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DAY TWO

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The verbatim transcript of the Meeting of the Scientific/Technical Advisory Committee held at the Jacob K. Javits Federal Building, New York, New York, on November 10, 2011.

C O N T E N T S
November 10, 2011

TRANSCRIPT LEGEND

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P R O C E E D I N G S

(8:29 a.m.)

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

DR. WARD: Elizabeth Ward.

DR. NORTH: Carol North.

MR. CASSIDY: Steve Cassidy.

MS. HUGHES: Catherine McVay Hughes.

DR. ROM: Bill Rom.

MS. SIDEL: Susan Sidel.

DR. QUINT: Julia Quint.

DR. WEAVER: Virginia Weaver.

MS. MEJIA: Guillermina Mejia.

DR. MARKOWITZ: Steven Markowitz.

MS. DABAS: Valerie Dabas.

MS. FLYNN: Kimberly Flynn.

DR. DEMENT: John Dement.

DR. WARD: So before we start the public comment period, I'd just like to give a very brief overview of how we think the agenda

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

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

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

And for the research component, what we'll do is we'll think about -- we'll really try first of all to identify all of the main ideas or

topics for research that came up during the discussions yesterday, and then flesh those out a bit.

PUBLIC COMMENTS

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

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

(No response)

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

and, again, I will apologize for that but we have to follow those rules.

MS. SIEGEL DE HERNANDEZ: Okay, thank you very much. I wanted to take these few minutes to expand on one of the bullet points that we had in the PowerPoint presentation yesterday, and that is the bullet point relating to looking at all of the evidence that's available, not just an epidemiological study, in order to build a case around inclusion of cancer. And it looks like that's the way this Committee is going. We think that there are enough pieces of the puzzle right now. Taken separately they don't make that case but, put together, we think that there is much stronger evidence. And I know that this Committee is in a very tough position right now, and we also know that waiting is not an option for all of the studies.

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

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

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

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

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

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

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

So as you move forward -- and there may be

more. I mean I think that this Committee will probably come up with more pieces of evidence that could be brought into the record to make this case.

I think this Committee -- you have a limited time frame in terms of meeting, but the Committee has other powers, I believe, in terms of soliciting information that may be helpful. So if there's information about exposures, about particular cases -- I'm not sure exactly the procedures for that, but I think that that is possible, as well as subcommittees, sort of continuing work, between the regular Committee meetings.

So thank you. That's my comment.

DR. WARD: Our next commenter is Lee Clarke.

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

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

COMMITTEE BUSINESS

DR. WARD: Okay, so we're going to ask Emily to join us at the table and first for Emily to

give us an overview of the options that we have for responding to the petition, or for making our recommendations to Dr. Howard of how to respond to the petition.

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

New York State.
A recommendation from the board would typically take the form of an up or down yes or no vote. However, as a Committee you, in your recommendation letter, Dr. Howard has specifically asked you to give rationale and scientific basis for what you are recommending. So in this instance it's foreseeable that you could choose to say 'We don't see a basis for adding cancer at this time, given the two studies we have in front of us and the other information, and we are aware of future studies that will be coming out that we think will shed more light on this.' It's also possible that you not vote today. You have until March 2nd, and you may feel that more information will be coming forward between this time and that time. You could vote yes today, but you would need to give a rationale that the program administrator can rely upon in making his own determination. Because once he receives a recommendation from you all, he then has the option of moving forward with proposing a rule to add the condition or publishing a determination that it's not warranted at this time.

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

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

DR. MIDDENDORF: And could I ask a quick question or make a point? I think it isn't just that Dr. Howard would need to have a

petition. If there's evidence that comes out he could, of his own volition, come to the Committee --

MS. HOWELL: Yes --

DR. MIDDENDORF: -- and ask for it.

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

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

that you understand to have been present at 9/11. And then it's up to the individual physician to look at their patient's particular case and link the exposure to 9/11 with their diagnosis of that condition, which has been sent to the Administrator and the Administrator certifies that for treatment.

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

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

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

MS. HOWELL: I think it's up to the Committee --

DR. MARKOWITZ: Right, no, no, and then you said that we actually need to decide and define on the criteria we would use to make that decision.

MS. HOWELL: Yes.

DR. MARKOWITZ: So it's the latter instruction which pertains. Right?

MS. HOWELL: Yes.

(Pause)

DR. TRASANDE: I apologize, I wanted to be courteous in being acknowledged first. Thank you, that's extremely helpful.

I wanted to ask for some historical context. The World Trade Center Health Program is not the only program of its kind historically and legally. And I have to imagine there have been decision processes not unlike the one that we're undertaking that have been done before and there are perhaps criteria by which inclusions were made or not made. And while I find the Bradford-Hill reference in the first report extremely helpful, required reading, required context for thinking, and something

that is routinely done in the epidemiologic literature, I think that relates very well to Dr. Markowitz's point that at some level I'm wondering to my-- the same question: What degree of causation, what degree of linkage, epidemiologic data do we need to build upon to include such a condition in the historical context as well.

Thank you.

MS. HOWELL: I'm really not sure how to respond to that. I mean other programs that are compensation programs, whether they're providing financial compensation or health care, often do have standards, but oftentimes those standards are either statutory in nature or regulatory, so they've been set out and that's what a committee may have to rely on. Or there is no committee and that's what the program relies on, which in this case the program has a standard that it has applied in certifying individual conditions. However, in terms of the standard that the program Administrator will apply in determining whether or not to add a condition to the list, that has not been articulated in the statute, and also

has not yet been articulated in the regulations. So while I understand, you know, how it might be helpful to have other examples, there are legal and policy bases for those examples that aren't applicable here, so I don't want to muddy the water by pulling in a lot of other examples of other causations that have been used when that hasn't been done in this case.

Now you're welcome as a Committee -- I know that yesterday there was some discussion about the standard that the New York State Workers Comp uses in their -- in making their presumptive determination. If you guys wanted to look at that as a committee, you could. Again, the reasons that they're choosing for a presumption might be very different and have a really different underlying rationale when you're talking about workers comp versus this kind of a health compensation program. So those are things that I think there's really not a shortcut to. That's the kind of discussion that, as a Committee, you may want to have. Or you may want -- you may have a very clear idea of some standards that are

appropriate in the scientific or medical fields that you wish to apply, and then the program administrator will be struggling with those questions for himself about what the program standards to apply will be.

DR. TRASANDE: Thank you. I appreciate very much that this is a unique series of circumstances, but for all of us, who come from different backgrounds, I think that historical and legal context would help at least how I'm thinking about it. I would want to be somewhere in the range of historical context with regard to a judgment that a condition should be included or not included insofar as this Committee has a unique role in potentially adding -- playing a role in adding a list to -- a condition to the list.

DR. ROM: Thank you, Leo. I think now I have three questions instead of just the one. The first is sarcoidosis. So there's the prescribed list of conditions in the Act, and I've heard that sarcoidosis has been added and I want to find out if it really has and what -- what the process was for that.

And then second of all, this list in the

Zadroga Act lists conditions fairly broadly, like chronic respiratory disease. I mean that can cover a lot of possible conditions, and has that been clarified or do we clarify that.

And then the third thing is, NIOSH has had the nuclear workers program for years, and there are conditions that are compensated, like chronic beryllium disease and cancers, and can we get some information about that program that would inform us on how we recommend things, because that should have plowed this ground ahead of time. And it would be very helpful if John or someone could inform us about this.

MS. HOWELL: Okay, I will take -- let me see if I can remember all these questions. The second question was in regard to whose job it is to kind of define what the medical terms that are outlined in the Zadroga Act might cover since they are so broad.

That is within the sole discretion of the World Trade Center Program Administrator and his medical staff. So obviously that might be something that you all have opinions on, but -- and may want to discuss, but it's something that he would be in charge of, figuring out how

broadly that's applied.
In terms of whether -- I think your first question as to whether anything's been added to the list. Nothing has been added to the list. Sarcoidosis has not been added to the list at this time. I am not aware of specific instances where it may have been determined to be a medically-associated condition that therefore has received coverage. That's something that would be specific to an individual patient and therefore would not be discussed in this forum. But nothing has been added to the list at this time because rule-making would be required for any addition to the list, even with an advisory committee recommendation, et cetera, and that's a pretty long process. So the list is as it stands in the Zadroga list.
Your third question about the Energy Employees Occupational Illness Compensation Program Act, or EEOICPA as we refer to it at NIOSH -- EEOICPA has its own burden of proof that's statutory, which is what I was kind of hinting at with Leo there -- or Dr. Trasande. And so -- I mean I can discuss what that burden is, but

I have a hard time with you all using something that was established by statute as their basis that was not included in the Zadroga Act to try and figure things out. I just -- there's a hesitation there.

Now if you all discuss and decide that that's what you want to do as a Committee, that's one thing. But I just don't want for the absence of direction in the statute to then force you to look specifically at another one that was written for another purpose.

The standard of proof in the Energy Employees Occupational Illness Compensation Program Act is whether or not it's feasible to reconstruct an individual's dose, radiation dose, with sufficient accuracy. And there are standards that were then put into rule-making for what they have, which is a Special Exposure Cohort, and there's also dose reconstruction -- it's a different program.

There are two different -- two different ways in which somebody can be compensated. And this is a program -- for those of you who are unaware, EEOICPA is a program that compensates nuclear energy workers who were exposed -- or

may have been exposed to radiation on the job in weapons work. And the first way that individuals can be compensated, and it is a financial compensation as opposed to health care program like ours, is through a dose reconstruction which goes through and looks at the actual dose received. And using a variety of estimation measures, figures out whether or not the person had over a 50 -- met over a 50 percent threshold for their dose. And there are certain speci-- there's a list of cancer that's included to that. Until recently it only excluded a few, such as chronic lymphocytic leukemia which is now potentially being added. And then where there was not enough information to reconstruct dose with sufficient accuracy, there was a second way that someone could receive compensation through something called a Special Exposure Cohort, and that is where they show that as a class this group of individuals' dose cannot be reconstructed with sufficient accuracy. There's a list of 22 specified conditions, cancers, that are covered for that. You mentioned beryllium or silicosis, those are

under parts of the Act that are not under NIOSH's purview. They're run by the Department of Labor and NIOSH is not involved in those medical determinations generally.

So that's a very brief background on that. Again, like I said, those standards were established by that statute and the regulations from it, and so it's a very different system than this one is.

DR. WEAVER: So I guess I'm less concerned about legal differences in some of these other compensation systems, but given the complexity of having to grapple with the cancer issue as our very first charge, I'm looking for any boilerplate that we could come up with. And I'm not sure if I'm allowed to ask something this specific, but Dr. Melius is in the room and he has worked for a number of years on the atomic energy issue, and I'm wondering if it would be possible for him to give us any of the medical background or the scientific background that could have been involved that ultimately resulted in the legal acts following it.

MS. HOWELL: I mean I think what you're describing is someone giving you legislative

history on another act -- I mean because -- I mean, you know, if the Committee wishes to hear from Dr. Melius and he wishes to share, I'm just -- again, I'm struggling with the direct usefulness of something when it was a statutory provision that was put in place by Congress.

DR. WARD: I have a thought on that which is just a comment, it's not a decision by the Chair, but from what I understand, with the Department of Energy Act it was -- there was a huge amount of epidemiologic data available on which to -- you know, to work from in terms of --

MS. HOWELL: They had 50 years' worth of data.

DR. WARD: -- dose reconstruction and lots of data on radiation-associated cancers. So I don't know how helpful -- how specifically helpful discussing that particular program would be. I think the one that's probably a little bit more relevant to our situation is the -- if there's a background on how the comp decision was made, because even though it's not a precedent, there was a line of reasoning that -- that was -- that led to that decision and might be helpful -- I know we have several

members of the working group here on the panel and in the room, so that I think might be more helpful to the Committee than talking about the Department of Energy workers. But let's hear Guillia's comment and then we can decide what we want to do.

MS. MEJIA: I believe that the presumption on cancer for Workers Comp -- there is no presumption in terms of the Workers Compensation. The presumption comes in on the pension aspect of it, so I just wanted to clear that up.

Maybe you could clear this up for me, too. And I'm simplifying it. If we were to include cancer, recommend that cancers be a covered condition, the treatment is still left up to the program administrator? Is that...

