beginning of tomorrow morning, because that would add to the discussion, influence our thinking, so I would advocate doing a poll after that.

I would also like to have, you know, do some discussion before we do a poll because I want to hear what people think. So if you want to do a poll, we could do it. We could change the time, though, until tomorrow after public comments and after there's at least some initial discussion. I assume the purpose of a poll is to sharpen further discussion.

Another comment I have is about the choices of unlikely, possible, biologically plausible, probable, definite, and that is that actually I think biologically plausible stands with both possible and probable, and so I'm not sure that these are exclusive categories. And I understand that it's preliminary, a rough way of getting a sense, and I wonder whether one alternative approach would be to consider reasonably anticipated as a substitute for one of the categories.

DR. WARD: Maybe probable?

DR. MARKOWITZ: Well a --

DR. WARD: I guess, that's the thing, it sounds like probable to me but, so I guess if -- we can make any changes that you all want to make. It did occur to me that maybe the timing was wrong, but again, the timing was kind of thinking about how can we tabulate these results so that we could leave people thinking about how we're going to use our time tomorrow.

And some people may even want to, you know, think about ideas that they'd like to present or do literature searches tonight, or, you know, people could prepare to argue the main points overnight and so I did -- well, I did bring enough paper ballots that we could have more than one poll, so that's one option. Valerie?

DR. MIDDENDORF: I think Catherine had a --

MS. HUGHES: Yeah, I had a quick question.

DR. MIDDENDORF: So, Catherine, then Tom, then Valerie.

DR. WARD: I think I need to have my eyes transplanted so --

MS. HUGHES: I know we're all -- we're looking at actually what was in the dust and what was in the fumes. Are we going to look at also the impact of the temperature, because it wasn't as though the temperature was the temperature of the day, because it was just so hot. It was like 1000 degrees -- if people were close would have been impacted and how the items could have changed due to the

temperature, too.
DR. WARD: Yeah, and I think, you know, that would fall under the category of things where there's something that where there are critical issues that we haven't discussed. I don't know if anyone is prepared to talk about the temperature today or, you know, has really looked into that issue, but if you feel that that's an important issue, we can see if there's anyone who wants to comment on that further or we can put it on a list of things.
Again, I guess the question is do we feel like we have enough information to make a recommendation now, or are there things that we feel are so important that we need to wait until, you know, somebody really studies them well enough to talk about them.
I mean, I certainly couldn't talk about that today, and I don't know if anyone else could.
DR. ALDRICH: I was going to suggest, if there's going to be a poll, maybe two questions: biologically plausible, yes or no; and then the other four, pick one.
DR. WARD: Good.
DR. MIDDENDORF: We forgot Valerie.
MS. DABAS: Just because I am not a scientist, I just want to get the definition of biological plausibility just because I've seen so many different ones on the websites.
DR. WARD: That's a good question. My definition of it is that when you look at the exposure and what was -- when you look at the dust and smoke and you look at what was in the dust and smoke, and you look at what the toxicity of the, of that we've already observed in the events and, you know, when you look at all of those elements of data, it makes sense that this exposure could cause cancer based on what we know about the cancer process and the components in the material.
Now, that's my definition. Someone else may have a better one. Julia?
DR. QUINT: I think I agree with most of what you said except I'm not limiting it to humans, because I -- the animal data that shows that something is carcinogenic, to me, means I don't think –- there are only a few cancers in animals that are not biologically plausible in humans, so I think the animal data is a plausible mechanism in humans as well.
DR. WARD: Yes, and I totally agree with that, and --
DR. QUINT: I thought you did.
DR. WARD: Yeah. I am going to return to my seat until we are done

with --

MR. CASSIDY: Thank you. You've discussed a lot of topics, and one that I think is interesting when you look at this is, you know, is it blank that the exposure to World Trade Center dust may cause cancer, and I think it's hard to, you know, may be hard for some people to answer that unless you're talking about a level of exposure, right?

So you were talking about cigarette smoke, and I would think that the studies show if you smoked one cigarette and stopped before you had an exposure to tobacco that the likelihood of developing something from that would be different if somebody smoked five packs a day for ten years, right?

So I think it's important that the part or at least part of the discussion to the level of exposure, and I tie that in to when you said that the air sample data seemed to be inconsistent. Well, the question is where was that air sample data taken? And, you know, my personal recollection is I didn't see anybody standing on the Pile taking it.

So, I don't know where -- if they took it five blocks away or ten blocks away or where they took it. And on that note, the air sample data, I would remind everyone that is -- there was much discussion about whether or not that was a political decision to say quote, unquote, the air was safe because they wanted to open up Wall Street. You know, we had to get back to business, the country was shut down. So, I just wanted to raise that point.

I think people that were there working at the site knew the air wasn't safe no matter what **[identifying information redacted]** witnessed, so.

DR. WARD: Yeah, and I do want to, I mean, I fully acknowledge those issues and I didn't want to spend a lot of time on them today just because I really feel like, you know, both the committee discussions and the published literature both, you know, essentially give that same information. But it's really trying to come up with other approaches that maybe can be a little bit more revealing and make -- help us make a decision.

But I think, you know, there's at least, there's a couple of exposure scenarios and I think we should acknowledge that too so we have people who were -- we have a very heavily exposed group that was working directly on the Pile, especially in the early time period. We also have the potential for the community residents and the workers to have prolonged exposure to the dust that entered the homes and office

buildings.
Now, again, I don't know that you would expect to see exactly the same health effects in those two populations, but they're both populations that may have significant exposure, possibly to different substances and different concentrations.
DR. MIDDENDORF: It's easy to forget that we have some committee members who are on the phone, out of sight, out of mind, so I just want to ask if any members on the phone have any questions or comments.
DR. WEAVER: I don't, but we're moving along fairly quickly and I just want to point out that I'll be teaching from 1:30 until 2:50 and I'm scheduled to talk at 3:10, so, you know, we can just juggle when I talk around class, but when I am in class I'll have my cell phone, so I can listen in.
MS. SIDEL: I just want to say that because we don't have air samples from, you know, from the day 9/11, that's why Officer Harris's uniform is so fascinating, because it's like a snapshot in time of what, what was there, and I believe that this also -- another study of what FDNY, I think, equipment that I've seen that are also from the actual day 9/11 from people that were working. So, you know, I feel as though there's a lot of different air samples and they sort of collectively say the same thing, and that is that there were a lot of carcinogens down there.
And then we start talking about, you know, different zones of exposure, but you're never going to get -- that's never also going to be firm and there's definitely people that were super-exposed, but then there's also other things that can happen, you know, you can just be in your home and, you know, cleaning up your bed and there's a big pile of dust, so is that the same as working on the Pile the first day? What difference does it make?
Because if you get one little drop of asbestos, then you get that whether you get it on the Pile on the first day or you get it while making your bed, you know, three months later, so it's kind of, I understand from scientifically for us to have all of these categories but working in real-time in what actually happened to people, I think you have to be more open-minded.
DR. WARD: And I think we are trying to do that.
MS. SIDEL: Oh yeah.
MS. FLYNN: I, you know, I have to agree with Steve Cassidy and with Susan Sidel. I mean, a lot of us were involved in the EPA World Trade

Center Expert Technical Review Panel where the flaws and inadequacies of all of the government data were, you know, pored over at great length. Unfortunately, the public record of that panel has been removed from the EPA's website and Congressman Nadler's request that it be restored as a resource for this committee and for the public has gone unheeded.

But, you know, there have been many, many observations made in that process about the ways in which, for instance, when a monitoring instrument picked up benzene spikes on the Pile, the instrument was shut down and moved to another site.

The errors in the, in the asbestos air sampling for lower Manhattan residences that was conducted by ATSDR and the City Health Department were reported by residents who were eyewitnesses to the fact that fans were turned to the wall, that leaf blowers were not turned on. I mean, it almost borders on the level of sampling fraud. So, first of all, they were, you know, we don't have really good sampling data to fully characterize exposures in exposed populations. And second of all --

DR. WARD: But didn't I say that? I mean --

MS. FLYNN: Yes. No, I just -- I think it really bears reemphasizing and also to -- I know that some people saw this article that I sent in by David Newman, the industrial hygienist with the New York Committee for Occupational Safety and Health, and but I -- he said in this article, under the category of exposure assessment:

If just one thing is to be learned from the WTC response experience, it should be that an exclusive reliance on environmental sampling data can be misleading and even dangerous. There has been a fundamental disconnect between what the majority of the sampling data would seem to indicate and the breadth of health issues that have arisen. WTC-related illnesses manifested despite reassuring results that came from traditional methods of data collection and assessment. Tens of thousands of WTC responders, area workers, and residents incurred significant and persistent respiratory and other chronic and incapacitating illnesses.

And I just want to make one more comment, which is that, you know, not to further complexify (sic) the polling language, but in fact, the Zadroga Act sets a criterion for linkage of illness to World Trade Center substantially likely to have been a significant factor in causing,

exacerbating, or contributing to, so is there a way actually to map that language on to the polling language? Because I think we're looking at a real -- I think we're looking at contributing to may get us where many of us feel we need to go much more quickly.

DR. WARD: So we can definitely change the language with the poll. I guess I remember at the last meeting there was a little bit of confusion about the criteria for listing something as a World Trade Center-related condition versus the criteria for determining that a particular person's illness was World Trade Center-related. So I don't know if the language that you quoted was -- which one that was. I don't know if it matters, but I think we can certainly change this.

I think it really -- what I was -- what we were trying to do is come up with a way to express it where we can understand the diversity of opinions among the group so that we can figure out how we can have a more productive discussion tomorrow. Whether the, you know, if we have general agreement on the overall issue of the potential for carcinogenicity, then we can move on and discuss other things. If not, we need to stick on that point until we understand why different people have different views.

DR. HARRISON: Thank you. I wanted to say something else, but I wanted to thank you because I am going to change what I was going to say, I think, because I was not aware that there was the language.

And I would ask, maybe, if we could clarify that point because I think, at least in terms of my thinking about whether or how or what we would recommend as a committee, if we need to use certain criteria that is legislatively mandated, I think it's very -- it's significant, pardon the pun. So, if we could just clarify that because there are -- because it actually ties in with the comment that I was going to make. I think there's all sorts of perspectives on how to come to a recommendation in terms of cancer causation.

There's the individual patient that some of us, including myself, bring to that perspective when I see an individual in my office with an occupational or environmental cancer, what criteria do I use. There's workers compensation criteria. There are civil litigation criteria. There are cancer presumption law criteria. There are many different frameworks that I personally am familiar with and bring to this discussion.

If there are other specific criteria that in the legislation that directs us

to consider, then I think we should at least understand what that is and come to whatever straw poll with a reasonably common set of understanding so that -- and this is my comment -- it's sort of agreeing with Steve. It's that if you do a straw poll before we have some common framework may just give us, you know, 15 different ideas about what we are voting on but not a common set of criteria to guide our vote.

DR. QUINT: Yet another frame is a public health frame and the prevention frame that I come from and also the toxicology frame. I just wanted to tie some of this back to Liz's presentation where she talked about mechanisms because one thing to consider, when she talked about mutations is one -- a lot of these carcinogens are thought to have no threshold, so that when you're talking about amount of the carcinogen or substance that the person was exposed to, it's thought to be linear, so it's going through zero, so any amount could trigger a carcinogenic response.

Of course, you know, normally we talk about some risk above background, but to do that, you have to know the potency of the carcinogen plus you actually need to know exposure information and something about the exposure profile: how many days a week, how many years, et cetera, that the person was exposed to it; and we don't have those data.

So and the -- there's an article in our file, the folder, Guyton, et al, in Mutation Research which is very compelling because it talks about these carcinogens operating through many modes of action, so it's not just one. It's not just that they cause a mutation. They can act on, you know, promotion and different aspects of the carcinogenic process.

So read by my count have 72 carcinogens in the dust, at least the ones that NIOSH listed. Some of these are human. Some of these are animal, so I think, you know, we have to keep all of these things in mind when we talk about biological plausibility.

There are a number of in vivo and in vitro articles where people have actually demonstrated with very short exposures, you know, a triggering, mostly the carcinogens that act on an inflammatory process, but, you know, have initiated a process that ends up, you know, that goes through all of the steps and so -- and in very short time periods, some acute and some sub-chronic exposures.

Again, they're in mice, and they're in human epithelial cells, but I think

all of this enriches our understanding of the mechanisms of carcinogenesis and argues that this is a very complex process when you add, you know, high exposures, very high exposures with a multitude of carcinogens, you add to that complexity.

And also ingestion. You can't forget about the fact that some of the exposures probably occurred through ingestion when you have dust on surfaces, especially in offices and homes, you probably have added to that probably also with the firefighters as well, given the amount of contamination on their uniforms. So it's not just the air levels. It's a, you know, very rich mix of information that we have to consider.

MS. SIDEL: Just in terms of ingestion, my supply tent was right on the Pile and we were serving coffee and food and all sorts of things, so I'm sure that things were flying in there.

DR. WARD: So are you –- oh, Steve.

DR. MARKOWITZ: I just want to follow up on what Dr. Quint was saying. So we don't have a lot of experience with people with short exposures and long-term follow-up and cancer in particular, so could you just discuss a little further what experience there is with animals about certain carcinogens with acute or a very short term exposures subsequently relating to cancer?

THE COURT REPORTER: Can I say something real quick? If you'll get that microphone real close to your mouth it helps me a lot. I will appreciate it. Thank you.

DR. QUINT: I agree with you. Dr. Markowitz said that there isn't a lot of data. I was actually looking for some dose rate data in animals to sort of understand better whether or not we had those models, but there is a paper by Beaver et al that -- let's see, I have it right in front of me here. And actually, she was looking at the exposure to chromium and looking at lung inflammation and injury and then a proliferative -- or from repetitive exposures.

And I think in that situation, she was able to expose one kind and then get a response. There's also some information where people are looking now for other than animal models, and so the Hammer Institute had a study where they actually had a training set of carcinogens, NTP, and exposed after 90 days and was able to -- they looked for a marker which was a -- it was a gene expression biomarker, and they were able to see that within 90 days. I think other people have seen it within 24 days, so they're looking at different -- they're not looking at the

cancers, but they're looking at markers for carcinogenicity, very specific. There's the other study that I mentioned was the -- a study in human epithelial cells, and I have -- in that study, they were looking, I think, as short a period as 24 hours or maybe shorter than that, and they were looking at -- they compared both silica, crystalline silica and amorphous silica and were able to get a difference again in the whole process, you know, leading that was carcinogenic-like process.

So, no, animal models, I don't know of any in the regular bioassay models that would mimic -- that we could look at with this.

DR. WARD: There's also a lot of data on the cancer patients who were treated with radiation and chemotherapy, and there's very good data on their development of second neoplasms, and in some cases, you will, you know, there's enough data, let's say if someone -- there's a lot of data, for example, on young women treated for Hodgkin lymphoma with high-dose radiation to the chest who subsequently developed breast cancer.

So you could look at age and dose if that's -- but those are -- those agents are very strong carcinogens, but it is a very rich resource if you're into understanding how relatively short-term high exposures can result in carcinogenic effects, but...

Sorry.

DR. MIDDENDORF: That's okay.

DR. WARD: I keep forgetting about this.

DR. TALASKA: There are a number of studies that were done by intertracheal lavage of PAHs that were single-dose were able to bring lung tumors, particularly in strains of mice that were relatively sensitive, so there is -- there are data. I can't think of the citations off the top of my head where lung lavage of PAHs, benzo[a]pyrene particularly, has led to a, lung tumors in animals from a single dose, a single heavy administration of a material in liquid -- in corn oil or another vehicle.

DR. WARD: Yes, again, I think the other thing to keep in mind is what I mentioned in the presentation that for some of these exposures, they -- if there's a long residence time in the lung and thoracic lymph nodes, a very heavy short-term exposure can result in a long-term dose. And so -- and I think we have some evidence of that in some populations.

Okay, so any further discussion before we turn to John Dement's presentation on asbestos? Excuse me? Oh, sorry. Folks on the phone,

any further comments before we move into John's presentation? Hearing none, John, would you like to start with your presentation? Well, Paul will queue up your slides and let you know when they're ready.

ASBESTOS AND WTC

DR. DEMENT: Okay, very good. Thank you and my apologies for not being able to be at the meeting today.

DR. MIDDENDORF: They're ready any time, John.

DR. DEMENT: Okay, just move on to the second slide. I'm going to talk about the dust exposure, so there's clearly the type of dust cloud presented in this photograph is a major high-level exposure to a mixture of things that we have already discussed today.

Next slide. There were no measurements done, as we have already discussed, of concentrations in the initial cloud. I think **[identifying information redacted]** and some others have estimated that the concentrations were likely in excess of 100,000 micrograms per cubic meter, 100 milligrams per cubic meter.

And I've sampled some industrial operation as a hygienist where dust levels were consistently in the neighborhood of 20 to 30 milligrams per cubic meter, not as high as this. So I think this estimation is probably a reasonable estimation, maybe on the low side for at least the initial dust cloud.

[identifying information redacted] described what he considered, and I think is a reasonable consideration, five specific post studies on 911 exposure categories.

Go to the next slide. And clearly the highest exposed were those there during the initial collapse and the days that occurred afterwards. I understand there was a rain event like around the third day, which helped to dampen at least some of the dust exposures, but I think the scenario is something like this: We have high-level exposures initially, and then we have continued exposures to the individuals who were doing the recovery and cleanup longer term, and also exposures to a much more mixed of (indiscernible) and fires and materials in that.

Let's go to the relative -- next slide, please. One of the relatives to dust exposure is (indiscernible) based on the plume depicted in this slide. I think clearly the first day, extremely high exposure, followed by lower-level exposures during some of the recovery operations; however, if I could point out here, there were no dust measurements actually made

on this first day. So these are reasonably speculative.

I am going to talk about asbestos, and go to the next slide please. And I am going to talk about some of the measurements that were made.

First, I wanted to talk about the methods that have been used for measuring asbestos exposures, both historically and currently.

On the list on here is an old midget impinger method developed by the U.S. Public Health Service in the 1920s. It's been used, really, for exposure measurement in occupational settings for dust exposures up until about the mid-1960s. I mentioned that largely because the old dust measurements and the basis for a lot of the risk assessment for asbestos are based on the old impinger method.

First of all, it was a method that didn't collect fibers very efficiently. Secondly, the exposure method actually counted all particles, not just fibers in the dust and it did it at a low power using low power optical microscopes.

So there's some -- excuse me -- some severe limitations with regard to retrospective exposure assessments even in the occupational environment. The current method used has been used since about the 1960s. It's called phase contrast microscopy. Basically the samples are collected on a filter, membrane filter, and the particles counted by an optical microscope that has a special feature which enhances contrast called a phase enhancer. But still, it's relatively low magnification, 400 times.

There are certain limitations to this method. First of all, the cause of limitation with regard to being able to count short fibers. Only fibers longer than five micrometers are counted. Secondly, even if a fiber were longer than five micrometers, this counting system -- the microscope has no resolution or ability to actually see small diameter fibers.

So you could have very long fibers that were small in diameter and not be detected. Nonetheless, it's used as part of the OSHA, current OSHA standard, and it's the basis of a lot of the risk assessments. And I think it's -- the use of the phase contrast microscope has actually enhanced some misconceptions about the nature of exposures and what's important. That is, only long fibers or fibers longer than five micrometers -- I'm going to have more to say about this later.

Moving on to scanning and transmission electron microscopy. Scanning microscopy is better than phase contrast, but still not capable of seeing

the very small diameter fibers in an asbestos dust cloud.
The most useful method is transmission electron microscopy, and some of the measures of the World Trade Center exposures were done by TEM. There are different techniques that are used for expressing the concentrations. Some express structures per centimeter of surface. Some were expressed as structures for -- as a dust concentration measurement per cubic centimeter of air samples.
The limitation here is the fact that when you look at samples by transmission electron microscopy, you look at a very small portion of the dust cloud, and it's very expensive.
A little bit about the measurements that were done. The range of asbestos, primarily chrysotile, looks like from a less than one percent up to about three percent of the mass. And with most fibers being less than five micrometers in length, which you would expect given the length -- given the nature of the collapse, the pulverizing of material.
There's more to say about the less than five micrometer criteria as well because even in asbestos-exposed occupational cohorts, the majority of exposure is to fibers that are less than five micrometers in length, typically 90 percent of actual.
Again, no measurements were made of chrysotile during the extraordinary high dust cloud exposure. There was a range of exposure measurements done later and reported in the literature, some in peer reviewed publications, some in -- just in reports.
Most of these seem to show short-term exposures of not in excess of established criteria; however, there are lots of limitations of these as we've discussed already. One is reading the samples would be the preferable method for looking at exposures to individuals on the Pile. NIOSH did some sampling on these, used PCM and looked at some of the samples by transmission electron microscopy, and in general, when you look at the samples by TEM, the concentrations didn't exceed the OSHA PEL of 0.1 fibers per cubic centimeter of air. Again, that's fibers longer than five micrometers.
Realizing of course that the majority of fibers in the study are less than five micrometers in length. I think there is a disjoint, and I think Liz pointed that out. This dust cloud was extremely high in dust levels, certainly initially. No measurements, again, but we would expect that in that dust cloud, given a concentration of one percent or even much, much less, that the asbestos exposures to total fiber concentration

would be very high.

I'm going to talk little bit about the types of regulated asbestos because many of the risk assessments have just considered asbestos as one group of materials; that's a list of them. We're dealing largely with chrysotile here which was in the towers.

I am going to say there may not be amphiboles in there. I had the opportunity of being in the World Trade Center a number of years before 9/11, and I think there might have been at least some amphiboles in the building as well at some point in time.

Liz has already pointed out, I think, that asbestos is considered a carcinogen by both IARC and the National Toxicology Program. That includes chrysotile, certainly with regard to lung cancer mesothelioma. There's no question with regard to the carcinogenicity.

IARC also determined that there was sufficient evidence in human studies for cancers of the larynx and ovaries and limited evidence for colorectal and in the pharynx and stomach. And there have been a number of reviews of cancers at sites other than the lungs for asbestos. I think this determination by IARC is reasonably consistent with the data that exists, largely with regard to cancers of the GI system. Studies that show an excess risk of about two for lung cancer tend to show an increase, not a two, but an increased risk for GI cancer.

I'm going to talk a bit about the risk assessments that we have for asbestos. Nearly all of the risk assessments are based on populations occupationally exposed. Again, as discussed before, the measurement method is this phase contrast microscopy where the fibers longer than five micrometers in length are counted.

The typical metric is cumulative exposure expressed as the product of duration and concentration measured in fiber-years. I want to point this out because a lot of the data upon which risk assessments are made is really occupational groups with short exposures which are relative to high concentration, including the studies that our group has done of chrysotile-exposed textile workers.

Many of these workers had exposures of just a few months and nonetheless showed increased risk. Most of the models, including our own, were no-threshold models; that has been discussed already today. They seem to fit best to the actual data. And lastly, a point that needs to be emphasized is that there's no scientifically justified threshold for asbestos-related cancers, none that's been established in the literature

by recent studies.

Here are the limitations of the risk assessment, moving to the next slide. Historical measurements, as I said before, a lot of them were based on the old impinger method and unless you had some data to make a statistical conversion between the old method and new method, there's lots of misclassification in the data. And in most cases, in these types of studies, that tends to actually dampen the exposure-response relationship. So your effect is likely greater than you are actually showing in your data.

Again, the risk assessments were based on the phase contrast method wherein only a fraction, and typically less than ten percent of the actual airborne aerosol was actually measured. And as I said before, that's because of the diameter limitation of the PCM method and because of the decision to count only fibers longer than five micrometers. That decision is really not based on the decision that short fibers are without risk.

It's based on the fact that a practical method hasn't been developed for measuring exposures and enforcing standards. And NIOSH, in its 1972 criteria document for asbestos pointed out that the reason for the five micrometer cut was for reproducibility of the PCM count.

Lastly, mesotheliomas are not well captured in a lot of the mortality data that's been published at least through 1999. There was no code for mesothelioma specifically. Only in ICD-10 do we have a specific code for mesothelioma, so a lot of the mortality studies, including our own, looks at things like cancers of the pleura and assumes that those are mesotheliomas. And that's a reasonable assumption in most cases but likely does not capture well in other cases.

Next slide. I wanted to drive home the notion about what portion of fibers are actually counted by phase contrast microscopy. This is actually a slide from some of our data from a textile operation where they're using very long fibers, the best grade chrysotile. And even in textiles, if you look at this distribution of diameter to length, you see that the vast majority of the fibers are short and thin. So that's the nature of exposures, even occupational.

Next slide. I wanted, last, to point out two studies that have been published subsequent to the current risk assessments used for the OSHA standard. The two case-controlled studies, and these were for the mesothelioma, one in France and one in Germany, and they are of

reasonable size, particularly the France study. And what these studies are showing is that we now have measured excess risk of cumulative exposures that is fiber-years. In the France, study in France, less than one fiber-year.

Likewise, in the study in Germany we have an -- about an eight-fold risk for fiber exposures that are less than 0.2 fiber-years. There is a, I think, a legitimate discussion in the literature about the relative ability of chrysotile versus the amphiboles to produce mesothelioma.

I think, first of all, there's no question if chrysotile does produce mesothelioma. Whether or not it's less potent then amphiboles is a, I think, a subject for considerable debate.

Next slide. Lastly, I want to point out that the OSHA PEL, which is being used as a criterion in some of the assessments of the air samples from the World Trade Center on 0.1 fibers per cc as an eight-hour time-weighted average is not without risk. OSHA's risk assessment indicates that at .1 fibers per cc over a working lifetime, there's an excess risk of 3.4 cancers per 1000 workers, and of those 3.4 cancers, about two-thirds of them are lung cancers. The other third are mesothelioma.

So, the point is that we don't have a threshold for the cancer-producing effects of asbestos, including chrysotile. It's open for discussion.

DR. TALASKA: John, Glenn Talaska. Thank you very much. I've got a couple of questions for you on -- you cleared one up right at the -- in your last slide. I wanted to know the relationship between the numbers of lung cancers seen with asbestos exposure documented versus the number of mesotheliomas, and you said the ratio is about two-thirds to one-third.

But I also wondered what it was in terms -- if there were any data in terms of latency time relative to those two diseases.

DR. DEMENT: Well, I think the latency times are as Glenn just pointed out. Early in the lung cancer, in our own studies, we started to see a pickup in the relative risk, between 10 and 15 years and it really starts to escalate after about 20 years.

Mesothelioma has what appears to be a longer latency in many cases. The peak of that probably, in most states, hasn't occurred until 30-plus years after a person is exposed.

DR. TALASKA: Thank you, and I have one further question. You didn't talk about it. I am only going to mention it briefly in the next presentation, and I hope you will join me in the discussion then of the

interaction between things like PAHs and asbestos. Do you want to give a little -- if you had some information you could provide us right away or would you -- we could wait until after my talk, because I am going to just mention it briefly.

DR. DEMENT: I'll mention it briefly as well. I think in lung cancer, there's clearly an interaction with PAHs and particularly smoking. The question is whether or not that's a multiplicative additive or less a multiplicative fact, and I think most individuals, it may not be multiplicative but it's more than additive, so there is an interaction there. I guess we can discuss it later.

DR. WARD: Other questions or comments for John? John, I -- one question I had was if in the two case-controlled studies with mesothelioma, it was hard for me to conceptualize, you know, how small those units were. Can you help, I mean, can you compare it to like what a typical occupational exposure would be?

DR. DEMENT: Well, these levels are, if you look at the fiber-years, most occupational risk assessments are based on a 40 or 45 year lifetime risk, working lifetime risk. So if you take the current OSHA standard of .1 fibers per cc over a 45 year working lifetime, that's 4.5 fiber-years. These data, these case-controlled data, are clearly demonstrating excess risk at exposures that, cumulative exposures that are much less than that, which just really adds to the conclusions of the OSHA risk assessment. That is, these are not zero risk standards.

The OSHA standard includes lots of work practices in an effort to try to get exposures as far below this .1 fibers per cc as possible. The other thing I like to point out is the occupational cohorts. There are cohorts, including ours as I mentioned before, that do demonstrate excess risk with short-term workers at relatively high levels of exposure, of course. The one that was done in Paterson, New Jersey by **[identifying information redacted]** in Mt. Sinai many years ago demonstrated that individuals who worked down in that plant with one month of exposure producing asbestos, they had a significant excess risk of cancers, including lung cancers and mesothelioma.

DR. WARD: John, can you comment on half-life? I mean are the -- I mean, I know that different types or lengths of asbestos would have different residence in the lung, but is there -- I mean, there probably have been studies looking at pathologic specimens of workers exposed to asbestos. I mean, does it tend to stay in the lung for a long time?

DR. DEMENT: What it does -- there is some discussion, certainly in the literature with regard to the clearance rates of amphiboles versus chrysotile, and in general I think the amphiboles cleared less quickly than chrysotile.

There was a study done at Mount Sinai by **[identifying information redacted]**, who suggests that the clearing of chrysotile from the lung actually ends up concentrating in the pleura where we actually see mesothelioma in the study.

I think the studies that have looked at lung burden are sometimes problematic with regard to chrysotile because of its (indiscernible), and I think some erroneous conclusions have actually been drawn based on lung burden studies when you didn't actually have the estimates of the actual exposures to the individuals.

DR. HARRISON: This is Bob Harrison. Steve Cassidy, earlier this morning, earlier this afternoon, sorry -- I'm on West Coast time -- suggested that the samples may not have been representative of the type of exposures or type of activities that people had. I wonder, John, if you could comment on that.

You said that samples weren't taken, I guess, in the first three days. And then there were lots and lots of samples taken subsequently, but I don't have a clear picture of what people were doing, where those samples were taken, and whether there were other activities where we think exposures were probably higher that were not captured.

DR. DEMENT: Well, I don't have a good sense of that either. My sense of the data itself is that most of the personal air sampling that was done was either done by NIOSH or NIOSH contractors through NIOSH. Those were represented in the publication, I think, by (indiscernible) through NIOSH, and in the slide, where we showed (indiscernible) samples.

A lot of these were actually taken during the post-cleanup operation, but the extent to which they represent exposures of that group is really not known. I mean, an effort was made to do that, but, you know, I can't, you know, I don't know all of the cache that were not sampled.

DR. WARD: Any other questions or comments? Susan.

MS. SIDEL: Hi, John. Susan Sidel. Could you just explain again the different measurements that you used that -- you were saying a TEM is the -- is like the finest but it's also really expensive and it's not OSHA standard. So the OSHA standard doesn't pick up the tiniest particles, and what was used at the World Trade Center?

DR. DEMENT: The OSHA standard is based on the space contrast method.

MS. SIDEL: Right.

DR. DEMENT: So it's an optical microscope with a phase -- a phase illuminator or phase shift illuminator, and the problem -- just go back and place yourself in the 1960s. All of the old samples were collected by methods including (inaudible) with a routine sampling method that would first of all actually measure fibers, if not all particles, and measured a reasonable portion of the air samples.

So this method was the default method, and it measures, even in the asbestos industry, occupationally, it is really just an index of exposure. It's measuring a small fraction of the air blowing aerosol. Because of the limitations of the counting with regard to length and the resolution with regard to diameter.

So, typically, in an occupational setting with chrysotile in particular, because it tends to be more fine, you'd be lucky if you're counting 10 percent. In most cases, you're counting about five percent of the total number of asbestos fibers that are airborne that the workers are actually breathing.

If you move on to electron microscopy, it has the ability to look at these particles, but because of the high magnification, you're actually looking at a very small area of the filter, so you have a lot of statistical variability with regard to the count. It was not chosen as the method for routine occupational exposure assessment.

MS. SIDEL: So the method that was used in the World Trade Center is the method from the 1960s?

DR. DEMENT: Sorry, could you repeat?

MS. SIDEL: So the method they were using at the World Trade Center was the OSHA standard method that you talked about from the 1960s?

DR. DEMENT: No. Yes, most of the samples that were workplace samples. For example, if you look at the slide, 19,000 air samples --

MS. SIDEL: Uh-huh.

DR. DEMENT: Almost all of those were PCM, so they did not use transmission electron microscopy. So it's trying to measure these exposures against an OSHA standard. The NIOSH sampling used PCM, but they did -- didn't look at the ones that were in excess of the .1 fibers per cubic centimeter and looked at those by TEM. Samples which were mostly structures per millimeters squared filter area were TEM.

MS. SIDEL: Thank you.
MS. HUGHES: Hi. I just want to remind people, as a resident that lived one block away, the chaos that was there for a very long period of time, there was no electricity. So if you're going to do sampling or testing and there's no electricity, one of the concerns that some of the testers had was it could be done on a generator, and then you had to determine what kind of generator.
Would you be using diesel fuel, or would you be using a battery, and then where you would get that. So there was electricity on the east side of Broadway but not the west side of Broadway, and so when people are talking about the proximity of the testing, it took some time to actually get the machinery into place to actually do the testing.
And then one of the issues that has been argued about over the years was clogged samples, so the filters were clogged if there was a lot of material that was actually picked up. So I just wanted to remind people what it was like early on. Thanks.
DR. DEMENT: Those are good points to make. I think given a relatively low percentage-wise of asbestos in this material and the high concentrations of dust, one of the issues with regard to asbestos sampling is trying to optimize the ability to count it, and when you run a filter for a period of time, accumulation of dust on the filter can actually obscure the PCM count.
DR. HARRISON: This is Bob Harrison. I just wanted to make two points. I think both of them are probably obvious, but I think for the record, it's worth stating. One is that I think there's evidence that respiratory protection was not available, consistently used, and would not have afforded, in any event, protection against inhalation of potentially carcinogenic asbestos fibers.
I don't -- I'm not sure that there would be any disagreement about that point, but I think it's worth noting and if there's any, you know, any additional comment, we need to make that.
The second is that based on the lung disease that we've seen from other lines of evidence, (indiscernible) airways tends to show (indiscernible) lung diseases. I think we can use that as qualitative evidence that indeed inhalation of particles and fibers and smoke, et cetera, did occur.
I don't think we can make any correlation between those clinical effects and the dose of asbestos, but I think just qualitatively, we know that

this population had inhalation exposure, and I just think it's important to point that out as well.

DR. MIDDENDORF: John, this is Paul. I just want to ask if you would take a minute or so and address the issue of potency related to length of asbestos fibers.

DR. DEMENT: Well, I think, Paul, the issue of potency with regard to length, it really comes from some animal data. Now if humans are exposed to the whole spectrum of fibers, and so when I studied my textile workers, they're exposed to the whole dust cloud irrespective of how I choose to measure it.

Some of the animal studies suggest longer fibers are more carcinogenic, and those studies come from some inhalation, but mostly studies that are implantation are injection studies, some of the early studies from Merle Stanton at the National Cancer Institute, for example, and Dr. Hoch (ph) in Germany.

So with regard to cancer, I think longer/thinner may be more carcinogenic, but in the exposed aerosol, even if you consider an asbestos textile, the longer/thinner comprise a very small portion of the airborne exposure.

So I think the -- in terms of the actual effect of short fibers in that they greatly outnumber the long thin ones, even if fiber for fiber, they were a fraction -- had a fraction of the carcinogenic potential, I think the data doesn't support leaving those out with regard to risk assessment. We just completed a series of studies in the plants that we've looked at for many years in South Carolina and in North Carolina, and we did these in collaboration with NIOSH where we had the ability to go back and look at some of those old filters in the 1960s and to try to estimate a sort of size specific exposure measurement for these workers in these two cohorts and try to relate that to risk.

And when we did that, we found that all of the size categories by length and diameter correlated and predicted lung cancer risk. It's -- the longer, thinner fibers, when you look at them had a slightly greater impact; but nonetheless, all sizes that we were able to measure, including the short thin ones, impacted lung cancer.

DR. WARD: Any other questions or comments on this presentation? Thank you very much, John. We hope you can stay on for some more of the discussion. We appreciate you coming.

DR. DEMENT: I'll plan on staying on. Thank you.

PAHs AND WTC

DR. TALASKA: Okay, are we ready? How does that sound? Good? Everybody okay? Okay.

Well, I wanted to begin by making a statement about how being able to look at these data in detail, really it changed my mind about something about the exposure with the -- of the first responders at the Ground Zero site.

When I, as a scientist, and as a regular scientist with an interest in the area, but not an acute one, I looked at the abstracts. I looked at some of the tables, certainly of the ones with biological monitoring because that's my field.

And -- but I didn't look at the papers really hard, and the opportunity that I got today to look at them -- today -- in the past two weeks, at least, and certainly since being on the committee has given me a somewhat different -- considerably different perspective than I've had to begin with, and I will begin with this.

What I'm going to talk about today are the polycyclic aromatic compounds. These are the materials that are formed by the burning of any material as a fraction of the total mass of the stuff that's burned. Most of the stuff goes to carbon dioxide, but if there's not sufficient oxygen to go to complete oxidation of it, then these benzene rings fuse and form large plate-like structures that I give you three examples here. These are materials that -- from any kind of burning. I'll show you some pictures. PAHs are very lipophilic materials. They're well absorbed from both the lungs and the skin when they're contacted and from the GI tract, although there is a difference with the GI tract relative to these compounds that I'll get at later.

Just some examples from the occupational world first. You can see from here -- there it is -- that the upper left panel shows a coke oven. This -- the worker here is a topside coke oven worker -- these two workers. One of them is more obscured by the smoke than the others.

These are occupational exposures where we have both the knowledge of what the internal dose was for these individuals and the lung cancer risk, which is at excess. These people are in the worst possible situation because you're trying to make coke, not Pepsi-related coke, but coke which is used in steelmaking out of coal.

So it's burned in the absence of oxygen or almost the absence of oxygen and forms a dense smoke which escapes from the machine. It's a very

large structure. The right-hand panel is a foundry. And you can see, again, the hot metals are producing smokes which can be seen. The lower right-hand panel is an aluminum manufacturing site. At this slate, they're pouring.

The left one is extremely interesting from several points of view. One is it's a food product. Our PAHs are in many of the foods that we like. Barbecue, smoked foods contain PAHs from the prioritization of the materials, and we eat them.

But also look at this here. As you can see from closer examination of the walls of the smokehouse that this guy is in smoking fish, that the whole structure is coated with a tar-like substance. And those are -- that is often high in the -- very high in the PAHs.

Other examples are shown here. This slide shows an asphalt operation that we've all smelled. The materials that are coming off the gassing of the asphalt as we, you know, our body -- I think everyone uses orange barrels. And so the workers are exposed there.

One of the real advantages of the studies that have been done very much by NIOSH but with other players as well is that often times they will take area samples of areas near or around a -- some of these operations and then conduct personal samples at the same time. And that becomes important to us.

In the right-hand panel is the classic PAH exposure that causes lung cancer in cigarette smokers. Seven to ten-fold excess risk, depending on how many packs are smoked. It goes up with a various dose response that most of the toxicology is envious of, but it's from a very sad point of view that this is the major carcinogenic material in the United States and the world for causing lung cancer.

PAHs are also formed with the burning of any material, so the nasty smell that you get when the smoke comes your way at the campfire contains some of those materials and that's the stuff that stays on your clothes the next day when you realize that, you know, those were in a bar or where there was smoke.

The lower right-hand panel, of course, shows a more recent disaster caused by -- during the blowout last year of the oil rig in the Gulf, the Deep Water Horizon. And you can see -- and this is important from -- for our discussion because you can see two things. One is that here is where the closest you can get to this thing to do any sampling at all is the distance, several boat lengths between the fire and the -- and the

source of the burning itself.

And then you can also see the huge difference, if you collected a sample here, what would be the exposure level relative to what it would be if someone was at or near the plume? I'm not making direct comparisons, but keep this model in your mind is what I'm saying there.

And now we have the World Trade Center and slides that I have -- a couple of slides just to illustrate things about the smoke. Here we have a burning smoke which is -- probably has PAHs in it, almost certainly, and then the more general smoke that occurred, I believe, right after the collapse where the -- probably a multitude of materials in this one.

Also important here is that at this point you can see there are civilians inside of this where they -- where the work is actually being done. Now, I'm not sure, and I have to tell you I don't know as well where the monitors were put at Ground Zero relative to the work zone.

And -- but that's extremely important. Even at this point, you can see your, you know, the smoke is going up. Oh, that was the other thing with this one. I'll go back a minute. The smoke is rising here very rapidly. Persons that are in the plume are being heavily exposed, but persons very, just to the outside of it, outside of the convection currents that are occurring, are not being exposed to the same levels. Nor would any monitors that are placed in that area be exposed to the same level.

Okay. PAH exposures are associated with lung cancer in tobacco smokers. It's thought that 70 percent of the lung cancer in the United States and the world is due to tobacco smoking. Coke oven workers are also at increased risk. Aluminum smelter workers are. And the classical exposure to -- of soots, dermal exposure on the scrotum in chimney sweeps was investigated by Percivall Pott in 1776 and associated with the soots that were -- people, kids mostly, who were exposed to that by actually being run through the chimneys at the time.