MS. HOWELL: An individual -- although cancer would be a covered condition, or a specified cancer -- and I do want to clarify as well that it is within the Committee's purview to split the cancers; you know, to say there's a specific type of cancer which you believe at this time you have enough evidence to say should be -- to recommend it being added to the

list, but maybe not other cancers. I don't think I made that clear before. But once cancer, or a cancer, is added to the list, an individual member of the World Trade Center Health Program would go to their physician. The physician would examine them, diagnose them as having cancer and document their World Trade Center exposures, and then the physician would have to put together a determination that linked their World Trade Center exposures with the cancer using the substantially likely standard that the program has in place. That determination is then sent to the program administrator. The program administrator applies his own application of the substantially likely test to certify that condition for treatment.

But in terms of what treatment is received, the program has protocols for treatment that are established in consultation with the data centers. And so the actual -- you know, what kind of treatment is best for that patient is kind of a separate question. But in order for a specific individual to receive treatment for cancer, they have to have received a

determination from their physician that's been certified by the program administrator.
So anyone who is eligible for the program who has cancer is not necessarily going to receive treatment. They first have to take this additional step of having that condition certified as being substantially likely related to their 9/11 exposure.
Is that helpful?
DR. DEMENT: With regard, I guess, to the parallel with the DOE process, I'm not so sure that it's actually that much different, if you look at the Special Exposure Cohort side of it. And I think the criteria there -- and maybe Jim could speak to this -- is the inability to reconstruct a dose. I think clearly we have inability to reconstruct a dose here.
The other thing is that after you meet that threshold, the list of cancers are presumed to be compensable basically through an administrative process. And so I think there is a reasonable parallel here to some of it. And I think certainly we have, in the list of exposures, materials that -- if you look even at the IARC criteria for causality -- would

drop into that category. So I'm not sure it's inappropriate to think about that process.

DR. WARD: Thanks for that comment. I stand corrected, and I do think that would be an important thing to discuss, just as -- again, looking for precedents, 'cause I think many members of the Committee feel that we don't have -- you know, the framework for this situation is fairly unique, and I don't think -- while I think it's worthwhile discussing the IARC processes and NTP processes, it's just not a parallel situation, and so that might be one of the more parallel situations that would provide more precedence.

DR. MIDDENDORF: I just want to get back to Bill's question about sarcoidosis. I understand that's an interstitial lung disease. Is that correct? Okay. So it has the potential to be covered because interstitial lung disease is specifically listed as a covered condition.

DR. WARD: So -- so is -- I mean let's go through the questions and then we can see if there's someone in the room who perhaps could give us a little bit more background on the

specialized cohorts in the DOE process. Tom?
DR. ALDRICH: Did you want to know about the New York State -- the cancer was included from the very beginning as a -- one of the conditions that provided presumption of eligibility for pension, and that's all. There's no treatment component of the New York State program, and there is Workers Compensation, which has -- as been mentioned, does not include cancer as one of the presumptive conditions.
DR. WARD: So that means that if you were exposed at the World Trade Center, you're considered eligible for a pension if you get cancer, but if you were not exposed, you're not -- cancer is -- you're not el-- you --
DR. ALDRICH: If you're not exposed, you don't have the presumption, which doesn't necessarily mean that you don't get a pension. But it means that you're going to have to go through additional hoops to qualify for a pension.
DR. WARD: Okay.
MS. MEJIA: But I do -- if you don't mind, I do have to -- it's a matter of determining whether it's an accidental disability or a regular

pension, and that's where the difference comes in, so...

MR. CASSIDY: I was involved in actually negotiating this with then-Governor Pataki. The way the bill works, and I think it was signed in 2004 or 2005. The way the bill works is for workers who have proven, have been certified to have been at the site working for 40 hours, documented by their employer, they are -- they are registered under the World Trade Center Presumptive Bill. If they get sick and -- then it is presumed that that illness is related to their work at the World Trade Center site. But you have to be documented by your employer. You have to qualify. They required you to be there for 40 hours, so that's the exposure component of it. If you get ill, it is for pension purposes only. It is presumed that it is related to that. There is a process that you go through in your individual agency; therefore whatever pension plan you're covered under -- I do this all the time with firefighters. So it's not a guarantee, but that's the process. You have to have qualified. You have to have had worked 40

hours at the site to qualify. And then if you get sick, you get to apply before your pension fund and that pension board will then take that into consideration and make a decision. So you can actually get your pension upgraded -- you can be retired, get sick, file for an upgrade of a disability pension under the World Trade Center Presumptive Bill, and you were covered based on being part of the covered group that spent 40 hours down at the World Trade Center site. I think I could have done better if I had another cup of coffee, and I apologize.

DR. WARD: That was great. I have one follow-up question. So who maintains the list of people who have qualified?

MR. CASSIDY: It is now shut, so you -- there was a time frame that was extended for a few years. Anyone who had -- obviously the site closed. It's only covered from 9/11 through June of 2002, you had to work 40 hours during that time period, and you had to get certified by your employer. The bill didn't get passed till 2004 or '05 -- I think it was '04 -- and subsequently you had I think two years to get your paperwork in and get certified through

your employer. Once that was done, once the deadline was cut, nobody else has added to that list. You were either qualified or not qualified. If you get sick in the future or you were already -- been sick and covered under the presumptive bill, so be it. But it's a limited group. It's not an expanding group.

DR. WARD: And how many people are in that, do you know?

MR. CASSIDY: I don't know the answer to that, but we certainly can find that out.

DR. WARD: The reason I'm following up on this is, when we get to research recommendations later, I think one of the things that's really important to think about doing is ways to recreate denominators. Not -- you know, I think all of the information that's coming from the treatment programs is important and all of the information that's coming from the voluntary programs is important, but really, you know, the most impor-- the most meaningful epidemiologic data is generated when you start with a defined population and follow it. So I think, you know, one of the things we may be recommending as a Committee is that we look for

opportunities to define cohorts of people in the past and so that we can get clear enumerators and denominators for future studies, and that sounds like such an opportunity. Yes?

MS. DABAS: (Off mic) ...there within the first 48 hours, you would also -- so if you didn't meet 40 hours but you were at the site within the first 48 hours, you are also presumed -- covered under the presumption.

MS. MEJIA: I just want to clarify that this only covers public sector workers. It does not cover private sector workers at all. And there is a registration that does occur, so it's not automatic. The worker still has to go through the system. There's still a lot of papers that have to be filed. There's a lot of notices -- records that have to be reviewed. So it's really the extension that -- right now it's true it was closed, but we're looking at opening the extension for additional people to be covered under this, but -- so...

DR. MARKOWITZ: I suggest that actually we're going to need to carry on this conversation about criteria that we want to use into the

future, because -- in part because of the DOE precedent, in part because of Agent Or-- treatment of Agent Orange and veterans of various wars, so we need some mechanism actually for continuing this so we don't deci-- you know, this is a crucial decision, what set of criteria -- accepting Emily's instruction that there's no prescription here as a particular set of criteria we need to use, but the utility also of looking at precedents in terms -- just in terms of considering the universe of criteria to be used, whether it's NTP, IARC, IOM, DOE, et cetera. So I think we're going to have to put this into some sort of committee that we can carry on and -- the conversation.

DR. ALDRICH: To make a few points that I think are relevant to ways that we can start to make a decision, the first point is that, you know, a cancer diagnosis is tragic, no matter whether it's World Trade Center-related or not World Trade Center-related. And the purpose of the World Trade Center Health Program is to deal with the World Trade Center-related conditions, and so it is important to know if there's a

major increase in cancer. A minor increase, tragic for the individual, is not something that the Committee should be tremendously concerned with because -- well, I -- that's the one point I wanted to make.

I think we have to acknowledge that the state of our knowledge is just not good enough, and is not going to be good enough in the next several years, to make a determination if there's a major increase in cancer as a result of the World Trade Center, and which cancers those are. We're just not going to have that information. It's been only -- well, the data from the fire department is only seven years. The data from the registry and Mt. Sinai is only going to be about eight years. And that's -- given the latency of most cancers, that's just not going to be enough. We have to wait five, ten more years to really know the answers to the questions that we want to know.

Another sort of related point is that there's been a lot of discussion about multiple myeloma and whether or not it could be World Trade Center-related, and the data are only anecdotal. The data come from a study that

showed a small increase in persons under 45 years of age, and a small decrease in persons over 45 years of age. Is that decrease over 45 years of age supposed to tell us that the World Trade Center exposure was protective for older people? Of course not. And so we shouldn't make too much of a very small increase under 45 years of age in a cohort that has serious concern about selection bias.

And so I think our consideration should be only -- or should be, from an epidemiologic point of view, based on data where we can have some understanding of selection bias, denominators and things along those lines. We have to be concerned with other issues like biological plausibility and exposures, and that's very important.

The final point that I wanted to make is that -- well, I think it's sort of related to what we've already talked about. There's perhaps a 20 to 30 percent increase in total cancers from the one epidemiologic study that doesn't have selection bias nor a problem with denominators. And among those, the best estimate of odds ratios greater than two were for pancreas,

kidney, thyroid and close to two for non-Hodgkin's lymphoma. But all of those odds ratios -- the confidence intervals crossed one, so we still don't know whether those things are related.

I think our final decision for now ought to be in some -- should not be irrevocable. Either we should decide that some cancers or all cancers should be covered but that can be revisited in the future if it turns out that there's no substantial increase, or we should decide that they're not coverable at the present time but that decision should be revisitable in the future.

DR. WARD: So let me just ask -- one other comment 'cause I think inherently these decisions can be revisited in the future. In other words, we can respond to this specific petition -- let's say we said 'No, we don't think there's enough evidence to cover cancer' in response to this petition. Then the issue can be raised again at any time by another petition, or by decision of the World Trade Center Administrator. Is that -- that's correct, right? So certainly we're not being

asked to make a decision that's irrevocable.
DR. ALDRICH: But I think we should explicitly acknowledge that we're not going to be able to make a fully informed decision and that we should plan on revisiting, not just wait for another petition.
MS. HOWELL: You can't revisit the issue at your own initiative. I mean there is a deadline associated -- there's a statutory deadline associated with the request you've received from the Administrator. However, Dr. Ward is correct that, you know, at any time the same condition could be put forth to you through a petition, by a request from the Administrator either through a petition or at his own initiative, so it is likely that the issue would not be over. But I just want to clarify that the Committee, at its own initiative, can't take something back up after that -- you know, after it's voted and/or the time has elapsed.
DR. ALDRICH: But surely we could present as the sense of the Committee that this would need to be addressed.
MS. HOWELL: Certainly. And you know, I think

we're all aware that this is a very thorny issue. I think the program knows that, the Administrator knows that, and the sense is that this is not going to be the end of it.
I think they've been waiting over here for a while.
DR. WARD: Susan?
MS. SIDEL: And my question is, each time we see a cancer where there are people going to an oncologist, does it get started with their occupational medicine doctor and then they go -- I mean I don't understand what the process is and what -- how the cancer committee is involved in this.
MS. HOWELL: That's probably a question for someone from the program.
MS. DABAS: (Off mic) ... you guys because I work with a lot of people that have been diagnosed with cancer. Most people are going to their oncologist, and the reason being is that back in 2004 and early on many of these physicians were saying that it was improbable for them to develop cancers. So one of the -- when people say that, one of the things that happens is we get a lot of people that are

going to physicians and these physicians are not looking for these things. So a lot of people felt that -- from what I've been hearing, that a lot of their conditions were overlooked and not properly addressed at the beginning. I have always advised members when I speak to them to go to another physician if they feel like their conditions have not been properly addressed.

So from there, the way our program -- the way we've been working with Mt. Sinai is we get a call saying that they've been diagnosed with cancer. I send them a HIPAA release form to try to get them into the program at Mt. Sinai. The hurdle that we've come upon now is that Mt. Sinai's cancer study is saying that they are not going to include you in the study if you are not part of the treatment and monitoring program. Now they have to get certified in order to get into the monitoring and treatment program, which can take six to eight weeks, and then Mt. Sinai will then consider them for the cancer study once they have first filled out a HIPAA form, and then there's a second form that they must fill out in order to get into the

study. So there is about now -- to date, if you've been diagnosed and you call me, I would say the lag to get into the cancer study at Mt. Sinai is possibly three months, the earliest.

DR. TRASANDE: Thank you. I'm going to wear my pediatrician hat with these questions, which is going to probably develop another dust storm, if you will, about this issue.

My understand -- these are questions directed to you, so -- is there any history with regard to pediatric exposure setting or pediatric disease monitoring and/or inclusion program?

And then my second question is, is a decision of an included condition applicable to all age groups or all subgroups of populations?

There's been a little murmur through this discussion about talking about subpopulations with cancer, but my read of the statute is that if you include cancer, you include all cancer.

Thank you.

MS. HOWELL: Okay, so the first question as to pediatric groups, I'm aware of financial compensation programs that are largely -- I'm not sure that they're solely directed at pediatric exposures or patients. I'm thinking

of the vaccine compensation program. However, that is largely for pediatric patients and that is again a financial program. I would have to look further to see if there were any programs that made health care available to pediatric patients. And again, the standards used in that program may be different.

The second question, you're correct. In terms of adding a condition to the list, it's not a ratified list. It's not -- if a condition is added to the list, it's a condition that would be covered for responders and survivors, or adults and children, for people within the World Trade Center disaster area, people who are eligible within the physical geographic bounds of the program, so it's not something where the Committee needs to look at that there's certain people -- the place where that comes into -- plays a role is going to be in the individual physicians' determination and the World Trade Center Program Administrator's certification of that condition, that there is a link between the exposure and the condition.

DR. TRASANDE: Brief follow up in that regard in that I know from old work history, having

worked a little bit on the Vaccine Injury and Compensation Program, that the specificity of adding a condition to the so-called vaccine table is very regimented, much more so than what we're dealing with here. There's a condition that is added, but it relates to -- it asks specific questions regarding the nature of the condition, timing with regard to vaccine, particularly associated symptoms, fever level, things like that, for example. So we're -- I agree, we're in a very different situation, but that clarification is still nonetheless very helpful. Thank you.

DR. WARD: Four tents up, and I would suggest we go through your comments, and then I think it might be helpful if we asked Dr. Melius to give us a description of the Department of Energy program, if he's willing to do that. Okay, great.

So let's go through the comments, and I'm not sure who -- I think -- who was next? Okay, Guilla?

MS. MEJIA: I just wanted to know whether we can make a recommendation that we actually need additional time to look at this matter? I mean

we are under a time constraint. We have to -- I believe we have to have a recommendation by March. Why can't we just make a recommendation that we need additional time to look at, you know, whatever literature might come out?

NOTE: Extreme electronic interference with dial tones, sounds of dialing, et cetera throughout the following comments.

DR. MARKOWITZ: I just wanted to comment on Tom's remark that major versus minor increase and relates to actually something Bill said yesterday, that -- you know, let's talk when we have a three-fold increase in cancer, not a 20 percent increase in cancer. I think it really relates to the criteria that are used for deciding. We could decide, absent any epidemiology, that it's reasonable to conclude that cancer is likely among WTC-exposed workers. That wouldn't be a crazy decision. In fact, if you look at National Toxicology Program criteria, they're reasonably anticipated to be a carcinogen; all you need is animal evidence. If you look at IARC, they're -- probable carcinogen; all you need is animal evidence and maybe -- maybe a little bit of

limited -- what they call limited human evidence. So we don't necessarily need epidemiology. This is really -- so this is why I'm suggesting that we need to take a careful look at the range of possible criteria and then deliberately decide how we want to approach that.

DR. WARD: Julia?

DR. QUINT: My comment was very similar. You know, I said yesterday it seems to be a heavy reliance on epidemiological data. And you know, we have the latency, you know, as an issue, and these studies are hard to do.

I just had a question since, if we do list cancer -- and in response to Leo's question that survivors, children, all of these folks would -- I mean all of these W-- exposed people would be a part of that, and we -- talking about getting denominator data, which I think would be helpful, are those studies being planned, or -- you know, I don't underst-- I know about the firefighter study. There has been some reference to a Mt. Sinai cancer study. But I'm not sure if the survivors -- who's involved in -- what these studies are.

Because if we revisit this, if we make a decision and we can revisit it, it should be based on some possibility of getting more data or -- or something. And I'm not sure where we are in that spectrum so I -- you know -- if we're even able to get studies done.

DR. WARD: I think that the two epidemiologic studies that we heard about yesterday, one was being done by the New York City Health Department, and that registry included residents of lower Manhattan. No? People are shaking their heads. Right, right, okay. Well, anyway, but just to -- I mean all of these studies will have limitations, but just to address the question so we have that one study and then we have a study that's being done by Mt. Sinai, which is...

UNIDENTIFIED: (Off microphone) (Inaudible)

DR. WARD: Yeah, so what we'll -- what we'll do when we turn to the research -- and so I think if we reviewed the slides that were presented yesterday we'll -- you know, we can -- I think the nature of those studies was explained, but I think when we get to the research part of the discussion there may be a recommendation for

additional epidemiologic studies or epidemiologic studies done differently than those that are currently being done. But as far as I know, there's at least those two, which have large population sizes -- relatively large -- and which are attempting to link with the National Death Index and the cancer registries to ascertain cancer incidence.

DR. MARKOWITZ: (Off mic) ... next study of the FDNY, which is going to be smaller than the firefighter study, but similarly conducted -- although I'm not sure they have pre-9/11 data, but in any case, that's the third.

DR. WARD: But I do think it would be help-- that one of the things that would be helpful for us would -- as homework is to really come up with a summary of all of the existing -- all of the ongoing epidemiologic studies -- you know, who's -- you know, what population is included, its strengths and limitations. I think that's something that the Committee will be looking at in the future as well. So -- yes?

MR. CASSIDY: So I'd like to comment a little bit on what Dr. Aldrich said and what Dr.

Markowitz said, and to kind of summarize what I think we know for sure. Right? The fire department did a study. It's a seven-year study. By all accounts, most experts don't expect it -- would not expect to see a significant cancer spike for 10, 15 years, maybe longer. So we could say, until we have the numbers, come back and see us in ten years. We could take the approach, which I think is reasonable and common sense, to look at those statistics -- 32 percent, or 23 percent, depending on how you look at it -- and factor in the one thing that we know for certain, which is shocking, that New York City firefighters lost 12 years' lung capacity in the blink of an eye. Now that's a documented fact. That cannot be dismissed.

So if we're going to say that we know that's amazing and startling, but we're here to talk about cancers and we don't really have the numbers for cancers, we're just going to have to wait. But I think common sense would say to anybody that those numbers are so startling that you can't possibly think that you could do that kind of permanent damage to your lungs

through this, you know, unbelievable exposure -- which hopefully is a once in a lifetime thing -- that there is no comparison to, and say the cancers aren't really where they need to be for us to say yes now. I hope we're not there. I hope we take a much more common sense approach and look at it and say 'Of course cancers are likely to come.' Of course they are plausible to say we're going to have a spike in probably a wide range of cancers. I mean the blood-bornes seem to be jumping out more than any others right now. And I'm not a scientist, but I do know that the damage that was done to people who were there, with the severe exposure, is unmistakable. And I hope we take a common sense approach and do not dismiss the 12 years' lung capacity which was lost on New York City firefighters. And I would say anybody who was there for an extended period of time probably has similar results, so I don't want this -- I don't want everybody to think that I'm saying firefighters and firefighters only. But I will say the 12 years on average -- think about that. There are firefighters who were there for 400, 500, 600 hours. They

didn't lose 12 years' lung capacity; they lost 18 years' lung capacity.

Now if you lost 18 years' lung capacity and you get sick, but we're going to say 'We don't really have the data to say that your cancer is related to your exposure', I say that's crazy, and I think that a plausible response, a common sense response, is to say 'Of course it is linked to this horrific event.' And I hope we consider that when we decide where we're going.

DR. WARD: So Jim, can -- is -- come up to the microphone?

DR. MELIUS: I will try to be brief. This is EEOICPA-like. I think Emily actually gave a fair amount of good background, and Emily and I have talked about this a lot in public meetings. I serve on the advisory board that deals with that.

Legislatively the DOE workers, the EEOICPA Act, deals with cancer, and it bases -- as it has been mentioned, though a dose reconstruction process. That dose reconstruction process uses a methodology that was developed by the National Cancer Institute, essentially a -- sort of a life table approach for calculating

your risk of developing cancer based on what your past exposures to radiation were. And the data that -- the epidemiological data that went into that approach, calculation was based on the people in Japan -- Hiroshima/Nagasaki, the lifetime follow-up study that was done there -- plus the uranium miners study that was done by NIOSH and NCI over many years and follow-up of those workers. And it then, for an individual, can make a calculation that, based on a certain radiation exposure, you will have a certain risk of developing cancer. And the criteria that is used for the -- determining whether or not you get compensated in that process is a -- that the calculation that's done through this what's called IREP model is greater than 50 percent chance that you will develop cancer. So roughly a two-fold risk.

However, the IREP model as applied through this legislation takes into account the error in making that estimate, both the error in terms of the epidemiology estimate of risk which, despite all we know about radiation -- I mean it's probably studied as much as anything in terms of cancer, epidemiologically, when it

comes down to estimating individual risk, the error is quite large. And on top of that, it also takes into account the error in the dose reconstruction, the dose estimation. So essentially the greater uncertainty there is about your -- what your dose -- actual dose was that was calculated based on your work history at these atomic facilities, which is nuclear bomb facilities, which is very complicated exposures, they -- is also quite large.
So it ends up being a -- won't say -- don't know if generous is the right term, but it is -- certainly does not require that you have -- demonstrate that you have a very -- a significantly high risk epidemiologically of developing cancer. In fact, you can -- the actual studies that have been done of Department of Energy workers would probably not document the same degree of risk that has been provided through the compensation program.
Now there are problems doing those studies, and basically because of past dose records, size of populations, all the usual caveats on that, and of doing epidemiological studies, but the fundamental model that's used here is one that

does not require the worker show that they were -- would have been at very high risk -- you know, really far below a two-fold risk of developing cancer, you know, as measured through some sort of an epidemiological study. This was adopted from legislation and methodology was being used for atomic -- military veterans, people -- veterans that were involved in some of the atomic testing, where there's a presumption that if you were -- worked or were stationed within a certain distance of the above-ground testing that you would be compensated for certain cancers if you developed certain cancers. Again, this was post facto -- after the -- many years after the testing was done. And if you were -- actually had other forms of cancer or if you were a little further distance away where you were stationed, then there was a dose reconstruction process that was established, in some ways more simple to do than what NIOSH now has to do in terms of providing and estimating dose -- exposures now in this program 'cause these DOE facilities are so complicated.

There's also a provision that was put into the

legislation that -- so-called Special Exposure Cohort, which is in instances where NIOSH found that they were unable to reconstruct dose for a particular group of workers, those workers were then automatically compensated if they had worked essentially at least one year at the facility and had a list of 22 cancers that were sort of broadly defined as radiogenic. There was a list developed within NIH many years earlier, but radiogenic is sort of a slippery term for this -- you know, and what's radiogenic changes over time and -- depends on your perspective, what you're looking at and so forth. So -- but that's provided.

To give you some, again, perspective of the people that have received cancer compensation through this program, I recently looked at the data, about a third of them received it through dose reconstruction, about two-thirds have received compensation through the SEC process. I think it's roughly 15,000 and 30,000 or 18 and 36, something like that, that have received compensation there. But it's -- again, I think the differences to keep in mind, it's based on radiation which is certainly obviously a known

and proven, you know, carcinogen -- do that. It's a relatively -- not a very strict criteria in terms of proving that your cancer is related to your work or you're at great risk -- greater risk -- significant risk because of your exposures at that facility. There simply isn't enough data to be able to do that, even though these DOE facilities actually have been -- many of them have been fairly well studied, but the amount of information it takes to develop one of these tables and make, you know, somewhat accurate predictions of cancer risk is quite large, so it's just not possible to do with it -- and the system works.

The committee I now chair, been on for ten years, we spend a lot of time trying to figure out when you cannot do dose reconstruction, which is also quite common.