The PAHs are absorbed by the body and they are metabolized to compounds by the body that combine to DNA. So PAHs themselves are not carcinogenic. It's the PAH metabolites that are carcinogenic, bind to DNA, and cause mutations that initiate the carcinogenic process. So it is biologically plausible that PAH can cause cancer if there is sufficient exposure.

What are the sources of combustion materials at the World Trade Center? This has been reviewed in a NIOSH document, and I'm just

showing it for you.
There was approximately 90,000 liters of jet fuel, 500,000 liters of transformer oil, 380,000 liters of diesel and heating oil, and approximately, although no one knows for sure, the same amount of gasoline which was burned in the parking structures when the towers collapsed and over the next several days as those cars heated up and exploded or were demolished and then the gasoline leaked all over the place and then burned.
Area samples were collected and for PAHs specifically, not for dust in particular, but for PAHs in particular, were collected at the fence line beginning on 9/16 through 9/23/01. There were no personal samples taken at this time by these investigators. So the first samples seem to be five days after the exposure. There were biomarker samples collected once on October 1st, approximately, in a study that was reported by Edelman et al in 2003.
But I think it's also interesting, and I'm going to bring up the set of studies that I found in the Butt et al 2004, a Canadian group who looked at the window films and extracted the materials from the films of windows at various places in New York City and found considerably different levels of PAHs on them than were collected in the air samples.
So these are the data of Pleil et al at the fence line, and again, area samples. You can see many samples were collected throughout.
Samples were collected at the perimeter of Ground Zero, not in the work area, but at the perimeter and again, no samples for the first five days.
They were also collected distally at Broadway, so away from the site.
And one of the things that you can see clearly is that these two exposures have parallel curves. They run together down here, but they're parallel pretty much out here. So we have a difference between the two of them by at least a factor of two because based upon the distance.
So -- but again, they were area samples, stationary samples collected not following any particular worker, not following any particular activity at all, but sitting at the fence line, some distance from where the activities were being taken -- taking place.
So all of these samples are -- were air measurements and estimates based on area samples collected at the fence line, and these types of samples typically underestimate worker exposure and the differences

can be anywhere from three- to 40-fold, that if you take an area sample at a periphery, depending on how far away it is from the active sites of the workers, it generally is known to underestimate the exposure.

Now, that difference can be even greater than 40-fold, but it can be less than 40-fold as well, and the way that it can be less than 40-fold is if the study design uses an area sample to capture the worst case. So many times in my career, I've stationed an area sample in the worst possible exposure place where there are no workers, but to capture the worst-case scenario to see -- and the idea being if there's no problem at the absolute worst designed place, then there might not be a problem where the workers are.

But one has to consciously design their study to do that to be able to catch a worst-case scenario, and I don't believe that was done in the studies that were collected. Secondarily -- so we have a difference here that could be fairly large. Secondarily, only the PAHs that were in the particulate phase were counted because they captured the 2.5 micron samples, extracted those samples.

There's also PAHs in the vapor phase. PAHs, if they're heated, turn into a vapor, like steam, and then that steam rises into the air. And that is -- sometimes it binds to particles and it does bind to particles, but some of it stays in the vapor phase as well.

And depending on the type of study -- in Burstyn et al there was -- they found 10 times more PAHs found in the vapor phase than asphalt workers, but other workers have seen things much lower.

So they have seen 10 times more in this one study, but Quinlan et al, for example, in coal liquefaction workers saw that the amount that was in the particulate, bound particulate, was about equal to what was found in the vapor phase. And there are estimates all over the place between those extremes.

Okay. So what effects weren't measured? Well, the first question is what is the impact of being in a plume and how much more would that be, and how much greater, and again, I refer you back to the picture for the Deep Water Horizon.

If you're working right above the smoke as opposed to being away from it at the periphery, then the -- what would be the impact? And I have -- unfortunately, I wasn't there, and I can't tell you.

What is the effect of exercise and exertion, and I'll show you a slide about how important that can be. But if somebody is working hard,

they are breathing hard and they are breathing several times more than what the, on average, if I am working really hard riding a bicycle or jogging, you know, the worst place to jog is along city streets. Fortunately, the lead's out of gasoline but, you know, the worst place to jog is around there because you are breathing several times more and that means you are breathing more of this material into your lungs where they can be collected.

So that's an impact that one might want to consider, especially if different groups of people were working harder. From what I can gather, and I think in the paper, in the Pleil et al paper, they estimate that -- the purpose of their sampling was to look at some general environmental effects. They weren't looking for what was happening to the workers at Ground Zero, okay, so -- and they made no attempt to capture the peaks or assess exposed worker exposure, and they stated specifically that exposure to the workers at the site could be quote, much higher, end quote.

So there is a big weakness with the best PAH studies that were done at the site, and now -- oh, yeah, but here is something that I believe is illuminating as I was going through the voluminous literature that was provided us.

Butt et al did a series of studies where they washed windows with solvents, and they washed the windows to be able to extract the PAHs and other materials. They were looking for PAHs on them, okay? And what they saw was that there were different zones and -- as you might expect.

So within one kilometer -- they are Canadian after all -- which is 6/10 of a mile, the average was 77,100 nanograms per square meter. We were seeing in the other study, in the Pleil et al study that they were talking about 35 nanograms per cubic meter, so a meter is three feet approximately by three feet by -- a cubic meter is three feet by three feet by three feet. A square meter is three feet by three feet, but on average, Butt et al were seeing on these window films which admittedly collected samples for several days, they -- I forget the day that they collected them on -- they were considerably higher, thousands of times higher.

In fact, downwind sites within one kilometer averaged 130,000 nanograms per square meter. Upwind sites were much lower, averaged 18,500, still within a kilometer. Upwind sites that were greater than

two kilometers away averaged 6000, and this might be considered the background for New York City windows, okay? More than two kilometers away, and upwind, so the wind from the site probably wasn't blowing very often on these windows.

So you can see the types, now, you know, you can't use this for exposure estimates, obviously, but these are windows that may or may not have been in the major plumes at all. By luck, they sampled these, and I don't believe they had any selection other than they had access to the buildings. So I thought this, this was illuminating to me.

Here's some of the data about work rate. So, if you are working, light work is what we consider for most of our standards where the work load in watts is about 50 watts that the alveolar vent -- so, at rest, the people that are in this room are breathing in about five liters of air per minute, but someone who is working very hard can breathe seven times that. So they bring in seven times the amount of air. They pump the blood around much more efficiently. And so you can see the exposure metrics can give you another twofold over that if you're worried about heavy work as opposed to light work in terms of the amount of air they're breathing in and the potential for absorption.

Okay. So now I am going to change gears a little bit and switch to the biomonitoring data, and I have to tell you I am going to focus on one compound, pyrene. Pyrene is one of those PAHs that was in the first slide. It's an important component of PAHs. It -- of -- and it's representative of the four and five ring carcinogenic PAHs, okay?

So, of all of those type of compounds, pyrene is the most abundant. So it's oftentimes the easiest measured, and we do have a biological exposure indices for 1-hydroxypyrene, the major metabolite of pyrene, which is an ACGIH BEI. That was developed in -- I'm not sure it was in place in 2001. It may have been. We'll have to go back and check that when we think of it.

But biomonitoring can account for differences in absorption, distribution, and metabolism and elimination if it's done correctly. It can take into account both the skin and inhalation exposures and one very important thing with biological monitoring is that exposure can be reconstructed.

If you know the material that you are exposed to and you know the half-life of that material in the body and you know the relative time between when the sample was taken and when the exposure occurred, you can

reconstruct the exposure based upon the half-life.

On the other hand, it is a method that is easily misused, if not in terms of interpretation, if you don't know exactly what you're doing, so.

Let's look -- and this is an example of a biological monitoring on a model system. This has nothing to do with the Trade Center. This is just a model that I made up. So you see if you have exposure on Monday morning and the exposure during the day on Monday equals to a hundred, and the half-life in the material in the body is 24 hours, then the material -- you will increase the amount in the body, and then in the 16 hours the person is off until the next shift on Tuesday, that level will decrease by a fraction based upon the half-life.

So you can see right that you get a -- with each additional day, you get an increase, but it's not a doubling. So you don't get 200 on Tuesday; you don't get 300 on Wednesday and so forth. And then the other thing to notice is that because of the half-life -- and what is half-life?

Half-life is -- most of you probably know -- is the length of time a material resides in the body. Most of the materials that are absorbed by humans as xenobiotics are eliminated. And they are eliminated fairly rapidly because the body doesn't want to keep these things if they do nothing for it. I mean, some materials have long half-lives; cadmium has a 30-year half-life. Lead has about an eight-to-ten year half-life in the bone. But these materials tend to be eliminated fairly quickly and with fairly well-defined half-lives.

Notice what happens after work on Friday. So after work on Friday, the level in the body goes way down before Monday morning, and that's because there are several half-lives involved here, okay. So when would be the best time to sample for this material, something with a 24-hour half-life?

Now you wouldn't want to sample on Monday because the body hasn't reached steady state yet. Oh, and by the way, this continues every week. It doesn't get much higher. It never gets above 200 for this compound as long as that dose is the same.

When would you want to sample? Well, you don't want to sample here. You really want to wait until the end of the week. Sample in here and you'll have less variability, and you'll capture the exposure because that's when the exposure reaches its peak.

You wouldn't want to sample down here at this time because that would -- without knowing when the peak occurred -- because that would

underestimate exposure dramatically. So let's look at the data. These are the 1-hydroxypyrene data from Edelman et al, and this is one table I looked at, and I'm only giving the 1-HP data. And I've changed the numerals that have been used, and in that I use micrograms per liter and I'll tell you why momentarily.

They use nanograms per liter. Micrograms give smaller numbers, fractional numbers, but it's important because the BEI is set at one.

Okay, so all exposed workers at the site when they were sampled on October 1st, 2nd, or 3rd had a level of 0.092 micrograms per liter. The controls had a level of 0.062 micrograms per liter, and that seems like a small difference, but it could be a significant difference and it was in fact significant. It was significantly higher.

If the firefighters were at the collapse on day one, then their average was about .11. If they were -- if they didn't come at the collapse, but came after the collapse on day one and two and started working, then it was slightly, slightly higher, so maybe if you could say the real fires that were happening at ground level didn't happen until here, at least in the majority of the -- after the collapse. That's when all hell broke loose.

There was a subgroup that was studied which was called the Special Ops Command, and they were considered to be the highest exposed, and indeed, they had the highest average level. Their level was .159.

Okay, now the reason when I looked at these data initially I thought that well, you know, you can see there's a significant difference here but it's not a big deal, was because the standard that occupational exposures are based on, the level is 1.0, okay?

So the occupational standard is much lower, but it specifies an end of shift, end of workweek sample and as I found out by reading the paper hard, one, they did not capture the peak. Samples were collected 20 some days after the exposure, which would be -- and also they reported no variances and other people can maybe reinforce this, but when we were worried about people who have exposure, it's the outliers that are really important, and the outliers weren't given in the paper.

Four percent were said to be in the upper five percent of the NHANES values, but I wonder how many of the controls were in the same upper five percent. It wasn't represented. Because then there's no comparison there. But there was no variation given. There was no standard deviations, no ranges that were given in the data, and no exposure time was indicated or no sampling time was indicated. They

did not indicate whether they sampled at the end of the shift, at the beginning of the shift or when they sampled at all. It's just unknown, and that really threw me, okay?

So we have a situation where the exposure may have occurred many days before and also -- and so you would expect them to be relatively low relative to the decrease in exposure that one might see with that decrease in the PAHs that were reported.

Going back to the -- if I may, this slide. So, regardless of what the true levels were if these were just area samples, you can see that the shapes of the curve are similar. So one may anticipate that if there was a higher level inside of Ground Zero, then it would follow a similar shape, so the levels that -- this is when the -- the highest level would have been reported here. The first samples weren't taken to here, out 25 days, and you can see what the shape of the curve looks like in terms of the exposure. It's already winding down at least.

Now how can we -- can we do anything with this data and -- okay. So the sampling time wasn't given. Firefighters -- and this is from my own experience that firefighters haven't -- in the studies that we've done in Cincinnati, the firefighters have a higher level after a fire than before, but generally they are not in the really high exposed level and I'll give you an idea of what that means here in a moment.

And then the question becomes are -- could absorption from the lung be complete? What about the large particle masses and the fact that PAHs might not be absorbed rapidly, and I'll show you some data on that in a moment.

So first things first. This is what happens in a workplace in an aluminum plant, and I showed you what those look like. In aluminum plant workers, and their exposure to 1-hydroxypyrene. These samples were taken pre-shift, so there was a baseline sample taken every morning and an after work shift, and you can see that their exposure follows the model for a 24 -- very similar to what I reported earlier.

But look at the magnitude of their exposures. By the end of the workweek, these levels are greater than 10 micrograms per liter -- per liter of urine, which is 10 times the standard. But notice that every day before the shift, they drop down considerably, so that if this is the peak -- and what this shows is that like in many workplaces, aluminum reduction workers don't produce as much on Friday as, you know, it's Friday.

But you can see that after Thursday's peak, that there is a significant drop in the 16 hours between the next day. So if you didn't sample, if you sampled in the morning, you would see a much lower sample by design, much lower level by design. And these are data that were developed by the BEI committee in running up, in developing the BEI for 1-hydroxypyrene.

And what they show -- it looks complicated, but what it shows is how exposures could be the sum of all of the different compartments for these things. It's known that PAHs have three compartments in the body: the blood, which is cleared very rapidly with a half-life of five hours; the lean tissues, which are cleared within 24 hours; and then the -- probably the adipose tissues which are cleared very slowly, just every -- the half-life is 23 days approximately.

And so what you see is that with every exposure, the major impact on the urinary levels shown in black is the sum of the three of them, but it's largely dependent on the lean compartment and the -- and what was in the blood, and then that rapidly disappears causing a drop in the urinary levels.

This was an example I found extremely illuminating for this discussion. This was a group of people, patients in this case, who go to the Mayo Clinic for what's called the Goeckerman treatment where they have psoriasis, and their skin is painted with as much as 70 percent of the total body volume of -- their skin is painted with coal tar in the treatment of psoriasis. It apparently works.

And what I'd like to focus on -- the slide is more complicated than it needs to be. I'd like you to look at the -- the values here for 1-hydroxypyrene. So these are the baseline values in this group of people. After one treatment, that baseline jumps up to 170, okay? Now this is applying it on the skin.

After five treatments, because they're given eight hours a day of this treatment, five days a week, and then it's stopped. After five treatments, it goes up to 270, approximately, but after one week of no treatment, this is the level. And it goes down -- remember there's a break here between 10 and 100 -- and it goes down between 275 and down to less than 4 within a week.

If you calculate that, that means that the half-life for this is about 24 hours, which is very consistent for a group of people who haven't been exposed chronically. Their exposure was just five times. So it drops

very rapidly with an apparent half-life of about 24 hours.

Why this is important is that if the half-life was indeed 24 hours, one could back calculate from the levels that are given to the levels that may have been at the peak on 9/11, 9/12 at Ground Zero.

What this slide shows is the data from Gerde et al, who looked at the impact on particle size. PAHs were absorbed onto particles and then they -- and then they modeled it into the lungs based on -- and then actually did actual measurements in the lungs, and what they saw was the smaller the particle that the PAH was held on to -- so these are particles with PAHs on them -- when they were deposited in the lung, a very small particle had a very short half-life.

So if it was .1 micron, the half-life is approximately less than a minute, probably 30 seconds; but if it was a very large particle, the half-life could be more -- much more extensive. So we're talking on the orders of a month or greater if it was 1000 microns.

Now how might a particle get to be 1000 microns in the lung? Imagine that -- and what we used to see in tobacco smokers was that you'd get these agglomerations of tars at the bronchial -- where the bronchia would split and tars would accumulate, and that makes the particle much larger and makes absorption from it much smaller.

So the idea is that an exposure even one time can result in a very prolonged exposure based upon the fact that it comes off a larger particle much slower.

Then there's the part of how with the amount of deposition, and I'm not going to go too long in this, but what it really shows is that if you breathe regularly, you -- regardless of the particle size, this is the fraction that's collected and deposited in various areas. But if you breathe a lot faster with a much higher tidal volume, breathing in deeper, then you're much more effective at collecting particles. So people who are working harder not only breathe in more air, but they also deposit much more readily.

So PAHs do absorb on particles. Soot, particularly, so on diesel exhaust and those types of things, they -- because of their lipophilicity, they are very much attracted to those soots. But they are also attracted to concrete particles, and that's been shown in the literature, to a lesser extent, but still, they're absorbed onto the particles and then deposited and held in the lungs.

The particles may accumulate in the lung and slow their absorption into

the body, and particles may be coughed up, expectorated, spit, or swallowed, but this, in fact, seems to be more of a detoxification pathway than an exposure pathway for a complicated reason dealing with the liver first pass. Okay, you know what I mean, but...

On the other hand, PAHs have known to interact with other exposures. PCBs and dioxin were found on the site. In fact, the highest ambient level of dioxin ever measured was measured in the world after 9/11. Dioxin is known to be used as an enhancer of the carcinogenicity of some PAHs, so if animals are treated with dioxin, they are more likely to get tumors than if they're not treated with dioxin and given the carcinogen.

Silica is something that we haven't mentioned too much, but PAHs are known to enhance the carcinogenicity of silica exposure. And in this case, when I'm talking PAHs, I'm really talking smoke. The interaction seems to be additive or additive plus, and then unlike what John mentioned, the data that I looked at saw that PAHs, again, smoking, enhanced the carcinogenicity of asbestos, but at least the studies that I -- the consensus was that it was multiplicative but I would certainly -- he's much more experienced in this than I am.

So the conclusions that I would make are that exposures to workers to PAHs within the Ground Zero site was almost certainly higher and maybe substantially so than was indicated by the majority of exposure studies. A fuller report of the biological monitoring data is needed to predict what exposures may have been during the early periods after 9/11 and who may have been at the highest exposures.

The people who are the outliers are the key. If the people who had the highest levels of 1-hydroxypyrene are the ones who later -- they have the highest dose, and they may be the ones who are at the highest risk, and understanding who, not who the outliers are from our point of view, but what the range of the outliers were and then moving that back is an extremely important thing, at least in my mind.

And if the effective half-life is 24 hours, then the 1-hydroxypyrene levels on 9/12 could have been well above the BEI assuming that there was no exposure, assuming that there was no exposure. Now, that's not the case. There was exposure afterwards.

The best thing to do would be to model that exposure, and the half-life would be -- with the curves that were used in the exposure studies. You'd have to integrate those together. I didn't have the time to do

that, and I -- yeah. It's something that one could do, though. Thank you.

MS. FLYNN: Thank you, Glenn. A quick question. What would the exposure metrics be for a 10-year-old child?

DR. TALASKA: No idea. I'm sorry, I shut it off, and I killed it. I've got it. I have no idea.

MS. FLYNN: Because in general, as I understand it, and maybe Leo could comment on this, but children actually take in more air than adults, so I wonder --

DR. TALASKA: Well, again, and you do have to realize that at the fence line, they were measuring those exposures and the exposures were tending to rise. I can't tell you, but kids weren't inside of Ground Zero, okay, so I don't know what the exposure would be because the data are so -- but kids tend to breathe more. They have larger surface area relative to their body, so they do tend to sometimes take in more materials. They do eat things.

MS. FLYNN: Kids were not inside of Ground Zero, but, we actually, you know, do have available -- I'd have to find them on the site, the High School Parents Association website, but information that show that on days when debris was being dumped on the hazardous debris barge outside of the Stuyvesant High School ventilation system, the particulate concentrations were comparable to Ground Zero.

So, I mean, there were lots of -- there was just tremendous potential for different kinds of exposures that have not been captured in the data, so we just -- this is something that -- I know I sound like a broken record, but I think it's really, really important to keep in mind number one, number two. Children were caught in the dust cloud in the initial collapse cloud, so I don't know if Leo if you want to add anything.

DR. TALASKA: I didn't look at that. I'll be honest. I was focusing -- there was more than enough here to cause me to -- so I really didn't look at that in a really hard way.

MS. FLYNN: Can I just make a plea on behalf of the stakeholder members of this panel? We actually -- we're not experts and we obviously defer to the scientists here, but we're equal members of the panel and we know a lot of things because we've been basically engaged with, you know, the facts on the ground from the very beginning.

So if it's possible for us to have in advance the drafts of your presentations -- I'm sorry I keep popping my keys -- the drafts of your

presentations, that would be tremendously helpful. I know that Susan Sidel provided extremely valuable information to -- to Virginia Weaver, and we want -- we didn't want to load you guys up, because we know that, you know, you're like, you're trying to condense a tremendous amount of material, but there were times when we actually can bring a useful perspective and we really appreciate that opportunity.

MS. HUGHES: Also, it seemed like most of the sampling was done at street level, and if you look at the topography downtown, it's surrounded by very large skyscrapers. So if the plume actually expands would the results of the testing might be different higher up? You have families living in these high rises in very close proximity, so I just wanted to mention that as an exposure route.

And the second thing is, it wasn't as though the only fire was where the two towers were. It spread, and you had gas lines feeding -- pardon me -- but there was gas lines feeding the World Trade Center site. So there is exposure within the area, and it went on and on and on, so I just wanted to put that in for the record.

DR. WARD: I suggest -- a suggestion, we are running late, and maybe we'll take one more comment and then we'll have a 10-minute break and then resume, because we do have a fixed time when we need to start the public comments.

DR. MARKOWITZ: So, John, John Dement made a point on discussing asbestos as there is no known safe threshold. So the question, since you frame the exposures among the firefighters around the biological exposure index, what's the relationship between the BEI and cancer risk for PAHs?

DR. TALASKA: It's not really known. The BEI is based upon specifically the level that is associated with occupational exposure if you -- and not with environmental exposure. There wasn't sufficient data to be able to say that there was any level of -- that was related to disease yet.

There weren't simply enough data there. There are data that shows at that level since then -- we've put out -- we've done studies showing that at the level of the BEI of one microgram per liter, there's an increase in PAH, but we don't know what it is relative to cancer as of yet.

There aren't sufficient data, but -- so that the level was set just so that it would rule out things like tobacco smoking because you can't get -- smokers don't have levels that are that high, as high as you want. Does that answer?

DR. WARD: Okay, we'll take a 10-minute break.

(Recess taken from 2:52 p.m. until 3:12 p.m.)

DR. WARD: Let's start. I think everyone's, virtually everyone's back at the table and we'll start with the presentation by Bill Rom.

PARTICULATES AND WTC

DR. ROM: Thank you, Elizabeth. Does Paul have some slides? My task is to talk for five minutes about particles, particulates or particulate matter. My job is to talk about exposure assessment, what were the exposures; second, how bad are these particles, are they really toxic or are they not toxics; and third, what is the evidence for these particles in humans, did they get exposed and how much; and lastly, for gravy, are these particles going to cause cancer, since that's the question we have to address soon.

On this slide you see the particles on the left and then you see the fires on the right. The point I would like to make is that there were two kinds of exposures here, but I don't want to make that point so much as to say that they overlap. This was a fire that was extremely hot, that burned the particles, and we have a particulate exposure that really has never been seen before. This is unique. This is a disaster medicine and these particles really can't be classified basically like coming from the mine or source 'cause they've been altered.

Next slide. So this is a grab sample of the dust particles on the right. This is WTC dust but a third of that dust comes from wallboard. So all this stuff that we're seeing right there. So that's gypsum, and gypsum is calcium sulfate. It's not -- it's what we always call with NIOSH, nuisance dust. We chuckle about that 'cause we wonder what it is. Calcium sulfate is not known to be very toxic; it's mixed in with calcite. Calcite has calcium carbonate and calcium carbonate is not very toxic, but it forms little crystals and when you see it in tissue, can actually be birefringent, and that's important to remember in regard to silica.

Third, there is some cement dust mixed in here and the cement dust is calcium hydroxide. And that is a basic salt and it's alkaline, so we know the pH of this World Trade Center dust was around 11 so it's alkaline and it's irritating. It's irritating to the mucus membranes, to your eyes, to your mouth, to your throat, makes you cough. So is that really something that's going to cause lung disease and cancer?

I had the good fortune of being funded by NIOSH to study trona miners, and trona miners were exposed to a sodium sesquicarbonate that we use for the New York Times and Coke bottles and things like that. And the trona mines are in Wyoming, so I had to go to Cheyenne and have a personal interview and get a medical license, and then spend a couple weeks in Rock Springs and Green River with cowboys, and

they would mine trona.

So we studied 230 trona miners and we looked at shift studies to see if they would have a drop in lung function over shift and any alterations in their breathing, and it was really a negative study. So pure trona, sodium sesquicarbonate, is a rather benign dust.

But they all complained of skin itching and dermatitis and irritation, and we got a second paper on just trona dermatitis. So that shows you that alkaline dust can irritate the mucus membranes. So in its pure form these dusts are rather benign.

But then you also notice on the left of this slide that a lot of this dust was respirable, less than 2.5 microns, that's not mm, it's microns, so there's a lot of respirable dust that gets down into the lungs.

Last week **[identifying information redacted]**was visiting us at Bellevue, and we spent an hour looking at eight lungs that were from open lung biopsies of World Trade Center dust exposed people, and we looked for silica and we really didn't see birefringent particles sharp and bright like silica, so I'm going to dismiss silica as really being a critically important particulate exposure to the workers. And I'll point that out by looking at the next slide.

So we've documented an exposure and now I want to go on to the toxicity of these particles. So we had a firefighter who came within the second week of 9/11 to Bellevue who was critically short of breath and ended up in the medical ICU, and he had bilateral infiltrates and effusions, and we didn’t know what he had so he was treated with antibiotics and steroids, and was getting better. But since I'm a physician-scientist and I'm the boss, I like to yell at my faculty, I said, you need to get him consented and do a bronchoscopy, you know, lavage and make a diagnosis.

So fortunately he agreed to the consent and we were able to get some cells. And he had all those red cells on the right, that's acute eosinophilic pneumonia. So he had a very unusual disease that may be related to dust exposure. The important thing is we got those cells and you can see they're pretty clean. They don't have smokers' particles in them, so we sent these cells on the next slide to Victor Roggli down at Duke to analyze them for particles. And we said, this is a firefighter exposed for two weeks in the Pile, and this is the first lavage, and these are cells from his lung and we want to know what particles are down there.

So first of all, he showed us a fiber, and that's an amosite fiber on the left because he did an x-ray dispersive analysis for elements and found iron as well as magnesium and silica, and pointed out that that's an eight-micron-long fiber.

The important thing is it's not coated. It's an uncoated fiber which means it's freshly inhaled, which is very unusual. You never see that in asbestos workers unless they're from the mines in Quebec.

The middle particle I want to point out to you, is what I think is a really toxic WTC particle 'cause that is something that looks like from outer space. I called it fly ash particle 'cause it reminds me of a clinker coming out of a coal fire. But I think that's a burned particle. And in your packet there's an analysis of particles from the Deutsche Bank building, and the analysis shows a lot of these particles are coated with other substances from the fire, and that probably enhances the toxicity of these particles, so that's a burned particle.

On the right is what we think is fibrous glass, and you can see it's not parallel on its sides. It's probably been exposed to 100 degrees temperature so it's been partially burned.

The fourth thing I want you to look at is on the bottom. There's 305 commercial asbestos fibers per ten to the million macrophages. So how much were these people exposed to? So in my tenure at the NIH, I lavaged about 500 coal miners and asbestos workers and silica exposed workers, and I had to do some normal volunteers. So I had eight normal volunteers and they had a mean of 30 asbestos fibers per million macrophages. So this firefighter has about ten times the normal number of fibers in his macrophages. And the asbestos insulators I would lavage would have about a thousand. So he's, you know, just after a couple weeks, he's up to a third of the way to what an insulator has in his lung.

Now, I would say that breathing the air with your nose and your lungs is probably a better measurement than the samples that EPA took, and we couldn't find any fibers in their samples. So this guy was on the Pile and trying to rescue that -- this whatever could be done to save others.

Next slide. So this is what chrysotile asbestos looks like, and the reason there was an amosite particle there, is that in New York, when we put chrysotile asbestos in the sprays and on the steel girders, we always threw in about five percent amosite. Reasons, I don't know why but they always did that so that's why you find a mixture.

Next slide. So this is from the asbestos insulators and the kind of fibers you normally find. That fiber has a coated iron and protein surface and that's what those beads look like. So this is a fiber that's been sitting in an insulator for 20 or 30 or 40 years. And you see the body tries to protect itself by walling off the fiber. And the other cells are macrophages, and this is a nonsmoking asbestos insulator, and there's no other particles in there. So he's a clean asbestos insulator from being nonsmoking, at least. Not clean in terms of fibers.

Next slide. So Dr. Selikoff taught a number of us in this room about asbestos insulators, and his very famous study about all of the North American insulators showed a five-fold increase of lung cancer and almost 10 percent had

mesothelioma.

Next slide. And when I was at the NIH I would spend weekends recruiting patients for a lavage, and I would sit with **[identifying information redacted]** at the Baltimore City Hospital recruiting in study subjects, and he had one of his patients from Sparrows Point Steel Mill who had silicosis, those are the nodules on the right, and he also had mesothelioma with the left, if you reverse looking at this patient, with a big pleural effusion. So mesothelioma is the other disease along with lung cancer that you get from asbestos. How much asbestos causes mesothelioma, I remember when I was working for **[identifying information redacted]** , he had me interview a 55-year-old man with mesothelioma, and he worked in a flower shop in Brooklyn, and I couldn't figure out any reason he got mesothelioma from flowers. And I remember that in Tyler, Texas, the flowers came in gunny sacks and maybe the gunny sacks were used for asbestos. I asked him about gunny sacks, he said I don't know. I never saw gunny sacks. Then I asked him if he worked in the shipyard, and he had worked in the Brooklyn Navy yard for one summer in 1942 as a helper, and had two and a half months of shipyard exposure. So very minimal exposures can cause this disorder.

Next. The marker for asbestos are pleural plaques, the blue and purple around this lung are pleural thickenings.

Next slide. And if you have those, Hillerdal in Sweden showed that if you have pleural plaques, you have a slightly increased risk for lung cancer and an increased risk for mesothelioma, so this is a marker of your asbestos exposure.

Next slide. And importantly, **[identifying information redacted]** would take us to Paterson, New Jersey, where there was an asbestos factory, making fire hoses for New York, and he followed a hundred men who worked for just two months, from 41 to 45 in this factory, and followed them to the end of the 1970s. And on the right you can see with the dotted line that 25 years the lung cancer observed rate increased over the expected, so just for two months of exposure 30 years earlier, you have an increased risk for lung cancer.

The project that I was involved in was doing lung function on the wives of these workers. And I did about 300 spirometries showing that they had a reduction in their spirometry from doing the work clothes washing of their husbands and hugging them when they came home from work from Paterson's factory. And among those wives, four of them ended up getting mesothelioma from that exposure.

Next slide. So Dr. Ward wanted me to go over particles and lung cancer, so the small burn particles that we have from diesel exhaust have been studied in the American Cancer Society cohort. The American Cancer Society enrolled over a

million adults in 1982 about the risk for cancer. But these people lived in metropolitan areas throughout the U.S. that had EPA-collected data on particulate matter of 2.5 microns in size. So almost half of this cohort had data on particulate exposure through the end of 1998 from 1982.

So in the next slide on the left, you can see the lung cancer mortality. On panel A is cardiopulmonary mortality; panel B on the lower is lung cancer mortality. The three circles on the far left are above the line of 1.0 so all three dots are statistically significant over time for an increased lung cancer mortality of approximately 8 percent from PM(2.5) exposure, which is the burn particles from diesel exhaust.

Next slide. And these are what the particles from diesel exhaust look like in macrophages from the lung. This is a collection from sputum in children in England. And these macrophages were looked at under a light microscope and you see the black particles, particularly in D and E, that are very tiny, less than 2.5 microns.

The next slide, we'll skip and go to the slide after it. These are from families, next slide, that did not have any smokers in the household and they were on at least a second level, so they were a little bit away from the street level. And on the slide on the upper left you'll see a declining FEV-1 in those children as they had increased numbers of those particles in their macrophages. Next slide. So these diesel particles cause adverse health effects.

And lastly is cancer. So cancer in the lung starts off as abnormal proliferation and survival of injured cells in the respiratory epithelium associated with genetic defects, whether they are specific genes that are up-regulated, down-regulated, insertions, deletions, mutations, amplifications and so on, that you end up getting a clone of cancerous cells.

Next slide. And the last point I'll make is that there are now ways to diagnose these cancers with a blood test. And you can now target proteins in the blood to diagnose these cancers. On the top in the white are little aptamers, that are nucleic acids designed to pick out a protein in the blood, and you can make more than a thousand of those aptamers to pick up specific proteins in the blood.

And next slide. This assay has been looked at in 1300 lung cancer patients and matched controls, and you can see that a panel of about 13 biomarkers can very accurately pick out the lung cancers with area under the curve of .9. So in looking forward at lung cancer and mesothelioma, there are tests at the early and past research level to identify these people both at risk and of getting the disease. And this test is about to be commercialized for mesothelioma as the first disease to look at.

I think that's it.

DR. WARD: Questions or comments for Dr. Rom?

(no response)

METALS, VOCs and WTC

Okay, is Virginia on the line?

DR. WEAVER (via telephone): Yes, I am.

DR. WARD: Are we ready to...

DR. WEAVER: I am ready. Can you guys hear me if I stay on speaker phone?

DR. WARD: Paul just cautioned me that we only have 14 minutes before the -- before the public presentation -- public comment period. And so why don't we get started and see if we can wrap up your presentation in that time frame and then if necessary, can you come back and we can have questions after the public comment period?

DR. WEAVER: Yes.

DR. WARD: Okay, great.

DR. WEAVER: You have my slides up?

DR. WARD: Yes, we've got the first one up.

DR. WEAVER: So after the title slide, moving to the second slide, I wanted to simply give you some of the thoughts that were going through my mind as I was looking at data related to volatile organic chemicals and metals. And one issue in my mind was the shortest exposure duration that results in a measurable increased risk for cancer, and I've been very happy to hear discussions about increased risk in very short time period. I was not aware. I'm not a cancer expert, and I was not aware about that data, and that's very helpful to us in thinking about risk from exposures that are of -- that occur only when you're actively exposed, which would be the volatile organic chemicals.

The other point that I was thinking about as I prepared these slides are that we are now learning that a steeper exposure rate may result in greater risk, so for the same overall accumulative dose, if you get the exposure faster, the risk may in fact be greater. And so what that means is that the exposure construct for cancer outcome differs from that that's been used in World Trade Center research for pulmonary outcome, so rather than looking at where you were at the time of the collapse and shortly thereafter, we have to think about burning tile, diesel exhaust and carcinogens in dust.

So on the next slide I had simply shown an example of one type of exposure characterization and I know Liz has already showed this type so I'm going to move right on to the next slide on key concepts and questions.

We've already heard that cancer of course varies by time since exposure onset, and so it is the nonsolid tumors that are the ones we could be seeing, even at this point,

from World Trade Center exposures but specifically the leukemias. And then a point that I think others have already made so far is that we have very little data about chemical mixtures overall, particularly in the World Trade Center yet. This is a common exposure scenario overall and of course clearly at World Trade Center. The next slide I simply wanted to show the group 1 and 2A IARC carcinogens that are in the volatile organic chemical category. I took this from NIOSH's summary. I want to point your attention to benzene, which has been classically linked to what we used to call acute myelogenous leukemia but we now call acute nonlymphocytic leukemia as our ability to analyze these types of cancers has improved.

I also want to point out that there is limited evidence that benzene causes acute lymphocytic leukemia, chronic lymphocytic leukemia and importantly multiple myeloma. That is from IARC and it's also supported by a meta-analysis published in EHP in 2008, again, supporting that. Other VOCs that were of concern from World Trade Center would include 1, 3-butadiene, which is a combustion product like benzene, from the Pile and also from diesel exhaust. Again, this has been linked to leukemia and also non-Hodgkin lymphoma, formaldehyde, nasopharyngeal cancer, and there's increasing evidence that formaldehyde is linked to leukemia as well. That's considered strong but not sufficient evidence based on the NIOSH summary and vinyl chloride. And then I've listed some of the 2A, which are -- Group 1 of course is known human carcinogens, Group 2A is, I think the categorization is probable, and it's based on adequate animal data but inadequate or limited human data.

So in the next slide, the important aspects about exposure to VOCs is that they're common in combustion products. I think about this a lot in the work I do for the firefighters union. So you'd think about this from working on the Pile, from the smoke and exhaust from that, and also diesel exhaust.

In general VOCs, as the name implies, are not persistent in the environment and they do not accumulate in the body so the exposure duration would have been while you were actively working on the Pile. But also importantly, these exposures are associated with some of the shortest latency cancers, ones that we could be seeing.

Next slide. As far as I can tell, and I'm no expert on World Trade Center exposures, there are very limited data on VOC measurements. There were grab samples that were taken on the Pile to try and determine if it was safe for rescue workers to enter. So Lorber et al noted that when samples showed, quote, extremely high concentrations of VOCs, end quote, entry was prohibited. I don't have levels about exactly how high those were. Lorber notes that for a number of the VOCs found elevated levels outside of Ground Zero but still within restricted zones, and when

they used 24-hour samples, which should give a little bit better measure. You know, generally in a work place we measure eight-hour samples. When they compared grab samples over four minutes to 24-hour samples, they found that levels were much, much lower for a number of the VOCs of concern, including ones from butadiene. However, that was not the case for benzene. The benzene monitoring showed many more grab samples that were higher and 24-hour samples that, rather than being a thousand times lower, were about ten times lower.

I'm not sure if I said next slide but I have a separate slide on benzene monitoring. And on that slide I included the samples for benzene in 24-hour measurements that were above the detection limit, and so apparently there were only fourteen 24-hour samples that were done for benzene, which doesn't seem like many. Six were above the detection limit and of those, a few were fairly close to the Agency for Toxic Substances and Disease Registry intermediate minimal risk level, which would apply for folks who were working for more than a month, more than 14 days up to a year.

In the conclusion in the Lorber article, which as the data suggests in exposures to benzene at levels that approach the intermediate MRL were not likely to have lasted longer than 45 days.

There's a few samples from truck drivers, done by my colleagues at Hopkins, that were not extraordinarily high either. You know, in the low parts per billion compared to workers are allowed to be exposed a thousand parts per billion.

And I was going to make the point with the text below that the monitoring levels seem inconsistent with the descriptions and pictures of the site, but I think others have already made that point more eloquently before me. There is an inconsistency between monitoring and what was visualized.

So in thinking about the potential implications of VOC exposures, in my mind it would be workers who were on the Pile would be at most risk, and obviously the longer they worked on the Pile, the more risks they would incur.

I was thinking about how much time you would need to work there in order to have increased or measurable increased risk, and with the understanding that probably the exposures were much, much higher than any of the monitoring data that we have. And so I guess it would be a matter of thinking about individuals near and on the Pile and the length of time that they worked in those capacities and that would be how we would consider risk relating to VOCs as an important consideration because this exposure that could be resulting in cancers early on.

And then I'm going to shift gears and talk about metals so that's the next slide.

There are a number of metals that have been associated with carcinogenicity in a

variety of different organs. I've listed those for you here, again, from the NIOSH summary document.

On the next slide, I want to step back quickly and thank Susan Sidel for helping me come up to speed over the course of the weekend on World Trade Center exposures, and I want to just make a disclaimer that this is totally outside of my area of expertise so the metals exposure levels are very complex in World Trade Center. And I tried to, in the next few slides, give you a sense for some of the concerns but I don't have any kind of a conclusion to the extent that I did for VOC.

So on the next slide, Cahill and colleagues have thought a great deal about the metals and other exposures generated at the World Trade Center site, and they've developed an incinerator hypothesis which provides an explanation for the very fine aerosols that were liberated. And a number -- and just basically it would be the temperature that would be involved in these very fine aerosols and there were, his quote, unprecedented levels of several metals. Also, his quote, and this again is from the very fine aerosol chapter in the American Cancer Society book that Liz had referred us to, he's commented that the health concerns focus on workers at the site, as plume lofting protected most of New York City. What I don't know in that regard is the impact on residential -- residences that were very near the site. I know others have commented this afternoon on high rises that were right near the site, so that's something to think about.

And the next slide, he comments that some metals, and lists a series occurring at unprecedented levels in these very fine aerosols, and then goes on to note that levels dropped off dramatically, even over the course of the month of October and definitely by the end of May.

There are other slides listing a variety of metals that have been found both in dust, but the concern that dust is present after the fact may not be representative of what people actually breathed in at the time. I'm told indicating that lead levels do not appear to be a huge concern.

Skipping to the next slide, Lioy's comment. The concern that deposited material with metals in it could lead to ongoing exposure -- because in contrast to VOCs, metals are very persistent in the environment. Lioy commented that concentrations of arsenic and cadmium were relatively low but still in the parts per million range, so we need to keep that in mind when thinking about dust.

Next slide, a little bit of data, some of the small amounts that I found regarding airborne levels other than in the plume.