For other parts of the program there are some other diseases that are covered. The criteria are in some cases specified in that, and then there's a basic sort of compen-- Workers Compensation for other diseases that these former nuclear facility workers have that then the requirement is substantial likelihood that

their disease is related, and it gets quite compli-- you are -- you can be sort of doubly compensated through this.

But that's sort of EEOICPA light -- do that. I think there's some good background information on the NIOSH web site under -- that would explain some of that. As I said, the legislative history is they took the criteria from I think legislation -- sort of adopted it from what was already going on for atomic veterans, but essentially upgraded. And then the Special Exposure Cohort was added because it was, you know, documented that DOE's records were extremely poor in terms of even keeping track of what materials went to what sites. While the legislation was under consideration they suddenly discovered three of the major sites had handled significant amounts of plutonium and nobody had bothered to tell anybody about it, so...

Any questions? Anything I misstated or -- clarify, Emily?

DR. ROM: Could you recall whether multiple myeloma was part of that list of 22 radiogenic cancers?

DR. MELIUS: I believe it is, yeah.
DR. ROM: Do you remember any others on that list?
DR. MELIUS: Oh, it's the, you know, lung, leukemias, the -- that it -- it goes fairly down the list -- I mean it's broad categories of cancer on that. The list is on the NIOSH web site under the -- it's called the DCAS program, Division of Compensation and Analysis or -- is that right, John?
DR. MIDDENDORF: I just want to make sure that they understand, the list of cancers are listed in the statute that are covered. Is that correct?
DR. MELIUS: Correct, it's a -- it's a --
DR. MIDDENDORF: And it's based on a lot of scientific data which has a fairly high degree of scientific certainty. Is that an accurate statement?
DR. MELIUS: Well, it's based on radiation epidemiology. The criteria for the list is not what risk you -- what risk needed to be found in epidemiological studies of radiation is not clear, and you -- if you look up -- if you look at various review articles on radiogenic

cancers, various lists, they vary quite a lot. It depends on sort of which kind of exposure you're looking at and what criteria, so -- so they adopted something that the NIH had used and was -- it had been used, I believe, in one of the atomic veteran compensation programs.

DR. MIDDENDORF: And just a last point, I think what you were saying is that whether or not an individual is compensated is based on their individual exposures.

DR. MELIUS: Or the fact that one can't reconstruct their exposure, it's one or the other. It is different in that and is certainly different in it is based on a, you know, carcinogen that's -- you know, substantial amount of other evidence for, but it's not based on epidemiological studies of those particular workers. The criteria's not that they have to meet, you know -- you know, a study at Hanford doesn't have to show a two-fold risk of lung cancer to demon-- for those people to get compensated. It's based on their exposures.

DR. MIDDENDORF: And I was just trying to make the distinction that what this Committee needs

to deal with is whether or not to make it -- something a covered condition, which is similar to the list that was in the statute for the EEOICPA. That's what they're --

DR. MELIUS: Yeah, yeah -- no, I -- yeah, fine. Any other -- yes?

MS. FLYNN: I actually have a Zadroga-related question. I know that you were involved, as other people in the room were, in the crafting of the Zadroga bill, and I guess I would -- I would hazard this statement that in fact it is the intent of the statute, out of a recognition of the unprecedented nature of the exposures and also the lack of comprehensive environmental measurements, to provide for great flexibility, that the statute recognizes that we are on uncharted territory. And I'm not saying that we should not entertain any useful precedents. I think we should. But I also think we have to recognize that we are on some new ground here and that the -- and that in many ways it sounds like this Committee is being asked to structure these deliberations in recognition of the unprecedented nature of exposures and resulting illnesses. And I'm

think that there should be a group that gets together before the next meeting that comes up with position papers -- possibly two, maybe more, position papers expressing the different points of view. And then the Committee will have a chance to digest that in advance of the meeting. And rather than just start from scratch, we'll have some starting point.

MS. SIDEL: I just wanted to say that there's so -- you know, we all know what the carcinogens were that were at the World Trade Center site, and there's so much information about how so many of those cause cancer that I just don't understand why this is such a stretch to say that they caused cancer in some people and they caused certain cancers. I mean I'm not saying that everybody and every cancer should be covered, but there's -- you know, for example, NIOSH's own guide, chemical guide, what is it called, the chemical -- guide to chemical hazards. And you know, I have a copy and it's like Zagat's only it lists the chemical and then what -- you know, what -- what the health effect is of exposure to that chemical. So I just wanted to put that out

there.
MS. DABAS: I actually wanted to see if we could go around the room and kind of just get where each person stands because I'm kind of -- I know where some people stand, but -- on -- they've been vocal, but I'm not sure where everybody stands on how they -- what they would need to make this decision or whether they've already kind of come to a conclusion.
DR. WARD: Someone make a motion and second it, and then we could do that. Do -- well, maybe you can phrase -- frame the --
DR. ROM: I think Elizabeth phrased the motion best. I'll try to rephrase it.
I move that we have considered cancer as a listed condition and that we have not found enough evidence to either list it in favor or against, and that we need an additional round of information to our next meeting before deciding further.
DR. TRASANDE: Can I suggest a potential minor amendment to that in that I would just simply move that we have a subsequent discussion -- I'm just concerned that if we state there's no evidence either way at this time, that that --

wondering, Dr. Melius, if you could reflect on that.

DR. MELIUS: Only I think it's been stated already -- I mean it is a unique situation and the criteria for -- I think the statute was developed in a way that it was expected that there would very well be additional conditions that would be added as time went by because -- just simply latency and follow-up of these people and the natures -- unknown nature of their exposures and effects, and so it was left open and it is -- it is something -- you know, it was not -- there was no model that would -- legislatively that would -- was an exact fit for this.

I would urge you, having been through this process at the other end with the DOE program, it is important what Emily and John have told you. It is -- I think it is important when you make a decision to include your rationale for that decision because that's important in carrying this forward through the process and in the decision that the Administrator has to make. So some careful thought to how you're approaching it is also important -- and

important to document.
MS. FLYNN: Thank you.
DR. MELIUS: Thank you.
DR. WARD: So I think at this point it would make sense to take our short morning break, and then reconvene. We do need to get on to some of the other items on the agenda, but first we need to make a plan for how we're going to proceed on the cancer petition when we get back from break.
(Recess taken from 9:55 a.m. to 10:08 a.m.)
DR. MIDDENDORF: As I was just -- it was just pointed out to me that -- and I've noticed it, I just haven't said anything about it, is that there's about a one-second lag time between when you turn the microphone on and when it actually starts picking things up. So if you'd either turn it on early or, you know, just wait a second or two before you actually start speaking so that our reporter can take down what you're saying.
Okay, for purposes of the roll, just a note to the record that all the Committee members are at the table. Dr. Talaska, did you happen to join us on the phone?

(No response)

I guess not. Okay.

DR. WARD: So in this phase of the meeting we will be trying to wrap up the cancer discussion and figure out what our next steps are. It is -- you know, there is a provision for us to follow the formal procedure of someone making a motion, the motion being seconded and voting. So it may be appropriate to do that in the course of this discussion.

I can summarize what my sense of -- from the Committee discussions is and -- I mean my sense is that most people who've spoken do not feel comfortable making a recommendation to include cancer or to not include cancer in the -- among the covered conditions based on the evidence that we have in front of us and based on our discussions today. So that my sense is we probably will want to have at least another meeting to discuss that issue, probably one in person where there can really be good communication, in part because (a) it's a very difficult issue, it's a complicated issue. Our group is just forming. We're really still struggling to understand the exact nature of

the Act and what our determination means in that context.

I also think, though, that we need as a Committee today to define what are the pieces of information or perspectives or data that we really would have -- would like to have in front of us when we come to that final determin-- our final recommendation so that we can have workgroups or individuals working on pulling that information together for us. We do have the oppor-- the possibility of forming workgroups that we can have -- you know, we can have workgroup telephone calls in between meetings, and we can have those open to the public and transcribed if we feel necessary. So that's my general sense from the group, and I don't know if that is true for all of us or if people want to speak to that, but go ahead.

DR. ALDRICH: I think that, from my point of view, that's correct, that we're not quite ready to make a decision. But I think we have to say something. And we're going to have to have another meeting. I think we should -- you know, in advance of that next meeting, we should have some material to react to. And I

I'm not -- just for a process protector, I'm not sure whether that's already information to the Administrator. I would actually rather have the time to have another meeting, and I was also going to further suggest that -- you know, in scientific conferences you can pre-release information for discussion among groups in a privileged fashion. And I'm wondering why the entities that are pursuing such research might not be willing to do that in this context. I think that that -- it could be tremendously important, and there is precedence for this.

DR. MARKOWITZ: So actually I don't see the need for a motion. We have till March 2nd. We haven't made any decisions. So I'm not sure that, you know, what we would accomplish by moving ahead on any sort of motion. I'm not sure that gets to Valerie's request to get us sort of a preliminary sense of where people sit.

DR. DEMENT: I think -- to address your question, I think we need a -- before we form committees to do this and that, I think we need a discussion of a criteria or what criteria

will we use to make this decision. For example, if it's just going to be the epi studies, then we may as well go home because it's not there. I think the question is, given the list of exposures -- some of which are reviewed pretty well in the NIOSH document -- what of those exposures do we -- and what do we know about those exposures and the risk of cancer, and will we consider those exposures' biological plausibility in coming up with our final decision. So perhaps there are two committees, one to look at the epi data and evaluate -- particularly the new study that came out. Maybe the other committee is the one to look at the issues of exposures and what data do we have and the plausibility that these will increase certain types of cancers but probably not all.

MS. DABAS: (Off mic) to make a motion and was actually piggyback offing -- piggybacking off the generalization that was made that it seems that there was a consensus, there was some reason to believe that people -- and I just -- there were some people I haven't heard what their take on this was, and I was interested in

their opinion and not necessarily a vote on it.
DR. WARD: That's the -- you know, the three ways we can go in this decision would be to vote to include it as an eligible condition, to vote to not include it as an eligible condition, or to decide that we need further information and another meeting to make that determination. So maybe -- why don't we start off by maybe asking a raise of hands, how many people would support the notion that we should defer the decision and have another meeting to make this recommendation?

(Committee votes by show of hands.)

So that's a pretty large majority. But I really like the idea that we may want to approach -- I mean one approach that we might want to take is the position paper approach, because I think very clearly we have, you know, a difficult question here and the way you -- and so I think it would -- that would be very helpful to articulate all the reasons why, you know, one would argue that it should be less considered a World Trade Center-related condition and all the reasons why -- you know, all the evidence and rationale why we don't

have sufficient evidence to do that at this point. That might be a helpful approach in this.

DR. MIDDENDORF: Just a note to the record that when Dr. Ward asked for people to raise their hands, 13 people raised their hands and two did not.

MR. CASSIDY: If we're going to look for position papers or additional information, we're going to come back and discuss it in the future, I think that it might be helpful if we have -- someone could do a review of other major exposures and how long it took for cancers to show up. I don't know -- there is no, obviously, similar event to the World Trade Center. There's nothing quite like it. So I don't mean to imply that we can find something that's similar and therefore do an A/B comparison. But maybe there are some large exposures that happened, and when did cancers -- if cancers popped up, when did they pop up? Because if, as some experts have said, you're looking at 15 to 20 years and this Committee is going to make a decision strictly on numbers, then somebody already said it: We might as

well go home.
But I think if we have some background that shows that previous disasters and/or serious exposures -- cancers came, but they didn't come for 15 to 20 years, then I think it gives us some leeway to be more flexible in terms of using the common sense that -- I think most people expect us to come out with some kind of approach that includes a common sense look at what we know now. And what we know now is really a seven-year study. It's not 2011, it's July of 2008. And the only real study that has pre- and post-9/11 is the fire department, and you can't dismiss the 12 years lung capacity, there's nothing quite like that. So I think if we're going to come back, I think it's important if there's other -- if somebody can do some research for us that would present to us similar events -- there are no similar events -- disasters that resulted with cancers and how long it took for it to happen.
DR. DEMENT: You know, there aren't any similar events. The major events that occurred that are these rapid exposures, then follow-up, largely are radiation-related events. And

there are a few others, but not to any great extent like this one. I'm not advocating that we use the epi. I think we use epi only to substantiate a positive. To go the other way and say there's no risk I think is not appropriate. And I think whatever review of the studies that would be done by a subcommittee needs to point out the limitations of the epidemiology in trying to make this decision. That's all.