And then finally metal implications. So the metals data are hard for me to synthesize in terms of thinking about risk to individual workers. There's been a lot of characterization of the plume, and I'm not up to speed on all of it at this point,

but the thoughts that I have in terms of the metals at this point are the potential risk for toddlers who spend a lot of time on the floor and do a lot of hand to mouth activities from persistent metals in dust in residential areas. And then my other concern is the impact that these metals in dust, these very small particles, being deposited in the lungs, and I'm wondering, you know, some of these metals do bioaccumulate. We, you know, lead and cadmium clearly reside in the body and accumulate but I'm wondering if that very high initial load could change the half-life of some of these metals in the body, and I'm also wondering about the potential for interaction with the very high pH, although I don't know that if some materials that I read commenting that the smaller particle size had a more neutral pH, so I don't know how significant that concern is. But I did want to mention that.

So that's all I have.

DR. WARD: Thank you. Where do we stand on time, Paul?

DR. MIDDENDORF: We need to get started.

DR. WARD: Okay. We're going to start public comments now and then we'll get back to Virginia with any questions.

PUBLIC COMMENTS

DR. MIDDENDORF: Okay, each of our public commenters has signed up on a first-come-first-serve basis, and each of them will have up to five minutes to present. I remind people that it's often surprising how quickly five minutes can go when they talk about a subject of great importance to you so when you reach four minutes, I'll let the commenter know that they have one minute remaining, so they can be sure to make the points that they want to make in that last minute they have.

If they get up to five minutes, I'll have to rudely interrupt them and thank them for their comments. I apologize up front to anyone to whom that happens but we have to be fair to all of our commenters.

We do have one commenter this afternoon who will be on the phone, and just remind them to keep the phone on mute until I call out their name, and then they can unmute the phone and they'll have the same five minutes everyone else does.

Also want to point out that everyone has the option of submitting written comments to the docket for this committee. The docket number is 248, and information on how to submit comments is in the Federal Register Notice; it's also in the NIOSH docket page, and it should be on our committee web page as well.

Lastly, I want to remind our commenters of the redaction policy for public comments. The policy is stated in the Federal Register Notice for this meeting; it's also on the committee's web page and it's posted at the registration table if anybody wants to look at it. And the policy outlines what information will be kept and what information will be redacted before it's posted to the docket.

So when I call your name if you would kindly come up to the podium. We need to get the microphone up there, wherever it is, handheld mic? Our first speaker is Micki Siegel de Hernandez.

MICKI SIEGEL DE HERNANDEZ: Good afternoon. My name is Micki Siegel de Hernandez. I'm the Health and Safety Director for the Communications Workers of America in District 1. Our union represents several different groups of 9/11 responders as well as area workers affected by 9/11 exposures. I'm one of the designated labor reps on the World Trade Center Health Program Responder Steering Committee and a member of the World Trade Center Health Program Survivor Steering Committee and was the sole labor liaison for the EPA World Trade Center Expert Technical Review Panel.

First, regarding adding cancer to the list of World Trade Center-covered conditions, our union supports that. The time is now and I believe that today's presentations, thankfully, provide ample support and rationale.

Secondly, regarding the research agenda topics, it was good to see such a breadth of topics suggested by the STAC. We support research on cancer, heart disease and other chronic conditions, mechanisms of inflammation and disease persistence which could hopefully lead to more effective treatments, immunological disorders including autoimmune conditions and nervous system disorders.

We would also like community-based participatory research projects involving affected responders, area workers and residents to be encouraged.

While funded research is important, it can't be the sole source of our understanding of World Trade Center-related disease, and I cannot emphasize enough the need for improved and continuous disease surveill -- disease and symptom surveillance in the World Trade Center Health Program. This deserves a closer look.

A couple of examples are headaches, loss of peripheral vision, symptoms which are nonspecific and can have many causes but are frequently described by responders.

While aerodigestive disorders may be the most common World Trade Center-related conditions, they are not the only ones. However, if you are not looking for other illnesses, you will never find them.

And then I have some sort of random comments that were taken from the presentations today regarding exposures. First, in several presentations it was mentioned that there were no samples that were taken during that critical first week after the World Trade Center collapse. I think that needs to be revised to say that no measurements were reported rather than none taken.

In a joint statement of the EPA and OSHA on 9/14, they stated that sampling data for asbestos were below levels of concern, not likely to cause long-term health

effects. Christie Whitman's famous statement on 9/17, declared the air and water safe based on initial sampling. EPA pulled early sampling data from their website, the New York City Department in Environmental Protection hazmat team was onsite that first day, took samples that were never reported.

So this is indicative of a stance taken by government agencies that they have stuck to this day, and in part explains the disconnect between reported sampling, or non-reports, and actual health effects.

It also, as was discussed in several of the presentations today, it matters what you sample for, when you sample, where you sample, how you sample and how samples are analyzed.

This also explains in part the inconsistency with levels being reported as safe and the health effects. Sampling was not conducted in a consistent or even comparable way. It was done by several different agencies, much of the sampling was done by private entities and therefore not in the public record.

I would also argue that a wrong model was used. Individual contaminants were measured when the World Trade Center dust and fire, the plume from the fire, is a very complex mixture. There were different standards that were applied that were not health-based standards, and these were used to make statements about health; such as the OSHA standards. The PELs are not health standards and they are also based on 1960s science and knowledge.

Ambient air exposures are also but one part of an individual's exposure. In some of the articles, there was an article that was distributed about, the Lioy article, about environmental conditions and human exposures at a current post-September 11th, 2001, in 2006, --

DR. MIDDENDORF: You have one minute left.

MICKI SIEGEL DE HERNANDEZ: One minute? And in that it said that the second rain event washed much but not all of the remaining outside settled dust and smoke away; this is simply not true.

Lastly, the duration of exposures were short-term for many people. This was repeated in a couple of presentations, the committee should be careful about how it defines or thinks about short-term exposure, what is known and not known about exposures.

Is it short-term for responders working up to eight months at Ground Zero for 10- to 16-hour or more shifts? Is it short-term for responders who continued response and restoration activities in contaminated areas well after the site was closed? And you should also know that there is no known end date for any given individual or for areas since levels of contamination and exposures, particularly in indoor sites, were not assessed. Thank you.

DR. MIDDENDORF: Our next speaker is Bruce Edwards.

BRUCE EDWARDS: Thank you for giving us the opportunity to speak at this meeting. My name is Bruce Edwards. I am a permanently disabled IBEW Local 3 journeyman electrician. I was asked to work at the Verizon building at 140 West Street. The building is across Vesey Street from where the North Tower and Building 5 stood. 140 West Street was severely damaged by falling debris of the towers on its south side and the collapse of Building 7 to its east.

I arrived at Ground Zero early in the morning of September 14th. Our arrival at the site was delayed due to fear of instability at the site, and we were originally scheduled to arrive the previous day.

I was employed by an electrical contractor that was known as a Telco contractor, very knowledgeable in the operations of telephone central offices. We were tasked with the temporary restoration of electrical power by means of portable generators. The reason this work was so important was due to the antiquated underground cabling methods of downtown Manhattan. The Verizon building at 140 West Street was the main path of communications in and out of the Wall Street business district, and most importantly, the New York Stock Exchange.

The president at the time, George Bush, had ordered Verizon to restore communications as soon as possible. Due to our efforts, the Stock Exchange was up and running on Monday September 17th, before the opening bell.

We continued working at 140 West to permanize (sic) the temporary work to safety and then actually repair the building. It was many weeks before Con Ed could get power to the area at Seven World Trade Center, was the substation, the power substation, of the area. Our portable generators were needed to operate the building.

In the first few weeks, we worked 16 to 18 hours per day, seven days a week. And then as our numbers increased, we went to two shifts, 24 hours a day. As a supervisor, my responsibility extended to both shifts.

I'm sorry about all the background but I believe that is important to understand that the reason that I was asked to work there, and believe me, you didn't have to ask me twice. I felt a bond to the World Trade Center, as my father and brother had both worked on the construction, and we had been attacked. Nationalism and patriotism was at an all time high.

Ultimately though, I was a civilian required -- requested to work in a disaster area with little protection and no knowledge of the long-term problems that could occur. My original crew on the first day consisted of myself and seven other electricians, basically an advanced team to lay the groundwork. Within a few days, we had well over a hundred electricians on site.

Now, if you ask me would I do it again, my first instinct is yes. Like many, I took this personally. But in further review, I'm afraid I might not do this because the price I paid was steep. In April 2007, I was diagnosed with stage IV, non-Hodgkin's lymphoma.

I spent nearly two years in and out of hospitals for chemotherapy treatments, and fortunately I was able to have a stem cell transplant in December 2008. I'm currently in remission but remission isn't a cure. I live with the constant thought that the next low-grade fever I get is a return of my disease.

But even then I consider myself lucky because of the original eight, **[identifying information redacted]** (ph) didn't fair as well. He succumbed to his disease in 2010 at the age of 50. I was 50 when I was diagnosed also. Now I'm no scientist but I do see of our original crew two cancers out of eight. That's a 25-percent disease rate in relatively young men.

I was forced to retire from my career at least ten years early. The financial hit was crippling. I had two children in college and practically no money flowing in.

The next problem was clinical depression from all the problems there. Fortunately, with some good doctors, I was able to clear that.

DR. MIDDENDORF: One minute, please.

BRUCE EDWARDS: In the time since 9/11, some troubling items have emerged. Our government seems to have downplayed, and I use the term graciously, some of the conditions at Ground Zero. **[identifying information redacted]** the air is safe declaration and the release of some information about the accident exposure. The report released around the tenth anniversary showed dioxin levels 1,000 times higher than normal, and the highest the EPA has seen. What is especially troubling is the sampling began on September 23rd. That's almost two weeks after the attack.

The next two months the sampling continued and showed steady decline, so I can only imagine what the levels were on day one, or day four for my crew.

The report from the fire department is also an eye-opener. Here's a segment of the population that is generally in good physical condition and well-monitored, and yet the cancer levels for those exposed at Ground Zero is well above normal.

What I have come to learn is that --

DR. MIDDENDORF: Your time is up --

BRUCE EDWARDS: Okay. Well.

UNIDENTIFIED SPEAKER: Let him speak.

BRUCE EDWARDS: I'd just like to let people know here that the cancer rates are very high for a young population where normally they would be in an older group. And I implore you to add cancer to the bill as the Senate, I should say the Congress,

has done with this letter that they sent to you. Thank you.

DR. MIDDENDORF: Our next commenter is on the phone. Rich Dambakly. If you would unmute and begin your presentation.

RICH DAMBAKLY: Hello?

DR. MIDDENDORF: We can hear you.

RICH DAMBAKLY: Okay. My name is Richard Dambakly. I'm an underground worker for Verizon, at least I was an underground worker for Verizon. I worked at Ground Zero from the moment of the disaster, every day for six months straight, 12 to 16 hours a day, no days off.

I developed the World Trade Center cough. And for those of you that are unaware what this feels like, it's a cough where your chest is exploding out of your body that doesn't stop.

In March of 2002, it had gotten so bad I had to go to emergency. After being diagnosed with lymphoma cancer, I started intense chemotherapy treatment that lasted five months.

Just recently someone mentioned to me that the actor Andy Whitfield from the television show Spartacus had died from lymphoma, and it was his second occurrence. And here I am with no CAT scan for three years because I have -- I can't afford one. I have no medical insurance. How do you think that makes me feel?

I'm a father of five children, my oldest being 15. My family needs me. I want to be around to walk my daughters down the aisle and play ball with my son. Should I become a beggar and maybe raise the money for a CAT scan? Just like our Vietnam vets, that they were forgotten?

So many have died already from cancer. Their families need help now. This can't go on. When other countries are in need, we don't waste a minute. Immediately we send them money. We ask for nothing in return. When President Bush arrived at Ground Zero, I stood and listened to him speak to us and tell us to stay strong, stay here, help us, do whatever it takes, whatever you have to do, work any amount of hours. We need you; we'll be there for you. And we did it, each and every one of us that stayed strong. Anything we could do in our power. No one said, I can't help or that's not in my job description. No, we did whatever we were asked and more. The country needed us and that's all that mattered.

So now that we need the help and when you should be strong for us, instead you're taking the position that covering us for cancer is not in your job description, and that's wrong.

On 9/11 terrorists came to our country and were responsible for thousands of deaths. Don't give them more reason to celebrate by not responding to our

country's aid and causing more American lives. Don't allow them more victory than they already have.

We were there when our country needed us, and our country should be there for us when we need them. God bless all my fellows and other survivors and first workers in the World Trade. God bless you all. Thank you very much.

DR. MIDDENDORF: Thank you, Mr. Dambakly.

Our next commenter is Alex Sanchez.

ALEX SANCHEZ: Good afternoon to members of the committee; my name is Alex Sanchez. This good? I am a 9/11 responder, clean-up worker. On September 11th I had a very close encounter with terror. I was standing not very far from where this building is today.

On September 13th to March 15, I performed cleanup with other cleanup workers in the skyscrapers surrounding the pit. Ten buildings in a period of six months. Twelve-hour days, seven days a week. Some of the buildings I worked in included 1, 2, 3 World Financial Center. I had a ringside seat to what police officers, firefighters were doing at Ground Zero. When I went past those barricades, as a citizen, as a New Yorker, I knew what was expected of me.

When men and women started getting sick and dying, I also knew what was expected of me. Since late 2003, early 2004, I've been walking the halls of Congress alongside many of the men and women who are in this committee and who are also here today. **[identifying information redacted]**, my mentor, president of the FealGood Foundation, an officer and a gentleman, paratrooper, United States Army. We do not leave ours behind. What message are we sending to future generations and to the international community when we overlook and not appreciate the work and the efforts of those who served at Ground Zero?

Let me give you some facts. Basically you should know these by now.

Seventy percent of the men and women who came to Ground Zero are suffering from lung disease, chronic gastric disease, post traumatic stress disorder. I'll give you another example.

[identifying information redacted]. Both on the same office, Senator Lieberman, two months later, I asked my assistant director, **[identifying information redacted]** (ph), who is this gentleman **[identifying information redacted]**disintegrated in a period of two months.

We don't need bigger government or smaller government. What we need is responsible government, government that takes care of the people. Enforce and enact laws, current laws. I am a single father of an amazing 10-year-old. This is not the message I want to send to my son, my country cannot get it right. Ten years down the road cancers are killing the men and women who came to Ground Zero.

Exposure science tells us that when you are exposed to high level of toxicity, you need 15 to 25 years of medical treatment. We only got five. We cannot continue to play games with human lives. We need to stand up. We need to serve those who serve our country. We shall never forget and may God bless the United States of America. Thank you.

DR. MIDDENDORF: Thank you, Mr. Sanchez. Our next commenter is John Feal.

JOHN FEAL: How's everybody doing today? Good? I don't think I need a microphone. I'll introduce myself when I'm done. This way I can get my five minutes in.

One, I want to thank NIOSH for doing this. I want to thank the STAC committee for hearing me today.

I'm not here to ask you to add cancer to the bill. I'm here to ask you add certain cancers to the bill. I'm getting a little tired of hearing we need to add cancer to the bill. You cannot add every cancer to this bill; that's impossible. I get it. I worked on this bill for eight years, more than most people in this room. But there are cancers, unequivocally, undoubtedly, that need to be added to this bill yesterday.

I am never the smartest man in the room and I'm not even the smartest man at this podium probably, but it doesn't take a scientist or a doctor to know that 9/11 and its toxins have caused these blood cancers.

For years when we walked the halls of Congress, we were applauded for the way we approached Congress to get this bill passed. And when we were lobbying to get that bill passed, we were lobbying to get cancer added to that bill. But during the negotiations, that was taken from us. But I am going to use the same zest and the same energy to help get those certain cancers added to this bill. I will occupy Ground Zero. Don't worry about Occupy Wall Street. I will do whatever it takes because at the end of the day, I care about human life. I don't care about what you're having for dinner, I don't want to go to your house for coffee. I care about human life. I care about adding cancer, certain cancers, to this bill.

And as for epidemiology, let that not be your only role model. Epidemiology can only do so much, like the cancers that we know that should be added, use epidemiology on that. 9/11's unprecedented. It never happened before. So use something else other than an epidemiology. And believe me, I can't even spell the word, that's how smart I am not. Okay? So I'm asking you guys, with power comes responsibility. You have a responsibility today, tomorrow and from this day forward to do what is morally right.

I just came from a press conference at City Hall, and I almost threw up on myself listening to people who do not know what they're talking about. But appreciate the magnitude of this 'cause I do. I lost half a foot ten years ago. Eleven weeks in

the hospital. I'm lucky but I feel guilty that I can go to Sheelar (ph) and say I want to apply for the Zadroga bill 'cause I lost half my foot. Boohoo. Say that to **[identifying information redacted]**, who have leukemia and blood cancers. That should be added yesterday. You're playing God right now. Our fate is in your hands.

I am the nicest guy in the world. I want to be your friends. But like I told every member of Congress and every member of the Senate when I met them for eight years with this bill, I will do whatever it takes to get cancer added to this bill. Thank you.

DR. MIDDENDORF: The document which you handed out to the committee members will be added part of the docket. Just wanted to let you know that but it may be redacted to some extent. We'll have to look further.

JOHN FEAL: Do what you please with it.

DR. MIDDENDORF: Okay, our next commenter is T.J. Gilmartin.

T.J. GILMARTIN: Good afternoon. My name is T.J. Gilmartin, and I'm 32 years as a foreman and a shop steward building high rises in New York City with the union. Now, I had to go to so many OSHA classes for these high rises of stuff they taught us was cancerous and, you know, don't do this, don't do that. Everything, everything I been taught to and told is dangerous and cancer-causing is being thrown out the window on this World Trade Center. I mean, I know what goes into building a high rise and one thing that was -- and the Trade Center was built prior to 1973, when the asbestos was in the pipes, it was in the cement, it was the silicosis, the heavy metals, the chemicals and the PCBs.

Does anybody know about those electrical vaults in the basements of those trade centers? You know that's totally cancer-causing chemicals inside those -- the vaults and the transformers? Okay? All that was there and we never hear of anything. Anything about any of that.

I mean, all this stuff is concern -- is confirmed as a federal cancer-causing chemicals. The building was totally filled with all these chemicals. The fire department, the PDA have done studies showing that their men are dying a lot more than they are usually dying fighting fires.

I mean, OSHA would lock me up if I was -- if I was grinding concrete on a high rise and that powder, if I didn't have a battery-operated respirator, I'd be locked up by OSHA, either thrown in jail or fined for having my men do that. I mean, you had 220 stories of pulverized concrete besides everything else that, God forbid, was going to happen in another nine years with the asbestos, with that 20-year lag time.

It's been over ten years since the World Trade Center was destroyed, and that's

been a time so many first responders have paid with their lives. The percentage is out of whack compared to how many first responders just tried to help their fellow man. It seems to me that this is all about the money. I mean, I understand that you'll have everybody claiming that they got cancer from World Trade Center but like John said, there were certain cancers from the ears, nose, -- I mean, your mouth, your nose or absorption that should be covered by this.

But it's -- you know, I mean, that's basically what I have to say. I mean, just that I been in the business of high rises and I know what causes cancer on these things and, you know, you put up a high rise, OSHA's there, you're doing it, you know, you're in a lot of trouble if you do it that way. Everything that could get you cancer on a new high rise was all down at the Trade Center, and it was a lot worse because it was built before 1973 when the world was changed. Thank you.

DR. MIDDENDORF: Thank you very much, Mr. Gilmartin.

Our next commenter is Thomas Fay.

THOMAS FAY: Good afternoon, ladies and gentlemen. Is this the speaker here? My name is Thomas Fay, and I come from a town at the Jersey shore called Spring Lake, New Jersey. On September 11th I was getting my wisdom teeth pulled; and the planes hit the building and I raced home and proceeded to watch on television for about 36 hours. And after the 36 hours, I couldn't take it anymore so being a volunteer fireman for over 37 years in the Spring Lake fire company in Spring Lake, New Jersey, I decided to go get my gear, jump in my car and race to New York. I got there in 50 minutes, which is unprecedented.

I was directed down to the south end of the city and parked my car on 14th Street and I walked in. Two other firemen drove by this desolated area of lower Manhattan and picked me up. I never knew them before but I know them now. Both are very sick.

They drove me down and they went out to get a camera that day to take pictures. I didn't want any pictures taken of me that day; I was there to work, not to have any pictures taken. But lo and behold, they took two pictures of me and those two pictures ended up being the proof that I needed to show that I was there.

The disease that I contracted from my 12 hours working on the south tower pile, solely on September 13th, was non-Hodgkin's lymphoma, stage II, B-cell aggressive. The way that was found in me was that I, in 2007, after the disaster, a friend advised me that I needed to go get checked out at the World Trade Center medical monitoring treatment program they had at Rutgers, which I did.

I went in 2007, 2008, and in 2009, I noticed a lump in my left leg. I showed it to **[identifying information redacted]** out there. She said you've got to go to New York City, Mt. Sinai immediately. Within a week the tumor was taken out. Four days

later I was told that I have cancer.

I fought the battle brave and hard. I'm in remission now which is a good thing, but for people like us that went up there and put our time in, I being a volunteer, I was paid nothing, I would go again tomorrow because of one thing: I love my country. That's it, pure and simple.

Being a guy from the Jersey shore, a popular person everyone knows who comes from down there is Bruce Springsteen. He has a new album out. And he has a song on it called, *We Take Care of Our Own*. That's the theme song for us first responders. We want our government to take care of us.

We went in there. We fought hard. I worked 12 hours on that burning pile. If I fell once, I would have been cut to shreds. But that wasn't on my mind that day. On my mind that day was to help as many people as I could. That's why I joined the fire department, to help people. I didn't join the fire department to get cancer.

My cancer's in remission but as of Monday, a recent trip to the doctor, has shown that I now have skin cancer. I'll fight that battle on my own and take care of that as I should. But it is my hope that this -- people here, grouped here today, do the right thing, which is to include blood cancers in the Zadroga bill. Thank you very much for your time.

DR. MIDDENDORF: Thank you very much, Mr. Fay. Our next commenter is Arthur Noonan.

ARTHUR NOONAN: Hello. My name is Arthur Noonan, retired now but back in September 17th, 2011, I was employed by the Chicago Fire Department. As the last speaker, we were watching on television nonstop at the firehouse. Finally we couldn't take it anymore, we saw what a devastating effect this had on the country as well as to New York, and we decided to come here. I believe there was a group of 14 of us. We flew in and we spent seven days working here.

I was a pretty healthy guy as well as the rest of the people that came with me. A lot of young firemen from Chicago, good firemen, and we did everything from cleaning tools and changing blades and batteries in the tool shed, until we finally got to work on the actual Pile. Some days we would cut aluminum off of steel beams so the iron workers could cut the beams in sizes small enough to fit on the trucks to haul them away.

Eventually we got to work on the Pile. You'd start at the back of the Pile, there might be a hundred firemen in front of you. You'd pass buckets forward empty, and backwards full. Finally you'd get up to the point where you were the one that was digging. You'd be on your hands and knees; what respirators we had didn't work, they kept clogging up or from the sweat would just turn like a mud on there. We finally had to take those off. But you kept working because you knew your

brother firefighters, policemen and many loved ones of civilians who were also in that Pile. And all we wanted to do was try to close a part of life for a lot of people.

In December 2004, I became ill at work, was taken to the hospital. Thought I had a bad touch of the flu; everyone was sick in the firehouse then. It was the day before Christmas Eve. They let me go home for Christmas Eve and Christmas Day, I had to come back the following week, and I was diagnosed with AML, acute myelogenous leukemia.

I went from 210 pounds to about 140 pounds in six months, had several chemo treatments, and luckily I am now in remission. But remission is not getting better. It just means they're holding you steady so every day you hear something on the radio, whether it be a celebrity or sports figure, just recently we had a famous singer die of leukemia. Every time you hear that word leukemia, it all comes back to you.

When we came to New York, we did it on our own. We did not expect to get anything for it. We just wanted to help our country. We wanted to show the world the support that New York and the United States, how they all come together in a time of need.

Personally I have taken a tremendous loss on my medical benefits. I've gone through about three-quarters of what I'm entitled to in my lifetime for myself and my wife and if this comes back, I probably only have a few hundred thousand dollars left in my medical plan from the City for treatment. After that, I don't know what I'll do.

So I'm hoping that cancers, certain cancers, will be included in this so people that came to help do not have to have that constant worry in their mind if their cancer comes back, they won't be able to get any treatment. Thank you.

DR. MIDDENDORF: Thank you very much. John Walcott.

JOHN WALCOTT: Hi. My name is retired detective John Walcott. Like everyone else here, I'd like to thank you for this opportunity.

I also was diagnosed at 38 with AML leukemia. As I stand here in front of you I've had six months of chemotherapy, stem cell transplant, and I have other illnesses that are recognized in the Zadroga Act. But looks are deceiving. All my nerve endings are burnt out all my -- in my hands and my feet. There's not a day that goes by I'm not in constant pain.

The City retired me due to my leukemia, which they said I got from 9/11. Social Security recognized it. It seems that only the country doesn't recognize it.

Before 9/11, I was approximately 36 years old. I was never sick a day in my life except for the common cold. I was a very extremely active narcotics detective, well over 3500 arrests in my career involved in. I was a high school hockey coach. Used

to do physical activity, lift, run every day. No longer can do any of that. I was on the fast track to probably becoming a hockey coach in college. We had an exceptional team, exceptional record and I turned down many jobs which I planned to take when I retired. Which, that's been cut short.

On 9/11 itself I wasn't scheduled to work 'til late that evening. I was told what happened, I was woken up, and I was down there in 93. So without hesitation, I ran right down there to help my fellow detectives or policemen at the time. Shortly after the second tower had collapsed, I arrived.

Did -- from recovering bodies, body parts, to Mayor Giuliani even assigned us one day to VIP tours for all his friends. So I've done everything, cut steel. You weren't a policeman when you were down there; you were just somebody trying to help.

As I told you before I had the transplant and everything else.

Well, you know, let's talk a little bit why we're down here. We all know that the benzene and asbestos and all over cancer carcinogens were down there. That's no secret. I mean, that's been for a hundred years. We don't know what they do if you mix them all together nor do I think anybody really cares because if they did, it wouldn't have taken us ten years to get to this point.

We know there's a usually high number of early responders that are diagnosed with cancer. Yet no one seems particularly interested in trying to corroborate any of these findings at the site, at the cancer rate. The large population of responders and workers are being looked at, which I think you guys are doing a study of over 50,000 people. But I think that study's wrong. I think you should study guys and girls and everybody who was down there the first day, first week, first month. And if we do that, you're going to see that the 362 PBA Study, that rate is going to be astronomical. It's probably going to be in your 60s to 70 percent of cancer rate.

There's many reasons. We all know there's many reasons why the City's and the country's not releasing these numbers. Because they're doing you a 50,000 population rather than a 2500 to 5,000 population. So that statistics are going to be extremely less and it's not going to prove cancer. But if you did, if there was actually 2500 to 4,000 that were down there the first week, day or month, it's going to be astronomical. And then the red flag is going to be up.

But when there's litigation going on and there's hearings about to happen, what do we do? We have to make the numbers look bad because the City kind of painted themself in a corner right now with this.

DR. MIDDENDORF: One minute left, please.

JOHN WALCOTT: Okay. You know, I think that's where we need to concentrate. We have to concentrate on -- let's concentrate on 2500 to the 3,000 that were down there versus that. I don't -- there's a part of me that envies you folks and

there's a part of me that doesn't envy you folks. You have to make a tough decision. But luckily for you folks you have ten years and weeks of hearings to make this decision.

I had a phone call and I had to rush down. Now I'm sick, my daughter'll never see me walk her down the aisle. I can put my head on my pillow and go to sleep at night knowing I did something that in the recovery that meant closure for people. You folks have that same power now. Twenty years from now if the cancer isn't added, and my grandchildren, that I'll never see or hear, do you say you made the right mistake? Did you make the right decision? Thank you.

DR. MIDDENDORF: The next commenter is Reginald Hilaire.

REGINALD HILAIRE: Hi. Good afternoon. I'm a police officer with the NYPD for 11 years. I was a rookie when 9/11 happened. I'm currently assigned to PSA 5, which is a housing precinct up in East Harlem. I worked over 850 hours combined at the World Trade Center and Sandman Landfill.

In 2005, shortly after my son was born I was diagnosed with thyroid cancer. I immediately asked my primary care physician if this was related. He said, he looks at my lump and said, what were you exposed to down there? I've seen him since 1999, before I became a cop. So 2005, I had total thyroidectomy, radiation and ever since then I take a pill, a synthroid, and it regulates my thyroid.

Winter of 2005, I go back to my primary care physician, he noticed my blood count was pretty low. He refers me to a hematologist and that hematologist does a bone marrow biopsy, and he comes back and he says, the pathology report -- I disagree with the pathology because it says you have multiple myeloma but I disagree. You're too young to have this. He repeats it in 2006, it comes back multiple myeloma. He's still confused.

I go -- I sent everything to Sloan-Kettering. They do another biopsy, bone marrow biopsy, April 2006. They confirmed it. I thought okay, great, treat it. No, we can't treat you because you have smoldering multiple myeloma, early stages. So I'm like, is there anything out there for me? No, you can't -- there's nothing. We have to wait until it gets worse in order to treat you. He says within two to three years, you have 50, 60-percent chance of it getting worse.

Thankfully every four months now I go to Sloan-Kettering, they do blood work, urine work, and if I get the phone call, that means it's not good. So far, knock on wood, everything's okay.

I have no family history of cancer. I'm pretty much the healthiest one. I am a son of Haitian immigrants. I am the only member of my family that's a police officer. I was born and raised here, still work here in Harlem. I can't retire because, even though I'm not really sure if I want to, but I can't retire because I'm not sick enough

so it's an oxymoron right there.

I have two red cancers. I don't -- I work with a lot of cops in PSA 5. I don't know why I have it. It's just one of those things I've come to accept it. In 2006 I read an article in the Post saying that there's other first responders with cancer. I contacted that reporter who introduced me to one detective who has lymphoma. He introduces me to others. I got to know about 11, and I'm pretty close to about four of them. Three of them have multiple myeloma. I never met them before in my life.

I met one police officer through the PDA who (unintelligible) I did. His name was **[identifying information redacted]** (ph); he had (unintelligible) cancer. We got to talk for about a year and then he eventually died in 2010. So I always think about him, think about his family, I'm still close to his widow.

I don't -- I'm not a scientist; I'm just a cop, I just want to do my job. I think a lot of us want to do our jobs. I don't think it's coincidence. I never met these people before in my life.

Someone asked me before if they had to do it again. I, like I said, I'm still with the NYPD. I'm doing clerical work. I'm pretty now senior now. If it happens, again, and I'm pretty sure it would, would I do it again? Would I tell my junior cops to go? I don't know. I love New York City, I love the people here. I'm not fond of the government. They showed so careless without a doubt.

What's really insulting, I could deal with cancer, I could deal with questions, how you doing. As a New Yorker, how you doing could mean ten different things. How you doing or in my case, so how are you doing?

DR. MIDDENDORF: One minute, please.

REGINALD HILAIRE: What I can't stand is politicians, everybody can say, okay, great, great job; you're heroes but when it comes to treating us, hold back. It's just too early to step up the study; it's not there yet.

I try to tell the cops in my precinct get yourself checked out. They look at me. We can handle perps, we can handle perps with guns, we can even handle bosses that are rough. We can't handle our own mortality.

So I urge all of you, just like us, when they call us heroes, all of you can be heroes by just saying, adding cancer. You will save lives by putting cancer in the bill because it will tell first responders to get checked out. You don't know how much of a difference you guys will make if you add cancers. You will tell somebody with the public -- when the report comes out, that one person would say maybe I will get checked out. That can make a difference. Thank you very much.

DR. MIDDENDORF: Thank you very much.

Next presenter is R.J. Lee.

R.J. LEE: I do want to thank the committee for giving people the opportunity to testify. I've been asked on behalf of the Policemen's Benevolence Association to speak on their behalf about the composition of the World Trade Center dust and some analysis we recently did on the uniform of one Officer Harris.

By way of background, R.J. Lee group worked in New York City for about four years following the disaster, characterizing, analyzing and characterizing samples of World Trade Center dust and exposures and things like that.

Today I want to talk about Officer Harris. Laboratory testing of Officer Harris's clothing worn on the morning of September 11th, clearly demonstrates the presence of what's now referred to as World Trade Center dust. And you can see the uniform on the first slide that he was wearing that day.

Fortunately, almost by, I don't know what fate, Officer Harris had the presence of mind to go home that morning and double bag his clothes so we have a virgin sample of World Trade Center dust. One that hadn't sat out in the rain, whatever, for months, and one that you could look at as it was created.

As you can see from what's called the World Trade Center well, the World Trade Center dust is a unique mixture of heavy metals, asbestos, fine cement dust and chemicals produced by burning, including PCBs, dioxins and furans. The chemical species found in WTC, chemical and physical species, found in World Trade Center dust can cause many harmful effects on the body including effects on the nervous system, kidneys and cancer.

It's, as you've heard it's widely believed that there's been an insufficient amount of time to assess the potential for increased cancer risk. However, I believe there's certainly reason to assume that the acute exposure experienced by first responders are significant and unique.

There are a number of factors to be considered that could play a role in increased cancer risk to individuals and the potential for more rapid progression than you would expect.

First of all, the initial dose, acute exposure was enormous.

Next slide? This is the dust we found on Officer Harris's clothing. You'll note that in something like two or three hours, about 59,000 structures per centimeter squared had been deposited on his clothes. Chromium was at 347 micrograms per foot square. That's a lot in a two or three-hour exposure. If you put that cast an imaginary membrane through the breathing zone, you can translate that kind of deposition rate into exposures and they're large.

There's an abundance of respirable particles in the dust, far more than ordinary.

What's interesting, and one of the prior speakers mentioned it, in the analysis we did of these hundred thousand samples, and including Officer Harris, many of them

were coated. The asbestos was coated with lead; the asbestos was coated with mercury. The machines don't analyze for dioxins in the electron microscope but obviously dioxins and PCBs were there.

DR. MIDDENDORF: One minute, please.

R.J. LEE: The presence of dust on Officer Harris's uniform clearly demonstrates that the first responders were exposed to extreme conditions. There was reason to believe that you could postulate a model in which the dust carried, the caustic cement dust, carried toxins and those toxins and that interaction of the pH 11 or 12 cement dust could well interact with the lungs and deliver toxins much more rapidly than believed possible.

I think it's important on behalf of the PBA to say that given the service of the first responders that we've heard about today and the trauma they're going through, that any potential disease that could be covered should be covered on their behalf. And secondly the information they're seeking from the City and the government should be released anonymously so that it can be used scientifically. With that I thank you.

DR. MIDDENDORF: Our last commenter is Philip Landrigan.

PHILIP LANDRIGAN: Good afternoon, Madam Chairman. I'm Philip Landrigan, I'm a physician and occupational doctor. Chairman of the Department of Preventive Medicine, Dean for Global Health at Mt. Sinai School of Medicine. For six years I directed the Division of Surveillance Hazard Evaluations and Field Study at NIOSH, so in other words for those six years, 1979 to 1985, I directed the National Occupational Epidemiology Program for the United States of America. So we, we know for a certainty from multiple lines of evidence, that you've heard a great deal of data here today, and I thought that testimony presented just now about the contaminated police uniform was striking. We know that the responders to 9/11 were exposed to a complex mix of known and suspect human carcinogens. We know that the air sampling data that were collected undercount the true level of contamination. I think the testimony just heard substantiates that, but it stands to logic anyway that there were no sampling units extant in the first hours and days after the attack when the concentrations were highest, so we know that the responders were, especially those who were caught in the dust cloud, were exposed to unprecedentedly high levels of airborne contaminants.

Now, our group at the Mt. Sinai School of Medicine, in partnership with people at UMBNJ, Stony Brook, Queens College, North Shore LOIJ and Bellevue have just completed an epidemiologic analysis based on approximately 20,000 responders, and we looked specifically at cancer in them. This is an analysis that follows on our earlier studies showing persistence of lung disease and mental health problems and

GERD in the responders.
I'm not going to present great detail because it's going to be submitted for publication in the next couple or three days, but I am going to give you a broad sketch of the findings.
Overall we found approximately a 14-percent excess in cancer at all sites combined in this population, and we found statistically significant excesses of thyroid, prostate and hematolymphatic, hematolymphopoietic cancers, in this population.
In broad outline our findings parallel the findings that were released on September 10th of this year, that they would present from the fire department.
It's, I think, the 14-percent excess in overall cancer is striking given that in this population, we had a 58 prevalent -- 58-percent prevalence of never smokers, and we had sharp deficits for lung cancer and laryngeal cancer and yet despite those deficits in some of the most common cancers, we had an overall excess incidence of cancer in the population. These are striking findings.
Going back to your taxonomy this morning of the straw poll, I think we've reached a point where, to use Steve Markowitz's phrase, we can say with a high degree of certainty that the exposures that the responders experienced down there at Ground Zero, and at the other World Trade Center sites, can be said to -- we can reasonably anticipate that those exposures are going to cause cancer.
So I think, I think it puts you in a very difficult policies (sic), but you clearly don't have the kind of epidemiologic proof that you would like to have to declare with 95 percent certainty that there's a cause and effect relationship here. We're not going to be there for some time yet. But you have to bear in mind that in legal cases, you don't have to get to 95 percent; you have to get to 51 percent. It has to be more likely than not that the exposure caused the disease. And I think we're at, or very close to that point.
And what I'd like to ask you as members of this committee to weigh that as you make your decision. Thank you.
DR. MIDDENDORF: Thank you very much, Dr. Landrigan.
You have about 15 minutes left.
DR. DEMENT (via telephone): This is John Dement. I'm going to have to leave the meeting so I just want to make that note.
DR. MIDDENDORF: Okay. Thank you very much.
DR. WARD: So Virginia, are you still on the line?
DR. WEAVER (via telephone): Yes, I am.
DR. WARD: So I did want to give the committee an opportunity if they had any questions or comments on Virginia's presentation.
(no response)

DR. WARD: Okay, so --
DR. TALASKA: Oh, I have one question, if I may. I have one question.
DR. WEAVER: Okay.
DR. TALASKA: You mentioned a statement early on when you were talking about the VOCs, about that when the levels became, quote, extremely high, that people were removed from the area. And I just have to ask was the concern -- you know if the concern for that was because of explosion?
DR. WEAVER: I don't know.
DR. TALASKA: Didn't say it in the paper.
DR. WEAVER: I don't think so but I was reading seriously in the last week and I could have missed it, and perhaps others on the committee who spent more time with these data could weigh in.
DR. TALASKA: Thank you, though.
DR. MARKOWITZ: So I have another question for Virginia. So in your experience working with firefighters from previous studies, how common is it to find benzene at fires?
DR. WEAVER: It's extraordinarily common. We often use data that's now rather old but still very valid about the components, the VOCs in smoke; and in one study conducted by Harvard, benzene was present in about 92 percent of smoke samples obtained. And it's routinely found at levels well above the OSHA panel. Butadiene is also very common as a combustion product.
DR. HARRISON: This is not really a question for Virginia, just maybe an observation and a prelude to further discussion that we'll have. I guess I haven't heard anything from the presentations today that would lead me to understand that there was a minimum dose or duration of exposure that we could identify from the knowledge that we have to draw a line.
I think it gets, you know, back to maybe something that, Liz, you presented earlier about latency and duration of exposure. I guess I just would throw that out there just for an observation, that we really don't have, based on the limited amount of exposure data, you know, that we have from the site, the fact that it wasn't captured in the first several days, a way to define a minimum length or vocation related to the occurrence of cancer.
DR. WARD: So there is one question for Dr. Landrigan.
DR. MIDDENDORF: Yes, well, there was one question.
DR. WARD: Is he still there? Dr. Landrigan?
Okay, so would someone like to ask a question of Dr. Landrigan?
DR. TALASKA: Thanks for coming back, Phil.
DR. LANDRIGAN: No problem.

DR. TALASKA: I was wondering if you had done any analysis on the subset of people who were on the Pile early on relative to the whole group.

DR. LANDRIGAN: Yeah, we tried to do that. We certainly, in our previous paper that you've probably seen, the one that was published in September in Lancet, we saw a very clear gradients in most diseases according to intensity of exposure. The people who were caught in the cloud had the highest rates of pretty much every disease we looked at; the people who arrived in the first 48 hours but missed the cloud were the second highest, and then on down through several more gradations. We saw that for most types of lung disease, most mental health problems, for GERD. It was not so striking for cancer. And it may be because of smaller numbers of cases. Thank you. That's it? Yeah, thank you.