MS. MEJIA: You know, there's a saying in the field of occupational safety and health that an injury to one is an injury to all. And we know that there are cancer cases out there, they've been diagnosed. We have members who have that diagnosis. They may not have made it on a chart or on a pie graph or been assigned a dot somewhere on an X/Y axis, you know what I mean, as -- so we can't ignore the fact that there are people out there that have the diagnosis. So with that said, my question is how much weight can we put on the clinical observations that were made by -- at the -- you know, by the doctors that are treating these workers? Now clinical observations were the basis for

establishing the original list of covered conditions, so why not -- you know, can we consider that as, you know, as a way to look at this?

DR. DEMENT: I think the clinical observations are helpful for some conditions, and particularly those that we, a priori, know they're related to dust exposures. But when you come to cancers, the clinical observations may or may not be helpful. If it's a very rare cancer and we know the relationship with an exposure and you see the sentinel event, then I think it is, you know, very helpful. But simply observing lung cancers in a population over time doesn't tell you what the risk really is. It just simply says you have a numerator, but you don't know what you would expect in a normal population. So that's just the limits of epidemiology. It's not to dismiss the importance of these observations. So I think we have to back up and look at the exposures, are they biologically plausible with regard to these outcomes, and make some determination on how we're going to use that prior body of information. The Bradford-Hill criteria -- you

know, we're not going to be able to apply that to our studies in any real meaningful way. I think it's going to be supportive information from the epi studies, but to use a negative is not the way to go.

DR. WEAVER: You know, I think the diversity reflected on this Committee is a really good thing because it illustrates the complexity of the exposure. It's -- we're very polarized. You know, we have the community members who very eloquently have stated that they've had -- you know, this massive exposure has occurred and cancers will result. And you know, I kind of think that's true.

But then we have the scientific view where we've sort of been entrenched in looking for P values of .05, and so I think maybe we should see where we can find middle ground, and Mr. Cassidy's comment about latency may be one such area. Because we could look at the exposure data to the extent that we have it, and that's challenging, too. You know, we have a huge range in who was exposed and where they were exposed and how they were exposed, and it was a disaster so there are no exposure data that

were carefully taken like there would have been in a factory. It was mixtures. We don't know very much about mixtures.

And we learned yesterday that it's controversial. There's a lot of concern about the exposure assessment and how adequate it was. And so I think that's kind of where we have to start.

But I think then moving forward and thinking carefully about latency and what kind of short-term cancers might we expect to see, and then whether -- whether we move from being strictly scientific, even though that's our title, to addressing the fact that this is an incredibly unique exposure and people are caught, given our current health care system, in a situation where they may lose their jobs and they may not have health care to support their cancer care. So you know, that's not strictly scientific and it doesn't have a P value of .05, but that's what I'm thinking.

DR. ROM: Well, I'm a scientist. For better or worse, I'm stuck with myself. There are things that would move me off the dime. And about case series reports for rare tumors or uncommon

tumors, I could be moved on those kinds of things. Multiple myeloma, I'm not there yet with eight cases and 6.8 expected. But if those twos and twos and twos that are 16 are really cases, and there are 16 over there at Mt. Sinai, that's getting more impressive. And if that's published as a case series, then I think that's more compelling.

Non-Hodgkin's lymphoma is another one, and these are related to the polycyclics and benzene and the mixtures that were in the fires and in the aviation fuel and it's biologically plausible, so non-Hodg-- so multiple myeloma did not come up in the FDNY study. It was not significant, it was way down there. Non-Hodgkin's lymphoma was significant, and it almost made it when it was corrected for bias. But I think a case series on non-Hodgkin's lymphoma would also be compelling.

The other ones that came up in the firefighter study, thyroid came up -- you know, that's radiation-induced, and I have a hard time with that one. And melanoma came up, and it's the -- FDNY play basketball all the time, gets UV exposure, you know. And then the third one

that came up was prostate, and prostate had 30 excess cases -- it was 90 observed over 60 expected, and that made the whole paper and that got them in The Lancet. It was all prostate, and prostate has nothing to do with anything other than you're a male and you're old, and that's the most difficult for an environmental exposure. So prostate, I have a hard time compensating those folks.

So we may have some sentinel cancers that might be doable, but I don't think we're there as of today to do that.

And the other thing is that there are tremendous opportunities here for research, 'cause this dust is really -- I don't know if toxic is the word, but it's caustic and it's got a lot of things in it and it's very inflammatory. It's a good inflammagen, if you will. And we know that inflammation and cancer live right next to each other, and COPD lives as the third agent there, so there's opportunities for research on COPD and inflammation and cancer that you wouldn't believe.

One of the problems of this is that we can't do

animal studies very well because this mixture is hard to reproduce. I mean we can take WTC dust and expose animals to that, but it was the fires and all these polycyclics and everything else, and that we can't do. And I'm not so sure just the WTC dust itself would be that convincing to cause cancer, so animal studies are kind of out.

So we're really left with human studies, and so we have a lot of opportunity to do human studies, but to really get at the answer we have to do pretty invasive things, like bronchial brushings and stuff like that. Maybe sputum would be something that you could do, but these invasive studies get you the samples that you can then study for inflammatory markers and mediators and gene expression and mutations and all of these things, and it opens up a very interesting door. But I'm getting a little bit -- I'm segueing into the next session on research.

So those are my thoughts.

DR. WARD: Is there anyone with their tent up wanting to speak? I just want to double check that nobody's -- okay. I don't know who's

first. We'll have time for everyone, so why don't we just go in order around the table. Leo?

DR. TRASANDE: Thank you. I just wanted to make a couple of generic comments about pediatric cancer because that needs to be in the discussion. First of all, we'll never get a three-fold increase in the context of any population that one could study, so I think our threshold for including that category of cancer -- and I'm not arguing that should be our basis for deciding whether to include that condition, but I just wanted to voice that, that for all environmental cancer studies that I've seen for children, with the rare exception of some radiation, you're never going to get to a three-fold increased risk factors. I wanted to put that reality check in there because I keep hearing three-fold as a -- as a criterion, and I find that a little hard to accept.

So I'm going back to Dr. Dement's comment that we need to look at biological plausibility and the scope of exposures we best can characterize it as our guiding force here. So I'll leave it there for now. Thank you.

MS. FLYNN: Yeah, I mean I am coming from very much the same place as Leo. I think that we need to look at bio plausibility, and I actually -- and of course we would also need to think separately about pediatric cancer -- bio plausibility in the context of pediatric cancers. And I'm wondering if this Committee should seek expertise -- you know, seek the most advanced thinking in making its bio plausibility arguments on the impact of synergies. So yes, I agree, we have PAHs, we have benzene, we have, you know, known bad actors. But we also have concentrations and combinations that haven't been seen before and I think that that could very much strengthen a bio plausibility argument.

MS. DABAS: My concern has been, one, I think Mt. Sinai has benefited and scientists will benefit from the ability to treat some of these ailments. And if we don't allow them to treat the cancers, it makes their research that much harder. When you have people -- the people that are studying in one institution at Mt. Sinai, and the people that are treating at Sloan-Kettering, who has not really been part

of this discussion, there is a bridge that's just not there. So the information will always be muddled. And so if we keep asking for this information and this information and we don't build the bridge to get the information by looking at cancers and creating an avenue for the physicians that are studying these cancers to actually treat these cancers so they can learn more, then we're crea-- we are becoming part of the problem. We are kind of -- you know, Dr. Rom says he's a scientist. We're preventing scientists from doing what scientists do, and I think that we need to be careful that, in trying to prove something that seems to be, you know, 25 years from now before we can make a definite scientific proof and not provide the tools for science to do what it needs to do, then we're really going to hurt the process.

DR. MARKOWITZ: I am not terribly hopeful about the epidemiology that's -- we're going to get in the next year because those study designs are not as favorable as FDNY. The EMS study's going to be smaller, and even the fire department study clearly had some problems with

statistical power and having enough people. And then there are problems with Sinai and DOH having to do with selection and et cetera. That's not to say that they won't be worth something, just that it's not necessarily such a hopeful situation in terms of clarifying it. So then we're left with the rest of the case. And for me, the rest of the case -- I think about a hypothetical. If this were -- if we -- if Ground Zero were opened for ten years and there were benzene down there and people -- we knew what the benzene level was, and then six years later somebody developed leukemia, we wouldn't be even thinking about epidemiology. We would say that yeah, the exposure was there, there's a known relationship, the disease occurred on time and we're good. And so the question is -- in my mind, is in nine months, which is how long it was open -- Ground Zero was open, is a short period of time for occupational studies. It was a long period of time for people down there, given the pictures of what we saw their exposure was like, but in our normal occupational epidemiology it's very sma-- it's very short.

So this hinges on are there data we can point to, not our feelings about it, but a scientific argument we can point to that acute or sub-acute exposures, relatively short-term exposures, can cause cancer, and can cause cancer in an accelerated time frame. And if we can find something that supports that, then I think that builds an argument. And if we can't, then we're stuck with this is a unique situation and -- which is acknowledged, but what do we say next when we say it's a unique situation? What can we say beyond that, that it's unique, we haven't seen it before, and therefore we conclude -- what?

MS. HUGHES: Hello? I agree with a lot of what you say, but I just want a point of clarification as someone who's lived downtown, one block from the World Trade Center, for the last 23 years. The exposure did not necessarily stop after nine months. A lot of this -- the chemicals dripped into the surrounding area. There's been construction and digging for the last ten years. Deutsche Bank was finally only down, not even the foundation, not even the complete foundation,

and transferred so -- not even transferred, it was -- Port Authority was given access this January in 2011. And so the concrete -- even R. J. Lee with their $30 million toxicology study on contaminants, showed contaminants in the concrete. And so the surrounding area -- they had been digging it for the Vehicle Security Center so I don't think we need to be bounded by just the nine-month exposure. It might be nine months for -- depending on certain type of occupational exposure, but I believe it's a lot longer and even people in surrounding buildings that were not necessarily cleaned out in nine months.

For example, I don't know about the Verizon building, which is right there, or the World Financial Center. This -- only recently -- also about Fehrman (ph) Hall was there for years. You know, maybe it was finally completed two years ago, and you have all the debriding truck through the community.

DR. MARKOWITZ: I overlooked that point, and I apologize. And I thought that Jo Polett did an excellent presentation yesterday portraying the continued -- the likelihood of continued

exposure. Obviously it does not apply to the workers who ended in mid-June, but for the residents, sure.

MS. SIDEL: I just wanted to say something really quickly about the combination of chemicals that I just find -- nothing good is going to come from the combination of chemicals. So if it was like, you know, benzene and dioxins, I -- and they're pushed together, it's not going to be good. They're not going to cancel each other out, so it's just going to make it worse. And I mean I don't know how you prove that scientifically, or even why that's important because obviously it's just going to be more caustic. It's not going to be good. So when everyone keeps talking about the combination and we don't know how that affects people, it's going to be worse, that's going to be the effect. I mean I -- thank you.

DR. WARD: There's at least two large issues. I guess one is, you know, what can we infer from what we know about the material that was there and the extent of exposure to that material. And I think -- you know, a lot of

the information that we have is basically a list of what was there, and there's some exposure concentrations, but it really -- I'm not sure what additional extrapolation or data you would need to kind of come up with a probabilistic statement about 'we believe that' -- I mean do -- what kind of chains of evidence would you need to say that, given the nature of this exposure, we believe it's not only possible but likely that this -- I mean I think already there's probably enough to say it's -- it could happen. So how do -- is there -- you know, is there someone who would like to volunteer to kind of either be on a workgroup or try to address the question of how much inference can be made about cancer from the composition and the exposure data that's available to date and bring that back to the Committee? Or --

DR. MARKOWITZ: You're asking -- you're asking about exposures, about taking a new look at exposures?