DISCUSSION ON PRESENTATIONS

DR. WARD: So, I guess we're close to the end of our day. And I guess one, it was suggested earlier that maybe we look separately at the question of biologic plausibility and the likelihood of cancer but I think one of the issues I'm struggling with, and I don't know if other members of the committee are struggling with it, too, is that we are -- whatever opinion we come to, we do have to define a scientific rationale, and I know that in a lot of the presentations this morning, you know, it would be more possible to build a scientific rationale around upper respiratory cancer, lung cancer, esophageal cancer, areas of the body where we know that there was direct contact with the carcinogenic substances and we know that there have been other kind of health effects, but I think the difficulties we, we don't -- I mean, I guess, and maybe Dr. Landrigan's study will help with that but with the hematologic cancers and the lymphomas, we don't as yet, I think, have strong epidemiologic evidence, and I'm not sure we have, you know, an exposure -- you know, we have a strong argument in terms of biologic plausibility, and I guess -- so the argument about -- I think we can say that, you know, it's in shorter -- it's observed that they have a shorter latency period but in terms of -- so I guess what I'm seeking is, are that -- do people have thoughts on that. How should we approach the question of the blood cancers given that that seems to be something that people are highly concerned about? Excuse me? Does anyone care to comment on that?

DR. WEAVER: So this is Virginia, and you know, blood cancers are the ones that based on latency alone, we could be seeing now from World Trade Center exposures. You know, ten years out, those would be the first wave of cancers that you would see. Those are also caused, or closely connected, with a number of the VOCs. And if you look at VOCs in combustion products, they ask -- there are a number. So you have an exposure mixture going on there. And so from that point

of view, I can see the biological plausibility and that being an initial concern.

DR. ROM: I think by definition, volatile means volatile, that these compounds probably were very high, right at the beginning with the burning of all the fuels, and they evaporated into the air and they weren't measured, and exposures were probably way higher than any of the standards so that it's biologically plausible that you're going to see non-Hodgkin's, Hodgkin's lymphomas and the acute leukemias, acute myelogenous or non-lymphatic leukemia and probably chronic myelogenous leukemia. I think the ALL and CLL are different biologies, and that may be something totally different 'cause ALL is in children and CLL is in the elderly associated with a lot of genetic mutation defects. But the others, and multiple myeloma, I would add, probably all are very biologically plausible at this time.

DR. MARKOWITZ: Also the firefighters study in fact was positive for non-Hodgkin's lymphoma. It showed a relative risk of 1.58 -- and actually whether you use the corrected one, which tries to take account of the surveillance issue or not, it showed a 50- to 60-percent increase when compared to the general population of men, and when they looked at it compared to the firefighters who hadn't been exposed, it was still elevated; it was 80- to 90-percent increase. Not statistically significant at that point because the numbers are smaller, but when it was compared to the general population it was elevated and that was statistically significant, so there was real epidemiologic evidence that blood cancer was increased.

DR. TALASKA: I think we might want to look more, too, at some of the other compounds that we haven't really spent any time with: the furans, the dioxins; what sort of impact they have, both animals and -- in animal studies for the most part, to see if there is a link between those -- or perhaps an interaction between those. And I don't think anyone has looked at those as hard as maybe we should.

DR. ALDRICH: (Indiscernible) the document that's not biological plausibility (indiscernible). Mesothelioma sometime in the distant future and probably lung cancer in a little bit less distant future, relative to the asbestos exposure. It's hard to quantify but certainly potentially a factor.

The fire department study did not show an increase in lung cancer; it actually showed a decrease in lung cancer possibly related to the health worker effect, but that was seven years of study, and that was probably too early to see the effects.

DR. WARD: So I guess I'm getting a sense. I know some people have not spoken very much today but the sense of the comments I'm getting is that many people on the committee feel that it is certainly biologically plausible that we would be seeing some cancers in excess, either now or in the future, and I guess the question is, is there someone who wants to state, you know, make a statement -- or are there

people who would like to speak to the question who have not spoken on it? Or we can go back to the, you know, the poll, but I guess I'm just trying to get a sense of the committee, of where we stand at this point. Time, again, so we can think about how we want to frame the discussion tomorrow in the maximal -- you know, in a productive way. Valerie?

MS. DABAS: Just from my observation, I understand that the latency period for blood cancers is short. I think we get into a very funny situation when we start piecemealing each part out. Both the fire study and Mt. Sinai seem to indicate that thyroid and prostate, they're seeing increases, and so if we start going by what is easiest and not looking at the whole picture, then I think we may start asking too -- well, I guess you can't ask too many questions but then it gets very confusing.

For me, I've seen, you know, from taking information from responders, I've seen an increase in thyroid, I've seen an increase in prostate. I was told that, you know, thyroid is common, prostate is common, but when we look at the ages people are being diagnosed, it's very uncommon for a 38-year-old man to even be tested for prostate cancer, so when they come up with prostate cancer, I think it's significant. I also have seen an increase -- you know, how do you deal, then, with the blood and liver canc -- kidney cancers that we're seeing? Liver cancers with people that are not hepatitis C and do not have cirrhosis of the liver. You know, we had four cases reported in that instance and, you know, so you have to really look at the whole picture as opposed to just saying well, the blood cancers are a four-to-six year latency period, we're at four to six years. If that's the case, that's just assuming that the dust is the same exposure as we've seen with all these other studies, and I don't think these studies take into effect the concentration of chemicals, metals and so forth, and we keep saying the dust is different than anything that we've seen before, and therefore I think we have to treat it different.

MR. CASSIDY: I just wanted to add that I think it's clear that we need to remember what was highlighted today, which is that this type of exposure to the variety of different things, the concrete, the dust, the metals, the benzene, all the chemicals, really hasn't been -- we haven't seen that anywhere before so when you want to start breaking down studies and say well, exposure to benzene means this. When you add them all together, you really have a toxic stew that, I think, is so biologically plausible to say that blood cancers and these other cancers are a result of that exposure, and I do think the severity of the exposure, you know, bears out clearly that, you know, those who were caught in the dust, in the cloud, in the collapse, those who were there in the 48 hours, those who spent extensive times there, clearly have a more likely coming down with these cancers, but I think it's biologically plausible that anyone that was subject to this is going to have an

increased rate of cancer so that my view now, given everything that I've heard, is that that cancer should be included.

We need a better mic system.

DR. HARRISON: Steve, this is Bob Harrison. Were you saying that we should recommend that all cancers be covered regardless of site?

MR. CASSIDY: I'm sorry? I think to say all is a broad statement; it really is. But I think that clearly the blood cancers, which are showing up early, I think anything related to the lungs, the respiratory system, anything that you can possibly inhale, so the esophageal cancers. You know, the fire department study proves that firefighters lost 12 years' lung capacity in the blink of an eye. That can't be dismissed as -- if that didn't exist people would say well, maybe this dust cloud really isn't going to do anything to us. But it proved what happened. Twelve years lung capacity, so to say all? I'm not saying all but I think we should err on the side of, if there's any evidence, we should err on that side.

MS. FLYNN: I really appreciated **[identifying information redacted]** comments, and I just want to say that I think that this is obviously not a deliberation that should use, you know, scientific certainty; this has been said before.

As his basis, he talked about a 51-percent of, you know, using the phrase that Steve Markowitz used earlier: We can reasonably anticipate that these cancers are linked to World Trade Center exposures, and right now that sounds pretty right to me.

I also want to add that the community cannot be left out of this deliberation, and also that the James Zadroga Act, and I can provide pages to folks if they want them, provides for one list of World Trade Center-covered conditions.

And we all know as erratic and full of gaps as the sampling information was on the Pile, you know, how much more is not known about community exposures. But what we do know is that members of the community, residents, students and area workers have the same respiratory and the same set of aerodigestive 9/11-related illnesses as responders, and it's more than reasonable to anticipate that they would develop the same set of cancers.

MS. HUGHES: I also just wanted to -- I'm not a biology expert, but I did go online and if we could break the body down into different body systems, like respiratory, and then look at the different things that could be impacted, so it is not just necessarily the lungs but it's the throat, so we're looking at a comprehensively wide body system so I just wanted to add that as well.

ADMINISTRATIVE ISSUES AND ADJOURN

DR. WARD: So we do need to leave the building shortly. So again I'm trying to sum up the sense that I'm getting. It seems that many people are in favor of listing at least some cancers of some systems as World Trade Center-related conditions, so I

guess, you know, your homework assignment is to really maybe clarify your own position as much as possible, and try to come up with potential statements that you think the group could agree on, and y'all certainly be thinking about it, but I'd like, you know, others as well to come in with, I think this is the sense of the committee and we can capture it in these words. That would really I think move us along in the morning.

So well, I did want to thank everyone who's here, both those who spoke and those who did not speak. I think, you know, the public comments are very informative. I think the discussion today was very informative, and I hope we've moved towards -- we've moved forward in the process of making a recommendation.

DR. MIDDENDORF: Let me also express my thanks and thanks for NIOSH and the World Trade Center Health Program, for the participation of everyone.

Steve, your wish is our command. We will be in conference rooms A and B tomorrow. And the speaker system will be better. It's not perfect but it will be better. So for any members of the public who intend to come back, we will be at the other end on the same floor. Thank you and good night.

(Meeting adjourned for the day at 5:05 p.m.)

CERTIFICATE OF COURT REPORTER
STATE OF GEORGIA
COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Master Court Reporter, do hereby certify that I reported the above and foregoing on the day of February 15, 2012; 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 9th day of March, 2012.

_____
STEVEN RAY GREEN, CCR, CVR-CM-M, PNSC
CERTIFIED MERIT MASTER COURT REPORTER
CERTIFICATE NUMBER: A-2102

This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held in New York City on February 15-16, 2012, 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 TWO

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

VOL. II

DAY TWO

THURSDAY, FEBRUARY 16, 2012

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 February 16, 2012.

C O N T E N T S

February 16, 2012

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TRANSCRIPT LEGEND

The following transcript contains quoted material. Such material is reproduced as read or spoken.

In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (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

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

Industrial Hygienist:

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Toxicologist:

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Research Scientist Supervisor II and Chief, Hazard Evaluation System and Information Service (HESIS), Occupational Health Branch, California Department of Public Health (retired), Oakland.

Epidemiologist:

Elizabeth Ward, Ph.D.
National Vice-President for Intramural Research, American Cancer Society, Atlanta. (Advisory Committee Chair-Person)

Mental Health Professional:

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Cincinnati, Ohio

P R O C E E D I N G S

(8:36 a.m.)

COMMITTEE BUSINESS

DR. WARD: Okay, we're going to get started and call the meeting to order, starting with Paul doing the roll call.

DR. MIDDENDORF: If the members around the table would just state their name for the record, that would be great.

MS. HUGHES: Catherine McVay Hughes. Hello? Catherine Hughes.

DR. ROM: Bill Rom.

DR. QUINT: Julia Quint.

MS. MEJIA: Guillermina Mejia.

MS. SIDEL: Susan Sidel.

DR. WARD: Elizabeth Ward.

DR. HARRISON: Bob Harrison.

DR. ALDRICH: Tom Aldrich.

DR. TALASKA: Glenn Talaska.

DR. NORTH: Carol North.

DR. MARKOWITZ: Steven Markowitz. Steven Markowitz.

DR. MIDDENDORF: And then on the phone we have anyone?

DR. DEMENT (via telephone): John Dement.

DR. MIDDENDORF: I heard John Dement. Did I hear Virginia also?

DR. WEAVER (via telephone): Yes.

DR. MIDDENDORF: Okay. Thank you very much. Let me also point out since we're in a different room we do have different evacuation routes. The easiest way to get out of here is to go through the double center doors over here, to my left and in the back of the room, you go straight through the next set of glass doors and immediately turn to your left, and the fire exit is marked on a door down that hallway. In case we need to evacuate, that's where we need to go.

DR. WARD: Okay, so we have a short time before we start the public comments, and we'd like to ask Dori Reissman to speak to us about the question that was raised yesterday regarding the language in the Zadroga Act.

DR. REISSMAN: Good morning, everyone. So I'm Dori Reissman, I'm the medical director for the World Trade Center Health Program. And what I wanted to try and do for you was to clarify, I think, the questions that I heard yesterday regarding whether or not there are certain criteria that you need to meet within this committee in order to make a recommendation regarding cancer.

So what I wanted to clarify was that in the Zadroga legislation, the following quote is: World Trade Center-related health condition means a condition that is an illness

or health condition for which exposure to airborne toxins, any other hazard or any other adverse condition resulting from the September 11th terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of the World Trade Center-related health conditions, is substantially likely -- this is the part that really should catch your ear -- is substantially likely to be a significant factor in aggravating, contributing to or causing the illness or health condition as determined.

Now what this means, that quote specifically refers to the job of the clinician in the program to individually assess somebody's exposure and disease relationship. It is not your charge. Your charge -- the only language actually in the statute about your charge had to do with the administrator's discretion to request input from you, advice from you, as to whether to include cancers or type of cancers in the list of covered conditions.

Once that list is established, which we already do have quite a number of conditions there, then the clinician within the program can assess the individual's exposure disease relationship for that individual's determination. Okay?

What the administrator asked you to do, and charged the committee very specifically, was to give him a scientific basis for your recommendation. That didn't restrict you to any definition of what the scientific basis meant. So I wanted to be very clear about that.

Yesterday I heard a variety of interpretations of what that could be. Some of it is reasonable, I think, was a word that you used. One of them was more likely than not. Whatever it is that you decide, you need to use those criteria along with how you're scientifically arriving at your recommendation. Does that answer the question?

DR. WARD: Are there any questions for Dori? Yes, Glenn. John, you have a question as well?

DR. DEMENT: I didn't check but I (indiscernible).

DR. TALASKA: So we can take -- from what you understand, then we can decide what level of recommendation to make to the administrator about the disorders that we're considering.

I just wanted to be absolutely clear. It's up to the committee then to set the strength of recommendation to the administrator as to what we feel is the relationship between the exposure and the disease then, right? And the condition?

DR. REISSMAN: Yes, you can comment on what you believe the strength to be.

DR. TALASKA: Yeah.

DR. REISSMAN: And if you feel that there are criteria that you'd like to see

continued to be used, you can make a statement about that as well.

DR. TALASKA: Gotcha, okay.

DR. REISSMAN: Do I need to repeat anything since this microphone was not on? Or are we good? Okay, thank you.

DR. WARD: Okay, so were there any questions from the committee members joining us by phone?

DR. WEAVER: So, we couldn't hear that, or at least I couldn't hear it.

DR. WARD: Okay, so we'll ask Dori to repeat that.

DR. MIDDENDORF: We don't have time.

DR. WARD: Well, we don't have time for the whole thing but maybe she'll give us a quick summary.

DR. REISSMAN: I'm sorry about that for the people on the phone, I thought it was on. The bottom line was yesterday in the meeting there was a question about a specific criterion for scientific relationship between a health condition and an exposure, and it was a specific quote of the health condition or the exposure is substantially likely to be a significant factor in aggravating, contributing to or causing the illness or health condition.

And what I was saying to the committee here was that that is for an individual clinical assessment of exposure disease relationships. That is not your charge. Your charge is simply to look at whether you think cancer or a type of cancer is appropriate to add to the list whereby a clinician can then apply that criteria of substantially likelihood test, if you will, to that individual clinical assessment. And the criteria that you can use are up to you; it could be more likely than not, it could be reasonable, it could be whatever words you choose but the advice that you give to the administrator needs to have a scientific basis and rationale.

PUBLIC COMMENTS

DR. WARD: Well, I'll turn it over to Paul for the public comment period.

DR. MIDDENDORF: Okay. Thank you. I want to point out that each of our commenters is signed up on a first-come first-serve basis, and each of them will have up to five minutes to present.

I want to remind our commenters that it's often surprising how quickly five minutes can go by when you're talking about a subject of great importance to you. So at four minutes I will let the commenter know that they have one minute remaining so they can make sure that they have the opportunity to make the most important points and make sure they get that across to the committee. If they have not finished at five minutes, I will have to rudely interrupt them and thank them for their comments. I apologize up front to anyone to whom that occurs but we must do that to be fair to all of our commenters.

We do have several commenters who are on the phone, and I just want to remind them that they should keep their phone on mute until I call their name. Then they should unmute and make their comments; and again, I will give them a warning when there's one minute left and let them know when their five minutes is ended. Also I want to point out to everyone that you do have the option of submitting written comments to the docket to this committee. The docket number is 248, and you can find the instructions on how to get to the docket in the Federal Register Notice, it's on our committee web page, it's also on the NIOSH docket page.

Lastly, I want to remind our commenters about the redaction policy for public comments. That policy is also published in the Federal Register Notice; it is on the committee web page and also the registration in the back here, if you want to look at that.

So, with that we will go to our first commenter who is on the telephone, Jeffrey Stroehlein.

JEFFREY STROEHLEIN: Hello, I'm right here.

DR. MIDDENDORF: Okay, can you go ahead and start?

JEFFREY STROEHLEIN: Yes. I'm Jeff Stroehlein, retired New York City fireman, May 9, 2011. On September 11, 2001, the United States and the world was struck with an incredible, terrible tragedy. Two planes crashed into both towers of the World Trade Center. The loss of life on that day was incredible. It would affect the lives of many as the world watched in horror.

I'm here to represent firefighters and first responders with the after-effects of that day, the cancer that has followed in the 9/11 path. On March 16, 2011, my life was regular: go to work, hustle the kids around, pay bills, enjoy family life when time was available, as we both worked and tried to mix our schedules so we could have one of us with the kids and pass some length of times.

The problem was that for about ten to 14 days I was having headaches. I'm pretty tolerant of pain and not a guy who gets sick a lot. My wife had had enough and on March 17, St. Patrick's Day, earlier I was at the doctor's office. My wife then convinced the doctor to send me for an MRI. She's in the nursing field.

Later that day the doctor called and said he wanted to see us. My wife knew that wasn't good news and we headed right to North Shore Hospital.

The next day, March 18, 2011, I was in surgery getting a brain biopsy. Our world would change as I was diagnosed with large-mass brain lymphoma (indiscernible) CNS lymphoma.

My head had been cut open and I had ten staples in my head as I was medicated for pain. As I got my senses back and was given terrible news of my cancer diagnosis, I did not sit and cry and feel sorry for myself. The first thing I told my

wife was I will not lose to cancer. Then for my three children and my little girl who turned four the next day on March 19th, I would not be there to celebrate as I lay in the hospital bed. This was just a start as we decided to transfer to Sloan-Kettering Hospital.

It was in that time there was much to do in case the worst would happen and I was to pass on. We needed a healthcare proxy, a will and a power of attorney. But when (indiscernible) support there was absolutely no help from FDNY as far as what to do. It felt like our world had just been turned upside-down. I would not lose any of my spirit as I would fight the fight. I would stay positive through all my chemo treatments, and I have no plans of anything different. The side effects have been no bargain. As much as I have told you about me, this isn't about me; it's about us, the first responders, who are still being diagnosed with cancer ten and a half years later. I am the voice for all first responders.

FDNY doctor, **[identifying information redacted]**, did a study the first seven years after 9/11 and cancer was at 19-percent higher rate in (indiscernible) responders than those who weren't there. That's just firemen.

I was diagnosed in the ninth year after 9/11 and still hear of first responders being diagnosed with cancer every week. My stats and others are not even in the 19-percent stat. The percentage is higher than that and still growing. Although sad, there will be more first responders diagnosed with cancer.

All FDNY vehicles that responded to 9/11 were loaded with dust and debris. They all went back to their firehouses uncleaned. Now the firehouse was contaminated. Where was a fireman's gear after his day on the Pile? Uncleaned and back in the firehouse.

Ten and a half years ago -- I'm sorry, all FDNY members were ordered on the chart down to the pit and clean-up. There were so many contaminants, poisons in the air, two airplanes disappeared, glass, computers, desks, jet fuel and even human body parts were in the air that day for months and who knows how long after. As my friend **[identifying information redacted]**would say, for any of those toxins individually in a bottle, and it would have a skull and crossbones, with a do not inhale. These were many unknown amount of toxins. In the early stages the city was unprepared with little paper painting sheetrock masks. Twenty minutes of breathing and moisture, and the mask would be torn open over your mouth.

Later we were told the air was safe to breathe. Why would you give out masks if the air was safe to breathe? Many lung and breathing problems have occurred. Many in first responders. How is cancer not caused? Are the people who make this decision blind? None of them were on the Pile, no politicians were digging on the Pile.

Ten and a half years ago, FDNY, police officers and all the first responders were getting pats on the back and 'atta-boys as politicians praised them. They couldn't do enough for them.

DR. MIDDENDORF: One minute, please.

JEFFREY STROEHLEIN: Now you can turn your back and deny, deny, deny. Cancer cannot be caused from all these toxins of 9/11? There is no doubt cancer was in the air on 9/11. I speak for all first responders but mostly FDNY as that's where I worked. As more and more first responders die of cancer every week, something must be done. I will not be one of the first responders who loses his fight with cancer. Thanks for all my support and my wife, my family's, and to (indiscernible) 162, many other firehouses and the FDNY and all my friends. I'll be here fighting the fight. God bless.

DR. MIDDENDORF: Thank you, Mr. Stroehlein.

Our next commenter is Jim Melius.

DR. JIM MELIUS: Mic working okay? I have a head cold, my ears are plugged up so hard to tell. Anyway, good morning everybody on the panel, everybody here. I'd like to thank Dori who saved me about three minutes by going over some of the same territory and now I don't have to go into long definitions as much.

What I'd like to comment on this morning is what your task is here, and I think it's very important to recognize it's not the usual review of a carcinogen, what would be done by IARC or NTP or some regulatory agency. Rather, you're being asked to make a determination whether a medical condition should be added to the list of World Trade Center medical conditions.

That list is going to be used to determine whether or not people in this program will be treated for that medical condition, but only after a physician determines that that patient has that condition, the definition that -- criteria that Dr. Reissman just spelled out, and that that condition for that particular patient is World Trade Center-related. And even after that physician makes that determination, that will then be reviewed by someone at NIOSH and following a, you know, some sort of a standard pattern of criteria so there's -- there will be consistency in that certification process.

And this kind of setup was deliberately put in place in the legislation, this sort of two-step process: one, there would be a list of medical conditions; secondly, there would then be an application of a physician diagnosis determining whether or not for that particular patient, their condition was related to their World Trade Center exposures.

Because, and I think it's sort of obvious that you cannot expect a panel such as yours to make a determination for every single person, every single circumstances.

This is a complicated situation, you're going to be look at -- you covered much of this yesterday that came up; it's a complex exposure, many carcinogens in it, it's not very well documented in terms of levels of exposure, many different types of work that went on. There's a high rate of respiratory and other illnesses that don't really track with the exposure measurements that were made, at least quantitatively. You have a limited time of follow-up so a full determination on what will be the disease experience for this population will go on for many years, 20, 30 years.

However, you know, Congress didn't ask -- expect you or the administrator to wait 20 or 30 years. They actually asked for an annual review of whether or not cancer was a World Trade Center-related condition and a determination and a report to be made on that by the administrator. And I think it's -- as you look at this evidence and make your scientific and medical evaluation of that evidence, I think it's important to put that in that context. You're making a determination on really whether or not a condition'll be covered for medical treatment in this program. And I think as we heard yesterday, we'll probably hear more tomorrow, that determination has significant consequences for the people in the program. We don't have a perfect healthcare system and as all of us -- you know, and many of you experience daily is that coverage is limited for many people, and there's an economic and personal hardship for people if this isn't covered. And that that should be -- the context should be simply is this -- should this be added? Should there be coverage provided given the process that's in place.

I think it's obvious you shouldn't -- you know, you're not going to be adding a condition that it's not possible for a physician to make that determination based on the evidence or something, so there's some rationale to it.

DR. MIDDENDORF: One minute.

DR. JIM MELIUS: I know I have one minute, yeah, to go, but at the same time I think it's a much different level of evidence than you would require for a IARC carcinogen or whatever, and it's hard; it's even hard for me, I know, thinking about this, I think possible-probable, I can of certain types of evidence. You know, and so forth that I think you have to think about this and approach this differently.

Finally just briefly I want to say one piece of advice I think -- and I appreciate the public comment period, I appreciate you adding more time. I think we're hoping for next time to be able to have some more convenient times for people coming in. The committee that I chair we do -- we allow people ten minutes, and we do that and, you know, sometimes people go on long but it's not for people like me 'cause I can probably try to tighten up what I say and get it in five minutes, but for the people that are affected by the program they need -- they really do, many of them

do need more time to explain. They don't know what you're looking for and it really does help them. And I'll end there.

DR. MIDDENDORF: Thank you very much. Our next commenter will be Michael Barasch.

MICHAEL BARASCH: Good morning everybody and thank you for the opportunity to speak this morning, and thank you for your time and volunteering on this committee. I'm an attorney and I'm with the firm of Barasch and McGarry. I'm proud to say that my firm represented Jimmy Zadroga, and we currently represent his little daughter and father. We've represented thousands of rescue workers at the first victim compensation fund in the subsequent years after, and currently thousands who are now in treatment and hoping to apply to the new victim compensation fund.

I'm very familiar with the respiratory illnesses sustained by the Ground Zero workers and for better or worse I get calls every day from guys and women afflicted with cancer.

This morning I have brought with me three of my clients. They have asked me to speak on their behalf. First, **[identifying information redacted]**, would you stand up, please? **[identifying information redacted]**. On September 11th John was 44 years old, living in Staten Island and an active member of the Ladder 103 in Brooklyn. He responded to the attacks and worked over 300 hours on the Pile. His boat from Staten Island that morning was one of the first to arrive as the towers fell. His group of firefighters dug out **[identifying information redacted]**, who was one of the few to survive the buildings' collapses.

Prior to September 11th John was very healthy and a nonsmoker. He currently suffers from chronic bronchitis, chronic cough and last September -- I'm sorry, September of 2010, he was diagnosed with non-Hodgkin's lymphoma.

He wants me to say that the cancer has taken an enormous psychological toll on his wife, his 11- and 13-year-old daughters, who have watched him sick and go through chemo. He's most scared of course of not knowing whether he'll be there to see his daughters grow up.

He wants you to know that notwithstanding his illness he's proud of his service and would do it all over again.

[identifying information redacted]. **[identifying information redacted]**? On September 11th, **[identifying information redacted]**was 47 years old and had retired three months beforehand. He had worked for the FDNY Engine 23 in Midtown. Selflessly he responded to the attacks before the first building collapsed, and he worked hundreds of hours at the Pile.

He's currently suffering severe reflux and leukemia and being treated at

Sloan-Kettering. Prior to September 11th, he was very healthy and a nonsmoker. He has a wife and two daughters, and he wants you to know that he, too, would do it all over again.

And **[identifying information redacted]**. On September 11th, **[identifying information redacted]**was 43 years old and an active member of Ladder 172 in Brooklyn. He responded to the attacks and worked 45 days on the Pile. Last year **[identifying information redacted]**was diagnosed with lung cancer. Recently he was devastated by the news that the cancer has spread to his brain and his spine. He knows that the chances of him being alive in five years are less than two percent, and prior to September 11th, he was a healthy individual and a nonsmoker.

Look, we all recognize that the risk of adding cancers to the victim compensation fund and to the treatment program are real. It will reduce the money available for care, treatment and compensation available to those who are suffering from respiratory illnesses which are already accepted as illnesses caused by the Trade Center dust. On the other hand, to wait another five years for indisputable proof of causal connection means that many of the rescue workers in this room or listening from their offices and homes, will not live to see the benefit of what seems to be a foregone and logical conclusion. With all due respect, I'd like to suggest that this committee accept what some of the experts, such as **[identifying information redacted]**and Prezant have opined. To wit, there is a high degree of certain that toxic dust exposure has and/or will cause cancer.

DR. MIDDENDORF: One minute, please.

MICHAEL BARASCH: I submit that at this time, at least for the rescue workers who were on the Pile, you should recommend immediately that the respiratory cancers, esophageal cancer, the blood cancers, thyroid and prostate cancers be recognized as being caused by the toxic World Trade Center exposures. Thank you.

DR. MIDDENDORF: Thank you very much. Ask our next commenter to come up, David Howley.

DAVID HOWLEY: That's an act to follow, good lord. Okay. Well, I'm going to be, I guess, the first police officer; I mean, everybody else was a fireman. Good morning, everybody. My name is David Howley, and I'm retired from the New York City Police Department.

A lot of this stuff is covered so I'm not going to try to make you hear all the same things, you know, two and three and four times, however many times people speak today. So I'm going to try to make this personal for you guys at your level, what you guys have to think about.

So the first thing is just real briefly about me. In 2006 after retiring, I was diagnosed with squamous cell, head and neck cancer. From that point on, first

oncologist told me basically I was dead and didn't know enough to die yet, and that's a true statement and you can look at my wife's face back there and I'm sure it's registering horror. The next doctor wanted to, because they didn't know where the primary was, because squamous cell only shows up with PET scans, they didn't know where the primary was; they couldn't find it. So next doctor wanted to cut me up into little pieces to try to find, and do biopsies everywhere, to try to find where this thing was 'cause it didn't show up. I've had two strokes and I was overdosed on chemotherapy once and almost died from that, too. Basically my doctors now call me the miracle patient 'cause none of them thought I'd be here. So, okay, well, I am and we're moving forward and we go from here. So let's put this in your guys' ballpark. You guys have been given a responsibility that should never have been put in your doorstep in the first place. There's no question about that. Cancer should have been in the original law. Congress people were told it should have been put in the original law, and they refused to do it. Why? God only knows about that one. But so here you are.

So you have to make the determination not only about the facts that are in front of you, which as the good lawyer said, you can't do with a hundred percent certainty because this kind of stuff, and a lot of you I know are doctors and researchers, and you're used to dealing with long studies and drawn out, clean sterile environments, you guys are used to working with them. Many of you are that I know. You don't have that here. You're not going to have that here; it's never going to happen, because the disaster itself was at such magnitude that there's nothing for you folks to compare it to. This is all brand new. Nothing of this size, scope, amount of concrete, glass, steel, toxins, dust, office equipment and everything else has never -- then burned at 3,000 degrees, has ever happened before in the history of mankind. So you can't go back and go, well, this happened in 1924. It's relatively close, let's compare and see what happened to those people. It was -- there's nothing to compare it to.

Our grandchildren, if we're lucky enough to have grandchildren, will wind up doing thesises (sic) on their own when they're going to medical school, and try to put all this together for us. And they may still not have 100-percent concrete answer. It's that, it's that bizarre what happened that day.

So you have to look at it as well, what's the best possible evidence that you have? What seems to be what's going to happen? So you really, the only wrong decision, as far as I can tell, I think it's pretty much a ground ball, is to go -- is to not do this. Because by not doing it, you're going to be slowing down the research or stopping the research; you're going to be stopping people from getting the treatments that they deserve, you're going to be stopping the families from getting the support that

they needed. And you also quite frankly have to be able to look in the mirror for yourselves and go, you know what, did I maybe not save somebody's life today or this person down the road and maybe today, maybe tomorrow may have died because they weren't able to get the treatment that they need.

I was very lucky, I had a great support system that I was able to get it, and I still went through hell. But I'm here. Other people might not be that lucky.

And last but not least, so I don't take up too much of your time, you guys also unfortunately have to look down the road. What if this hap -- we're basically fighting a world war. We're in the middle of a world war. We don't call it that but, being politically correct as we are this day we probably wouldn't, but if this was the 1940s, this would be considered a world war. And we're still there today. And you guys have to look and go, if this happens again, are those same first responders, guys like me, guys like these three firemen, guys like the fireman on the phone, are we going to go down there? Are the guys and girls that are out there on the street today gonna go down there and do the same thing? Ninety-eight percent of the people that were below the floors where the planes struck got out of that building alive. Will that happen again? It rests on your shoulders. Thank you very much and God bless you.

DR. MIDDENDORF: Thank you very much, Mr. Howley. Our next commenter is Michael Winter.

MICHAEL WINTER: Good morning. This is extremely difficult for me so I apologize in advance. I've been affected by post traumatic stress disorder due to September 11th.

On September 11th I was in charge of the operations control center at United Airlines. I was in the job to manage the people who were legally responsible, along with the captain, for every flight operated by that airline and every airline in this country. Every flight operated by U.S. airlines is required to have a licensed aircraft dispatcher managing the flight on the ground along with the captain in the air. The reason dispatcher is highly trained and licensed is they have to know the same thing as the airline captain does. Dispatchers take their job very seriously. I took the job of managing aircraft dispatchers for United Airlines very seriously.

Like most people I remember seeing the pictures of the hole in the side of the first twin tower hit. I knew it was not a small aircraft as they had reported on my commute to work on the radio.

I can still feel the impact of the second tower on my body as I stood and watched it on the overhead screen in the ops control center. There have been many times I wish I would have died on that day. It would have stopped the pain, the feeling of responsibility, the never-ending questioning of what we could have done

differently, what could we have said differently for the flight attendant that called from the back of Flight 93, telling us that the aircraft was in control of hijackers. The emotional numbness I feel while trying to be a good husband and father. The difficulty being with other people, the total loss of interest in doing things I used to enjoy. The nightmares and sleepless nights are too numerous to count anymore. Fortunately a small piece of me still wants to live and make a difference in the world. My therapists say it is possible for people with PTSD to recover to a point where they can function in the world but not without consistent treatment. I've had to pay for the treatment thus far out of my own pocket, as my wife's insurance plan does not cover mental health for family members.

I just want to read a couple excerpts from summaries written by my therapist and by the MD that diagnosed me with post-traumatic stress disorder. Michael Winter first presented with his wife, **[identifying information redacted]**, for family therapy on 1/15/2009; primarily presenting issue was children's symptoms. Secondary issues reported by **[identifying information redacted]** were multiple family problems related to changes in Michael's behavior that began in 2001 and continue to present. Michael's behavior changes that affected work relationships and lifestyle.

Michael had moved upward in his career until he reached a career path in April 2001, when he became the head of the flight dispatcher organization for United Airlines, overseeing approximately 300 employees. As a flight dispatch manager, Michael was present on the flight control floor and directly supervised the flight dispatcher who monitored two of the flights that were crashed by the terrorists on September 11th. During the hours that followed the first plane crash, Michael was at the center of United Airlines' response to the terrorist take-over of aircrafts. He encouraged the supervisors to get flights safely landed, helped draft a message to the flight crews in the air, warning of possible terrorist attacks.

By the way, the message from **[identifying information redacted]** to Flight 23 leaving JFK with six terrorists on the airplane was stopped before it got off the ground. Our messages were sent prior to anybody in the air traffic control system, and we stopped that flight from taking off. Michael was at his post helping to bring home the surviving planes and doing damage control for the company hit hard by terrorist attacks.

He continued to work for United Airlines, following 9/11 and initially responsible for reorganization and down-sizing directly related to 9/11. Gradually he was demoted until he resigned after sick leave was exhausted. **[identifying information redacted]** reported that the marriage had been very satisfying and life had been good up until then but constant changes in mood and the ability to deal without anyone locking himself in a room for days.

Michael's presenting symptoms include irritability, physically withdrawing from the outside world, lack of joy in daily living, panic attacks, moodiness, constant vigilance, emotionally withdrawing from his wife and children, avoidance of discussions involving 9/11, emotional numbing, memories intrusive sleep.

One other just comment -- well, actually this is the end of her letter. It says in my opinion that Michael Winter continues to suffer PTSD symptoms that are directly related to the events of his professional position responsibilities with the aircraft that were hijacked on that day. Michael was indeed a first responder on that date and a professional who stayed on duty to begin the remaining, the remaining airplanes home safely.

DR. MIDDENDORF: One minute, please.

MICHAEL WINTER: One minute? My final comment will be --

MATTHEW MCCAULEY: Mr. Moderator, I have -- I'm up next; I cede two minutes of my time to Mr. Winter.

DR. MIDDENDORF: No, you cannot cede.

MATTHEW MCCAULEY: Okay.

MICHAEL WINTER: Thank you. People on the ground that had not been directly involved in the terrorist attacks on that day are covered for PTSD, and my request is I be covered or just treated as a first responder. All I'm asking for is health benefits to get me back to living at least a somewhat normal life.

I'm lucky to be here. A lot of people as you know, don't make it through severe PTSD; they end up killing themselves because the pain is just too great. I know that a lot of people, you know, certainly the people that are there have been hurt, and I understand that, but I'm just asking for some compensation ben -- just for benefits and health benefits, not compensation.

DR. MIDDENDORF: Thank you very much. I do want to point out to our commenters that if there are additional -- there is additional information that you're able to present here while you're giving your public testimony, you do have the option of submitting to the docket, and any of the comments that come into the docket are shared with each of the members of the committee. So that's another way that you can get your information to the committee. Our next commenter is Matthew McCauley.

MATTHEW MCCAULEY: Good morning, ladies and gentlemen. Thank you for permitting me to address this panel. My name is Matthew McCauley. I'm an attorney with the law firm of Parker and Waichman, and we represent numerous health -- numerous first responders, many of whom suffer from cancer. Wasn't always a lawyer and I won't always be a lawyer. I started out as a New York City police officer and I will always be known as being retired from the job. I've also

been a paramedic for over 20 years, and it's what drives me to see through my clients' eyes because I was a first responder at the 1993 and at 2001 terrorist attacks. I'm one of the few attorneys you can say that they've seen the same things through their clients' eyes, as many of them have served beside me and also beyond me, beyond my days at the World Trade Center.

I come here to ask you to support the suggestion that at least certain cancers make it into the fund and for healthcare benefits. As you heard over the last two days, a lot of statistical issues that are there, trying to evaluate whether or not there have been reported cases or non-reported cases. Three people -- two people you heard from are out of state: **[identifying information redacted]** in North Carolina and **[identifying information redacted]** who came up from Chicago.

There are many others like them that I also represent, who have cancer. They're not counted because they came in from out of state, whether they be a member of a USAR team in Florida or Chicago or if they came in from Pennsylvania. If they fell outside the bell curve when the first reports came in and they're not part of organized labor, whether it be NYPD, FDNY or their brother and sister labor unions, many of them have fallen through the cracks because they went home. They came here to New York, they did their job, they supported everybody, and now they have cancer.

They went on about their lives, they continue to go on about their lives, but many of them need the healthcare benefits and the compensation that goes along with including this.

They should not be forgotten and I am here today because I represent many of them, some from California, some from Florida, some from Chicago. They were not part of the people who were accounted for. **[identifying information redacted]**, who testified yesterday, is not in the World Trade Center (unintelligible) fund because he has cancer. He was not counted.

He tried to contact them a few years back, they didn't take his information because he wasn't having any qualifying injury. **[identifying information redacted]** is the same way. **[identifying information redacted]** in Florida, USAR team, same way. These are gentlemen who didn't come in with thousands, they came in one out of seven, one out of ten, two out of eight. Small numbers of people who came in from fire departments, police departments and first responders from around the country to help us. They're not part of thousands of people. You know, they came in in small groups and yet their small groups have been affected, and they're not spoken for.

With that extent, I work in a world of data and Daubert and all these other standards when it comes to epidemiology, and epidemiology is a lot of things, but for epidemiology, as you all know, you need to have good studies, good bases,

good ideas that go behind them. The problem was that there's a lot of different conflicts that are there. And we have issues as to whether or not we'll ever have a substantial amount of epidemiology. But the one thing that I think the researchers on this board know is that absence of evidence is not evidence of absence. And it should go forward. There's enough support out there for it, there's enough information out there for it.

We could never conduct a study with all of these toxins put together. There would be no reason to and a study to mash everything together as far as one that has never been done and likely can never be done in that setting.

Please look to the people who were not accounted for. Similar to the way adverse events are looked at from drug companies, it's those that are not counted that are the most important. Underreporting is pervasive here.

I've also come in support of Michael Winter. Michael is an outlier. Michael's here looking for healthcare benefits. He is somebody who absolutely was involved in protecting the skies over everybody's head. He was absolutely involved in the actions that took place at the World Trade Center, at the Pentagon and at Shanksville. He should not be denied medical benefits because he wasn't physically within the confines.

DR. MIDDENDORF: One minute.

MATTHEW MCCAULEY: Okay. He was not --

DR. MIDDENDORF: Also please try to speak in the microphone.

MATTHEW MCCAULEY: He was not physically within the confines of what is defined there. He was there. He was at every single one of those locations, and I think that every fireman, every police officer who was on the ground the moments after it happened will tell you that they looked up ‘cause they were afraid. He was one of the people protecting them from above. He was one of the people clearing the air space. Do not leave him out. He should not be left out because a spectator -- sorry, a bystander who was in the Millennium Hotel, who was looking out the window and unfortunately may have PTSD, that person's qualified, that person is qualified. They were evacuated from the hotel, they left the scene. I feel sorry for that person, I really do, but Michael Winter is somebody who was involved in this. He does not fall under the guidelines of an exact first responder, that we all consider a first responder; he was there.

I just ask that you please include cancer into the qualified injuries and that there be some sort of mechanism to include the exceptional special circumstances like people like Michael Winter. Thank you very much.

DR. MIDDENDORF: Thank you, Mr. McCauley. Our next commenter is, excuse me, on the telephone, John Fassari. Are you there, Mr. Fassari?