DR. WARD: Well, I mean we have data on exposures, and I think many people have said is it biologically plausible that these exposures

could cause cancer. And I think for -- many people would say yes, it's biologically plausible. The question is how likely is it. I don't know if -- I mean I think one thing we need to do is frame the -- you know, we've made assertions about what we know -- we've made assertions about we can -- what -- we can make inferences from the exposures, but I guess the question is to refine a little bit what inferences -- how to make those inferences and what those inferences are. So is it -- is it the fact that, you know, eight known carcinogens were present? Do we need more data to develop a rationale based on levels of exposure or concentration or -- you know, what is it that we need beyond what we have now to make more -- firmer conclusions about that? Leo?

DR. TRASANDE: Let me take a step back. How I'm thinking about this is maybe a bit different. There is a medical certification that follows from listing that needs to be performed before a condition would actually be, in practice, covered. So I'm -- to me, that takes some of the burden off of us insofar as

we might add a condition to the list. There still is a step, a medical certification. I'm about to start filling these out myself in my own work, and they are serious -- from what I've read, they are very serious documents. Now if that represents a conflict, I'm laying it right on the table, just in terms of saying it. But anyway, so what I'm struck by, rather than going into a workgroup I think we -- I still -- I'm still struggling on what are our core criteria for inclusion first as a condition. And the only other point that I would like to make about epidemiologic evidence is there are some suggestive other studies that don't themselves look at outcome but look at biological markers, and especially -- I'm always struck by Dr. Ricky Preher's (ph) study on PAH DNA adducts in relation to World Trade Center proximity. Now that was not an occupationally exposed population. I'm not saying PAH DNA adducts jumps you down the line to cancer, but it's a marker of PAH exposure. So you know, I'm not answering the question that I posed to the group about criteria just yet, but I think what I'm also suggesting

nonetheless is that if there's -- there's going to be very weak environmental monitoring data that we can work from, there's probably not a need to revisit the literature in full and come back with a consensus. There are a lot of review publications that have examined this, including the first report. But I -- and so I would urge us to think about what might be enough to push us over that -- push us off the dime, to use what Bill Rom said. And I'm already signaling that if you had decent biological plausibility in the context that we -- we can't identify a subpopulation that actually has an increased risk of cancer, it's not our job -- that if we can identify it within a subpopulation that we think is highly exposed, that that may move us off the dime onto the list. And if there are other suggestive evidence of sufficient carcinogen exposure to potentially increase risk, then that might push me off -- off of that dime. So I don't know if -- I'm not being completely eloquent, but I think I'm starting to move -- try and move us towards a definition of what would lead to an inclusion of a condition.

Others should feel free to amplify, criticize and comment. Thanks.

DR. WARD: I mean, you know, one of the things that IARC considers is that when there's animal evidence of carcinogenicity but no human epidemiologic studies or weak epidemiologic studies, they look at mechanistic data and they specifically look at evidence that a mechanism that can -- you know, that whereby something causes cancer in animals or known to cause cancer is -- is present. So looking at the biomarker studies, DNA adducts for example, would be one of those indicators that would make the link between potential carcinogenicity based on what's in the mixture, and the fact that the population had exposure at a level that is increasing this marker, you know, that's related to cancer. So I think that is something that we should definitely look at more carefully, as well as consider in our research recommendations, is what biomarkers have been looked at and do they in any way contribute to how we evaluate the existing data.

Tom?

DR. ALDRICH: Well, I acknowledge the weakness of the epidemiologic data, and the issues of latency are a really big problem. But I don't think we should be too sanguine about the exposure data at all. I mean we are all exposed to asbestos. We are all exposed to benzene. It's a matter of dose, and we just do not know the doses that workers or residents or anybody received of any of these potential carcinogens. And so I just don't see that knowing a list of chemicals that were present is really all that helpful.

MS. SIDEL: I just want to say that I'm not sure why dose -- as a scientist, I can understand why that's an issue, but everybody is so different, everyone's body is different, so the way you respond to the same dose that I get could be totally different. And you know, I may have a genetic predisposition to something and this exposure triggers that predisposition. I just think people are too different and to say that one dose is going to affect everybody the same when there's just such a varied population there, I don't understand how that works and why that's

critical. We do know that there was -- we do know that there was a -- we have like all that information about the data of what was out in the neighborhoods, what was done on the Pile, you know, and what percentages. We have a lot of information about that stuff.

DR. TRASANDE: I was going to comment -- and maybe I'm in a middle place between the last two commentators, but I'll -- but try me here. I'm of the philosophy that if you're above -- environmental monitoring levels need to be above background. That drives me in a way that if they're in the range of background, that's -- that's important to me. And I think there are a number of studies that we have that suggest that for a number of key chemicals of concern for carcinogenicity, we do have evidence of levels above background. Now we also have biomonitoring data for dioxin and for perfluorinate, if my memory serves me correctly, in at least one population of biomonitoring evidence above background as well. And now that doesn't sway me for the whole population of WTC-related exposees, but I think it -- we don't have that -- the luxury of

dividing up the population with regard to what's an eligible condition at this point. We either have to or -- or don't. And I think we have to act in that mode, and I think then from there it goes back to biological plausibility and some of the other arguments that we've had before. At least that's how I'm thinking about it. Now I may not be on base there.

DR. DEMENT: I think in some ways we're at the limits of what we can say about cancer risk related to dose. I'm yet to know a cancer where there's actually a threshold. Certainly we have background exposures and we have some risk. Take some examples that came from this exposure, asbestos and benzene. It's been controversial for years whether or not there's actually a level of exposure that you can have that you don't have some risk. The more studies we've had going on over the years, that level where you can actually demonstrate risk has gone down and down. And with benzene you go back to some of the models that look at the mechanistic process in terms of activation or deactivation of metabolic pathways, and there's still no evidence that benzene has a threshold

for the -- especially for leukemia.
So I -- you know, I like the idea of exposures that are significant being related to potential cancer outcomes. If you ask me down the road do I think that we'll have excess cancers in this population demonstrated by epidemiology, yes, I do. To say, a priori, which ones there'll be is quite another question. I would probably guess we're going to probably see some lung cancer excesses out of it down the road for sure.
DR. WEAVER: I just wanted to ask John if -- apparently you were on a cancer committee that met within the last year relating to World Trade Center? Can they bail us out at all with this?
DR. DEMENT: I think one of the studies you have before you actually came about -- at least a part of the discussion of the design for that and how it would go forward and some of the others that are already planned were -- that was the object of that discussion -- how would you characterize exposures, and maybe across the studies you can actually compare them a bit, and sort of the methods for linking up

with some of the registries.

DR. WARD: So I mean it -- it sounds like, in terms of forming the workgroups, that we could have one or we could have two. And I would say that maybe we do think about framing it, because I think a lot of -- ultimately we're really going to be -- it is going to be an opinion, no matter what. I mean there isn't enough data to say, based on any external criteria that already exists, yes or no. But I think it's going to be an opinion, and I think what's -- so I think we would charge the Committee to really develop a case in favor -- what are all the arguments that could be made in favor of including cancer as one of the conditions, and what are all the arguments or the factors about the existing data that would make us hesitate to make that recommendation at this point, because I really think in the end it's going to be -- this recommendation is going to be built on opinions. And then I do think it's critical for us to try to identify what are the pieces -- the most critical pieces of data that could be used to make a more -- to have a more informed decision and to look at

whether those studies are underway or they actually need to be initiated or recommended by the Committee.

Does that sound reasonable to folks? Does anyone have an opinion as to whether we should have two committees, one focused on exposures and toxicology and another focused on -- I would say epidemiology, biomarkers, with a little toxicology, because I think toxicology's relevant to both. Leo?

DR. TRASANDE: I don't know what others' thoughts are, but my sense is that this is a job for the Committee of the whole. I think segmenting -- I don't think this is something that the epidemiologists should go into one corner, the medical people should go into another corner, and the community advocates should go into another. I just think that's a dangerous proposition. This is a tremendously significant decision for the group, and I think in the interest of enhancing transparency and having open dialogue like this that's been really helpful, I would prefer we go forward with this as an ongoing conversation. If that means teleconferences, if that means

alternative modes of communication, so be it.
DR. WARD: I think that's a great point. I do think that we do need some people to commit to do some actual work, and so in that sense I was proposing workgroups, but you know, it's fine if the Committee wants to do that, as long as we have people who are tak-- you know, are willing to take on some defined tasks to prepare between the meetings for specific discussion topics.
DR. TRASANDE: I'm struggling a little bit with what work tasks. I mean I think we're at the point that -- you know, if we -- you know, one of the things that I prepared for this meeting, knowing that cancer was going to be a point of discussion, was the Administrator's first report, and I actually think that's a fairly thoughtful, fairly presented discussion of what we know to date. I just hesi-- I'm just not sure what the work products are going to be. I think we need to have more dialogue discussion about criteria and start to move towards a judgment call. I think that would be a more fruitful process. So my own opinion is we need dialogue, not reports on reports on reports. I

respect that mode and at some point when we get to writing, I think we're going to want a companion opinion, maybe there's a small subgroup of people composed on this Committee who do the actual writing. That's just my perspective.

MR. CASSIDY: I think Leo's right. I think it needs to be the entire group. One thing I -- you know, we can't get away from is that there really is a failsafe built into this system. Right? So if we were to decide to include cancers, there is a failsafe. It's not like we then green-lighted this process where anybody who lives below Canal Street is in. We can't dismiss that because it's critically important to the process. I mean it's almost like when one of my kids comes to me and says is it okay if I go to the movies tonight, and I always say yeah, it's okay with me as long as you get your mother's approval. So in effect, you know, I've given like a half a green light. And there's some sense of reality to that because -- you like that, Leo? Good -- because that's the truth. I mean we're making a decision based on common sense.

If there was no failsafe, if -- if there was no failsafe, if no individual -- if we were to grant cancer or add cancers and there was no failsafe, then I think it would be reasonable for a lot of people in this Committee to be skeptical about that decision. But because there is a failsafe, a real failsafe that requires a review and a confirmation by a physician, and an ultimate decision by the Administrator, I don't think that that is such a great leap that we are making, given the fact that we know what happened. We all watched it unfold on TV. It is a disaster of unknown proportions. And the exposure to thousands and thousands of people are documented, and some results -- although preliminary on cancers -- show an increase. The lung disabilities for firefighters is documented beyond belief. And I think when you factor all that in and you have a failsafe, I think that gives us leeway to make a decision to include it. But no matter what, I think that should be part of the discussion when we talk about where we're going.

DR. ALDRICH: Well, I generally agree that we

should not be segmenting into an epi group and a toxicology group. I think what would be useful, though, is position papers taking -- I don't want to say extreme positions, but defined positions. And for me personally, I believe that the data at some day is going to show that there are increased cancers related to World Trade Center exposure. I have little doubt about that.

But I think that there are some -- that there's good reason to be cautious, and that is -- and there's very good reason to base our decisions on evidence. And furthermore, I think that it's not all or nothing. I think that it's extremely unlikely that a cancer that comes up in December of 2001 -- a lung cancer, let's say -- is related to World Trade Center. It's extremely unlikely and we should acknowledge that, along with the other things, that there's -- that the further out we get, the more the chances that a given cancer is related to World Trade Center exposure. The closer to the time of exposure, the less likely. And that has some importance for public policy, I think.

I don't know what's the right answer, but I

think we should stake out some positions, even if they're a little bit more extreme than we really believe, just to take positions so that people can react to them.

DR. ROM: All of us have time constraints, so joining working groups is something that's almost impossible. But I do think there's a program administrator who does have a staff and could provide us with some information. And I would suggest two or three areas where we need more information.

First, we have these exposures, and there's a lot of measurements on benzene, polycyclics, asbestos and perhaps some other carcinogens, like dioxins, that could be brought together. And how much was in the building, like how much asbestos was there, and then all these measurements I've seen by the EPA -- generally they don't find anything. But I'd like to know what measurements have been made and have one piece of paper or a couple of pieces of paper that tells us what the exposures -- what the exposure data is.

And the second thing is -- so we'll have the FDNY study, the Mt. Sinai study and the

registry study on cancer coming out in early '012, but I think it would be nice if somebody is going to capture that data and whatever else is out there and -- and have that for us at our next meeting.