JOHN FASSARI: Yes.
DR. MIDDENDORF: Okay. Go ahead and please begin.
JOHN FASSARI: Good morning. Thank you for taking my call. My name is John Fassari. I am a retired lieutenant from the New York City Fire Department. Operated at 9/11 for months, and I have to tell you that I have non-Hodgkin's lymphoma, a terminal cancer, something rare but also something that many of my fellow coworkers have gotten since operating at 9/11. And I just think that you need to hear that all of us, and many of my coworkers and friends that are not here today to make a telephone call or respond to this hearing because of the sicknesses and cancer that they had gotten and are no longer here.
I myself being somewhat lucky and still being here, I'm just only waiting now for the axe to drop. But I just had to respond to this and, you know, let anyone that is going to make this decision about cancer that I just can't tell you how many of my coworkers, friends and first responders have gotten sick.
Now, not only is it, you know, cancer and post-traumatic stress and all those other disorders that go with being sick, you know, it's a terrible thing, and I hope they reconsider and add cancers to the Zadroga Bill.
I know many families are looking for help and need help, and I hope in the future, and I hope that this conference will be strong enough to make the decision to help these families in need. And again, especially for the families that have, you know, lost their first responders, their dads, their moms, anybody else that operated there and is no longer there today.
New York City Fire Department chief medical officers believe that cancer is a big part of these guys being sick and I just wanted to let you know that, you know, we're sick and we're hanging in there. Thank you.
DR. MIDDENDORF: Thank you very much, Mr. Fassari. Our next commenter is Frank Tramontano.
FRANK TRAMONTANO: Good morning. My name is Frank Tramontano; I'm the research director for the New York City Patrolmen's Benevolence Association. Now more than ten years after the attack on the World Trade Center, this committee is searching for medical and scientific evidence to determine if cancer should be added as a covered illness for treatment under the James Zadroga Act.
There has only been one cancer study published to date, and other than some of the testimony heard here yesterday, there are no studies that analyzed the effect of the World Trade Center dust that was inhaled and ingested and its connection to cancers.
The testimony yesterday also revealed that there were no samples taken of the air for the first four days after the attack. So this committee has to decide on a cancer

petition with less than perfect information. There should have been more cancer studies and those that are about to come out, like the one **[identifying information redacted]** testified to this committee yesterday, has serious limitations.

It is mind boggling to me that the City of New York has not done more with the information they had regarding New York City police officers. On March 30, 2007, **[identifying information redacted]**, the then chief of staff of New York City deputy mayor, **[identifying information redacted]**, testified, and I quote, that the New York City Police Department did a particularly thorough job identifying who from their ranks responded to 9/11 or took part in the recovery and cleanup at the World Trade Center site.

Until yesterday, after days of getting beat up on this issue in the press, the City has finally agreed to release the data to Mt. Sinai. This is after denying them the information months earlier. If the City wanted to, we could have applied for research funds from NIOSH and hired staff and conducted an NYPD cancer study of its own. It is quite surprising this was not done, knowing that the City is constantly searching for ways to get more federal money.

The City has also failed to release its department of health cancer registry report. The report is not only late but it will also be severely limited since it has been closed to new registrants since 2004, and contains, according to our sources, only approximately 4,000 police officers. There were six to seven times that number of police officers who responded to the 9/11 rescue and recovery effort and were exposed to the horrific environmental conditions in and around Ground Zero.

Sadly the City of New York is not alone in its failures toward the 9/11 responders. The cancer study being released by -- shortly by Mt. Sinai Medical Center, which was briefly summarized yesterday by **[identifying information redacted]**, includes only those responders who are registered with the World Trade Center medical monitoring program, a program that doesn't treat cancer. We know of at least 70 police officers with cancer who should be in that study but are not.

As mentioned, there has been one study released on this issue. The past fall, the fire department published a study entitled, “Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks.” While that study demonstrated an increase in cancer rates among firefighter first responders, the study included an adjustment in the data to delay the date of diagnosis by two years. When taking this adjustment into account, the study would cover a period up until 2006, resulting in a period of time after the study being longer than the period actually covered by the study. Frankly I don't understand why this committee does not have an updated analysis from the fire department. It seems to me it would qualify as medical evidence.

As you know, the report did show a 32-percent higher cancer incident among exposed firefighters when compared to non-exposed firefighters before the adjustment.

DR. MIDDENDORF: One minute.

FRANK TRAMONTANO: The study also demonstrated an increase in incident of cancer for a later period after 9/11 when compared to a period immediately after the attacks, a trend that is likely to continue.

These are significant facts and along with some of the presentations yesterday represent scientific evidence that should be sufficient for this committee to support the addition of cancer as a covered illness. It clearly represents a higher evidence threshold than some other illnesses covered under the Zadroga Act.

But there is more evidence out there. Through the PBA's own cancer registry, we have recorded four nasal cancers when the annual rate of nasal cancer in New York State is .1 for every 100,000. There are approximately 30,000 police officers who filed a notice of participation with New York State, saying they worked at Ground Zero. The police pension fund has seen a rate of increase of more than three times the cancer accident disability applications since 2006. There would be more evidence to the City if others had done a better effort, but unfortunately they failed to do so.

Please do not make the responders with cancer suffer any more because of the lack of effort.

Finally I believe this committee must consider the financial implications of not recommending cancer. If you are like me and others in this room, and believe that there is just a matter of time before the scientific evidence unequivocally proves the cancer link for the sake of the financial implications or for the families of these responders, I beg you to recommend adding cancer as a covered illness.

In the end the treatment for this disease bankrupts families, even those with good medical plans. There are yearly medical spending caps and lifetime medical spending caps that for the responders -- for those responders that are lucky to survive with this disease wind up depleting their family assets. How can we in good conscience --

DR. MIDDENDORF: Your time is up.

FRANK TRAMONTANO: -- hesitate another day to add cancer to this list of illnesses when these selfless individuals do not hesitate a moment to the call of their duty. Thank you.

DR. MIDDENDORF: Thank you. Our next commenter is Keith LeBow.

KEITH LEBOW: Good morning ladies and gentlemen of the panel. My name is Keith LeBow. I am a sick World Trade Center first responder but I'm not here about

what's wrong with me today. I'm here to address the issue at hand, which is to add cancer to this act that we fought for. Excuse me.

Everyone knows and understands now that the dust of Ground Zero was toxic and contained many, many cancer-causing materials. Among them asbestos, hexavalent chromium 6, mercury and cadmium. These are not only cancer-causing but mutagenic as well, which means the cancer will be passed to future generations to come, mutating or changing as each new generation is born. Studies have been done, published but yet the fact of the matter is they are not being released to the people who need them the most.

The doctors who are working to figure out ways not to just deal with that, with what is wrong, but to heal us in the best ways that they can. Excuse me. Studies are fine for gathering data but to ignore the problem means that all the data in the world that you collect is worthless unless put to a good use. Now what I have right here in front of me is just a sample of what I was able to find online about this particular issue. To me that's great. It means to use this data means to save lives. That's the best thing in the world. We just need to -- you know, we just need better medical treatment.

What will it take to accept the fact that we were subjected to a very toxic environment with little or no protection at all? More deaths from various cancers? Cancers that normally take 20 to 30 years to manifest themselves are wiping out and have taken many people's lives in less than ten years. Many people need this to be added, especially people like construction workers who, unless they work, do not get paid, do not get benefits and have no way of paying for any of their treatments. To deny them this coverage means that once they are found to have cancer from the dust, must continue to work even though they are in dire need of this treatment; otherwise they must face mounting medical debt because they have no coverage. You don't work, you don't get paid, you are no longer covered. To ignore the obvious is to condemn many to horrible deaths.

Just imagine one day you wake up to find out yourself, your loved one or someone close to you has gotten cancer from breathing in toxic fumes at work. The doctors, as well as many others, know what caused them to develop cancer, but you were told that the studies must be done than to hear you were denied any kind of help necessary to help them.

You would want to move heaven and earth to do everything you could to save them, not only to have your pleas fall on deaf ears but just be denied completely. That is what is being done to us now.

So please, for the sake of sick and dying World Trade Center responders, victims, survivors and their families, please accept cancer as being a part of the Zadroga Act

so more do not pass on from it. Thank you very much for your time.

DR. MIDDENDORF: Thank you very much, Mr. LeBow. Our next commenter will be Tracy Conte.

TRACY CONTE: Good morning. My name is Tracy Conte and I am the daughter of retired FDNY Lieutenant **[identifying information redacted]**. My father worked at the Trade Center site for 16 consecutive days, sleeping inside of a body bag for a few hours at a time to escape the choking dust. He passed away on July 20, 2010, of the most aggressive case of metastasized prostate cancer that the oncologists and hematologists who treated him had ever seen in the history of their practice.

My father, Lieutenant **[identifying information redacted]**, developed the Trade Center cough right away and the lung issues. But there was no signs of cancer.

He remained active -- he retired in 2002 but remained healthy and active throughout his retirement, participating in his community, bringing a Memorial Day parade to his town after a 30-year hiatus, revitalizing the membership of his local American Legion, taking care of his grandchildren, taking care of his elderly neighbors.

On Memorial Day 2010, my father started experiencing back pain and difficulty breathing, and felt weak. By early July he was diagnosed with prostate cancer. Just five weeks after his symptoms appeared, he had lost 30 pounds, could barely walk and barely breathe. He entered the hospital on July 8, 2010, and what happened over the next 12 days was mind-numbing, like a freight train running out of control. His body stopped manufacturing blood, he received platelets and blood transfusion and still his blood oxygen level was dropping. The doctors could not figure out what to make of his advanced breathing difficulties and how his oxygen levels were dropping. They were scratching their heads, an entire team of doctors, all specialties.

A bone marrow biopsy uncovered that his marrow had been replaced by bad cells. The sample extracted during the biopsy was dust. His PSA score nearly doubled every 24 hours. Five days before he died it was 300. Four days before he died it was over 500. The day he died it was over 3,000 which was the highest score the doctors had ever seen.

Doctor after doctor told us that he was one of the sickest, if not the sickest, patient they had ever encountered in their careers. Every major system failed at the same time: lung, bone marrow, kidney, renal, heart. According to the doctors it was as though the cancer had bloomed throughout his body.

He had no family history, was the most aggressive case and was -- he was the sickest person that the doctors had treated and the doctors were scratching their heads. They had never seen anything like it. It was like a force had taken over.

The greatest human risk of exposure to the environment comes through our lungs, and if there is a shadow of question and an ounce of inconclusive evidence, then the commission needs to do the right thing. Cancer needs to be included in this bill, and I don't know why any compassionate person would choose not to. My family suffered the premature and sudden loss of a loving husband, father, grandfather, a man who always gave to his family, his community, the FDNY, the citizens, not only of New York City but anywhere he went, and his gift to all of you was that he risked his life every day to save yours, not just when he was at work but every living day. And just as every first responder does.

To exclude an entire group of people, people who showed up to help, based on a technicality that they didn't have the good fortune to come down with the right illness related to the World Trade Center would just be a sin. I urge you to reflect upon the choice that you make here and to include cancer in this bill. The amount of funds that have been allocated is the amount of funds. That will not change. So do the right thing, please, and that is to include cancer in this bill. Thank you.

DR. MIDDENDORF: Thank you very much. Our next commenter is Collin Ecosta (ph). Mr. Ecosta, are you on the phone per chance?

(no response)

Okay. If he happens to come in, we have a little bit of time at the end, we can move him to that time period. We'll move on then, and the next person is Mr. Alonzo Harris.

ALONZO HARRIS: Good morning everyone. My name is Police Officer Alonzo Harris. I was a first responder on 9/11.

Today I want to take you back to 9/11 and what it was like. I was a first responder when the plane hit on the building -- hit the first building. I also was there when a plane hit the second building. After being tumbled and buried under a car, I made my way back to my precinct and then I was taken to Bellevue Hospital. But the reason I'm here today is I wanted to express and show the panel what it was like. I have something very significant today for all of the thousands of first responders that responded here, and this is the uniform that has been tested by **[identifying information redacted]** who yesterday was here and he showed you some examples, I would like to bring out the uniform. I don't want nobody to get scared of anything; it's sealed. But I just want you to know what it is like for the first responders, the firemen, the policemen, all the city workers who was down there, what they accept and this is what it is. This is what they exposed to.

When I got home on that tragic night, I just sat back, my body was full of -- it was like I was full of an electric person 'cause when the building, the second tower came down, my whole body was just electric. So I said, you know, this is not good.

Let me put this uniform up. I put it in the bottom of my closet and I was going to put a harsh memory, a damp, damp, memory away. And I stayed home for like a week and a half.

After several years, one of my good partners, her name was **[identifying information redacted]**, she worked in PSA 5, she succumbed to cancer at Sloan-Kettering Hospital. And last year I said you know what, we got something, I'm going to reach out to this doctor, **[identifying information redacted]**, who's been doing scientific study down there, and give him this uniform just so he can test it and see what's going on, with a lot of people who has been diagnosed with this.

This was a vehicle, this is a vehicle on how and what people were facing. Can I pass it around? This is not a do-right or do-wrong situation to the first responders; this is a life-or-death situation for the first responders. That's why you see so many of -- that's why you see so many of the police and firemen and all the other city workers and first responders coming down here to support this situation.

I'm not going to take up a lot of time. It's very emotional. I have been also diagnosed with asthma today but it could be cancer tomorrow. I just implore you that could have been your husband or your wife, your son or your daughter, your child, your family member. This is a real surreal situation. This is why I want you to bring -- I brought in the uniforms. Just imagine you being down there, you on the panel being down there, succumbing to all this smoke, this dust, covered in this. And now ten years later, we here to fight for putting one thing on the bill. The right thing to do is to add cancer into the bill. Thank you so much.

DR. MIDDENDORF: Thank you very much, Mr. Harris. Mr. Harris? Is it possible to get a copy of this photograph that you're sharing with the committee?

ALONZO HARRIS: Yes, it is. Sure.

DR. MIDDENDORF: If you could send it to me by email or whatever, I would appreciate it.

ALONZO HARRIS: All right.

DR. MIDDENDORF: The reason I need it is that we need to be able to put it into the docket.

ALONZO HARRIS: Can I walk around with the uniform so they can just see -- for you guys to see, if who wants to see it, they can see it --

DR. MIDDENDORF: Sure. Sure, go ahead.

ALONZO HARRIS: -- on a close-up basis.

(pause)

DR. MIDDENDORF: Thank you very much, Mr. Harris.

Our next presenter is on the phone. Ken Zevekus (ph). Mr. Zevekus, are you on the phone? If you are, please unmute it.

KEN ZEVEKUS: Yes, can you hear me?
DR. MIDDENDORF: Yes, we can hear you now.
KEN ZEVEKUS: Okay. Good morning. Thanks for giving me the opportunity to speak to you, today. I'm a retired New York City chief officer. I was there on 9/11, and I would like to share something with you. I don't know how old the panel is but I'd like to give you some new information that you may not be aware of.
Ironically in 11 more days it will be the 37th year anniversary of the infamous telephone company fire in New York. Over 440 of my brothers responded to that fire that day, and within five days of that fire, roughly 200 of them had chest pains, couldn't breathe, all other types of respiratory maladies. And approximately ten to 15 years after that, half of that number, roughly 100 of those guys, were dead from cancer.
Now in the ensuing years, through the federal government and various OSHA and NIOSH programs, it was determined that there was -- this was our first exposure to a hazardous material, polyvinyl chloride, and in the early 90s, some other unique information was discovered that the New York City Fire Department had the highest cancer rate in the nation -- in the world, because we responded to the most amounts of incidents and fires that any city that would ever have.
I was part of a small group; I was part of 14 unique individuals who were given over 225 hours of training, brought up to what they called the technician level; and it was our job to transmit to first responders: police, fire, all first responders, military, that the exposures that we were likely to have at chemical fires, hazardous material fires, things like that, never thinking that ten years later, roughly 2001, it would be deja vu; it would be all over.
You talk about going numb? The second that plane hit I knew what was going to happen because I knew every single one of us who were going to be there, all the firemen, all the cops, all the innocent bystanders who got caught up in that whirlwind, that we were going to become a new panel of statistics, and sure enough, just like at that World Trade Center -- I'm sorry, the telephone company fire, approximately ten years after that fire, all of a sudden this stuff starts to manifest itself again.
I don't know why it's taking a brain surgeon or a nuclear physicist to even think about that that cancer didn't come because of what we all were exposed to on that date. I think it's criminal; I think it's immoral for anybody not to admit that, that that's a possibility.
We didn't go there because we were getting paid. We were professionals, we were highly motivated, we were motivated to save human life, something that only God, I was brought up, could do. But we were trying to be like God that day and we

were trying to save as many of our fellow citizens as we could.

And a lot of us now are starting to pay the price for that. I'm asking that you, I'm asking that governments, municipalities, whoever, step up and do the right thing now for us, like we did the right thing for you on that day. Thank you.

DR. MIDDENDORF: Thank you very much, Mr. Zevekus. Our next commenter is also on the telephone, Victoria Gilles (ph). Ms. Gilles, if you're there, please unmute.

VICTORIA GILLES: Yes, good morning.

DR. MIDDENDORF: Morning.

VICTORIA GILLES: I'm a good will ambassador from Washington State, and after 9/11 I did, with the Seattle Benevolence Association, I did a big event raising $50,000 for the widows' and children's fund for the FDNY. Deputy Chief Nick Visconti, at the time, attended that, along with Assistant to Chief of Department, **[identifying information redacted]**, who died on 9/11, **[identifying information redacted]**, attended this event.

After we had raised the money I took the check back to New York City. I visited a lot of stations, seeing a lot of the memorials, listening to a lot of stories from a lot of the men and women that were telling me about their brothers and sisters that were lost. A lot of the men would say to me, would -- they're not going to remember us. They're going to forget. And I would say to them, who could ever forget this? Who could ever forget this tragedy? But they believed that they would be forgotten. In April of last year when bin Laden was caught, on the day he was caught, my friend, **[identifying information redacted]**, when I talked to him on the phone, had told me he was diagnosed with esophageal cancer. His comments to me were: I'm a Vietnam vet, 9/11 vet, I watched my best friend die on 9/11, and I took care of his kids from there on out, they lived across the street from me. This is what it comes to for me at 58 years old, this is what it comes to my brothers and sisters that are dying in record numbers.

I made a promise to him, that his government did care. And he kept saying they don't care. They don't care about us. I said I will help you with whatever I can. He sent me a newspaper article that was telling me about the James Zadroga Bill. He asked for my help. He said, I will be dead in two months, Vicky. But whatever you can do to help me and to help my brothers and sisters that this is going to happen to, because rest assured it's going to happen, would you please do it? I said absolutely, I will do what I can.

I am married to a first responder, to an incident commander, who, as he watched the World Trade Centers come down, as we all did on that horrific day, kept saying to me, where's the respirators? Where are the respirators? Why do they not have

respirators on? There were very few people wearing those respirators in that toxic dust. Of those towers that were built in the 1960s, that it was obvious that with asbestos and everything else that was going on, there was going to be problems later.

The U.S. needs to take care of their own. I wrote letters to 14 senators and congressmen. Senator Steve Hobbs, from Washington State, is the only one that spoke up. He sent letters to U.S. Congressman Adam Smith, who spoke up and has been letting me know what they're -- what they've been doing since then.

It is shameful as people from the United States that we are not taking care of our own, our own heroes, when we take care of everybody else out there. It is shameful it's been ten years. It is shameful that politicians went to bat for the James Zadroga Bill, which had to do with cancer, and then took cancer out of the bill.

First responders are not meant to go to war. They are meant to save lives in fires and accidents and things like that, but not war. We owe it to them as our heroes to do the right thing. Do we actually expect, as a police officer before me said, for them to go back into anything that might happen, and with terrorist attacks happening right now around the world, this could happen again in the State of Washington. Does it need to happen in our own back yard before we get the big picture? Do we actually expect them to go back into buildings such as the World Trade Center, the Pentagon, whatever, and do the same thing over again, when we are not taking care of them?

I want to say to the people on the phone, I understand what you're going through. My husband and I care. We care. There are people that care. And we will fight this until something is done. We are not going away. Thank you.

DR. MIDDENDORF: Thank you very much, Ms. Gilles. Our next commenter is Stephen Levin. Okay, I don't see him here. You don't happen to be on the phone, do you, Mr. Levin? Okay. Again, I'll move him to the back of the list and then we'll call on him to see if he happens to show up.

So we'll go to the telephone again. Eric Ashlie. Mr. Ashlie, are you on the line?

ERIC ASHLIE: Yes.

DR. MIDDENDORF: Okay.

ERIC ASHLIE: Can you hear me?

DR. MIDDENDORF: Yes, we can hear you.

ERIC ASHLIE: All right, thank you. My name is Eric Ashlie, and I'm calling today on behalf of Washington State Senator Steve Hobbs. First I wanted to thank the committee for allowing testimony on this matter. It's extremely important and I appreciate that. More importantly, thank you so much to those of you that have

testified before me yesterday and today.

Those who were at Ground Zero on the front lines over ten years ago deserve more than what Congress has offered them in the current legislation. The first responders of 9/11 are America's most courageous men and women. Victoria Gilles, who just spoke, came to us back in August and said, she basically said exactly what she just said to us, and we were astounded that cancer had been taken out. While I understand that the first review that came out did not establish presumption of cancer, since then we have seen a series of studies that do so. Now is the time for the committee to recognize this opportunity and recognize the men and women who were brave enough to step up for their country -- for our country, back on September 11th. I know there are a lot of people that want to testify today so I'm going to keep it short, and we've already provided written testimony. God bless all of those of you that have been part of this experience and have family and friends that have been affected. Thank you so much. That's all I have.

DR. MIDDENDORF: Okay. Thank you very much, Mr. Ashlie.

Our next commenter is Esther Regelson.

ESTHER REGELSON: Hi. My name is Esther Regelson, and I live three blocks south of the World Trade Center site. I was caught in the dust cloud on September 11th and moved back into my apartment five months later.

The EPA conducted no testing or cleanup of our building, although it said it was contaminated. To this day I am uncertain to what degree my apartment and the rest of my building were cleaned of the World Trade Center dust, raising concerns about further exposures long after the events of 9/11.

Although I had preexisting asthma, my asthma worsened significantly after 9/11. Subsequent tests at the World Trade Center Environmental Health Center showed that my lung capacity was only 43 percent of normal. Thankfully that capacity has increased due to the specialized treatment that I have received at the WTC EHC.

I'm a member of the World Trade Center Health Program survivor steering committee. And on behalf of the committee, I would like to summarize our ideas regarding NIOSH's WTC research approach and priorities. The survivor steering committee plays an advisory role in the administration of the survivor health program, and represents the community of affected non-responder WTC stakeholders.

First, there are a wide range of knowledge gaps with respect to science, biology and treatment of WTC-related illnesses. NIOSH should close these gaps by supporting a diverse portfolio of studies at different levels of funding that includes pilot studies, clinical trials, studies of disease mechanisms, epidemiological studies and basic science research. We urge the creation of key resources that are useful to multiple

investigators.

Second, NIOSH should encourage and fund proposals that address health effects to survivors as well as responders. Studies of survivor populations should address health effects on those living, working and attending school in the impact zone defined by the Zadroga Act and represent the diverse populations and geographic areas affected. Wherever feasible, cancer incident studies must include survivors as well as responders.

Third, NIOSH should recognize that WTC research is disaster science. Especially with respect to the survivor community, researchers are operating in the absence of preexisting baseline data or comprehensive environmental measurements from which to assess exposures. These limitations must not become an insurmountable barrier to meeting the health needs of 9/11 survivors.

Fourth, NIOSH should encourage researchers committed to collaborating with affected communities, using a community-based participatory research or CBPR model for their studies. The benefits of the CP -- BPR model are well established.

Fifth, NIOSH must strengthen the surveillance function of the data centers to gather and analyze data in a timely fashion. Otherwise there is little chance that important trends, including the emergence of new conditions, will be recognized.

Sixth, NIOSH should ensure that all research proposals receive proper peer review by including appropriate specialists. We also have the following recommendations regarding WTC Health Program research priorities for the survivor population: one, given children's increased susceptibility to harm, especially in critical periods of development, it is imperative that NIOSH move quickly to support in-depth studies of respiratory, developmental and endocrine health impacts for this rapidly dispersing cohort; two, we recommend that blood samples be collected from WTC-exposed children and preserved for later analysis including the freezing of live cells containing genetic markers. These samples could prove useful in at least three ways: as potential source of biomarkers for exposure to WTC toxics, as a source of protein markers of disease with potential use in diagnosing and understanding WTC-related illness, and as a source of genetic material which can be analyzed for evidence of genetic alterations relevant to disease that may be detected many years after exposure.

Strong protocols to protect privacy of all data must be developed in consultation with the survivor steering committee.

Three, because so little is known with respect to inflammation and other underlying mechanisms for WTC illness such as sarcoidosis, cancer and asthma, it is critical that NIOSH support studies of disease mechanisms.

DR. MIDDENDORF: One minute, please.

ESTHER REGELSON: I'm almost done. Four, cancer incidence and prevalence must be tracked across all WTC populations.

And five, last, in addition to -- in an analysis of WTC EHC patients, 60 percent screen positive for mental health condition, 40 percent of whom had symptoms of PTSD, anxiety and/or depression. Those with lower respiratory problems seem particularly vulnerable.

There is a growing literature on the impact of parental PTSD and depression on children's mood, anxiety and behavior, including one study among 9/11 survivors. It would therefore be valuable to investigate the impact of parental mental health disorders on their children's mental health as well as children's mental health on their parents. This would provide essential information about the intergenerational transmission of mental illness after a terrorist attack. A version of these comments has been submitted by our committee co-chairs to the NIOSH docket. On behalf of the committee, thank you for your time.

DR. MIDDENDORF: Thank you very much. Next commenter is Fred Krines.

FRED KRINES: Good morning. My name is Fred Krines; I'm employed by the New York City Police Department. On September 11, 2001, as the disaster occurred at the World Trade Center, I was one of the first responders, thereafter as a volunteer. Me and my coworkers responded over there without hesitation. We dug through the piles and thereafter that I also was ordered to go over there.

2010 of June, I was diagnosed with follicular dendritic cell sarcoma, a very rare cancer. (Indiscernible)-wise, there's 50 of them in this world today. I had a radical (inaudible)-section performed June 2010 with (indiscernible) treatment after that, chemotherapy and 45 days of radiation. I'm asking you to add cancers in the bill for medical treatment.

I was very lucky that the doctors caught this on time, and they performed surgery. 'Cause if it wasn't, I would have been dead today. And that's all I want to say.

UNIDENTIFIED SPEAKER: I couldn't hear what kind of cancer it was.

FRED KRINES: Follicular dendritic cell sarcoma.

UNIDENTIFIED SPEAKER: I don't know what that is.

FRED KRINES: It's a very rare cancer; there's maybe 50 of it known worldwide. I have documentation over here for it, if you want to see it. And it's just, like the doctor said, it's just I have to go for PET scans every six months because it's a rare cancer that nobody knows about. I just want to have the doctors of the panel over here just to recommend cancers in -- when they go in front of Congress next month so people could have a chance to live. Thank you.

DR. MIDDENDORF: Thank you very much. Micki Siegel de Hernandez.

MICKI SIEGEL DE HERNANDEZ: Good morning. My name is Micki Siegel de

Hernandez, I'm the health and safety director for the Communications Workers of America; we represent mostly nontraditional responders as well as area workers.

I wanted to make a few comments about the Sinai study results that were reported on yesterday by Dr. Landrigan, particularly for those of you on the panel who are still wedded to the idea that epidemiological studies are the ultimate proof needed to add cancer as a covered condition.

I wanted to comment on the ways in which these studies, lake the Sinai study, are an underestimate and an undercount of the true rates of cancers.

When I consider these limitations, it makes the Sinai analysis and their results even more striking. For one, the results are for a portion of responders, not the entire group of responders, the true number of which is actually unknown. As you heard testimony today, none of the national -- the thousands of national responders are included in any of these studies. And this is especially important with regard to rarer cancers, but certainly for all.

The results are also based upon patient matches with cancer registries, the Sinai results. The New York State Cancer Registry has a two-year lag time. The New York State Cancer Registry -- in other words, the more recent, these past two years, cancer cases reported to the New York State Cancer Registry, would not be counted in the Sinai results.

The New York State Cancer Registry is also better at capturing certain cancers, solid tumors, less so for others. Blood cancers, one of the World Trade Center cancers of concern, most concern, are less likely to be reported and counted in the New York State Cancer Registry.

Fourth, as other commenters have talked about today, many responders with cancer are not part of the World Trade Center Health Program for many, many reasons. When I speak to our union members with cancer, and there are many, some of which with multiple cancers in addition to their other World Trade Center-related disease, I always ask if they are a patient in the World Trade Center Health Program and if not, why. These are the two most common reasons for nonparticipation: first, obviously when a person has cancer, their life is consumed by their disease and their treatments. The World Trade Center Health Program does not currently cover cancer and so many people see no reason to be part of the program. And to go for more doctor visits on top of what they are already dealing with in their lives.

The second reason for nonparticipation for many people is that they are just plain angry, and understandably so, that their diseases have not yet been recognized and covered in the program, and they refuse to participate for that reason alone.

Finally, I would like to comment about the selection of certain cancers, and I worry

about cherry-picking which cancers to include given the incredible range of carcinogens and other contaminants that people were exposed to. This would be a huge disservice to those people who were simply unlucky enough to get the wrong cancer at this time, like the gentleman who just testified. It also worries me because it is hard to imagine a way in which additional cancers, one by one, especially rarer cancers, will ever get added to this list unless record number of responders and others contract a particular disease, get sick and die.

As Dr. Melius said earlier, your decision is ultimately about enabling those affected to receive care to get that care. I personally would rather fight for adequate funding for both the World Trade Center Health Program and the victims' compensation fund than exclude those deserving of this care. I hope you keep all these things in mind today as you deliberate. Thank you.

DR. MIDDENDORF: Thank you very much. Bill DeBlaiso? Apparently he was held up downstairs. We'll move him to the back of the line again. Jo Polett?

JO POLETT: My name is Jo Polett, and I live at 105 Duane (microphone issues). How's this? Okay. My name is Jo Polett, and I live at 105 Duane Street, a 52-story high-rise located seven blocks north of the World Trade Center site. Constructed in 1990, the building has no asbestos-containing material.

Yesterday we heard panelists and members of the public note the disconnect between reassuring government sampling results and the health effects of many of those exposed to World Trade Center dust and smoke. The 2002 ATSDR NYC DOH final technical report of the public health investigation to assess potential exposures in settled surface dust in residential areas of lower Manhattan. A good example of that disconnect is cited on page one of the NIOSH February 2012 WTC OPC document prepared for this committee.

I'm concerned that someone hoping to learn something about residential exposures might read the ATSDR NYC DOH study, so I'll spend a few minutes telling you what I know about it.

In November and December of 2001, ATSDR NYC DOH sampled in and around 30 residential buildings for asbestos, SVF and mineral components of concrete and building wallboard.

You may recall that at the last meeting of this committee I provided you with asbestos and lead sampling results from my building. I'll quickly reprise some of the asbestos results. On December 3rd, 2001, CIH sampled the supply air diffuser on the tenth floor, sample was collected by MicroVac and analyzed by TM for asbestos. The sample tested positive for asbestos at a level of 550,000 structures per square centimeter; that's 50 to 500 times above expected background.

Additional subsequent sampling of the entry door frame of a fifth-floor apartment

yielded a result of 123 asbestos structures per square centimeter, indicating that the ventilation system was circulating asbestos through hallways and into apartments, sampling of the fan coil unit of the living room heating and air conditioning in that unit yielded a result of 37,000 asbestos structures per square centimeter. Not only was my building one of the 30 buildings sampled by ATSDR NYC DOH for their study, but the fifth floor apartment, the results I just cited, was one of the two residences in the building that was sampled.

Yet according to the ATSDR NYC DOH report, no asbestos was found in the common areas of the building or in either of the apartments that were sampled. How is that possible?

According to the comments of **[identifying information redacted]**, an asbestos expert who reviewed the study when he served on the peer review committee for EPA's exposure in human health evaluation paper in 2003, quote, I think that asbestos was likely present in all of the bulk samples collected and that the failure to detect asbestos in many of the indoor settled dust samples or the outdoor samples was a question of deficiencies in either the analytical method or the conduct of the method.

So what was the purpose of conducting such sloppy sampling? Well, we were informed of these results in January of 2002, during a dispute with the landlord about whether and how to clean the ventilation system.

DR. MIDDENDORF: One minute, please.

JO POLETT: A letter from New York City Department of Health, stating that there was no asbestos at 105 Duane Street was distributed to every tenant in the building along with a 105 Duane Street fact sheet compiled by the New York City Department of Health, disputing the validity of our finding and condoning the landlord's plan to use a company that was not certified in asbestos and had never cleaned a tall building to clean the ventilation system. I mean, this looks pretty innocuous. Here's the study but this study, like the EPA sampling results, were weaponized and used against us when we tried to make our building safe for habitation. Thank you.

DR. MIDDENDORF: Thank you very much. The next presenter is Jewell Bachrach.

JEWELL BACHRACH: Good morning. I'm Jewell Bachrach. Can you here me? I live at 18 North Moore Street, which is the northern end of the accepted community that has -- is supposed to get response by government forces. I've lived the majority of my years down here -- lived and worked. I've lived here since 1968 of -- when the -- however, when the report came in after analyzing my apartment, it had asbestos, and now to -- and two years ago I was operated on for lung cancer, although I have lived a very healthy lifestyle. I never smoked in my life.

One of the problems is no one's ever cleaned, even though it's supposed to be the area which all this debris has fallen and which you know to be really serious problem -- no one's ever cleaned the outside of the buildings. I don't know what's happened in 2012. I bet you could find something now. I mean, even though I live a half a mile away, they found, they found asbestos and I mean, it shocked me that I have -- that I had lung cancer. It was luckily caught comparatively early. But I'm constantly bombarded with radiation because they need to take tests every few months to find out if I'm still clean. You know, I'd like some other way to die. I'm going to be 80 and I want to live a little longer.

I really think cancers should be considered one of the problems here, since that should not have been a reason for me to die. I mean, I haven't lived a life like that. Please, please do consider it. You've had very excellent people who have come up here, who have really analyzed the situation and where -- it's -- where -- further work could be done. That's fine. But no one in this operation knows that I had cancer. It was just lucky -- I mean, I was just lucky in that since I was more than 65, God bless Medicare, had paid for it.

One week in the hospital cost the federal government for me $92,000, and yet the only medication that I got, that I asked for was a vitamin pill and a stool softener plus a little numbing of my nerve endings after the operation. That's all I got. And the bill was $92,000. You know, come on, help. Thank you.

DR. MIDDENDORF: Thank you very much, Ms. Bachrach. Our next commenter is Bill DeBlaiso. Apparently he's downstairs in line and trying to come up. How about Collin Ecosta? Or Stephen Levin? Mr. DeBlaiso?

BILL DEBLAISO: Thank you very much. Thank you for the opportunity to speak before you today. I'm sorry I'm running a few minutes late, I'll be brief. Good morning to everyone and I'd like to thank the committee for addressing the critical issue of adding cancer to the list of World Trade Center-related health conditions as specified in the Zadroga Act.

As public advocate for the City of New York, I am reminded regularly of the horrors of September 11th, 2001, and the tragedy brought upon our city. Unfortunately many of our men and women who served as first responders on 9/11 and in its aftermath remember that day for a far different reason. They are currently suffering from cancer as a result of the toxins that were exposed to -- that they were exposed to during the recovery and cleanup operations.

Mt. Sinai Medical Center has treated thousands of first responders and it's conducted extensive research into the connection between illnesses these individuals have developed and their exposure to toxins at Ground Zero. I recently called on the City to provide Mt. Sinai with all available information regarding New

York City police officers who served at Ground Zero and subsequently developed cancer. But while the City obfuscates, these individuals suffer, and even more fear the day when they may be diagnosed further.

When the planes struck our city on 9/11, these brave men and women answered the call of duty, never once pausing to think about long-term health implications. In the days and weeks following 9/11 many of these first responders continued to work around Ground Zero and at the Fresh Kills Landfill, breathing in the toxins that cause their suffering today. They worked in difficult conditions surrounded by a cloud of dust that contained known carcinogens such as asbestos, benzene and dioxin. Any of these elements on their own would be extremely dangerous; mixed together in the air, they have proven deadly.

Research by the New York City Fire Department has found a 19-percent higher cancer rate among FDNY members who had been at Ground Zero than among those who had not. Mt. Sinai has already found four cases of multiple myeloma among responders under age 45, an extremely young age for diagnosis. Just recently cancer-causing toxins were found on the uniform of **[identifying information redacted]**, who survived being buried in the World Trade Center debris on 9/11.

I understand the purpose of this committee is to review scientific and technical information in order to make a recommendation to the administrator of the World Trade Center Health Program, yet common sense shows us the suffering is real. These individuals are struggling and dying of cancer right now.

The Patrolmen's Benevolence Association has found at least 297 officers who served in the World Trade Center operations have been stricken with cancer. Another 66 have died of cancer since 9/11. Before September 11th, 2001, an average of six police officers per year were diagnosed with cancer, so again, 297 officers have been stricken since 9/11, 66 have died. Previous to that an average of six police officers a year were diagnosed with cancer. Ever since the attacks an average of 16 police officers a year are now diagnosed with cancer, constituting an increase of nearly 300 percent.

The NYPD lost 23 officers on September 11th, 2001, but even more have given their lives since that tragic day as a result of cancer they developed in the aftermath of the attacks. Take the story of **[identifying information redacted]**. Officer **[identifying information redacted]**, a native of Mount Vernon, spent over 200 hours down at Ground Zero, working 12-hour shifts, breathing in toxic air that we know was filled with carcinogens. In 2007, while in his early 40s, **[identifying information redacted]** was diagnosed with a stage IV flat skin tumor, which is a cancer of the bile duct.

DR. MIDDENDORF: One minute, please.

BILL DEBLAISO: This is an extremely rare form of cancer that usually develops in

patients older than 65. Officer **[identifying information redacted]** had no history of cancer in his family. The only known risk factor he had for developing this rare type of cancer was exposure to toxins, including asbestos and dioxin, which were present in the air, dust and debris at Ground Zero.

As Officer **[identifying information redacted]** fought for his life, he also advocated for the passage of the Zadroga Act with specific inclusion of certain types of cancer on the list of World Trade Center-related health conditions. Sadly, he lost both fights. But here today you can right -- at least right one of these wrongs by recommending that cancer be added to the list of World Trade Center-related health conditions so that every first responder suffering from these rare cancers, can get the help and support that Officer **[identifying information redacted]** never had the chance to receive. Please don't let his story get lost in your analysis because the City refuses to turn over all of the necessary data for this study.

That our first responders are suffering without needed medical care is outrageous and shameful. As their advocate, I strongly urge you to include cancer under the James Zadroga Health and Compensation Act. Thank you very much.

DR. MIDDENDORF: Thank you very much. Mr. Levin?

STEPHEN LEVIN: Thank you very much, members of the committee, for the opportunity to testify before you this morning. In the interest of allowing frankly more important testimony this morning from first responders and professionals, I am going to keep my remarks very brief.

My name is Stephen Levin, I am a council member for the 33rd district in Brooklyn, and I am here today to strongly urge you to include at the very least some cancers, including but not limited to blood cancers, including leukemia, lymphoma and myeloma, nasal cancers, thyroid cancer and prostate cancer. And for those currently that -- and those cancers that currently meet less of an evidentiary standard, that this committee continue to study them very closely.

From the testimony that you have heard over the past day, the anecdotal evidence is absolutely overwhelming and in my opinion indisputable, that certain cancers are linked to work at Ground Zero. However, I believe that this committee is beginning to see clear scientific evidence emerge that even more firmly establishes that link.

I serve on the Lower Manhattan Redevelopment Committee on the City Council. Two and a half weeks ago, we held a hearing on the 2011 report of the New York City World Trade Center Medical Working Group. Frankly I found this report and the Bloomberg administration's answers to my questions to be very frustrating.

The report says, quote, the first World Trade Center cancer risk study to be published found that firefighters with World Trade Center exposures may be at a greater risk for cancer than firefighters who weren't exposed. I call that the

understatement of the year considering that the FDNY report found a 19- to 30-percent increase in cancer among firefighters who served at Ground Zero.

In response to my questions about how many studies would be needed to establish a scientific link strong enough for this committee to proceed with covering cancer, **[identifying information redacted]**, Deputy Commissioner of Epidemiology at New York City Department of Health, demurred.

While yesterday this committee heard some preliminary results from **[identifying information redacted]** of Mt. Sinai on their study -- on their World Trade Center Health -- their study of the World Trade Center Health Program, showing a 14-percent increase among a broad range of cancers. The question I ask is when is enough evidence enough?

I found his challenge to this committee to be particularly appropriate. And I won't try to paraphrase but I will put my own spin on it.

Knowing that you will never in many years achieve a 100-percent ironclad proof from epidemiological perspective of a Ground Zero to cancer link, when does this committee make the judgment based on overwhelming anecdotal evidence, a growing number of medical studies, and just plain old common sense, to vote to have certain types of cancers covered under the Zadroga Act, in accordance, I believe, with the intent and spirit of the legislation? I believe that that time is now and that this committee should listen not only to all of the growing evidence but also to its collective conscience. If you do not act, for far too many, justice delayed will be justice denied. Thank you very much for the opportunity to testify.