And the third thing is there may be additional biomarker data that's out there that would be nice to have, that could help us make a case. And I think staff helping us is not unusual for advisory committees, that that would be helpful, and we certainly would have the time to review documents, and to try to generate the documents ourselves would be more of a challenge.

DR. WARD: In the report that was generated by NIOSH there's a compendium of exposure data, but you're asking for another level of analysis, or an evaluation of each of the elements?

DR. ROM: (Off microphone) (Inaudible)

DR. WARD: Okay. So Steve, and then Leo.

DR. MARKOWITZ: I would propose a compromise. The request to us -- in the request to us, Dr. Howard wants us by March 2nd to include a description of our evidence, the quality of the

data, description of the methods used to formulate the advice, so we're going to have to write something up and we might as well begin sooner rather than later. So we could have workgroups that are open to everybody and that achieves, you know, both purposes. And those workgroups could try to take -- consider positions perhaps more extreme than they might naturally move to as a way of getting out all the issues, and I would volunteer to be on one of the workgroups.

MS. FLYNN: I just want to respond, Bill, to what you were saying. We went through, many of us in this room, a nearly year-long process with the EPA's World Trade Center Expert Technical Review Panel --

UNIDENTIFIED: (Off microphone) (Inaudible)

MS. FLYNN: What?

UNIDENTIFIED: (Off microphone) (Inaudible)

MS. FLYNN: Yeah, yeah. So the data -- let's -- let me just state it this way. The data from indoor environments that the EPA gathered was widely discredited by the experts on the panel and by people in the community who got up, who had -- had done their own environmental

auditing. The Stuyvesant Parent Association had hired a very well-known, highly accredited environmental auditor, and there also were a wide range of narrative accounts, eyewitness accounts by residents, about how the EPA's -- that the actual people entering buildings to do testing would not run fans and leaf blowers, would turn fans directly against the wall -- I mean it's -- the problems were legion, so I'm just going to -- you know, a very, very big red neon cautionary note on utilizing EPA data to draw conclusions about the exposures of residents, students and area workers.

DR. TRASANDE: Just thinking about the day and a half -- day and change so far, the one aspect of the World Trade Center disaster that we've not discussed in great depth, like what Bill said, is the environmental exposures themselves and what data we have for or against certain chemicals being above background, for instance. And there are experts in the area specifically who have thought about this in extremely great depth. There are some on this very FACA, as well. And that may help move our discussion in a facile way, in addition to what the Committee

-- the Administrator's staff can provide. I think that would really be helpful. At least that's the area I think I'm hearing of greatest uncertainty perhaps about exposure.

I think from there we could probably move through the biological plausibility, and other components of the logical chain to cancer, more carefully.

DR. WARD: I think we are going to have to wrap this up or we won't be able to discuss research at all. I mean I hear a couple of people making the specific proposal that we -- I mean I think in general people agree that the main body of work will need to be done by the Committee as a whole, but there might be some preparatory work that could be done either by making requests to NIOSH staff for specific information or bringing in experts to advise us on specific topics. And I think the idea of dividing up into two groups just to maybe draft the arguments for and against has kind of resonated with a couple of people, so -- so if -- I mean -- so if someone wants to make a motion to proceed in that way -- but I guess the -- essentially what we're saying is the

group wants to continue to meet, possibly by telephone, to deliberate on this further. But -- and people are opposed to workgroups going off in isolation and doing a lot of work just off on their own, but that they are not opposed to having groups that would help prepare position statements for discussion by the group.

Is that correct, Steve?

DR. TRASANDE: May I ask a question and then possibly propose a motion?

As far as I know, we haven't defined a next meeting date, and presumably that meeting would have to happen by March 2, so I'm -- I'm a big fan of walking back from the date certain and potentially working out a strategy to get to a point where there's -- where we do our job. So I guess one proposal would be to actually suggest a potential meeting date and try to march backwards from there, but that's just a thought.

DR. WARD: I don't know if we'll be able to decide an actual date, but we could say that we'd probably plan an in-person meeting sometime in February -- I mean if we worked

under that assumption. Yes?
MR. CASSIDY: I agree with Leo, we should work back, and I think sooner rather than later so -- you know, I do think there's a consensus that we all get in the same room. I don't like the idea of dividing into camps for or against because, to be honest, I want to hear the arguments of both sides and could change my opinion. And I don't want to think that I'm predetermined to be in a particular camp without hearing other people's arguments. But having said that, I don't think we should wait till February. I think we should try to get a meeting in January, in case it doesn't go as well as we would hope. And March 2nd -- you know, if you're in February, you don't really have a time to get another one going. So I think we should try to get something early/mid-January which would give us time to get back late February to finalize something, assuming we're building a consensus. And if we're not building a consensus, we've probably got to get back in a room and try to figure out where we're going.
DR. MARKOWITZ: At least to clarify, make a

motion that we do have two workgroups, one focusing more on the epidemiology and the toxicology as it approaches the epidemiology, and the other on the other side more on the exposure and then related toxicology; both workgroups be open to all, and both workgroups consider the various sides of the arguments, and that the workgroups produce a preliminary write-up that would serve the purpose really just of furthering and focusing the discussion so that we can advance more quickly.

MS. FLYNN: I think I mostly agree, as long as working group conversations would -- everyone would be privy to those.

But before we move -- and I'm sorry to do this, but before we move in the direction of defining a working group around exposure, I'd actually like to ask Micki Siegel if you could just briefly give us an overview of what's available by way of exposure data, 'cause I think everybody needs -- I really do think this is very important.

DR. WARD: Right, but I do think -- we have a motion on the table --

MS. FLYNN: Okay, we have a motion on the

table. We'll redefine the mission of the working group, the one that includes exposure data, after --

DR. WARD: No, and I also think it's important to understand that the group that addresses exposure data is going to look at the quality of data, look at the limitations of the data, and you know, people will have an opportunity to be -- to be represented and to share information. So -- so it -- but it's -- it's really just that that committee will focus on exposure data.

MS. FLYNN: I'm just not entirely sure that the people sitting around this table can -- because I'm not -- it's unlikely that the majority of people sitting around this table understand just how limited those data are.

DR. WARD: Well Paul, this is kind of a procedure question, so when we have these meetings they will be announced -- the telephone meetings of the workgroups, they would be announced in the Federal Register and open for public comment, and we also would have the option of asking specific individuals to come and speak to specific issues. And I think

that could be recommended by some -- anyone on the STAC, that we -- if we -- so I think it's covered. Tom?

DR. ALDRICH: I don't think it's going to be helpful to have two separate approaches, because I think we're pretty much in agreement about the epi data, that -- well, we're in agreement that there's some value to it, but it's not going to be definitive. And so what our decision really hinges on is the toxicology. And so I think we should focus on that and just have a -- because if we have too many groups, we're just going to have -- it's going to impede our coming to a decision. I think we should have a single discussion, clarify the toxicology, acknowledge the weaknesses in the data, try to determine if there are any data that are reliable, and present what we have and go from there.

MS. MEJIA: I really don't want anybody to leave this room thinking that there's a lot of exposure data out there because there really isn't. There's a big void there, and so let's not hang our hats on all this data that may not be there because there was -- there was no data

captured, I think from day one. There wasn't any environmental monitoring done on day one. There was no personal monitoring done on day one. So let's not -- you know, don't walk out of here thinking that you're going to find a whole bunch of data out there that we haven't really tapped into.

DR. DEMENT: This is at least the third meeting that I've been to, maybe the fourth, where data on exposures has been discussed, and the same theme comes across every time, that they are limited. And frankly, I think the publications that are already out there summarizes what we're going to know. I think we could waste a lot of time trying to dig into these data, and the people who really know it very well, they've already done that and some of it summarized in the NIOSH report is in reference to the original publication. So I don't know where we're going to go beyond that.

DR. WARD: Given what you know and where you've been, do you have a recommendation on how to -- we should proceed to come up with this recommendation?

DR. DEMENT: I think we're overwhelmed by the

exposure, both with regard to the initial magnitude of it and that which existed for a number of months, but also the complexity of it. Now there were like almost 300 different compounds that were -- and materials that were measured into the exposure, identified, and we can't -- there's no way possible for us to deal with that.

Now I think a sensible approach, at least in the way I see it, is pick the ones -- major ones which had a theme that went across most of the exposures, the ones for which there was reasonable exposure measurement data at least showing the exposures, and Paul LeRoy's papers have summarized a lot of that. And I think we have to base our decision on whether to include or not include cancer on those exposures.

DR. WARD: If we want to do that at our next meeting, we would really try to focus on those exposures and look at whatever limited quanti-- I mean look at the cancer sites that have been associated with those exposures in prior studies, and look at the extent to which we have data on exposure levels.

DR. DEMENT: Exposure is a three-part scenario.

Exposure levels, we don't have a lot of that. It's also where you were at the time. It's your duration of it -- frequency, duration and level, and we don't have a lot of personal exposures. The thing about occupational exposure measurement that you find typically is the general environment may or may not be very high. It's the environment that the individual's in. The breathing level samples, for example, closer to the source are typically much different from those that are far away. People generate their own micro-environments based on what they're doing.

So for us to hang a determination on some required exposure level I think is not doable. What I was suggesting, though, there are certain compounds -- and I think NIOSH has listed a fair number of them in their report -- where there's some repeated measures. The levels certainly were above background in many cases, most cases, so you can -- I think with a fair degree of confidence -- say these are exposures that most people at the site would have had.

Then the next question is what do we know about

those in the risk of cancer from NTP/IARC, largely.

DR. WARD: So that makes sense. I think what I was thinking of in terms of exposure is, and some of the things on the list are like vinyl chloride, for example, and I don't -- you know, you do need to get a sense of is this an important exposure in this setting or not, and I don't know if there's any data to know. But certainly we have benzene, we have asbestos, we have the silica-type compounds, we have -- there's actually a limit-- a pretty limited list of group ones, and then I guess we could go and include the 2-As and 2-Bs, and maybe start from that approach. Is that agreeable to everyone, so at least we have a direction that we're moving in, is look at those specific compounds that have substantial data on carcinogenicity?

DR. TRASANDE: Could I -- I don't know if we're still on a motion or not, so I'm a bit perplexed. But it might be good to continue this conversation on a call where we try to focus on a list of ten or so -- or something -- something that we can grab our hands onto and

get some committee help with regard to giving us maybe some -- a synopsis with a little bit more depth about exposure as we know it with regard to the World Trade Center, recognizing that we may only be able to do a binary above background/below background assessment as a Committee. And then, you know, I -- my instinct is that the rest of it from there is fairly judgmental. I mean it's based on -- you have IARC data, you have NTP, you have all these sources, and we have to just decide well, what class evidence are we going to accept as a basis for taking us to plausibility, at least at some level, from the standpoint of whether there was an exposure or not, recognizing that we can't even sub-segment the population, our task before us is quite straightforward. (Interruption regarding conference connection) What a pleasant interruption. So that's just my -- my suggestion is that we might move towards a conference call where we as a committee try to hone down. And then my suggestion would be to try to, after that conference call, start writing the -- start writing the document. It might be a very small

subgroup of lead writers, but then it would always be done in an inclusive fashion towards actually -- and I think inherently it would include abstracted data from the staff reports about the exposure with regard to these key chemicals and the implications based on knowledge from IARC, NTP, et cetera. Those are just some thoughts that I have.

DR. WARD: Then I think where we stand with respect to the motion is Steve made a motion for the two committees, and I don't think it was formally seconded, and then there were -- other people put forth different motions, so -- can't do that? Okay.

MR. CASSIDY: (Off microphone) (Inaudible)

DR. WARD: Okay. So how do we correct this?

DR. MARKOWITZ: Why don't we have a restatement of the motion.

MR. CASSIDY: Let him restate his motion and then you see if there's a second, and then it's open for discussion.

DR. MARKOWITZ: I'm not going to restate the motion because -- I think the motion died. But I would like to say something else.

So we have these group one carcinogens.

Everyone know-- everyone recognizes they're -- there are human carcinogens down there -- benzene, asbestos, PAHs, a couple of others. We know there was exposure. We believe there was exposure. We believe the epidemiology is not going to really help us yet. So what else do we need? And that's sort of a restatement of what Susan said. There's something else we need, and otherwise we're not comfortable, but apparently there is some level of comfort that I've heard two scientists say here that they do believe in the future that cancer will -- could be produced from those exposures and it will have evidence thereof. So whatever else we need, then let's focus on that.