DR. MIDDENDORF: Thank you very much. One last call for **[identifying information redacted]** ? Apparently **[identifying information redacted]**has decided not to provide his comments.

On behalf of the committee, let me thank each and every one of the public commenters of today and yesterday, both here in person and on the phone, and also those who have submitted their written comments. It really does provide the committee with a very different perspective than they can get from just reading the literature and I think it's, I think, very beneficial for them, so we very much appreciate you taking the time and effort to come and present your perspectives to them.

DR. WARD: Thank you. So at this point we'll take a 15-minute recess and be back promptly. We'll be back promptly at 10:40. Thank you.

(Recess taken 10:25 a.m. until 10:53 a.m.)

DISCUSSION OF PETITION ON CANCER

DISCUSSION OF PETITION ON CANCER

DR. WARD: So Paul is going to call the roll and then we are going to --

DR. MIDDENDORF: I'll just make a note of it.
DR. WARD: Or just make a note of it; and then Paul wants to say a few words about our overall charge and perspective.
DR. MIDDENDORF: Okay, I think as we begin to really think about the issue before us as to whether or not to add canc -- or make any recommendations or provide advice to add cancer or a specific type of cancer, make that recommendation to the program administrator, we need to know a little bit about what the needs of the administrator are.
It's important to recognize that whatever decision the committee makes and whatever recommendation it makes to the administrator, the administrator needs -- will then take that information and make a decision whether to move forward with the recommendation or how to move forward with that recommendation, anywhere from fully accepting it, going beyond it, not accepting it, whatever. What would be most helpful to him in help -- in making that decision is if the committee spends a lot of time really critically analyzing the underlying assumptions, the underlying science that they are making that decision -- or what they're basing that decision on.
So I think in this particular case, since we have a very unique situation where we all recognize that the available science is rather limited, there are large gaps in our knowledge, in fact the information is evolving rapidly as we're trying to make the -- this decision. So it's very important that all of the assumptions, all of the information, be critically looked at so that there is a robust record that the administrator can use to help make him -- to help him make a decision on where he wants to go with the recommendation.
I think the other thing that we need to recognize is that there's sort of a 600-pound gorilla in the room, and that's that each of the members, I believe, has a deep respect for each and every one of the responders and survivors who's been impacted by the attacks on 9/11. But, while each of us has that respect and we want to honor those people, we need to make sure that that does not prevent us or inhibit us from really looking at the science, understanding what it says, what is doesn't say and what additional information might be needed, what the assumptions are. So, while we want to honor those responders and survivors, we want to make sure that they understand that they are respected by the committee, the committee needs to feel comfortable having that open discussion, having a robust discussion, so that in the end the program administrator can make a good decision on what to do. And in the end it is somewhat paradoxical if the committee does not provide a good robust discussion, then what may happen is that things may not go forward appropriately, it leaves the administrator open for

attack or whatever -- not attack, for questioning. So that if he tries to move forward with a rule to add cancer or a specific type of cancer, what could happen is that it would be questioned more thoroughly. So paradoxically it may wind up actually hurting or inhibiting the ability of the administrator to provide the relief that the committee feels is appropriate if they don't do a good job of describing the science and the underlying assumptions.

DR. WARD: And I think you all heard -- or the committee at least heard yesterday, I did have the idea of taking a poll. That's one way to start off the committee's deliberations. I think in terms of where we are at the meeting, that's probably not a good way to go. I think the way the poll is constructed really doesn't capture the complexity of peoples' opinions, so what I'd like to do as an alternative, though, is to give everyone on the committee the opportunity to speak about where, you know, where they stand on the issue at this point of whether cancer in general should be listed as a World Trade Center-related condition or whether specific cancers should be listed.

What Paul and I will do, and I'm hoping Paul will do this, is I am eager to really record this in a systematic way. So even though people don't have to express a specific opinion about specific cancer sites, if they do express that opinion, we're going to try to tabulate it so at least we know where the committee stands in relation to specific sites.

I probably will take some notes, and what I'm going to be taking notes on is more some of the larger issues, such that when we do write up any recommendations to Dr. Howard, I can make sure that, and we will have the transcripts, and we will have the notes, but I'm not sure we'll have all of those things in the time frame that we need to write the letter, so I am going to take some notes just to make sure I capture some of the important ideas. So if that's agreeable to everyone, I'd like to start. And I don't, I -- Steve, did you?

DR. MARKOWITZ: I have a question. I have a question. The question is: I don't know if this is on or not but --

Does Dr. Howard want advice on specific cancers above and beyond a recommendation about cancer in general?

DR. WARD: I think the way he phrased his letter is yes but I'm sure Paul or someone else from the NIOSH staff... I think it said something like cancer or specific cancers but we'll verify that.

DR. MIDDENDORF: Yeah, it's right here.

DR. WARD: Yeah. It's phrased as, on whether to add cancer or a certain type of cancer to the list.

DR. MARKOWITZ: So if I could suggest a way of talking about it, perhaps we could

have an initial discussion on, in general, whether at least some cancers are related to exposures, and then secondarily talk about specific cancers, as opposed to mixing the two topics into the same conversation.

DR. WARD: So you're saying, just to make sure I understood you, first ask peoples' opinions about whether specific cancers should be listed and second, to talk about the issue of cancers overall? Is that what you're --

DR. MARKOWITZ: Well, in reverse order.

DR. WARD: Oh.

DR. MARKOWITZ: Yes, the different -- have a first, a broader discussion about whether any cancers are related and then secondarily what specific cancers, specific cancers we would recommend.

DR. WARD: Okay. So that's a little different from what I said but I think I understand it now. Okay, whether any cancers and then, and then if yes, which cancers. And Glenn?

DR. TALASKA: My question was about the process that we're going to go through with this. Are we planning, if we do make a recommendation one way or the other, that we will have subcommittees to draft the response, or what's your idea as far as how we're going to proceed if we do, regardless of what the outcome is? Paul's got an answer.

DR. MIDDENDORF: Yeah.

DR. WARD: Good.

DR. MIDDENDORF: Whatever you decide has to be done in an open meeting of the full committee. So either it needs to be drafted today while we're here or we need to try and establish another, a meeting. Those are part of the FACA rules. It's a federal advisory committee; it has to be done in an open meeting.

DR. WARD: So one option again, depending on how difficult the task is going to be and how much, I mean, this is not going to necessarily be a 50- page report; it could be a two- or three-page report so, so one option, I think, that might make sense is that I could draft something and then we could have a teleconference to discuss the draft and make any changes that we want to make.

DR. TALASKA: My only concern is with the documentation. If we're going to document this well, it's going to take some time to document and can't be done just ad hoc, at least from my point of view; I'm not that bright. So I can't provide all the references that one would consider including to make sure that the documentation is robust.

DR. WARD: Okay, well, why don't we wait until the end -- towards the end of the meeting to address that, when we have a better sense of what we're talking about?

DR. TALASKA: Okay.
DR. WARD: But I understand your concern and we'll figure out some way to incorporate everyone's input.
Was there anyone else who wants... Yes.
MS. DABAS: I just want to know if the recommendation had to be unanimous amongst the committee or just majority, and whether there was going to be your opinions written?
DR. MIDDENDORF: Whatever the recommendation is, it needs to be a majority of the committee, a majority of the voting members, according to our bylaws.
DR. WARD: Okay, so I think the question we'd like to address first, and I'll ask for volunteers, you know, to speak, but I would love to hear from as many members of the committee as possible so we really have a sense. And so the question we're going to address first is whether we think any cancers should be listed as World Trade Center-related.
And I'd like to give the people on the phone the opportunity to speak first, not to put them on the spot but just to make sure they have the opportunity. If you would prefer to defer until later in the discussion, that's okay, too, but let me know if you'd like to speak.
DR. DEMENT: This is John.
DR. WARD: John, John, sorry.
DR. DEMENT: I guess, I feel like we're sort of going a bit backwards with regard to any cancers, and if you're asking me for a comment with regard to I think it's reasonably anticipated that cancers will result -- will come about as a result of this exposure, my answer would be yes. But then I have some concerns about a general statement about cancers.
DR. WARD: So let me just paraphrase to make sure we understand. So you're saying you think it might be reasonable to say that some forms of cancer might reasonably be anticipated to occur but maybe not reasonable to say all cancers? Is that...
DR. DEMENT: Well, I, I think it's reasonably -- it's a reasonable anticipation that cancers will result from this exposure; however, I think we need to then go from there with some more discussions about types of cancers that have greater support for that conclusion.
DR. WARD: Okay. One thing we've done in the room is we put up kind of a standardized list of cancer types. We've put up a standardized list of cancer types and I don't know if there's a way to -- which is from the American Cancer Society's Cancer Facts and Figures, but it's the same kind of classification that's used by pretty much everyone for human cancers. So Paul, if you can get it to show the

full screen, that would be great. And this is just so that when we refer to -- if we want to refer to cancers of different organ groups.

DR. MIDDENDORF: That is full screen.

DR. WARD: This is just a tool to help us communicate. It's nothing more than that. And people can access this online if they're at home at an internet by going to the cancer.org website and looking for the facts and figures publications.

Okay, so Virginia, any comments now or do you want to hold off until later in the discussion?

DR. WEAVER: No, I do want to comment now because I will not be able to rejoin you after lunch, so... I would concur with John that I think that World Trade Center exposures will increase risk for cancer.

I think there may well be specificity within particular types of cancer, and I base that based on tox knowledge and work with firefighters exposed to combustion products.

I also think that in documenting our determination, there are some things that are critically important to include in that because no matter what decision we make, it will be -- it will generate a great deal of discussion, and so I think it's very important to document the discussion we had yesterday about measurable increased risk in cancer from only a month of asbestos exposure, about decreased breast cancer rate with cessation of HRT, and I also think Liz made some comments about radiation that -- I was trying to teach and couldn't hear all that well, but I think that it's very important that we document measurable increased risk from short-term or relatively short-term exposures.

And then I think that it's important that we, if we go forward with some type of cancer recommendation, clearly document that we are not sitting and waiting for epidemiology, that there are other lines of science that we can use to move forward.

DR. WARD: Thank you.

So now turning to other members of the committee, maybe you can signify with your tent cards when you'd like to speak. Steve has his tent card up.

DR. MARKOWITZ: I also think that at a minimum there's a reasonably strong likelihood that at least some cancers will have or will result from World Trade Center exposures. A reasonably strong likelihood that cancer has or will result from World Trade Center exposures, and I have a number of components of an argument that, if I can go through some of those.

One is the, the fact that many established human and suspected human carcinogens were documented to be present in the dust, or in the dust or smoke, at that time.

Secondly, we know that there were certainly ample exposure to World Trade Center dust and smoke, not so much documented through many of the sampling but documented through both knowledge about what occurred at the site, but also I'm impressed by the magnitude of the nonmalignant disease that's occurred among World Trade Center responders.

Third, we heard some information about the relationship between relatively short exposures and cancer. Not saying that all exposures there were short because we know that community exposure probably continued over a number of years. There were in addition some workers who worked outside of the World Trade Center after -- site after it closed in June or July 1st, 2002, but the majority, at least of the workers, had relatively short exposures. Although I'm impressed by if you worked 12- to 16-hour shifts, seven days a week for six months, that gives you a year and a half of exposure in a relatively short period of time. Nonetheless, by occupational standards, the exposures were relatively short but we've heard evidence, both from limited human epidemiology but also from animal studies, that short exposures can lead to cancer. That I think's an important part of the rationale.

I think Dr. Weaver raised an interesting point that we should explore about steeper exposure rates. Maybe that influences cancer incidence.

Another point is about synergy, which is, with so many carcinogens present, the rule in multiple carcinogens, even though it hasn't been thoroughly investigated, is that synergy seems to occur very commonly; and whether that's for PAHs, as Dr. Talaska mentioned, or Dr. Rom mentioned for asbestos, that the interaction when multiple carcinogens are present is the usual case, not the exception.

I think another point that Dr. Dement raised is there’s no -- current scientific thinking is that there's no safe threshold for the carcinogenic effect in asbestos or for that matter other human carcinogens as well.

A further point is that the hallmark of nonmalignant disease among responders and community residents has been inflammation, inflammatory disease in the respiratory tract. And it's pretty well established, and Dr. Aldrich and Dr. Rom know this a lot better than I do, but that inflammation is an underlying mechanism for the development of cancer and that's become an emerging hypothesis but there's a lot of evidence in support of it.

Then finally we come to epidemiology. It's limited but I think the firefighter study is a positive study. Positive, I don't mean positive for people who have developed cancer but positive in the sense that it showed an increased risk. It didn't appear to occur accidentally and isn't readily explained, I think, by confounders; it’s a modest increase in risk but it is there.

So I think when I put it all together, to me, this supports a case in favor of a reasonably strong likelihood that cancer has or will result from WTC exposures.

DR. WARD: Thank you, Steve. Leonard, Kimberly, do you know which one of you put --

DR. TRASANDE: Sure. I was third. I was third. I think Tom was first.

DR. WARD: Okay, good. Thank you, I was taking notes so I wasn't looking up. So which of you was first; do you know?

DR. ALDRICH: I guess I was.

DR. WARD: Okay.

DR. MIDDENDORF: Before you start, I just want to remind everybody, you need to hold the microphone up near your mouth for the entire time you're speaking. Otherwise the transcriptionist can't hear it, and we want to make sure that we capture everything clearly.

DR. ALDRICH: I'm sorry, I thought this was on. I was one of many authors of the fire department study. I was not the primary or secondary, I wasn't the senior author, but I do have a good bit of familiarity with that study and although it's a single study and only epidemiology so far, it does have a number of really important strengths: it was a well-controlled study with a known exposure, pretty well-known exposure, with good, maybe not perfect case finding, that means that the numerator was probably pretty close to accurate; and a known total population at risk, which means the denominator is pretty close to accurate; and furthermore it took surveillance bias and a number of other biases well into account. I would like to point out one thing that isn't clear from a cursory reading of that paper, that the cases that were found after 9/11 were not at an earlier stage on average; in fact, the stages were, if anything, slightly later-stage cancers for the post-9/11, which suggests that this was not surveillance bias that took -- that led to the higher level.

The finding was that total cancers were increased to a small degree. This is not an epidemic level increase in cancers but it was only seven years post-9/11 that were included in the data so rates may well be higher in future studies. Nonetheless the study was, did show an increase in cancer incidence, and so although it's only a single study and although it's quite preliminary, I think that there is some epidemiology that we should not ignore and so for those reasons I favor including cancers of some types in -- recommending the inclusion of cancers of some types in the health program.

DR. WARD: Thanks. Guille?

MS. MEJIA: Okay. I'm just going to jump into this. It's my position and my opinion that cancer should be covered. Whether all cancers should be covered, I

don't know. You know, that's something that we need to have further discussions on.

What do I base this on? Well, it may seem -- my rationale may seem elementary to some, I mean, I'm not a doctor, I am not a scientist, I am not a researcher, but I think it's a conclusion that any reasonable person would reach based on the presentations that we've had for the last three or four days, you know, the beginning in November to today.

We know a lot of things. Whether we can put them all together is something that we also have to work out but we know a lot of things. We know that there were lots of substances that were present in the environment and we know that many of these substances are very toxic and many of them are carcinogens.

We know how the exposures occurred. People were caught in the cloud and then there were workers who were responding and performing work that was necessary to rescue and eventually restore the area.

We know how and why these substances entered the body. I mean, right? We know the routes of entry; there was inhalation hazards. There were no controls in place so that, you know, the workers could not be protected against inhaling some of these substances or ingesting some of these substances or coming into contact with some of these substances.

We know that there are effects from these exposures based on the fact that we have workers in the program that have covered conditions. So there are some effects from these exposures. The fact when we're dealing with cancers, at least in the field of workers comp, there is -- there have been cases and causal relationships established between the disease and the work at Ground Zero. So there is some causal relationship there.

We know that, aside from many of these substances being classified as carcinogens, many of them are also -- can cause inflammation and can cause irritation that may be a precursor to cancer. All right, at least that's what I heard from the presentations.

We know that there are many gaps in the data but we should not hold that, you know, against the worker. It's not their fault that there are no -- that there is not enough data there. You know, they were just out there to respond and to take care of what they needed to take care of.

Yesterday we heard a presentation about short exposures to high concentrations of substances, especially in the textile workers. I think that's important to keep in mind, that just a short exposure can lead to cancer. So, you know, we don’t need to worry about latency. I mean, the traditional thought about cancer is that there's a latency period involved. I mean, it's like an old married couple. You talk

about cancer and you got to talk about latency. In this group they don't have the luxury of time to wait.

Just a few other thoughts. Just because the association between the exposure and cancer may not be strong at this time, I don't think that we should dismiss it entirely. I think there's enough out there to make a case for the coverage of cancer.

And finally I think that what I need to say is that even though the incidence -- if we deem the incidence of cancer among the population to be improbable due to a lack of studies or any other information, I don't think that it means that it's not plausible. And that's an important point to make. That's it.

DR. WARD: Thank you. I think Glenn was next, then Kimberly.

DR. TALASKA: Okay. First of all, I would agree that I think that cancer should be covered under -- for the first responders, and I think there's several reasons. I think Steve just did a great job of very systematically laying out why, and Guille did, too, why it might be the case.

I think some of the arguments against that seemed to be important were that the epidemiological data are not strong enough for causality, and that is an argument that, again, I think, on the other hand the data are starting to show some things. And in the studies that are being done they are trending in a way that is disturbing for an observer. Second, I think the other reason that one might believe that it would not be related is that the data today report that the exposures were relatively small. I think we heard yesterday from John Dement and I provided some evidence that that may in fact not be the case and that there's reason to believe that the exposures were, for the individuals working in the Pile certainly, that the exposures were quite large. And that there are data to support that from some of the biological monitoring that was done, and also the relationship between the personal and the area samples, and the history of that.

So I think, and then most importantly I think we've got a soup of carcinogens which are known to affect several sites, specific sites, and these are some of the sites that we're considering. So the materials that were known to be in the cloud and materials that were known to be at Ground Zero have caused disease which people, some people are seeing.

And then finally that the interaction between these materials, the soup included materials that were not only carcinogen initiators but were carcinogen promoters, and they tend to complete the package. And some of these materials were those which would tend to persist.

I agree with the others on the committee that the exposure apparently, if we have people that are working for six months, working long shifts and double shifts, that

in fact that's a significant exposure and a significant time that they were there. In some cases locally extremely high levels, it appears, so I think there's, for those reasons, I would support the inclusion of at least some cancers into the, into our recommendation.

DR. WARD: Thank you. Kimberly?

MS. FLYNN: I think that some cancers, and I am not expert enough to say which, but I think certainly non-Hodgkin's lymphoma, I will never hear the initials NHL as National Hockey League ever again. This has been a constant refrain but I would certainly go beyond blood cancers. I think that some cancers must be included for the exposed population of responders and survivors.

I want to remind anyone who was not present at the November STAC meeting to hear the survivor presentation, to please go back and read that presentation in the record. Survivors were exposed in myriad, myriad ways to World Trade Center dust and smoke, some of the testimony we heard earlier today went to the fact that survivors had, you know, intense dust cloud day-of exposures, they also had ongoing exposures in the area. Many people live and work in the area, as Jo Polett testified, there is World Trade Center contamination -- was World Trade Center contamination present in air handling units in her building. This is the case in many buildings.

Everyone here needs to understand that there was no proper testing and clean-up program by the Environmental Protection Agency, the only agency that in fact has the expertise, obligation and capacity to pull off such a program.

Fewer than 18 percent of apartment, individual apartments in lower Manhattan below Canal Street, were cleaned by the EPA. And there's a lot of people here who could tell you that in many ways that clean-up was flawed and inadequate. So, you know, when a cancer is added for responders, it's added for survivors under Zadroga for that reason and also for the reasons that survivors do not have a monitoring program.

Responders have a monitoring program. You qualified for that program if you were exposed. Survivors had a treatment program which became widely available to them in the year 2006, very, very late in the game. Lots and lots of survivors went elsewhere, saw private doctors. That is one of the reasons why the denominator, the number of patients in the survivor program is, you know, a little over, well is probably closer, actually at this point, to 6,000.

But shifting on to some of the testimony that we heard today and also a repeated refrain, which I think is very, very important, that the events were unprecedented, that the exposures were unprecedented. And I guess I want to challenge all of the experts on this panel to really very carefully think through what that means in

terms of constructing a robust rationale for cancers to be added. And I think that actually that Dr. Markowitz and Dr. Weaver have started doing that.

So unprecedented means that you are exposed to a host of toxic materials which are simultaneously carcinogenic, mutagenic, materials that simultaneously attack the nervous system, the immune system, the endocrine system; and that for many, many people these contaminants, their exposure to these contaminants, was in the form of an absolutely unprecedented assault. I had firefighters tell me that being in the vicinity, being on the site, when those buildings collapsed was like having somebody pull your head back, open your mouth and, like, load in, you know, three bottles of talcum powder, you know, at 150 miles an hour traveling into your mouth and overwhelming your airway, overwhelming your body systems and I'm not excluding cops, who we know were exposed and had no respirators. We know so many people had no protection whatsoever, but I'm saying that the insult to the body was absolutely unprecedented.

I'm saying also that these insults happen in ways that we know about because we saw them on television and they happened in ways that we don't know about, so I'm talking about, you know, as Dr. Weaver said yesterday, the toddler crawling on a contaminated carpet, the kids who were jumping up and down on a contaminated sofa. I mean, these things happened all over lower Manhattan and in fact we really do not have any idea whether or not there are still people living and working in the area who are subject to ongoing exposures from the fact that, for instance, the air handling units were never properly cleaned.

The other piece of this unprecedented -- so you have unprecedented exposures, you have unprecedented, you know, unfathomable exposure scenarios, some of which are ongoing, and likely ongoing, it's reasonable to assume that, and you also have this sort of new kinds of illness. So the medical director for the survivor program, **[identifying information redacted]**, has said many times -- I think she's also testified to this in Congress -- that we're treating it, we're treating World Trade Center asthma like regular asthma but really we don't know what it is. So there are ways in which the disease process and there are ways in which the kind of the end point illness is WTC-specific, and I think that's also something that the experts here really need to take into account.

What are all of the ways in which these unprecedented exposures may be shortening latency times? What are the ways -- I mean, I thought the idea that Dr. Weaver had, that we're looking at the possible impact of steepness of exposures. What are the ways in which we're seeing people who should not be getting multiple myeloma showing up with multiple myeloma in their early and mid-40s? What about these rare cancers that we're hearing about?

And I guess when we start to look at the epidemiological record, I would have to remind everyone here about Micki Siegel de Hernandez's testimony and the degree to which what we currently have by way of, you know, denominators and numerators is a partial perspective.

There are so many people out in the country right now who are not, whose cancers are not being counted in the monitoring program, whose cancers are not eligible for the World Trade Center health registry or maybe they didn't even know that the World Trade Center health registry existed. So there are all of those people out there and some of them actually managed to make it in here and talk to us.

So I think that we, you know, we understand, you know, I think that the FDNY study was very well designed and I'm very glad to hear Dr. Aldrich say that, you know, he considers it to be strong, strong epidemiological evidence, and as a non-expert, I wholeheartedly agree. I understand also that the FDNY needed to take certain steps to be able to say that look, we're controlling for surveillance bias. I understand that but we also need to consider, as Micki said, the numbers of people who are not being surveilled at all.

And I think that we have to base our considerations -- and it's very, very reasonable for us to make sure that we are not allowing this, this population to essentially fall into a data gap that was not created by them and that is not their fault and I think that we owe everyone, survivors as well as responders, deliberation here that looks at the available data in the context of unprecedented.

DR. WARD: Thank you, and I've tried to now make a list of tent cards 'cause we have so many of them it's hard to follow, but I think the order was Bill, Leonardo, Julia, Valerie, Susan and Catherine? So Bill.

DR. ROM: Thank you. First of all I think I would like to start off by seconding Steve's list of exposures. I do make the case that WTC dust and responders have a risk for cancer. The exposures included carcinogens, there were multiple carcinogens, there was broad exposure in the short term, and all of these increased the risk and these people will develop increased numbers of cancers.

Second of all, the issue of lumping or splitting, do we just say cancer or do we say specific cancers? I think the Zadroga Act answers that question. It doesn't just say lung disease, it lists lung diseases. So if you look through the list and you look for sarcoidosis as a specific lung disease, you don't find it. And the Zadroga Act did do a little bit of lumping and took sarcoidosis and put it under interstitial lung disease, which probably has a few diseases that may not be associated, so I guess we can do a little bit of lumping.

So going on to the specific diseases, I think lymphoma, leukemia and multiple

myeloma already are being seen. And even with such a short latency these cancers are coming up and we should probably list them. But then you get to splitting again and lymphoma has non-Hodgkin's and Hodgkin's. And you look through the firefighter paper and non-Hodgkin's is significant but Hodgkin's is not. And then if you look at leukemias, ALL occurs in children and CLL in older patients. It may not have much of a biological plausibility for environmental exposures so I'll take a pass on those, leave it as a lumping.

And then there's two big sites that are -- need to be addressed, and they're the major sites on the list you put on the board and that's lung, and then some other sites that came up positive in the epi studies. So for lung I'll start with that. That did not come up in the firefighter study and it did not come up in **[identifying information redacted]**line about the Mt. Sinai study of the responders. But I think lung is very biologically plausible, and we have the carcinogens and we are going to see lung cancer, and I think these people should be evaluated and should get support. And I would expand the lung to also include mesothelioma, even though we're violating our rule of latency on both of them as we don't have 20 years you need for lung cancer and 35 to 40 years for mesothelioma. I just don't think we can wait that long for proof.

And then there's three sites that popped up that I don't think there's any biological plausibility at all, and they're thyroid and prostate and some sites in the GI track. So these popped up in the firefighter study and **[identifying information redacted]** mention of the responder study. So I have difficulty in supporting sites that just don't have any biological plausibility for environmental exposure, WTC dust or otherwise. It just doesn't make any sense. That's too, that's a bit of a leap. And we have to provide the science to the administrator and we can't provide any science on those, other than data from these epi studies that probably represent surveillance bias and other confounding reasons they came up. And maybe the committee can address these further. Thanks.

DR. WARD: Thank you. Leonardo?

DR. TRASANDE: Thank you. I want to begin by supporting Steve and others' lines of argument and state my opinion that cancer should be included as a covered condition, leaving pending the second component of the discussion.

I wanted to add roughly five points that I think represent issues that have been glancingly addressed so far but I think are very important. One is that our legal direction, as I understand it from the Zadroga bill, is not to distinguish subpopulations, and my understanding is that we're still always relying on a clinician judgment once a condition is added to the bill for -- that is required in order to result in having a patient have care supported by the Zadroga fund.

And also my second point is that community exposures were highly variable in this context and likely overlapped in ranges of exposure with exposures experienced by many of the responders, and I think that's important to highlight and I think, much as we try to characterize those exposures with questionnaires and other methods, it may be impossible to really tease that apart very carefully. And I'm hearing a theme of well, we know in responders there's more plausibility for responders but I think there's a very large gray area here that we need to accept. And I think there's quite a lot of plausibility for community exposures leading to cancer in this population as well.

I wouldn't be here if I didn't raise a point about pediatric and perinatal vulnerability. That raises additional and worrisome concerns in what are likely less exposed populations. So that's my third comment, and I think the literature on that vulnerability is ample, I don't think I need to review it here.

I want to keep my comments brief and just proceed to my fourth point, which is that there -- we've talked about statistical capacity of the fire -- the department study of the responder study that was presented yesterday, there's extremely limited statistical power that exists, even if you use the whole 46,000 children who lived below 14th Street on September 11, 2001. That nearly eliminates the possibility of a definitive negative study in that population. And so I think I want to caution, voice my caution, that we will need to rely on plausibility and reasoning by analogy for pediatric and perinatal exposures and their association with cancers that may have even latency in the range of a 30- to 40-year range, given the uncharted waters that we're in. And though I would say it's worthy of further study and I'll leave that point there.

Following up on Bill's point, my fifth point is going to signal a concern I have about splitting cancers by category, and that's especially keen for the pediatric population. While I agree there are certain cancers that predominate and you would expect increases in patterns to emerge if they were to emerge for ALL and other conditions, and I agree with Bill's points that there are some concerns about plausibility. I am concerned that we are in, in an uncharted territory and may have to err on the side of biological plausibility as being the momenarm (ph) for our decision, and so I just would also raise further cautions when we're splitting on the basis of adult responder data. And my concern being that there will not be very good applicability of that coverage to a population that may have been affected at an earlier stage of life. Thank you.

DR. WARD: Okay. Julia?

DR. QUINT: First I do agree that cancer should be included as a covered condition for many of the reasons that Dr. Markowitz -- and I will third his notion of why.

Lots of carcinogens, many -- some human carcinogens, lots of animal carcinogens, and I want to say something about that in particular. We seem to be -- when we act as government agencies to protect workers and public health, we try to protect both populations from chemicals that have been identified as carcinogens based on animal data, and we do that by implementing regulations and policies. One of the commenters yesterday said that if he were under OSHA jurisdiction and were constructing a building and had to use many of the carcinogens that have been identified in the WTC dust and smoke, that, you know, he would have to use certain controls because we do believe that those cancers that are found in animals can cause cancer in humans. So that, you know, I think it's a false distinction on the public health side and the prevention side, when we have laws and regulations, to say that those are, those chemicals can cause cancer in humans on one side and then when we end up seeing a number of cancers, that, you know, we have a different rule for the covered conditions. You know, and in that the agencies which are tasked with identifying evidence of whether or not chemicals cause cancer, the National Toxicology Program and the International Agency for Research on Cancer are now classifying agents as human carcinogens based on mechanistic data in addition to epidemiological data and animal bioassay data; and in fact, benzo alpha pyrene was classified as a human carcinogen, is one of the WTC agents, is now classified as a human carcinogen by IARC where it wasn't before, and this is based on mechanistic data.

And in addition IARC has published a review in which they have identified 11 sites of cancer for which there is sufficient human evidence, and some of the -- for those 11 sites, WTC agents are implicated; in other words, if you look at, I don't know how many of the different agents, but asbestos for instance, they have said that there is sufficient evidence of human cancer for cancer of the ovary for asbestos.

So I think we should definitely look at that IARC review in terms of the cancers that they have had -- have deemed as sufficient evidence of human cancer for the agents that were in the WTC dust and smoke. Is seems very pertinent. They're a very prestigious group. But they are looking at lots of data. It's reviewed by a huge panel of people, and I don't think we need to repeat that review.

Again, you know, we talked about exposure. We don't have a lot of exposure data but we do have -- we operate on this premise, again, on the prevention side that if chemicals are genotoxic there's no safe exposure level. Many of these chemicals, most of them are genotoxic. And even for the ones that may be operating by an epigenetic mechanism, we have individual variability in terms of the exposed populations, both survivors and responders and the whole gamut of people who

were exposed, and we have different background exposures. And one of the ways in which this can play out is that some people have a very different ability to metabolize chemicals, toxic chemicals, to make them nontoxic, so that will contribute disproportionately to their risk for cancer. And we don't know a lot about that.

The other thing is we don't know how large the number is of people who may have developed cancer from these exposures because we don't have sufficient surveillance systems to pick them up. So I think that, you know, all of this is a developing science. The mechanistic data is developing as we speak. A lot of the cancers that are not deemed to be human carcinogens today will be in the future. So I personally have a very hard time.

Some cancers we have more evidence for. I would definitely go with the list of cancers that have been shown in epi studies where there is an increased risk, and definitely the ones that IARC has associated with some of the agents that we know were in the dust and smoke. But beyond that we don't know which cancers in humans will be caused by the chemicals that cause cancer in animals because they aren't concordant. And so I think that that raises the possibility that some of these cancers that we don't think -- that we don't have evidence for now, we might have evidence for in the future based on mechanistic data, and I have a very hard time leaving, you know, saying that cancers that -- for which we don't have human data right now and don't have strong biological plausibility may not be covered. That's my dilemma with all of this.

DR. WARD: Valerie.

MS. DABAS: I also looked at the IARC report and I found several things. One of them was ovary cancer linked to asbestos as well as larynx, colorectum, stomach. They also identified beryllium now as a human carcinogen and found that there was significant epidemiological studies that indicate a high risk of lung cancer in occupational group. Cadmium also had carcinogenic levels. On page 80 it identified prostate cancer as one of the things that it was -- that it linked to it. Urinary and kidney cancer were amongst the ones that they found. They identified lead and that it increased the risk of lung cancer, stomach cancer, urinary bladder cancer. When they looked at PCBs and they found Hodgkin's lymphoma in one study dated 1996 as one of the risks of being exposed to lead. Again, quoting from them, as in the studies reviewed by IARC, instead of risk of liver or bile duct cancers were reported in several cohorts and follow-up studies of capacity workers. One case control study also reported increased risk of bile duct cancer. They listed several others such as tissue sites such as gastrointestinal tract, brain, testes or skin.

When they looked at PNAs, they listed in animals that they found PNAs cause numerous types of cancers in animals including lung tumors, liver cancers, skin tumors, urinary bladder cancer, forestomach tumors, esophageal tumors, intestinal tumors, mammary gland tumors, nose tumors, larynx, pharynx, lymphoma, tongue tumors, anus tumors, cervix tumors, abdominal tumors, tumors of the blood vessels, kidney cancer, respiratory system cancer, ovarian tumors, cancers of the oral cavity and cancer at the injection site sarcoma.

So when we looked at that report we found that there was significant evidence and they had significant epidemiological studies to back their evidence in their 2011 report. I think it would be very dangerous if we start picking apart cancers, specifically for the person that came in today that had a very rare cancer. You know, what do we do with that person? Do they stay out for the entire time while they figure out whether his cancer specifically is linked to the World Trade Center exposures or what? And those people are the ones that are going to get drugs that are not covered by their health insurance. People with very rare cancers are under -- you know, they more than likely will not have drugs that, you know, are covered by their insurance.

You know, I had one guy, **[identifying information redacted]**, who spoke to me, and he has a very rare cancer of the pancreas and his drug is a test. And so it's $12,000 per month and it is not covered under his health insurance. So I think if we start picking cancers apart, we're going to leave the people that are most needy out to dry.

DR. WARD: Thank you. Susan?

MS. SIDEL: Thank you. I of course definitely think that cancer should be included and I think that, to make a case for this scientifically, I think that we're in fairly good shape because I think that one of the big things that has come out of this is that so much of the information we have is not like, it's not working in real time. Because even any of the studies that have been done, including the one that isn't even out yet, is already old. By the time they compile the people that have cancer and then match that against the New York state registry, which is two years behind, and then they have to submit it for publication. And then I'm sure the publication period, you know, that takes awhile because you might get rejected; you have to go some place else, and then your article has revisions, so anything that we can work with in real time is going to be way too old for it to be, to help people today.

The other thing that I'm very concerned about is that our committee and in fact the entire World Trade Center health program is over like 15 years from 9/11, right? There's, like, a statutory end to this. And that is when we're going to see --

that is when we are going to have the latency period for a lot of cancers come up, so if we did rely on epidemiological studies, we're not going to have them until we can't do anything with them. And that is really, really hard, you know, that is a shame.

I think that there's a lot of information in the articles we do have. On page 904 of the fire department, **[identifying information redacted]** article, in the first paragraph, I mean, the first column, I think it's the second paragraph, where he's talking about inflammation and how other diseases of inflammation that are affecting survivors and responders are the diseases that are covered, so that's like a big lead-in to what kind of cancers should -- you know, if you follow the same thinking, the same track, I think it's going to just naturally take you to covering certain cancers.

And then the other thing is that we have a lot of information that's just old established science on what carcinogens cause when people are exposed to them. And I think that it's out there, it's old established science and that we can just compile things based on that evidence. Thanks.

DR. WARD: Thank you, so what we're going to do is take the final comments, like, from Catherine and Bob and then we'll take a break for lunch.

MS. HUGHES: Hi. As I think the only local mom on this committee, I just wanted to provide a little insight 'cause I had two young boys on September 11th. And people talked about exterior clean-up. Well, one of the problems was the EPA was supposed to be in charge of the internal clean-up on spaces and then the DEP was responsible for the outside.

And every part of it was a process and we've heard about whether it's worked or it hasn't worked. But for example, finally the DEP did get around to requiring that roofs of buildings had to be cleaned. For a very long time roofs were never cleaned. And facades of buildings were hosed down, if they were cleaned, for months or up to over a year. So in the summer of 2006, if I hadn't reported into the DEP clean-up, the newspaper stand one block from the World Trade Center site, then the little top of that stand would never have been cleaned. They found six bags of World Trade Center debris over a year later on the roof of the newsstand. And a lot of people walk in that area.

When I had my son's birthday in October of 2002, which was over a year, in the dark, I see a guy in a white tie-back suit with rubber boots, bolted onto the roof, doing an asbestos or EPA, you know, exterior clean-up. So I just want to remind people about the inconsistencies of exposures, and they were ongoing for the community as well.

I agree with a lot of what our medical experts have said here and, you know, that

Dr. Markowitz had kicked off, and if we could also look at cancers so we're looking at systems rather than just picking one. Because that rare cancer we heard about, I'm not a doctor but it could have been related to dioxin exposures or from the dielectric fluid, I believe, 'cause I happened to be researching it the other day, but he should not be left. So if we're looking at systems, so it could be that you were exposed through the skin, so look at the skin as a holistic mechanism, look at the inhalation and the ingestion, so that's how we can start looking at the cancers. Thank you.

DR. WARD: Thank you. Bob?

DR. HARRISON: I agree, yes. I think everybody -- I've just been taking notes. So I'm a yes also in terms of the general inclusion of cancer but I had just -- I would add just a few other points.

I think there's some interesting evidence in terms of short-term exposure to benzene and hematopoietic malignancies that could be cited as evidence. As has been said, this is a relatively short-term exposure but there's some -- quite a bit of data, I think, is emerging on low-dose and/or intermittent exposures to benzene that could provide some, you know, additional biological bases to argue that there's scientific evidence to make a recommendation.

I would like to see somehow mention of certain premalignant hematopoietic disorders. The healthcare providers may see somebody with aplastic anemia, there's a premyeloma condition, there's myelodysplasia, there's number of blood disorders that, followed long enough, will lead to malignancy without the diagnosis yet of AML or multiple myeloma. So somehow I'd like to get across that, so it doesn't hamstring the healthcare provider in not being able to provide treatment for those conditions. Sometimes it's just monitoring.

Third is I think we should acknowledge that cancer is multifactorial, that there are individuals who develop cancer from multiple risk factors both environmental, occupational and personal. I think it's important to acknowledge, for credibility actually, that cancer is multifactorial, that not all cancer is the same, that we're going to have individuals who are eligible for treatment and compensation who have smoked for 40-pack years, who have dietary risks, who have genetic risk factors, and that to the casual reader I think it's not necessarily intuitive that -- or how three months of exposure is responsible for their cancer when they might have multiple other risk factors that seemingly are even more important.

This is a problem I face all the time with my patients who have occupational or environmental exposures, and so I would suggest adding something along the lines of, I think to echo what Dr. Markowitz says, that citing the abundant medical and scientific literature that acknowledges that environmental and occupational

exposures are an important cause of cancer, that the exposures from the World Trade Center are likely to be a significant factor, or if you'd like, a substantial factor, in causing certain cancer types. So this really acknowledges that cancer is multifactorial but the contribution of the World Trade Center is a significant factor.

I think that might help the clinician, frankly, in the second phase, where each of the diseases must be certified. I think that would give them clear guidance and might give NIOSH some context in which to understand a specific case.

My last point is childhood cancers, and Dr. Rom mentioned ALL, which although I would like further discussion whether ALL should be included for adults, what about the child, you know, in the community who's diagnosed by a pediatrician, who's eligible and who has ALL? Should we not include that as a covered condition as one of the most common causes of childhood cancer? So I just want to make sure that we address that issue in some way.

MS. HUGHES: So can I make one point of clarification? I actually, I was actually looking at the New York State Data Registry from 2008. That was online, and, you know, it's four years later, and just did a really preliminary, nonscientific report and broke it down by ZIP code, and it turned out, just for lung and bronchial cancer for the years 2002 and 2006, you know, I haven't verified this, but if you look for the breakdown, there was an increase between 15 to 49 percent of above expected cancer rate for the ZIP code 10282. In ZIP code 10007 within 15 percent expected, within the ZIP code 10038, which is east of the World Trade Center site, 15 to 49 percent increased, more in the financial area, ZIP code 10005, very sparse data, and then in ZIP code 10280, you know, there was again some lung cancer, but this is just very preliminary so it's, you know, just something to think about. Thank you.

DR. WARD: Thank you. So we will break for lunch. We're back on schedule so we'll reconvene at 12:45.

(Recess for lunch, 12:02 p.m. to 1:04 p.m.)

DR. WARD: Would the committee members please take their seats so we can get started? Okay, if everybody would take their seats so we can see who's here and who's not here. So we're still short a few committee members, Paul.

DR. MIDDENDORF: Yeah, we do have a quorum, though.

DR. WARD: Okay, so we do have a quorum, and what we're planning to do is really resume where we left off and have all the committee members who haven't spoken on the main issue have an opportunity to speak, and then move onto the next phase of the discussion. So Steve, would you like to start?

MR. CASSIDY: Yeah. Thank you. You know, I want to start off by saying that I too

support that cancers be included. I think the discussion of how we decide if we limit which cancers are covered or we try to eliminate certain cancers and say they shouldn't be covered is difficult.

When I look back at what was said yesterday, some of the testimony, I thought that it was very interesting, the presentation that Dr. Rom made about burnt particulate matter and how particulate matter clearly causes cancers and that burnt particulate matter was something he really hadn't experienced before. And we didn't have any real comparisons to that. And I think, you know, when you add that to what Dr. Talaska testified to about the exposure, about the pyrenes, about how the exposure was clearly greater than was measured, when you look at what the testimony from Dr. Dement about the asbestos and just about how much was in the air in terms of the concrete dust, I think it's just clear that this episode was something that is not comparable to anything in the past.

You know, I will point to something outside of the scientific things and think about what the New York City fire chiefs, the most experienced people in the world, did that day; they never thought those two buildings were coming down. The reason they never thought they were coming down was because they weren't supposed to come down. They are fireproof, high-rise buildings. We have fought thousands and thousands of fires in high-rise, fireproof buildings. So they did not believe that they would come down maybe at all and certainly not early.

When they came down, then you look back and say well, what was different? Well, what was different was two planes crashed into them at 600 miles an hour, jet fuel, all the things that we had never experienced. And I think that highlights for us on the committee that what we're dealing with, now in terms of trying to analyze the data and the cancers that have popped up, and we're doing it with only a short period of time, **[identifying information redacted]** study, the fire department study's only seven years; that when you look at that, you have to do it in the context that this is probably a once in a lifetime occurrence. It's certainly nothing to compare to. Uncomparable. There's nothing like it so I think when we decide on cancers, I think the consensus is yes, cancers have to be covered. You know, right now I would say I'm leaning toward saying that it's impossible, or very, very difficult, to say we should eliminate these cancers from the list or that we can, as we heard testimony from people here this morning who have incredibly rare cancers, how do you say well, we don't have any data that proves that that rare cancer is likely to happen and therefore you're out. I don't know how we do that; and I think there is enough scientific data that suggests that this exposure that people suffered was unlike any other one and because of that, I think that we could make an argument that maybe we should just include all cancers.

But I certainly believe that, you know, we're going in the right direction. I think cancers have to be covered. And I'm open to further discussion about how we do that but I want to do it in the context of reminding everyone that I think that the data shows and the testimony that we've had and the doctors who have made presentations to us are highlighting that the exposures that everybody faced that went down there are unique and significant and unlike probably anything else anybody has ever faced, and I think that's why we're facing such unique problems at this point in time. Thank you.

DR. WARD: Carol?

DR. NORTH: Thank you. I'll just be brief because it's been said. I'm in agreement with the other folks around the room that it seems appropriate to include cancers. I do want to say that we've heard a number of really moving and compelling testimonials that help bring a face to the diseases and the suffering, which has been a good thing. But I want to say that I make every effort to base my decision on science and I think we have good evidence in science both in the epidemiology and the biological plausibility of the known exposures that several of the other experts in the room have summarized very well. But that evidence leads me to believe that there is a substantial likelihood of excessive occurrence of cancers without sufficient compelling arguments of other explanations.

DR. WARD: Thank you. So I think we've heard from everyone on the committee. Virginia and John, are you still there?

DR. DEMENT: Yes, I'm still here.

DR. WARD: Thank you. And I think Virginia may have left for her class. So essentially what I heard pretty much, well, from every member of the committee is that they think cancer should be included, that there's a substantial likelihood of excess risk. I think many people made very, you know, compelling and convincing arguments of that. So the issue -- so that issue seems to be everyone has a common opinion on that.

I think the question then is between the decision to include all cancers and several people have spoken to, you know, to the fact that it's difficult to decide which cancers to exclude or that it's not appropriate to exclude any cancers. Other people have spoken to the idea that some cancers are much more likely than others and so we should try to designate certain cancers or organ systems as on the list and not necessarily include all cancers.

So my personal opinion, just I realize I haven't said it, is I'm in full agreement with everyone who said that cancer should be listed, and I still have some questions in my own mind about all cancers or selected cancers. And the one piece of information that is in my mind, and I know everyone's aware of it, but I think that

one of the things that's difficult for me is knowing that, over a lifetime, up to half of men and a third of women will get cancer. So even if the World Trade Center exposed populations had not had these exposures, you would expect a large number of people to get cancer. And so that's one of the things that's in my mind that makes it a little bit more difficult to decide if we should list all cancers or selected cancers, but I do agree with some of those arguments that we know something but we don't know everything, and so yes, it's possible to say well, if it's a cancer that's caused by asbestos, then it would -- there would be a very clear rationale for including it or if there's a cancer in a site where we've seen chronic irritation and inflammation, there's a clear rationale.

But, you know, again, I see the opposite, I mean, I see the other side as well that it's, you know, it's hard to exclude any cancers 'cause we really don't have a full set of information to make strong decisions about exclusion, so with that I'd like to leave the floor open to people who have opinions one way or the other on the issue of listing all or listing selected cancers.

DR. ALDRICH: I guess others have made this point but I think it bears repeating that other conditions that are covered under the bill, certainly bronchitis and asthma, PTSD and GERD, they all occur in many, many people absent World Trade Center exposure and yet they're covered. Nonetheless I think you make a good point that there is no way to know the exact causation or whether somebody who has a cancer was destined to get it in the absence of World Trade Center, but we have to work with what we have.

DR. HARRISON: Oh, I'm sorry. I think that there are some cancers for which the biological plausibility, the tox, the animal, the mechanistic, the human data are stronger for a connection and other cancers for which it's weaker or absent, and that I would like to see our committee make a recommendation that reflects the variety or the spectrum of evidence with some suggestion, and I'm not sure of the language with which to phrase this, but some suggestion that the evidence is stronger or that we see evidence for certain types of cancer that's greater than other types of cancer, and maybe not make a definitive recommendation on which absolutely to cover; in other words, transmit that notion, but I don't want to be so crass as to punt it back to Dr. Howard to make a final determination. The alternative would be to specify and to spell out very distinctly and create a list. I guess I don't personally feel like we either have the time or the charge as a committee to review the kinds of evidence in the detail that we need to really create such a specific list.

DR. WARD: Okay, any other comments on this? Steve? Sorry, Susan.

MS. SIDEL: Hi, I was just wondering if --

DR. MIDDENDORF: Before you start, could I do one thing? The reason we have the buzzing is because the microphones have to be turned up to make sure that you can be heard. If everybody will make sure that they put the microphone right in front of their face for the entire time they're talking, we can turn that down and hopefully get rid of the buzz.

MS. SIDEL: Okay, how's that? Thank you. You know, I was wondering from a practical perspective how specific we have to be because if we say cancer then -- and maybe some other people can help with what the process is, but then your doctor, I'm assuming your World Trade Center doctor, has to say that you have a World Trade Center-related cancer. Then he's going to send that to the feds, they're going to certify it. Then you're going to have a fight with workers comp or whoever is going to pay for part of whatever. So there's a whole process that's involved.

So maybe we can lay out some guidelines and say there's certain cancers that are well-known to be associated with the carcinogens that were at the site and here's some of those, but that we're leaving it open. So therefore if your doctor can make a biological plausibility argument.

But then I'm also wondering is that in the course of that like what if, you know, do you have your occupational medicine doctor do that, do you have your oncologist do that? Who does that? So that's another thing that's out there. But I'm just wondering like in the real world how specific this is going to have to be at this point.

DR. WARD: Steven, then Kimberly.

DR. MARKOWITZ: So just to answer Susan's specific question, in the real world, the World Trade Center health program has many doctors who are not even trained in occupational medicine, and certainly not in oncology, and will be looking for a lot of guidance on what's related to the World Trade Center or not in terms of particular cancers. Whatever they decide then has to be reviewed by NIOSH which has already asked us for guidance from this committee. The more we comment on this probably the better off everybody is.

When I think about this issue I think, well, we should rely, there are various approaches. One way is to think that to rely primarily on epidemiology 'cause after all that's, you know, that's the human outcome. The problem with that of course is that we have one epi study, we have the Mt. Sinai study which we don't have because all we have is a one-liner on that so we can't really say anything about that. But whatever we say, you know, the Sinai study will be available in a couple of months and we have to leave open to whatever new findings they may have. But if we were to rely on the epidemiology, specifically the firefighter study,

the cancers we would come up with are thyroid, non-Hodgkin's lymphoma, maybe colon, maybe stomach and melanoma. That's the list and I may be, you know, overlooking one or two, depending how you interpret the numbers actually, but that's the -- that would be the list.

An alternative approach would be, I think what has been discussed, which is it look at the roots of exposure and biological plausibility and look at where the nonmalignant disease is occurring among WTC survivors and responders, and then we'd look very much at respiratory cancers, upper respiratory cancers; we'd look at head and neck, pharyngeal, nasal, sinus cancers, laryngeal cancers. And the esophageal cancer because we know that reflux is increased among responders, and maybe skin cancer because all those PAHs got on people's skin when they worked down there. And that list, actually that list is virtually completely different from the list that you construct from the firefighters' study from the available epidemiology which is an odd problem.

Another approach would be, and I think this is kind of the broadest approach, is to look at the total list of chemicals that NIOSH in their first report on carcinogens listed as being of concern, it's in Appendix E or Appendix D of that report, and there are 287 chemicals. And I counted the number of IARC carcinogens, it's either A, or one or two carcinogens, but one is definite, two is -- 2A, 2B are possible, probable, and there are about 70 carcinogens on that list. So you could take that list of 70, and IARC has nicely spent the last few years updating that list and specific sites attached to that list, and then you can match up that list with those sites, including the sufficient evidence and the limited evidence, and you'd come up with a big universe of cancers that are plausibly related to what I told you has occurred down there.

There would probably still be some exceptions. It wouldn't include all cancers. I'm not sure that everything down -- if you match that up, which I haven't done, there are probably still a few cancer types that are excluded but it would be the broadest possible list that you could cite a rationale for.

I don't know which approach we should take but I think that sort of is -- or we could, you know, say we can't decide that, in the absence of being able to decide, then just include them all.

DR. MIDDENDORF: I just want to point out to the committee that the document similar to what you are suggesting has already been developed. It was sent out to each of the committee members roughly a few weeks ago. And I think that's the document that Valerie was discussing earlier.

DR. MARKOWITZ: And does it have the cancer sites attached to that?

DR. MIDDENDORF: Yes.

DR. MARKOWITZ: Oh, okay.
DR. TALASKA: Yeah, I've been using that document for the last little while while listening to testimony and coming up with some of the sites and some of the compounds that are associated with it; and it for example in the discussion that we had for respiratory disease, clearly asbestos, PAH for hematopoietic cancer that are on our list, would be butadiene and PCBs. For non-Hodgkin's lymphoma, PAH is butadiene, formaldehyde, silica and dioxin. From leukemia, benzene, butadiene, formaldehyde, soot, PAHs and PCBs. And for thyroid the ones that are on there are dioxins, in furans and butadiene.
DR. WARD: Julia?
DR. QUINT: I also did what Dr. Markowitz did, is I counted up all the carcinogens and all of the IARC 1s and 2As and 2Bs and got 70. And I was alluding to what you said exactly in my earlier, not so articulate discussion of using the IARC list as a guide to deciding which cancers and I think Valerie actually had a broader list than I did. They have sufficient and limited. I only said the 11 cancer sites were the sufficient evidence, but we could definitely do the limited as well, and would be a broader number. So I very much favor that as opposed to any of the other two alternatives he listed, which was epi data and I forgot what the other ones were. Either that or all would be my suggestion.
DR. WARD: Let me just ask one question for clarification. So are you referring to both animal and human sites or just human sites?
DR. QUINT: I was referring to human sites. I think, and I had even narrowed it further to sufficient in human, which is a much narrower list. But I would be in favor of, you know, broadening that to the limited evidence as well. And it's this paper by Jim, right?
DR. WARD: Right. Well, there's two separate documents. There's a paper by Jim and then there's a document that Paul put together that's much longer.
DR. QUINT: That one I didn't get.
DR. WARD: That actually lists all the sites in animals as well as humans. But what it doesn't have is -- what Jim's paper has that's unique is it has the carcinogens associated with each site.
DR. QUINT: Exactly.
DR. WARD: But this, but Paul's more extensive document has the sites associated with each --
DR. QUINT: Okay. I didn't get Paul's document. And the only thing I would say about the animal sites is that there's lack of concordance with human sites, so I think we have to be a little careful about that. Because it causes cancer in one site in animals doesn't mean that it's going to cause that same cancer in humans, so I

would use caution with that.
DR. WARD: Yeah, I agree and I think that's, but I wanted to make sure that's what you were thinking as well.
DR. QUINT: Yes.
DR. WARD: Kimberly.
MS. FLYNN: I don't want to interrupt this particular flow of conversation; I just want to say two things. Would it be possible for both those documents to just quickly be resent to everybody because I'm hearing a little bit that not everyone has one or another of those documents?
DR. MIDDENDORF: I just sent the NIOSH summary out to everybody. And you want the Cogliano?
MS. FLYNN: Yeah.
DR. MIDDENDORF: Okay, yeah, I'll send that one right now.
DR. WARD: And we can even put the Cogliano up on the screen.
DR. MIDDENDORF: Yeah. We can even put the NIOSH one up, too.
MS. FLYNN: The other issue is just something I want to mark and then we can come back to it later. As I understand it, and as the AFL-CIO understands it, there is provision in the Zadroga Bill for an individual's physician to petition the World Trade Center program administrator for inclusion of that specific case of cancer, you know, based on the specific argument that would be made.
Maybe we can come back to this later, Dori. I don't know if you're the person to whom this question should be addressed but this is just in response to a point that Susan had raised. But again, I don't want to really, I don't want to interrupt the flow at this point.
DR. WARD: So as I'm hearing it, there's at least three options on the table which are not mutually exclusive. One is to focus on the limited epidemiologic study, the cancers that have been seen to be in excess in the published epidemiologic study. One is to focus on cancers basically based on routes of exposure, biologic plausibility and the sites where we've observed nonmalignant conditions. Third is to really rely on the evidence that's been assembled by IARC regarding sites of cancer associated with carcinogens that were present at the World Trade Center site, and that idea would include both sites that were deemed to be sufficient and limited in humans.
So I wonder if anyone else has a different point or a different idea than those three? I mean, obviously the other option on the table is to just specify all cancers and leave it up to the judgment of the physician.
DR. ALDRICH: Well, then you could also look at combinations of those approaches but the one big, big problem with just looking at the epidemiologic data is that

this was male only, and so clearly there would be no ovarian carcinomas, and there's a question about asbestos relationship with that. And there will be very, very few or very little possibility for breast cancer so I think that would be a problem to rely on that alone.

DR. WARD: Valerie?

MS. DABAS: I think that's why I think we leave it up to the individual physicians. I've seen them, it's, you know, on the basis that I've seen physicians specifically tell responders that their particular cancer is not linked to WTC, so it's not a far stretch to believe that physicians, individual physicians, would tell their patients that these are the reasons why their cancer may not be linked. And so if they have to make a written request to the program to get it, you know, to get this person admitted into the program for cancer, I think that they would do it with caution and we do have to leave the treating physician some leeway to make determinations for their patients because they're going to know that patient's background, that patient's, not necessarily exposure but other risk factors that may be associated that might have made them more likely than not to get cancer from the World Trade Center exposures.

DR. WARD: Tom? Did you have a comment?

DR. ALDRICH: Just one comment. I think it's dangerous to give individual treating physicians too much power in this situation. I think we see that with the Long Island Railroad disability problem. I mean, those, all those doctors verified disability.

DR. WARD: Yeah, I guess as an epidemiologist, I think I probably have more of a skeptical view of the information that clinicians would have available to them to make those determinations, and I do think we have a few people who see patients and make, you know, comp recommendations in the room and maybe they can speak to it as well but for your, I mean, one of the complications, I think, is that most occupational cancers are difficult to distinguish from non-occupational, at least based on pathology or symptoms or really anything about them, and so in the absence of epidemiologic data or, you know, other strong -- it's going to be a hard call from -- for the physician to make that determination, I would imagine.

MS. DABAS: But on some instances at the NYPD and FDNY, they have had to. When they filed for three-quarter pension disability, physicians have been asked to make that type of determination and further their determination is looked at by their district surgeon which is hired by the City, so there is some scrutiny to what these physicians are doing and I think that again, if we believe that cancer has -- there are multiple sources and multiple things that contribute to somebody developing cancer, such as their past history, then we have to, in a certain way,

also bring the physician in because if somebody has, you know, a history of -- has some type of medical history since 9/11 where they're getting treated for GERD and they're getting treated for asthma and they're getting treated for all these other things, and they develop a cancer, I think that physician can make the determination that their cancer might have, more likely than not, is caused by the inflammation from those diseases and thus World Trade Center-related.

DR. MIDDENDORF: I do think I need to caution the committee that the question before you is not whether or not you can push the determination downstream. The question before the committee is: Do you believe that all cancers or a specific type of cancer should be added to the covered list and what is the scientific justification for that? Pushing it downstream is not something that you really need to be thinking about or focusing on.

DR. DEMENT: This is John Dement, can I just interject a comment?

DR. WARD: Yes.

DR. DEMENT: With regard to the comment previously about asbestos and ovarian cancer, that's based actually on human data. The original listing in IARC for lung and mesothelioma did not include ovarian but these data came about later and is now listed based on human data as well as the larynx.

I guess I, as a researcher, favor a list based on the IARC criteria that we discussed as opposed to all cancers. I think it's much more defensible. And I too have a lot of concerns about placing too much, too much weight on physicians who may or may not have training to make these determinations.

DR. WARD: Thank you, John.

DR. TALASKA: I would agree with that very much. I think that we help the administrator much more if we can give the list of either sites or -- that have biological plausibility with related to the exposures that we know occurred, and that would help them make much stronger and much more defensible case in the political realm or any other realm. The stronger the evidence that we can provide for particular things. We have already admitted there's limitations of what's out there. And we're acting on the -- but we have seen that there is other information that we can use based upon exposure, based upon effects and relationships that are known either through human studies with previous exposures or through strong animal evidence where things like soots, where there seems to be an indication. And I think we help much more and build a much more defensible case by doing some culling and not just allowing individuals to be able to -- physicians particularly be able to -- they can say which diseases.

DR. WARD: So it sounds like several people have spoken in support of the idea of using the IARC carcinogen list. Would anyone else like to speak either in favor of

that or as opposed to it?
UNIDENTIFIED SPEAKER: I'm sorry, I couldn't hear you.
DR. WARD: Oh, I'm sorry. I was saying that several people had spoken in favor of using the IARC list, you know, the list of carcinogens that were present in relation to the IARC list of sites affected to make a recommendation, and I just wanted to know if anyone on the committee either wanted to speak -- further speak in favor of that idea or speak against it.
MS. MEJIA: Can I just make a comment? I mean, I just got this article so I really haven't had the time to look at it, but I'm uncomfortable carving out certain cancers over others.
In light of what Dr. Aldrich said, you know, we still have some questions about cancers in men and in woman and in children and in others, and again, I think that there will be controls and guidelines built into this at the other end that could then address, you know, whether that cancer should be covered or not. You know, I'm just uncomfortable about carving out and then leaving out a population that really should have been covered. Those rare cancers that Valerie spoke of, I don't want to play God here.
DR. WARD: Steve?
DR. MARKOWITZ: Well, you know, I think if we recommend a scheme, whatever scheme we recommend, that rare cancers should be included because they're rare and we have no way of proving or disproving, never will have any way most likely or hopefully they will remain rare, so I think they should just be included.
One vulnerability of the approach -- I think the IARC approach that I'm a little concerned about is this master list of 287 chemicals which are, as we see on the title up there, chemicals of potential concern, which NIOSH inherited from 2003 proc- -- 2002 process, where these agents were assembled from EPA data from four sources. And the vulnerability is that there's the word potential concern. And it's a very long list. Clearly there's good documentation for certain things like PAHs, asbestos, dioxin, you know, important chemicals. And there may be relatively little documentation for other agents on that list. We don't have the capacity to look at that and evaluate, select out which are important and which aren't important. But it is a vulnerability because that list is very long. And if in fact some of those exposures were truly just potential and they weren't necessarily there, then it makes the approach, it undermines the approach. That's what I'm saying.
DR. WARD: Yeah, so let me just say one thing. So in terms of the IARC list, when we talk about identifying sites associated with exposures, you're really only talking about the group 1 and 2a carcinogens, which is a much smaller list because IARC

only designates sites, human sites, for those things that are thought -- that have sufficient evidence in humans. But on the other hand that approach leaves out a large number of substances for which there may be compelling evidence of carcinogenicity in animals but just no strong and enough epidemiologic studies to demonstrate a site- specific effect.

So there's pros and cons but I think, but it is important for the committee to understand that if we did take the approach of using the sites for the IARC specified carcinogens, that that would be limited to carcinogens which IARC believes had sufficient evidence in humans because otherwise they can't specify a site.

Yes.

MS. HUGHES: I also just wanted to remind people there was a meeting early on, I remember, at the Javits Center, where a lot of the air quality data analyzed was discussed. I remember one of these sampling people might have been from the EPA, I can't remember. He was like wow, we found chemicals that we never even knew existed before. So they might not even actually make this list because we didn't know that they could have been created or formed and what their impact may be, so I just wanted to put that information out there.

DR. WARD: Okay. Paul just pointed out there's 14 group 1s. Fourteen or 15, so we're talking about a relatively small number.

DR. HARRISON: What about 2As? I'm sorry, Paul, did you count the 2As?

DR. MIDDENDORF: I can try.

DR. HARRISON: Is it possible to sort of throw up some examples? I'm getting a little confused --

DR. WARD: Can we throw up the --

DR. HARRISON: -- about what exactly we're proposing now? Right. So we're talking about using the Cogliano paper.

DR. WARD: Well, let me just say what the Cogliano paper is. So the Cogliano paper was done after IARC re-reviewed all of the compounds that had been previously assessed as group 1, so it's mostly that but he's also providing data about, I believe, 2A carcinogens. But I think the sites of cancer in humans are only listed, I believe, for the group 1s. Yeah.

So basically what they're doing is they're taking the agents that are classified as carcinogenic for humans and showing the associated cancer sites.

DR. HARRISON: And that's in table 1 and what was their proposal? So use the table 1 which has both the sufficient and the limited evidence. From the Cogliano so it's table 1 if I'm doing that correctly.

DR. WARD: Right, and just basically that's just the most, I mean, it's the most up-

to-date version of all the IARC information.
DR. HARRISON: And then to cross-walk that with the evidence for exposure from the World Trade Center site? So the chemicals would have identified a concern from the World Trade Center site. Cross-walked against table 1 and then to derive the cancer sites?
DR. TALASKA: Isn't that what your paper did though, the NIOSH paper? Didn't you do that cross-referencing already on World Trade Center sites -- excuse me, with World Trade Center exposures?
DR. MIDDENDORF: Well, what's in the NIOSH document is a listing of the -- it's an extraction from the summary paragraphs in IARC identifying what the evidence is, both human and animal. So it identifies the human sites as well as the animal sites that were looked at.
DR. TALASKA: Yeah, so for table 2 it's for limited evidence in humans, which could be because sometimes it's complex mixtures and the individual components are then listed inside of that and there's never been any human data, just one compound in PAHs for example, so there's several PAHs listed there for example. And then but then sufficient evidence of carcinogenicity in experimental animals, so if we include both table 1 and table 2, and then those have already been culled because they've been compounds which were identified at the World Trade Center.
DR. MIDDENDORF: All right, you're talking about 2 or 2A?
DR. TALASKA: I'm talking about NIOSH, in your NIOSH paper, you're the lead author, table 1, which is sufficient in table 2.
DR. MIDDENDORF: Okay. In table 1 are the group 1 IARC compounds.
DR. TALASKA: Correct.
DR. MIDDENDORF: And table 2 is group 2A.
DR. TALASKA: Two-A compounds, correct. So that takes into account some of the exposure situation and actually if we use that particular table, then we have a built-in biological and exposure plausibility.
DR. WARD: Right. So we have four tents up and we'll just go in order. So, Steve.
DR. MARKOWITZ: Just to clarify. Is the proposal to include the 2As? Two-As are probably carcinogenic in humans. Is the proposal to include the 2As? Two-As include, PCBs is a 2A; it's not a 1.
DR. MIDDENDORF: Right.
DR. MARKOWITZ: So 2As, a site is specified, I believe.
DR. MIDDENDORF: It is.
DR. MARKOWITZ: In the -- right. A cancer site is specified so we don't have that problem with animal-only data where we don't know what site it causes in

humans?
DR. MIDDENDORF: Right.
DR. MARKOWITZ: We don't have that problem with the 2As. There are only a few 2As on this list.
DR. WARD: Right, so certainly then we should include them. If the site is just -- see, I think it depends. Some things may be 2A and not have a human site because it's not based on human data but I mean, if it's classified as 2A and there is human data and there is a site specified, then I think it should be included.
DR. MARKOWITZ: I agree with that.
DR. WARD: Yeah. Julia?
DR. QUINT: I'll be brief. The only -- the other cautionary note that we should put somewhere in the recommendation is that this is ever-changing because these, you know, chemicals are being moved up based on mechanistic data so we should definitely state that this is a dynamic process within IARC and now NTP as well in terms of, you know, moving class -- reclassifications of these chemicals.
And I also wanted to ask, there's another paper from the 100 IARC monograph, 100 monograph series that was published as a separate paper and I'm wondering if that's included. If we have all of the substances from that table. It's a special report on metals, arsenic and dust in fibers. Did your list include all of those as well?
DR. WARD: I would think it should because that was one of the six subgroups of the IARC 100.
DR. QUINT: Right, and you went through the whole series. Okay. Great. Thanks.
DR. WARD: So Steve, your tent is up. Did you have...
DR. MARKOWITZ: Oh, no, I'm sorry.
DR. WARD: So it sounds like there's no disagreement that we might -- that we would want to include kind of the cross-walk between Paul's table of the substances present at the World Trade Center and the IARC group 1 and 2A carcinogens for which they're site-specified. But I think we should -- I mean, and that may cover a large number of the sites that we would be otherwise concerned with. But I guess one question would be -- so that's one approach and it's very systematic but should we also -- I mean, I'm concerned about the cancers that might be associated with the sites of chronic inflammation and irritation, whether we want to call that out specifically, and this may be getting beyond our charge but I still think it's worth having in our minds, so for some of those cancers, like laryngeal and oral pharyngeal, if they're specifically called out then there may be increased scrutiny or screening.
Now as someone who's now devoted their life more to general cancer issues, I can

say that it's not a foregone conclusion that early detection and screening is beneficial all the time. Sometimes it can just result in longer survival with the cancer and not a reduced risk of dying of the cancer, but still there's an -- yeah, it can. Unfortunately, so. So I guess but I do think it's worth, 'cause I guess in my mind still from, and it's from, you know, many of the things we discussed yesterday, I do have a particularly high concern for cancers developing at the sites where there's inflammation and irritation just because of all of the things we discussed yesterday. You've got exposure to mutagens, you've got -- and then you've got these chronic inflammatory processes that could very well enhance the potential for developing cancers at those sites, so that's one piece -- that's one question that, you know, I'd like to hear some opinions on. Glenn?

DR. TALASKA: I'm in strong -- now I'm in strong agreement with that, now that it's on. The best case for cancer synergy in the world is the interaction between aflatoxin exposure in China and the hepatitis B1. Individuals who are positive for aflatoxin exposure have about a five-fold increased risk of liver cancer and individuals with hepatitis B1, have hepatitis B, have it was like seven- or eight-fold but the interaction is 60-fold, so if you're positive for both you have a 60-fold excess risk.

And that's the idea, again, of irritation, increasing self proliferation. And I'm in full agreement with what Steve said earlier about for those sites where cancer occurs in the organ systems that are already included in the program, where there is irritation, where there is chronic exposure, where there have been effects documented I think, are -- should be really highlighted. That should be part of the biological plausibility when we say these sites, there are data from the exposure to support these sites. That should be highlighted. Where we know the exposures are high, that should be highlighted 'cause it gives the administrator much more information in defense when they come back.

The more information we can provide them, I believe, the better. And for those sites we don't know, we can include all of these other sites as -- if we want to just say we approve cancer. And then these are the ones which have this level of biological plausibility, these are the ones that have this level, this is where we don't know, from a scientific point of view, and we can help them out.

It's all we have. We just can't -- it's not really up to us at this point, I don't believe, to assign that now this is related to this, if there's no evidence at all.

DR. WARD: Yes.

DR. HARRISON: I just have a question. I agree with what you said, Liz. I just have a question about using the IARC 1 and 2A: Is that sufficiently precautionary in its approach? I just don't know enough. I just don't recall the criteria upon which

2As are developed and whether we're --
DR. WARD: No, it's not really -- I mean, because the reality is there's a lot of carcinogens on the 2B list that are, you know, are known to be carcinogenic in animals; there is not sufficient human evidence. And typically that's because there's been no opportunity to do definitive human studies. It's not that there are no -- it's not that there are negative studies, it's that there are no studies or there are small studies. But on the other hand, so if you're trying to look for sites of cancer, of potential risk from specific exposures, it's really the only, it's the only source of data because you can't specify a site at risk if you don't have human data. But it is a real limitation, and I certainly think that it's, you know, in general it's not precautionary to just look at human -- carcinogens based on human evidence.
DR. HARRISON: So are you arguing that we should include 2Bs?
DR. WARD: I don't think we can, you know, in looking at -- I mean, I think we should consider 2Bs as potentially carcinogenic but they won't be of great help in looking at sites and focusing on sites of cancer of particular risk.
Steve?
DR. MARKOWITZ: But, you know, we can make that explicit in the recommendation that we considered 2Bs and we ran into this practical problem was that they're not -- don't coincide necessarily with specific human sites but that if there's some way in which to use that information in the future or -- so is the proposal then to use IARC 1s and 2As and then supplement that with additional cancer sites for which there is epidemiological information, data or otherwise biological plausibility?
DR. WARD: I think so. I think, I mean, for sure the 1A and 2As for the sites, and then I think several people spoke strongly on the inflammation, irritation, biologic plausibility. I don't think very many people have spoken about the using the results from the epidemiologic study but certainly that's something we should consider. Yes?
DR. ROM: I just want to make sure that we're all speaking the same language. I was going back to the Cogliano article, table 1 lists the carcinogenic agents. There are a hundred things listed. And the second column says cancer sites with sufficient evidence in humans. I take that now we're all agreeing that's IARC 1. Okay, the third column says cancer sites with limited evidence in humans. I'm taking it we're all calling that 2A from IARC. Is that correct?
DR. WARD: It may not be totally exactly correct but by and large it's correct because a carcinogen can be group 1 without human -- without sufficient human epidemiologic evidence. If it has evidence in animals and it has evidence of the

mechanism in animals also being relevant in people. So that's the group 1. And 2As for the most part will have limited evidence in humans and sufficient evidence in animals, you know; in some cases where there's limited evidence in humans, they will specify a site for that.

DR. TALASKA: I think all the ones in table 1 do say they all have sites which have sufficient evidence, but then there are also sites which have limited evidence in humans, okay, so they've already been listed as 1A carcinogens because they have sufficient evidence for one site, more limited evidence for the other.

DR. ROM: Okay, this table also lists occupations so I think that we can pretty much ignore. And then it also lists many different medications and I think -- and so that's something we can ignore.

DR. WARD: And we're only focusing on the agents for which they're on the list of agents that were present at the World Trade Center site, which is pretty exhaustive. It's listing everything but you could speak to how that list was generated.

DR. MIDDENDORF: Essentially what we did was we went back and we took the list that the EPA had developed, and it wasn't just the EPA, they had some other folks with them, identified chemicals of potential concern from four different databases that they had put together. And then we also added, based on the suggestions from the committee at the last meeting in November, selected other chemical agents. I think we added soot and some other things that the committee had suggested needed to be added to that list, so we added those as well.

DR. WARD: Steve?

DR. MARKOWITZ: But Bill, there are some 2As that are in -- I don't think are in table 1. I think to get into table 1 you had to be a one.

DR. ROM: Right.

DR. MARKOWITZ: For instance, tetrachloroethylene, which is a 2A, it's perchloroethylene. And I don't see it here, but it is a 2A. It would be included if we recommended 2A.

DR. WARD: Yeah, and I think that's the proposal is 1 or 2A. As long as there's a site specified in the 2A listing, either sufficient or limited. Otherwise it could be included as a potential carcinogen but it's not informative as to site.

DR. MARKOWITZ: In looking at this list that Bill drew our attention to, there is radiation listed in the IARC and we haven't really discussed that at all. Is there any evidence that there was any exposure to radiation at the World Trade Center? Exposure?

DR. MIDDENDORF: Yeah, the limited data is reviewed in the first report, the first review of cancer, first periodic review of cancer, and my recollection is that there

is very little radiation exposure.
What was looked at, trying to remember what it was. Yeah, tritium was looked at and there may be some -- one or two others, but the general finding was that there was very little potential -- there is very little identified exposure to radiation. And by radiation I'm referring to ionizing, not non-ionizing radiation.
DR. WARD: Yeah, the one question that I had yesterday, when the results of the analysis of the uniform were presented, was that barium was listed. And I don't know enough about barium to know if it's -- I know that barium, forms of barium are used for radiologic examinations because they are radioactive, but I don't know that -- but it's not?
UNIDENTIFIED SPEAKER: No. I don't think so.
DR. WARD: Okay. Good.
MS. HUGHES: I also believe that there were medical offices at the World Trade Center site as well so that they had x-ray capabilities.
DR. TALASKA: But if the x-rays aren't turned on then there's no exposure at all, you know, unless they had a sealed source site and those are pretty well protected, pretty well. But I don't know.
UNIDENTIFIED SPEAKER: Not after an explosion.
DR. TALASKA: Yeah.
DR. WARD: So I guess one question that would be nice to have the answer to is: If we did what we're proposing to do, in terms of the IARC match, you know, are there major -- are there sites of concern that were found in the epidemiologic studies or for other reasons that would not be included, and I mean, there was a specific question about childhood cancer; we obviously have not discussed childhood cancer very much but maybe if we like that approach, then we probably should also look at what's excluded and Glenn and Tom both...
DR. TALASKA: No, all of the sites that, at least the ones that I mentioned earlier, respiratory systems, hematopoietic, non-Hodgkin's lymphoma, leukemia, and thyroid are all included in the list that was in Paul's presentations.
DR. WARD: What about prostate?
DR. TALASKA: Prostate? I don't -- let me check. Prostate'll be one I check.
DR. WARD: Tom?
DR. ALDRICH: Yeah, I was just looking that up. I didn't get to prostate but two -- what I was concerned about is thyroid and melanoma, and both of those get cross-referenced so I was just going to look up prostate and have that for you. Looks like there's some animal data linking prostate to several ones but I don't see any human data. No, I don't see any human data with prostate.
MS. DABAS: Just uniform, the barium that you found, it was from Day 1 the

uniform -- his uniform so at that point the x-ray machines hadn't gotten there so it wouldn't be likely that that's where it came from. His uniform came from being on the site on the first day and then leaving shortly after for medical attention.
MS. HUGHES: Point of clarification, I meant there were medical facilities at the World Trade Center complex. That could have had radiation in it and that could have been a possible source.
MS. DABAS: Oh.
DR. TALASKA: Prostate is one that wasn't -- there lead and cadmium are the two that are listed for prostate.
UNIDENTIFIED SPEAKER: Arsenic. And arsenic as well.
DR. TALASKA: And arsenic. Okay.
DR. WARD: So that would be included as well.
UNIDENTIFIED SPEAKER: Limited for arsenic.
DR. WARD: Yeah. Susan?
MS. SIDEL: I was just wondering if there's anything -- if we should like be comparing this list to say the list that came back from Lee on what was on that uniform just to cross-reference it?
DR. WARD: I think we can do that. I think -- I mean, like I said, I noticed that many of them seemed to be the same. The one that popped out at me as not having been on some of the other lists was barium but certainly we can, we can do -- but I guess the one caution, now that we're thinking about this approach, is that much of the data on these carcinogens that IARC used was from occupational studies and it was primarily men, so it will under-represent cancer sites that might occur predominantly in women or only in women, so that, that is an acknowledged -- it's a universal problem. Yes, it's a universal problem. But it's probably something that we would want to acknowledge.
DR. TALASKA: But Liz, we, you know, the barium that's used in medical procedures, if that's what we're worried about, is not radioactive.
DR. WARD: Well, that was my specific question.
DR. TALASKA: Yeah.
DR. WARD: Yeah.
DR. TALASKA: It not radioactive, it's used as --
DR. WARD: They make it radioactive.
DR. TALASKA: -- a radio-opaque substance.
DR. WARD: I see, gotcha, gotcha.
DR. TALASKA: Okay? Okay, so that they can trace the line of the whole --
DR. WARD: Yeah, thank you. Yeah. Thank you.
DR. QUINT: I just have a -- can I? I thought we were going to include the cancers

that had increased incidence in the epi studies along with the IARC list; is that not correct?

DR. WARD: Well, that was what I was just trying to get clarification on. We heard several people speaking in favor of the IARC and several people speaking in favor of the ones that were affected by nonmalignant diseases but only a few people had specifically said to make sure -- I mean, many of them will be covered already.

DR. QUINT: Right.

DR. WARD: But I guess even if they're covered already, we probably, in our evidence summary, would like to specifically state that there's further evidence from an epidemiologic study.

DR. QUINT: I would agree with that. I want that included as far as --

DR. WARD: Tom?

DR. ALDRICH: From the epidemiologic study, there are only a few individual cancers for which there was even a suggestion of increased cancer risk because the numbers were so small. I mean, even though it was close to 10,000 people, the numbers of cancers were small, so non-Hodgkin's lymphoma, but that's already going to be covered based on IARC; thyroid, same thing; melanoma, same thing. The only concern is prostate. And the truth is the epidemiology for prostate is pretty weak because the prostate is one of those cancers that is really, really susceptible to surveillance bias. And post-9/11, people were getting a heck of a lot more exams and blood tests detecting prostate cancer. So I'm not sure there's a clear-cut -- any clear-cut evidence of prostate cancer has increased by the events of 9/11.

Now, we heard yesterday from -- that the Sinai study may show that but, you know, we can't base anything on a few words about what a study that has not yet been published will or won't show. So I find it difficult to justify including prostate.

DR. WARD: Valerie?

MS. DABAS: I guess my question on the prostate with the fire department study is just the average age in which these people were diagnosed. You know, we can say that the number is not significant when we look at the general population but do we look at the age of these -- you know, if the average age to be tested for prostate cancer is 55 and we're getting people that are in their 40s getting prostate cancer, is that not an area for concern and do we just dismiss prostate cancer in general?

DR. ALDRICH: Among the non-exposed people in the fire department study, they were all under the age of 60 at the onset of the study. And there were a substantial number of prostate cancers, both in the exposed and unexposed

group. What was not so clear was that there was an increase. So it's not like there -- prostate was one of the ones -- one of the highest represented cancers in the unexposed group, so I think the problem isn't lack of case finding and I don't think the problem is an age issue with prostate. There may be an increased risk of prostate cancer from World Trade Center but I don't think the epidemiology is enough to show that, and we don't have any chemical, what do you call it? Chemical risk data that shows a prostate risk.

DR. WARD: I thought somebody said lead, arsenic and cadmium.

DR. ALDRICH: Did I miss that in my search? If that's the case then we don't have a problem.

DR. WARD: Yeah. Glenn?

DR. TALASKA: Yeah, the cadmium one is going to be tough because there was biological monitoring data and cadmium is one of those things which persists. So once you're exposed to cadmium, you know, your first day of exposure to cadmium -- if you're going into a job making batteries, 30 years later when you retire, you'll still have 50 percent of that first day's exposure in your body. Okay? So cadmium is one of those compounds where it leaves a long trail. So basing it just on that, I think, is a little bit weaker and will set the administrator up for a bit of criticism from it because in fact cadmium levels were lower in the firefighters than they were in the control population overall. There were a few -- there were some firefighters that had had higher levels.

DR. WARD: Susan?

MS. SIDEL: I was just going to say, the one point that I wanted to make is that maybe, you know, the other factor is considered, that is this cancer unusual in someone in this age, and so therefore it was something that wasn't going to be included, it could be included because it's affecting somebody, you know, at a time when they shouldn't be having it. If they were too young to really have this cancer so then it's more likely that it's World Trade Center-related. That could be some sort of a caveat that maybe it's not just cut and dry, that there might be some other, you know, extenuating circumstances?

DR. WARD: And I guess where I don't -- so that, would that be something that would be considered in terms of an individual clinician recommendation or is that something that we would need to make in our, in our recommendation?

MS. SIDEL: I mean, if we're thinking about excluding something, I would, I would say that we should say, however, there is this factor that we -- that if somebody is below the age of whatever, that that's unusual, it's unusual to contract this cancer at that particular age, if that's the case, with what Valerie was saying about prostate, that the people that were getting it were too young to be getting it.

DR. WARD: Julia?
DR. QUINT: One thing that might be equivalent in toxicology is the time to tumor in animals. When you treat animals with, you know, with the chemical and they get tumors earlier, that's considered significant in terms of the findings, so we may have the human equivalent of that with some of these high intense exposures over a short time period in humans. I mean, that could be plausible.
DR. WARD: Yeah. Catherine?
MS. HUGHES: I'll pass for now.
DR. HARRISON: One advantage I can see to this approach is that it eliminates the need to deal with dose. So I think we're basically would be saying that if we're using a 1 and 2a and cross-walking with the exposures from the World Trade Center, if you have one of those covered cancers, you're eligible, after review by the physician and NIOSH, for treatment and compensation. So I think that has some real advantages because it gets -- you basically, I think, skirt the issue of how long were you there for, what the exposure intensity was and maybe even a latency period, although we haven't talked about the latency period yet. And I think I support that approach for its simplicity and its precautionary principle embedded in that; although, there's a part of me which says that -- there's a little bit of discomfort I have also with that approach because, you know, basic principle for many cancers, although there's certainly no threshold for carcinogens and some concept of dose response and dose risk, which we are not, which we are maybe not acknowledging this approach somehow. But I think I'm okay with it.
I guess I just want to say I think that that's a sensible approach that affords the kind of treatment and compensation to this population that I think we've heard lots of testimony over the last couple of days that's very compelling in terms of, you know, providing the services that people need.
DR. WARD: Tom? No. Steve.
DR. MARKOWITZ: I want to make sure I understand what you're saying. That we defer questions about dose and time factors to -- we don't make any recommendation about dose and time factors?
DR. HARRISON: Correct. I'm not proposing that we make any recommendation. It's almost like a presumption. Steve, you know, like there's a --
DR. MARKOWITZ: No, no, I agree with it.
DR. HARRISON: Right. Yeah, there's a cancer presumption here that if you fall into this group and this category by some scheme, 1A, 1 plus 2A plus a cross-walk to the exposure plus biological mechanisms and the other factors that we mentioned, that you're covered.

DR. MARKOWITZ: One other comment that I have, is one way of addressing Susan's concern about age is, if we do have kind of an escape clause for rare cancers, that we could define rare as being by site or by age, and that would cover that. That leaves a lot to the discretion of the treating physician but that's okay.
DR. WARD: I guess another question that I would have about this is, is in the end, are we going to come close to covering, by this approach, all cancers anyway?
DR. MARKOWITZ: No. I don't think so. I'd have to look at the tables but I don't think so.
DR. WARD: It would be nice to -- if we could -- I don't know how quick anyone can do it 'cause I -- I mean, if we're covering, if it turns out that we were covering 90 percent then -- you don't think so?
DR. MARKOWITZ: No.
DR. WARD: Even keeping in mind that lung, breast, colorectal and prostate are probably 50 percent of all cancers. So I mean, it's probably worth looking at to see which -- I mean, it's probably a majority of cancers that will be covered when we do this tabulation, I'm guessing, so then the question is which ones will not be covered, and then the other thing I think we need to be careful of is sometimes when IARC designates sites, it may -- they may not exactly match up to the sites that we know of today -- I mean, it's not going to -- I mean, we need to be careful, when we make these final tables, that we are not inadvertently excluding sub-sites or, you know, things that really should be included conceptually.
DR. MARKOWITZ: By the way, I don't see breast cancer on this list. I'm not advocating it, I'm just saying it's a big cancer that's not on the list, as an example. Most of the cancers, if you combine 1 and 2As are the respiratory cancers and the head and neck cancers, including pharynx, nasal sinuses, GI cancers, I think thyroid and prostate, melanoma and --
DR. WARD: And leukemia.
DR. MARKOWITZ: And the blood cancers.
DR. WARD: Yeah, blood cancers.
DR. MARKOWITZ: Including lymphomas and all the leukemias. I think that's it. And bladder cancer.
DR. WARD: Yeah, and I guess that really -- at this point one of my biggest concerns still is that we're not covering women, and it's not something that we did but I mean, it's going to be problematic, I think, as this recommendation goes forward that, I mean, that that is one of the limitations of that database so we should think about how to -- if we can address that and how. Bill?
DR. ROM: I have reservations of using the IARC list and I think it goes too far. And if you take the IARC list and you start with the first item, and the first item on the

list is arsenic. We're all in pretty good agreement that if you inhale arsenic you probably have an increased risk for lung cancer. But there's also a lot of toxicology violations here. You start off with oral arsenic, and then with oral arsenic, you've got bladder, skin, liver and kidney. Now we're getting what I would say is a reach that, you know, this isn't really relevant to WTC dust exposure in our experience of what we're supposed to be recommending.

So if we are to use the IARC list, and Dr. Rom says this is a reach, I think somebody needs to go through the list and annotate this and say what's relevant and what's not relevant, and I would say that oral arsenic, on the very first line at the top of the list, is not relevant to our WTC dust exposure.

DR. WARD: See then, I would argue with you. So this is why I get so difficult 'cause I would say well, a lot of the evidence for humans in arsenic is from drinking water; and people are working on the site, they're eating, they're drinking, they're touching their lips, so people have the potential to absorb arsenic through the oral route and again, I -- yeah, so that's where you get -- it gets so hard, when you try to fine tune it too much, you're going to have a lot of differences of opinion.

DR. ROM: I would argue that if you went to Bangladesh, where you've got the highest arsenic exposures in the world, you're going to have, you know, there's going to be some increased cancers, but trying to find these sites is going to be a real challenge.

DR. WARD: Well, I think where a lot of the data comes from is epidemiologic studies in countries where there is highly arsenic contaminated water, and so you do see excess bladder cancers, for example, associated with living in areas that have high arsenic content in the water.

And the other thing is that a lot of these same sites are related to some of the other carcinogens on the list.

So I also have qualms about the IARC list and the two of them are, there is, I mean, it's not really addressing women very well and it really is only those things for which epidemiologic studies could be done, and we know that that's not the whole universe of potential carcinogens. So I do think that it should be the IARC list plus, not just the IARC list.

DR. ROM: I would counter-argue once again that somebody needs to go through this list with some judgment about medical toxicology, about the route of exposure, the quantity of exposure, because you can go to benzo(a)pyrene and we think that has always been the big carcinogen in tobacco smoke, but when you get right down to it and look at adducts and all of this, you'll find that there are other carcinogens in tobacco smoke, like petroleum, which are in other aldehydes,

that are in huge quantities and make just as many adducts. And benzo(a)pyrene may not be the carcinogen for the lung cancer. And you go to the second line and we have benzo(a)pyrene as lung, bladder and larynx, so somebody's got to make some judgment calls about the sites related to what the exposures were, the quantity and the type of exposure, whether it was inhaled or skin or what have you. And that may be the job for the administrator and his staff.

DR. WARD: Tom?

DR. ALDRICH: I think you make a really good point about women being left out of much of the research that's gone on to generate the list, and mostly we're talking about breast, ovarian, uterine, cervical.

As far as ovarian they're probably going to wind up being included along with the asbestos risk. Breast seems to me to be the big problem. But aren't there enormous databases of breast cancer patients and wouldn't it be a quick, easy study to do a case-control study of breast cancer patients for World Trade Center exposure in the background? Wouldn't that be something that could be done from retrospective data that's already sitting in a database up at Sloan Kettering or somewhere?

DR. WARD: I doubt it.

DR. ALDRICH: Couldn't we marry that with our other research mandate to say you must do a case-control study?

DR. WARD: Well, I think it's an important issue but I don't know. I mean, it's usually epidemiologic studies are not, you know, there's no such thing as easy in epidemiologic studies.

DR. ALDRICH: True, but breast is such a common tumor that it might be one where this kind of approach would be very fruitful in a very short period of time.

DR. WARD: Right. And I do think that, you know, especially if we could do a population-based study rather than a hospital-based study, there might be some benefit. So okay, I think we need to figure out, I mean, I think there's concern about over-reliance on the IARC list. But, I mean, I'm not sure that it makes sense for us to recommend fine tuning the IARC list any further because I think we're going to run into the same problem we've run into before, that we don't have enough information about level of exposure and route of exposure and relevance to further refine that list. And in addition most sites will be listed -- will be on the list because of their association with many or at least a number of carcinogenic exposures, so their inclusion will rarely be based on one particular exposure. And even for benzo(a)pyrene, for example, benzo(a)pyrene is just one of many PAHs and a large number of -- or at least a significant number of the PAHs are carcinogenic. It's not just benzo(a)pyrene.

So I, I mean, so somebody else, I mean, could kind of, I'm looking at Steve 'cause he's been so good at pulling consensus together. Kind of summarize where you think we are from hearing the discussion, both what you think there's general agreement on and what there might not be general agreement on that we should discuss further.

DR. MARKOWITZ: So I gather there's some consensus around recommending the use of the IARC 1 and 2A categories in combination with the NIOSH list they've already published in their first report on carcinogens, the contaminants of potential concern, to identify specific organ sites where a cancer is likely to be related to World Trade Center exposures; and then secondly that that list be supplemented by additional cancer sites in which there's either a strong biological plausibility, strong exposure information or epidemiologic data that support addition of those sites; and third I would -- I'm not sure there's a consensus about this but that rare cancers should in addition be included, rare being defined by site or by age. Was there anything else?

DR. WARD: And I think the -- I mean, so two outstanding issues are, you know, we probably don't have to go further in defining rare, but I think we should acknowledge there is a big complexity there so, you know, I mean, is brain rare? When brain is rare -- and no, not rare. Okay.

DR. HARRISON: Liz, excuse me, I just want to say goodbye. I'm sorry but I have to really.

DR. WARD: Thank you so much. Sorry.

DR. HARRISON: And I do support what's being said.

DR. WARD: Okay, great. Great. Thank you. I'm noting to the record that Bob Harrison is leaving.

MS. HUGHES: Can I ask one point of clarification? Is there a list that talks about what the average age are for different cancers? 'Cause we haven't seen that table.

DR. WARD: There's actually lots of data and I can easily provide some of -- I mean, I can provide all of it basically from the work that we do at ACS. So we basically have age-specific incidence rates for pretty much every cancer and from that -- and we also have estimates of the number of people per year diagnosed with specific cancers at specific ages. Sometimes those numbers can be a little bit easier to digest. And these are not just our numbers, I mean, we share the numbers with the National Cancer Institute and the CDC, so that's pretty straightforward information to provide. I think what's more difficult is to know where to draw the line as to what we consider rare and common but I'm imagining that we won't get into that level of detail in our recommendations.

So the only issue -- one of the issues that I feel is not covered there and maybe we should at least address is, as Tom said, for breast cancer it, you know, I mean, we either could take no opinion or we could say it should be covered or we could say that it really needs to be a research priority because most of -- a lot of the data that we're basing our determination on is occupational studies where there were not sufficient women to address female, breast and gynocologic cancers.

DR. ALDRICH: Steve Cassidy just pointed out that the EMS fire department study is being analyzed as we speak and its results will be in the not too distant future and more than half the EMS workers are female. Now, the numbers won't be 10,000 but it'll be a lot.

DR. WARD: Great.

DR. ALDRICH: And breast is a common tumor, so.

DR. WARD: Great. And that fleetingly passed my mind, too, so I'm glad you mentioned it. But still for the recommendations at this point in time we have to decide whether to just let it rest or to make a specific comment about it, I think, just because it is one of the foremost common cancers in the population and we're really not able to address it with that particular database that we're relying on for most of our information. So even if we just say that, it should probably be addressed. In the context of whether the -- you know, why did we choose to take this approach and then what are the limitations of the approach. Steve?

DR. MARKOWITZ: I want to come back to Bill's point because I think it is a vulnerability for the administrator about adopting this approach, which is, you know, that list of 287 chemicals was, you know, contaminants of potential concern. I keep thinking about potential and thinking about what kind of exposure -- kind of sampling that was dependent upon and we heard about some of the limitations of sampling, and it may be that some of those exposures were not important at all or maybe even not have occurred at all. I don't know what potential means there. So it may be worth amending or putting in into the text around these recommendations that this list should be examined with reference to, you know, the validity; acknowledging that there are, you know, big problems with the measurements that were taken.

DR. WARD: Yeah, and I think one of the things that we presented yesterday was partly a selective view from me on, you know, what -- of the ones that are 1A, like asbestos, I kind of highlighted some of the ones where they were significant exposures so no one can argue that one percent by way of asbestos is not significant, and then they're also, you know, group 1A with very strong evidence of carcinogenicity and pretty strong evidence about specific sites, and some of the other ones that we focused -- that's one of the reasons we focused on the metals

because there were a number of metals that were there and a fair bit of -- and reasonably high concentrations that were group 1A, so I think when we look at it there will be some carcinogens listed that some might argue -- I mean, vinyl chloride is an example where I, at least, wondered you know, vinyl chloride is listed but was it really a significant exposure, but, you know, it would take deep digging to know that because, you know, if it was a product of pyrolysis of some of this stuff, then it might have been a significant exposure.

But yesterday I kind of focused on the ones where there was evidence both that there was -- the 1As where there was evidence of substantial exposure but it would be a lot of work, I think, to go through and try to look at the others.

And yeah, and it's probably a caution 'cause it's just based on evidence that it was there. There was no minimum set for the amount that was there. But I think that it's probably also true that many of the ones that were, you know, were facing a fair number of sites on, like asbestos, were there in large quantities, and that there were numerous lung carcinogens present. So it's really very few sites that will be based on, you know, one compound alone that had questionable exposure associated with it, I think.

Kimberly?

MS. FLYNN: I'm just wondering whether we need a special statement about children because children are not just little adults. I don't know if children cancer sites differ from adult cancer sites, and maybe Leo could speak to this.

DR. TRASANDE: Thank you. I think Steve's comments start to address this insofar as there are, if we -- and I think there's a delicate dance of how this is written that will -- we'll just have to keep a close eye on.

I think, I am -- I always have some caution about a blanket inclusion of all of the whole population without regard to any plausibility or scientific argument. But I think the argument that Steve has pointed out about the rare cancers for which there are potential benefits by including in a precautionary mode, that are real and important to consider, so my current inclination, and I think this needs to be a group process; I certainly shouldn't drive this, would be to include all pediatric cancer in the bill. But I say that with quite a bit of caution recognizing that there are a host of cancers that will occur naturally in an unexposed population. And that's a risk that we all -- I think we all are accepting across a host of other conditions as well.

DR. WARD: Julia.

DR. QUINT: I was just going to say that some of the uncertainty about the list of chemicals and which ones were relevant and some of the exposure route data is offset too by the large number of volatile chemicals for which, you know, we have

-- that are 2B carcinogens, a lot of them -- for which we have no human data so we won't be saying anything about the sites for those chemicals. So I think there's uncertainty on both ends where we're leaving some possible cancers out because we don't know -- we don't have the data, we don't have the studies to support them, and we'll overstate some other things maybe but there is -- and those qualifications have to be clearly stated in the document. I mean, we're still operating in an area of uncertainty; we're just doing the best we can based on the information we have.

DR. WARD: Right. I agree. And I think, you know, I mean, in some ways until we actually see the list and how it tabulates, we may still need some further discussion but it sounds like there's some agreement at least on the approach. So is there anyone who would still favor listing all cancers as opposed to the approach of trying to narrow down the focus somewhat by looking at the IARC or looking at the criteria that we've discussed, the IARC criteria, the nonmalignant irritation and inflammation, the epi studies, the rare cancers and the proposal to include all pediatric cancer? Valerie?

MS. DABAS: I guess my reasoning for saying all is because I haven't seen the list yet. You know, these are all lists that, you know, we're saying okay, well, the epi studies, biological plausibility; what does that mean? Which ones are they? Until I see it on a chart, then I can't say that I would definitely say okay, let's piecemeal it out because most -- 90 percent of the cancers are included, and there are 10 percent that we know for sure that will never be, you know, associated with exposure, that those are the ones that we're leaving out.

My concern is just, we won't have this list today. I'm assuming that once we leave here, you know, the list will go around. I'm not sure what the -- how we're going to take it from here but I mean, IARC plus this plus that. If I could see it, I think I might be able to have a better understanding of where we're going with this and not -- and move from all to that list. But until I can see that list, I can't move from all to this.

DR. WARD: Kimberly?

MS. FLYNN: Oh, I'm sorry.

DR. WARD: Oh, I'm sorry. Let's hear from Julia and then Paul suggested we have a break so that everybody can stretch and think.

DR. QUINT: I just have one -- do we have a list of all the cancers? I mean, even when we get the list of the ones we've mentioned, I'm not sure what universe that represents.

DR. WARD: Well, actually I mean, it's not all.

DR. QUINT: All cancers, I don't mean all cancers in the world. I mean, all cancers

that have been diagnosed or whatever that seem to be WTC-related. Because that's the denominator that we're --

MS. DABAS: I don't think we can 'cause while I sat here today I got an email from somebody that was diagnosed with sinus lymphoma, some type of sinus lymphoma, so every day I get a new call about somebody that is diagnosed -- has been diagnosed and hasn't come forward yet. Or, you know, lives in another state and is completely oblivious to the discussions that go on here or go on in New York City about cancer, and have convinced themselves, you know, that it's not related so therefore they shouldn't make a phone call to, to that.

And then again, you know, these monitoring programs are not monitoring for cancer so people are steered away from them. If you believe you have cancer, you're going to an oncologist, you're not going to Mt. Sinai. You know, once you've been diagnosed you're definitely not going to take four hours of your day to get the first exam and then follow-up exams because you're going from one oncologist to a PET scan to, you know, all these other appointments.

What I've been told by the people that are diagnosed is that they retired from the NYPD and became full-time patients as their second job. So in doing so reporting their cancer is never the first priority.

DR. WARD: But I think, yeah, there are lots of ways cancers are classified but the list we shared earlier -- so this is basically the classification by primary site and this is a standard classification and it should really capture all malignant neoplasms. There is going to be a category of other and unknown. There's other ways to classify cancer, by histology, but probably this would be the most logical way to classify cancer and it would capture all the histologies. Yeah, and then but the question of the rarity is you may be able -- a cancer may be rare based on its histology, not just its primary site and so we may have to grapple a little bit with that.

DR. ALDRICH: I think Dr. Harrison mentioned the premalignant conditions. I think it was -- and I think those are important, the hematologic premalignant conditions are important things to include in the coverage specifically because those people definitely need follow-up. They may not need expensive treatments, which is a good thing, but they definitely need follow-up and ought to be specifically included, even though they're not cancers. And maybe on the other end of the spectrum, of course, we wouldn't want to include basal cell carcinomas of the skin because it's really not the same kind of biology as other cancers.

DR. WARD: Yes, and I totally agree with you and I'm hoping -- well, so not only do I agree with you, and I think that opens the door to an important research area because I do think that, especially with multiple myeloma, there's a lot of new

research on the premalignant conditions, and so, but I would appreciate that one of the clinicians actually puts together a list of what those are because --

DR. ALDRICH: I nominate Dr. Rom for that.

DR. WARD: Good. I know some but I don't think we know all. Leo?

DR. TRASANDE: I just want to make a follow-up comment that, related to my comment in the earlier session about the possibility of adolescent and early adult cancers in pediatric or perinatally exposed populations for which we have no idea. I'm not saying for which we have no idea a priori as to which may occur. And I'm pointing this out as a potential research need more than anything else. I'm not suggesting it be included in the bill but I think it's certainly a concern that merits watching. It might be that early onset adult cancers arise in pediatric exposed populations insofar as there's greater proximity, greater time of exposure, acute subchronic and chronic types of exposures as well. Thank you.

DR. WARD: Okay, so I think we should take a break so everybody has a chance to move around and think about the issues.

(Recess 2:40 p.m. to 3:08 p.m.)

DR. WARD: So all the committee members take their seats. Hi, John and Virginia, are you still with us?

DR. DEMENT: This is John. I'm still here.

DR. WARD: Hey, John. Since we've been talking for a long time and I know you were able to interject once, I would like to give you the opportunity if there's anything you'd like to add to our discussions before we get in the thick of it again and forget you're there.

DR. DEMENT: No. I think I agree with the approach that we're taking. I'd like to hear a little more discussion of the rationale for including all of the pediatric cases, if that's the proposal on the table.

DR. WARD: Okay, it just happens that Leonardo's tent is up so we'll --

DR. DEMENT: Very good.

DR. TRASANDE: All right, I'll address John's question. The thought process flowed from the fact that we know that a number of members of the community, many members of the community had exposure ranges that likely overlapped with ranges seen in firefighters and other responders in which increases in cancer had been detected, and that raises the significant potential or plausibility. The fact remains that in a sample of at most 46,000 children below 14th Street on September 11, 2001, it's un -- it would be hard to be convinced by any study that would be negative for cancer associations, and accepting that as definitive. And in the absence of such a study, we have to fall back on biological plausibility and in the context of children's unique vulnerability to chemicals such as those identified

in the World Trade Center disaster, there remains an extra cause for caution and perhaps precaution in that population. And so I can't define for you a footprint of cancers that I would expect plausibly to be increased in a pediatric population because I don't think we've seen a pediatric population exposed to something of this magnitude. I suppose we could start to reason by certain disasters like (inaudible) but they're different.

And so that begins the line of reasoning towards supporting the inclusion of pediatric cancers, and it builds to some degree on the principle Steve outlined about including rare cancers. I think they're grounded in the fact that there's really not an epidemiologic platform on which to build and sustain a definitive decision, yea or nay, as to whether an association can be confirmed.

So John, clearly –- love to hear your thoughts -- you're much more expert in the world of carcinogenesis than I am.

DR. WARD: John, do you have any comments?

DR. DEMENT: Yeah. Yeah, I agree with the concerns and somewhat the rationale. I guess what we're talking about is cancers that would be different from the sites that we're going to identify based on the identified pollutants in the exposure and the IARC list. So it would be those that would be again, fairly rare, I would think in addition to those.

DR. WARD: Okay.

DR. TRASANDE: John, and my response would be that given what little we know about the causes of cancer in adults and what much less we know about the causes of cancer in children though, benzene 1,3-butadiene and a few others coming to mind, I think it's hard to a priori elaborate such a footprint that we would anticipate for pediatric cancers that might emerge or a unique pattern. Other than some of the increases in incidents that we've seen in the context of increasing chemical exposures at large, thinking of testicular, brain and leukemia being the three that I can think of. But that wouldn't be a reason for putting those three conditions above all of the others in the context of an acute World Trade Center-related exposure. Those are in the context of more sub-chronic or chronic exposures.

DR. WARD: Yeah, and I guess the other issue is that just the distribution of cancer types in kids is so different from that in adults that you really can't -- I mean they don't even line up very well, like there's not much lung, there's not much colorectum, so yes, so it would be hard to infer one from the other.

Okay, and I mean, I do want to make sure, I think, I don't know that we'll have a -- be able to make, have a statement drafted to read to the committee by the end of this meeting unless anyone else has had time to write one. I hope to write one.

DR. TRASANDE: So my placard was up for a different reason.
DR. WARD: Oh, I'm sorry.
DR. TRASANDE: It was process, actually, related.
DR. WARD: Okay.
DR. TRASANDE: And so I would be keen to see a draft consensus document, if we could achieve a rough consensus here. And I would see the need for -- I don't think we're going to get there by 4:00 p.m., given that it's 3:15. And so my anticipation is that we will need a conference call follow-up to review and approve a draft document. And that brings me to well, how is that document going to be created, and my -- and I'm certainly not committing to be a major author in such a document. There are others that probably are best suited to do that but I do think we need to resolve pretty quickly what's next in getting to that report and then having a discussion about it, but that's just a suggestion on my part.
DR. WARD: Well, Dr. Howard has already granted our extension for our comments to be submitted no later than April 2nd so we've moved the deadline from the March 2nd to April 2nd. I think there's a couple of components, I mean, two things that I think we can do fairly quickly after this meeting is write up a summary that will include the list of IARC carcinogens in sites, so everybody has an opportunity to look at that, look at the other sites that we've agreed to based on the lines of evidence that we've discussed. Then I think there needs to be -- and I'd like to do that sooner rather than later just so people can think about it. But then there needs to be an effort to actually write our recommendations out in a report. We will hopefully fairly soon have access to Ray's transcript of our discussions this afternoon, which he's agreed to put first on his priority list above the rest of the meeting. So we will actually be able to pull some ideas and text from things, you know, thoughts that people have expressed during this meeting. And then of course if there are people who would like to work on a draft specifically, then we can have volunteers to do that as well. I'm certainly willing to work on it, too. But then the idea would be to get a draft out that then would be the topic of discussion at a conference call after -- hopefully we would get the draft out long enough before the discussion so that people would have an opportunity to review it in detail and possibly even send comments so that we could try to incorporate them in the draft that we're reviewing on the conference call, but that is a pretty tight time schedule. Now our conference call will have to be announced in the Federal Register so Paul can talk a little bit about that.
DR. MIDDENDORF: As far as the Federal Register is concerned, basically just give you the short story, I'll need to draft the Federal Register notice next week, early next week, so if anybody has any suggestions on agenda items, I need to get those

before early next week.
DR. WARD: Yes, Leo?
DR. TRASANDE: I also just have one other -- I realize that this -- the other at least burning topic on my forebrain about this meeting was the research agenda and whether we as a committee needed to approve that document from which the draft was sent around. And my instinct would be to try to close that aspect of business, that the conference call would focus on the cancer document.
DR. MIDDENDORF: I don't think we need to do anything more with the document, it has been submitted. If there are new research ideas that the committee wants to forward on, they can begin developing a new document.
DR. WARD: Glenn?
DR. TALASKA: I was wondering, one thing I mentioned this to you once, Liz, and to other members of the committee, one of my concerns is that, really, to honor the people that were the first responders in this site that we learn something from the mistakes of the exposure metrics that were gathered for this particular catastrophe, and perhaps is it within our purview to be able to make recommendations of what things should be included for a national response, for the next -- to protect anybody else in case there's another catastrophe of this magnitude or a magnitude like this? Is that something that this committee can deal with?
DR. WARD: Well, I mean, my first question which, and then I'll turn it over to Paul, is I think to a certain extent that has been done in other venues so my first question would be to look for whether it's been done before and et cetera, if we really have something to add, but I'll turn it over to Paul in terms of our charge.
DR. MIDDENDORF: Yeah, I think if you look in the Zadroga Act and looked at what the charge for this committee is, it is a scientific and technical advisory committee, and that would probably be outside the scope. However, if you wanted to make suggestions to the program on things on an individual basis, you're more than welcome to do that.
DR. WARD: Right, it's also possible that members of this committee, if there's, you know, if they feel moved to, to get together and write a paper, then, you know, they -- because we are going to be immersed in depth in some of these issues and there's certainly no prohibition from taking that into a scientific publication with people who would like to work together on that.
DR. TALASKA: Okay.
DR. MIDDENDORF: It would not be a product of the committee, though. That would be your individual efforts.
DR. WARD: Right. It would be a byproduct but not a product. So I'd like -- I mean,

is that process -- Valerie.

MS. DABAS: Yeah, I just had a question for Paul. Did you want us to send you possible dates or how would it work in trying to figure out? You said you needed some time to put it on the docket, so I just wanted to know if you had directions for the committee as far as what they need to do to facilitate that.

DR. MIDDENDORF: Yeah, what I'll do is as soon as I get back in the office I'll send a Doodle request and try to identify times. One of my questions for you: Do you think that a four-hour time frame is enough? I'm getting a lot of head shaking, so. We will have to include a public comment session so that would reduce it to about three and a half hours. But I think we can make that a short public comment section but we do need to allow that within our agenda. And it would probably be close to the end of March because that's the only time frame that's available to us in terms of when I have to get the Federal Register notice in and how much lead time I have to give them.

MS. DABAS: And if the Mt. Sinai or the fire department study is out by then on the EMS workers, would we be able to see those and evaluate those, and if anybody from those entities wanted to present the findings, would that be okay for that date?

DR. MIDDENDORF: It's certainly an agenda item you can suggest. And I'm wondering is that actually going to be published or it's only going to be submitted at this point?

UNIDENTIFIED SPEAKER: Yeah, it's going to be submitted.

DR. MIDDENDORF: And so I doubt that it will be out by -- in the next month.

DR. REISSMAN: I just wanted to respond briefly to the question about whether or not your advice or your input would be helpful. You know, we're always interested whether -- it's outside the committee, but we've done a lot at NIOSH, and also within HHS in general, in response to the lessons that were observed, I'll put it that way, in 9/11. And one of the major projects that NIOSH tried to help coordinate in all of this was an emergency responder health monitoring system, and it's a guidance document that's in a -- I think it's in a docket with NIOSH, and I'll find that and give it to you so that it can be put out there. But it talks about all the lessons learned in all of this from a responder safety and health perspective. Not from the community perspective 'cause NIOSH typically doesn't deal with the community except within this venue. So I just wanted to let you know about that.

DR. WARD: Are there comments or questions about the process? Glenn?

DR. TALASKA: No, no. That was -- sorry.

DR. WARD: Okay, so any other questions or comments about either the discussions today or the process? Yes.

MS. HUGHES: Can you clarify a little bit more how the report will address the precancerous conditions? 'Cause I know that had come up. That it wasn't only the end result but sometimes something along the way.

DR. WARD: Well, I think we specifically talked about the precancerous conditions for the hematologic cancers and the lymphomas, where there's a very known -- where many of them do progress to the full-blown cancer. I don't know if there's any consideration of any other kinds of premalignant conditions and I'm sure there is a reason to think about them.

DR. ALDRICH: I'm probably the wrong person to ask. I'm not familiar with any other areas where there are well-defined premalignant conditions that have a, you know, inexorable progression the way they do in hematology.

DR. WARD: Well, the one I can think of is colon cancer.

DR. ALDRICH: Yeah.

DR. WARD: So if you, if we screen people for colon cancer, we're going to remove adenomatous polyps that then will be -- so it's not completely a moot question. I don't know that we want to go too deeply into it but it's -- the other question in this is just, I guess I want to titillate people -- I mean, the other difficult question is down the road is lung CT for screening. Not that that would necessarily prevent a cancer but it could detect it early. And obviously it's not going to be a yes/no answer because it hasn't been studied in this population with all -- but, I mean, these issues are going to be important down the line and it's good to put them on the table. Yes, Julia.

DR. QUINT: I have a question. How would this differ from medical guidelines which in occupational health are often developed to help physicians diagnose and recognize, you know, the work-relatedness of disease? Would this be different than that or?

DR. WARD: It could be because for some of these things we're still -- I mean, well, for colon cancer for example, you know, there are guidelines for the general population but it's really a question -- but we have to acknowledge that in the course of screening, we will be identifying premalignant conditions that -- and so and treating them. So that's one area. For lung CT, I think the problem is there's only now just recently been a clinical trial demonstrating that screening high-risk people, by virtue of their smoking history, with lung CT, it is a benefit in terms of reducing mortality. There is, however, both a question of radiation exposure, they're screening yearly, and there's a question of morbidity associated with --

DR. MARKOWITZ: False positives.

DR. WARD: The false positives. So and what's different about this population is it's, you know, we don't know -- first of all, we don't have the same degree of

confidence in our estimate that it's of high-risk. We may have pulmonary abnormalities that could make the reading of the -- you know, so there's a million questions that would come up and it, you know, I guess it's a good way to end the meeting to know that we -- we're certainly not answering all the questions about cancer and treatment of cancer and screening and early detection of premalignant conditions in this meeting. And we can't possibly but they are serious questions. So other comments or? Steve?

DR. MARKOWITZ: I think, you know, Barrett's esophagus is another premalignant condition.

I want to go back to the issue of childhood cancer just for a moment. The logic in covering childhood cancer is that kids were -- some kids were substantially exposed, that the population's so small that we'll never get a epidemiologic answer from that population and that kids have unique vulnerabilities. So in the adult population where we have this enormous, you know, decades of research on, mostly or a lot epidemiologic demonstrating this causal relationship between exposures and the cancers, which we don't have in kids. So is there anything beyond those three things that we can point to that would bolster the case for kids having cancer being covered?

DR. WARD: I think maybe expanding a bit on the increased vulnerability and biologic plausibility because you have, you know, I mean, kids by their very nature have more dividing cells and I think there is a pretty strong line of argument about -- I mean, even the EPA, I think, sets their, you know, has just kind of sets risk limits for kids differently than for adults based on vulnerability so I think those things could be cited.

DR. TRASANDE: Just to expound on that a little bit, and when I made that initial round of comments this morning, I had left the traditional line of arguments, what I call traditional because I just have used them a lot early on in my career, but children's ventilation rates are greater per pound and therefore they inhale and they could have inhaled more out of proportion to their weight than adults in the context of the World Trade Center disaster.

Their lungs are in a developing phase all the way through age 20 and so a toxic injury could have more significant consequences at that time of life. And there are others as you mentioned developing organ systems that could fail or be deranged as a result of chemical injury. And then there's the longer latency over which they can have cancer occur, which is a nontrivial component of the arguments. I think that's just elaborating on; I don't think it's adding anything intrinsically new, but I think it provides cement to the foundation of the argument and the literature is substantial in those regards.

DR. WARD: So let me ask one question of Paul and the NIOSH folks, so when we -- let's say if we wanted to address the issue of childhood cancer, do you want the committee to come up with really a rationale that cites literature or do you want us to just, you know, essentially say what Leo said and not cite literature? What is your -- what kind of documentation are you requesting for these recommendations?

DR. MIDDENDORF: The recommendations can be whatever the committee chooses and they can choose to document the recommendation to the extent that they want. But I think the point is that the more the scientific basis there is for it, so if you go into the literature and you do literature citations, that makes your case stronger. But it's up to the committee as to how strongly they want to make that.

DR. WARD: Yes, Catherine.

MS. HUGHES: I just want to give some background information generally on children downtown, because there was that great program for responders, they first came out with the guidelines for adults and they revised them, and finally after many years, the pediatric guidelines were developed, so it was many years later. And so there's a huge catch-up game going on here. And there's not has been as much attention in both time or money in doing the studies, just because there is such a limited population.

DR. WARD: And has anyone made an estimate of what -- of the number of childhood cancers that might be expected in the 46,000 kids; I'm talking specifically now about childhood cancers, not cancers as they get older. Has that been done or not?

DR. TRASANDE: (Inaudible) matter of public record. Not to my knowledge. It's simply a calculation exercise derived on SEER data would really be my basis as a starting point.

DR. WARD: Well, it might be useful I guess in terms of writing up the recommendations. It might be useful as just one of the reference points. But I guess I mean, my sense is that we don't -- you know, we're not being commissioned to write a 50-page paper but I think, you know, I think we all know what some of the more difficult points are and I think the childhood cancers may be a little bit more debated, so maybe we should, you know, we should think as a committee then for those things that we think will need a higher level of defense or of explanation, that we do ask committee members who have unique expertise in those areas to pitch in and help to draft those sections.

And maybe we could think about having kind of the main document which summarizes the key recommendations and then kind of supplementary material

that has the more detailed reference information supporting the -- supporting our recommendation.

So would people like to volunteer at this point to help with the drafting of recommendations or to help with drafting specific parts of the recommendations?

DR. TRASANDE: I'll help with something.

DR. WARD: Great. And Leo, we're counting on you for childhood cancers.

DR. TRASANDE: I can certainly provide -- pull from multiple sources a summary of the key literature that one would want to cite.

DR. WARD: Good. So.

MS. FLYNN: I have another process question which is at what point would the rest of us get to see the draft so that we would be able to comment on the call or even before -- I mean, is there a possibility for a daft to be circulated before the call and comments from some of us who are not among the original drafters?

DR. WARD: I mean, that would be ideal and I guess what we need to do is work backwards from the date of the call and see what's feasible. I mean, my hope would be to get at least a one-page summary out to the committee next week. You know, really just trying to synthesize what our main points were and also to make the table of the cancer sites from the IARC, you know, from all the different sources so the committee has an early preview of those documents; and then to work on the more -- and to take feedback on that and then simultaneously work on the longer rationale document so that it can be distributed and it can be commented on before, you know, before the call so that the call would really be mostly to discuss the more difficult areas and make sure we have the language exactly the way we want it, but that's what we hope for in an ideal world. And we'll certainly do our best to achieve that.

DR. TALASKA: As much as I'm loathe to nominate another committee member, I would really love to see if John help us with the asbestos section.

DR. WARD: John, are you still there?

DR. DEMENT: Yes, I am. And yes, I'll help you with the asbestos section.

DR. WARD: Excellent.

DR. MIDDENDORF: Since we're talking a little bit about process and timing, we also need to be able to post whatever document it is you're going to be discussing on the conference call; it has to be posted several days ahead of time so that people who want to comment on it and provide comments in our meeting, have a chance to look at it so, you know, that backs it up even a little bit more.

DR. WARD: Okay. Valerie.

MS. DABAS: I know you talked about summarizing but I think, I know for me, one of the things that I do want to see is that list because we talked about biological

plausibility, we also talked about rare cancers and defining -- having definition for that and then the IARC list. So I think once we get those three things and the list, I think that would be great if we can circulate that first, just in case anybody had comments on it. I'm sure I will.

DR. WARD: Yeah, and that is the idea, to give out the most -- you know, to distribute the most important information first while we work on the details. So unless anyone else has a further comment or concern, I think we're ready to close the meeting. I appreciate all of -- yes, Steve.

DR. MARKOWITZ: This has nothing to do with cancer. We had one of the persons during the public comment, I think an air traffic controller, talk about being eligible for the World Trade Center health program for PTSD and it's a question whether our -- the charter for this committee includes a request from the administrator to advise on eligibility, and whether it's something that we should take up or are permitted to take up in the near future.

DR. MIDDENDORF: I can address that the Zadroga Act does require the administrator to consult on the eligibility for Shanksville and for the Pentagon but I'm not sure what it says -- Dori, do you know what it says as far as eligibility is concerned?

DR. REISSMAN: I think the question that the administrator can ask of the advisory committee is if there should be any modifications to the Pentagon and Shanksville eligibility criteria, but I don't think it goes as far as to say in the act stipulates, must present at the site, so that's a dilemma there. And I think she might address that directly.

MS. HOWELL: The administrator can ask for assistance with the initial Pentagon and Shanksville eligibility criteria, which is what you all had the presentation on yesterday. He can also, if he chooses, to open it up to modification of eligibility criteria for the New York responders and survivors. Then he would come to you all and ask for consultation there but he would have to initiate that process.

DR. WARD: So is there some mechanism by which the committee can transmit that particular issue to Dr. Howard? Can we just call attention to that issue for him in a separate communication?

MS. HOWELL: I mean, the program administrator takes notice of everything that happens during these committee members -- I'm sorry, meetings, and has been listening to all the public comments, so I mean, I think he's aware of the issue already.

MS. FLYNN: Can I just --

DR. WARD: Yes, Kimberly.

MS. FLYNN: I spoke to him at some length, and he applied for enrollment and was

denied, and he appealed the denial, and Dr. Howard denied the appeal. And so, I mean, you know, denied the appeal based on his geographic location.

Paul, I don't know what we can do but we really have to do something. I mean, even if we have to go back to the main authors of the bill. I mean, it is not in the spirit of the bill to exclude someone who truly fits the definition of a first responder on the day of 9/11. I don't mean to put you on the spot but I -- we have to make sure that this individual gets the care that he needs and deserves.

DR. MIDDENDORF: Yeah, I think it's something that we'll just have to look into to see what -- if anything can be done and if so what. I can't promise anything more than that at this point.

DR. WARD: Yes.

MR. CASSIDY: Just on that note on the post-traumatic stress, I know from speaking to Sheila Burnbaum that one of her concerns was literally anybody could claim that they have post-traumatic stress, and they have it from watching the event on TV, no matter where they were. And although I'm not an expert, you are. Maybe you want to comment on that. Is that crazy?

DR. NORTH: There are specific criteria in our diagnostic manual that talk about how you can get PTSD, what are the qualifying exposures and just seeing the news on TV is not one of those.

But it's beginning to sound to me like this is complex enough that it might be wise to want to discuss it further, and I, with my expertise, I think I can help us clarify some issues, but I don't think we have time now.

DR. WARD: Thank you. Yes, Tom.

DR. ALDRICH: There's a small precedent related to the New York State task force on -- worker protection task force, where we included a group of dispatchers.

MR. CASSIDY: Fire alarm dispatchers.

DR. ALDRICH: Fire alarm dispatchers who were not at the World Trade Center site but were taking calls all morning from people who were about to die and had subsequent -- some of them had some subsequent mental health issues.

DR. WARD: Thank you. Well, thank you all for your full and active participation. I think we've had a great and robust discussion, and I thank everyone from the community who hung in there for the long meeting. And John, thank you especially. I know it's really hard to stay on these calls long distance, and we really appreciate your input.

DR. DEMENT: Thanks a lot. I'm happy I could contribute to some extent.

DR. MIDDENDORF: Let me just express appreciation from the program for all of your thoughts and inputs. We very much appreciate it. Thank you.

(Meeting adjourned at 3:43 p.m.)

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