Now maybe that's just a restatement of what Leo said, but let's get there and hone in on that -- you know, either way. I'm not prejudging the decision. I'm just saying let's get there.

DR. DEMENT: If you were to ask me my opinion, that should we include cancer as something that would occur as a result of this exposure, my answer would be yes.

But back to ask the next level is which sites are going to be included or not, I think that's

the more difficult question. Maybe it's not a question that we actually need to address, but it is an important question.

MR. CASSIDY: I just want to remind people, with reference to what Dr. Markowitz just said, that there were fires burning at the World Trade Center on St. Patrick's Day, and I was there, March 17th, 2002 -- March 17th, 2002, we were still putting out fires. So everybody knows that when you have fire, you have carcinogens in the air. The fact that stuff was still burning, you know, six months after the attack should say something about the level of exposure in the 22-acre site. And I think it speaks to -- you know, sometimes we can get bogged down in the technical data, the numbers, the benzenes. How in God's green Earth were things burning six months after? And the answer is: This is a once-in-a-lifetime event, and the exposures suffered by those who were there is, unfortunately, a once-in-a-lifetime event. And to think that cancers are not going to come out of it I just think are flat-out silly. They are. The early documentation indicates that. The fire department study on

lungs is -- is definitive. All these bad things can happen to you. You cannot be in a site six months after an attack and still fires burning, and think maybe nothing's going to come from this. So I don't want us to get away from the common sense and facts that are maybe not scientific, but real.

DR. WARD: But it is incumbent on us, if we make this recommendation, to rigorously define the scientific rationale for that recommendation. And so I don't think we've laid the basis for doing that at this meeting. It could -- and I think what we're trying to do is struggle with how to approach this large body of evidence and, you know, apply it to making this recommendation. Susan.

MS. SIDEL: This might be a situation where a lot of the legal community that's involved in this might be helpful because the writing recommendations for like say the victim's compensation fund or just briefs that they're doing, past briefs, Joel Kupperman's briefs, things that, you know, Michael Barish wrote for Zadroga when he was representing him, there's a lot of -- you know, where they had to connect

the dots to make a case, and that's essentially what you're saying here is that you're sort of making a case. And so what I sort of see is that we have the chemicals and now we're going to start -- you know, we have all this -- these things and we're just going to be connecting those dots. It's really like a brief, in a way. I mean it -- is that bad because it's not scientific? I mean but it is -- it's connecting the dots, putting it -- putting it together, sort of.

MS. DABAS: My question is, it goes back to Steve's question, which is what is it that is still missing that people need to -- for the science? What is it that is likely to be available within the next time that we meet that will make this case? And I pose that to the scientists. Like if -- if there is something that we feel that could be available or that will be available before March 2nd, I would -- I would love to know what it is because it doesn't seem that the fire department, Mt. Sinai or the WTC Registry will provide any information before then. It doesn't seem that there's anybody else that's

going to provide any further scientific information until then. So I'm wondering if -- what -- what would we need? And if that information is even available.

DR. ROM: Valerie was looking at me. All right, I'll tell you what I want. For lung cancer, which is really possible 'cause this was an inhalation exposure and we have defined carcinogens that are great for making lung cancer, so the firefighters had nine lung cancers in seven years and they had 21 expected, and their SIR, this incident ratio, was .42, so you know, we have a long way to go. I think lung cancer is not going to be seen to be increased for years. For at seven years, I don't think we're going to see much -- I don't -- ten years, 15 years, so it's going to be too long to wait. And the firefighters were the most heavily exposed for lung cancer.

I find the multiple myeloma and non-Hodgkin's lymphoma a little bit more likely and plausible 'cause they -- there's literature on them and I mentioned the numbers of cases. I'm not quite there yet. I'd like to see some at least case series reports, which probably will be

forthcoming in the not too distant future. I don't think that we should list other kinds of cancers, like prostate or even thyroid or melanoma. You know, there's a biological plausibility for these cancers related to exposure, and I have a real problem with prostate and a pretty big problem with melanoma, and maybe a little less problem with thyroid. And then for other sites like breast or colon or -- or maybe larynx I could think of, but brain -- I mean these sites just aren't biologically connected. The dots don't connect. So -- and to go for all cancers, I think that's too much of a stretch. So that's where we are with the science.

MS. DABAS: I just want to comment in that you said that firefighters were the most exposed. I think a lot of the pictures show you that firefighters and police officers worked side by side on that day, so to differentiate between fire and police or fire and whoever was on that Pile is going to be a hard differentiation to make. That would be one of my things.

Second, there are about four or five cases making their way through the courts right now

dealing with cancer, and I think it's important that the Committee kind of look at those cases as they come along. One of them that I'm familiar with is Mackery (ph) where somebody had a lung scan done two or three days prior to September 11th and it was a clear lung scan. And when they did it again in August 2002, their lung cancer showed. There might be some scientific reason for that, but that case is currently pending in the courts.

DR. ROM: Okay. I think the police would be an excellent cohort to study because, as you said, they were heavily exposed and I would make a research recommendation for someone to write a proposal to study all police in New York City and define the exposures and look at some of these outcomes.

As far as individual legal cases, there's -- you know, in the FDNY study there were nine lung cancers so, you know, there could be nine individual cases out there. I think that a surveillance program for lung cancer might be kind of interesting in some of this heavily-exposed cohort, like CT scans and maybe biomarkers, but that's a research study and I

think that would be a compelling one to look at and possibly fund. I didn't write one, by the way.

DR. ALDRICH: One -- you know, I agree with much of what Bill said about that not all cancers are likely to be consequent to World Trade Center exposures, but there are some that are. But there's also a time element, too. I mean notwithstanding the change in CTs between whenever it was and 2002, it's still quite unlikely that a lung cancer originating -- or discovered in 2002 started after 2001. So whatever recommendation we make should take that into account, that it's quite unlikely that a solid tumor in 2001 or 2002 was World Trade Center-related. Not impossible that a hematological malignancy was, and so there are important differences in that regard that make some sense to pay attention to from a public policy point of view.

DR. WARD: Any response to that?

DR. DEMENT: Yes. Yes.

DR. WARD: Okay.

DR. DEMENT: But I think that gets to the sort of the second level, that's the attribution of

individuals -- a cancer to the exposure. I don't think we've been asked to do that. I think we're just -- we're being asked if this exposure, or these exposures, can cause cancer, are likely to cause cancer. The attribution comes at the next level when you have your cancer and you're with your doctor and you say 'I was exposed last year; can this be related to exposure?' You know, doctors say a lot of things, but hopefully an informed doctor would say 'Very unlikely.'

DR. WARD: Leo? And that'll be the last comment and then I'll make a proposal, we won't make it a motion, of how to proceed.

DR. TRASANDE: Just a quick comment that if we start -- and I agree philosophically with what Bill said, as well, except to say that there -- we also have to consider the fact that cancers get chemo and there's such a thing as secondary cancer to consider as an associated consequence, which is in the language of the Zadroga Act.

And the other thought that I had has since evaporated so I will defer.

DR. WARD: Well, I mean what I would propose is

that we should set up a phone call sooner rather -- phone meeting sooner rather than later. We have not gotten to the research recommendations and I'd like to do that in a time frame that we can remember what we've discussed today.

I think we have gotten some suggestions about how to focus the discussion. One is to look at those specific carcinogens for which there is some data on exposure at the site and we can focus some discussion around that. We have a specific idea of maybe looking at particular cancers -- lung and NHL and multiple myeloma -- looking at those specifically, and perhaps there may be some others -- obviously mesothelioma. You know, that there -- that if we're not ready to make the recommendation to include all cancers, there might be specific cancers for which we would be more inclined to make a recommendation.

So I think what we can do is we'll need to still do some work to develop the agenda for that meeting, and maybe we could do that through exchanging e-mails and so on, but --

DR. MIDDENDORF: I would point out that for you

to have a meeting it takes at least one -- I'd have to have an agenda, or at least the matters to be discussed, at least one month ahead of time to be able to get it into the Federal Register in time.

DR. WARD: Okay.

DR. MIDDENDORF: So we have that kind of a lag time, and that doesn't include my time for developing the information or developing the Federal Register notice. So probably five to six weeks at least.

DR. WARD: Okay. So in the meantime is there -- is there a way that we could collect from the Committee, let's say their key -- the key things they captured from yesterday's discussion on research, or is it -- do we have to wait till the next meeting to get input from the Committee on -- or on their perspective on the discussion regarding cancer?

DR. MIDDENDORF: I think it might be helpful for us to delay the discussion of research, simply because it's one of those potential areas of conflict of interest and we need to review that more carefully in light of the individuals on the board -- on the Committee

and make sure that we can appropriately and properly address the conflict of interest issues there.

DR. WARD: Okay.

DR. MARKOWITZ: Paul, what's the timetable for that?

DR. MIDDENDORF: The timetable? We'll clearly be -- I think we'll be able to handle that probably within the next month.

MS. FLYNN: And when are the next BAAs issued? I just want to make sure that we have this discussion about priorities before --

DR. MIDDENDORF: Yeah, I'm not sure --

MS. FLYNN: -- the process happens around funding research going forward. No date?

DR. MIDDENDORF: I'm not certain when that date would be. Nothing's been established yet, so it'll be a while.

DR. WARD: Okay, so is there anything that we should -- can do -- I'm sorry. Leo?

DR. TRASANDE: Can I make a motion that we sketch out an agenda for our next call now?

DR. WARD: Yes, excellent motion. I'm sorry.

DR. TRASANDE: Yeah, is that seconded?

(Motion seconded by multiple Committee

members.)

DR. TRASANDE: Okay. Can I move we -- do we need a discussion -- this is Chair-- do we need a discussion about -- can we start to just -- I'll -- if I can, I'll just try to speed things up and suggest some items.

So I think clearly we need some staff input about a list of chemicals of exposure -- at least this is how I'm thinking, but maybe I'm an individual perspective on this panel, not the consensus. But if we could focus on a list of chemicals of concern, and focus on a list of -- that would fol-- so that would be one item. Would -- we have a discussion of a more in-depth description of what we know to date about exposures and the aftermath of the World Trade Center disaster.

Then I think what we would probably have is an agenda item that would follow that, hopefully would be a discussion of the carcinogenicity of those elements.

And then a third would be potentially going where Bill was going, potentially looking at what types of cancer might be on a suggested list if indeed we are to proceed to make a

suggestion to the Administrator of causation. I would also like to further suggest that we move quickly to, once we get the conflicts issue sorted, to have a research-focused call fairly soon in tandem, recognizing a five- to six-week lag, so I'm probably attaching that to the motion, but I apologize for doing that if I'm out of order.

DR. MIDDENDORF: And I'll say that you need to have just one meeting, not two separate meetings. One phone call, which is a meeting, and then it needs to be an open meeting.

DR. TRASANDE: I'm just suggesting that we try to schedule the two consecutively, but not have one meeting and then schedule another meeting with a lag. I'm just sensing that we -- that would take us to March or...

DR. MIDDENDORF: What I'm saying is that we will have -- we should have one meeting in which we discuss both the research needs and these other issues.

DR. TRASANDE: Thank you. That clarifies it.

MR. CASSIDY: If we have an approximate six-week lag time, then we really can only meet twice before March 2nd. Now that's the

reality, right?

DR. MIDDENDORF: Well, what I could -- if you make decisions on the need to have two additional meetings, we could put that into one Federal Register notice.

MR. CASSIDY: I mean I'm just thinking out loud, but it seems to me that we -- we should strongly consider, before we leave today, agreeing that we need a physical meeting, face-to-face, sometime in February as a follow-up to this phone meeting, so that -- you know, maybe we won't need it, but we should plan on having it. Everybody's busy. We should get it on a calendar. We should leave here either knowing shortly that we're going to have a meeting scheduled in February, we're going to have a phone conference four to six weeks from now, and that those two events are going to be what we have left before March 2nd, and I think we should do both of those things.

MS. HUGHES: So many people already in New York, the conference call -- maybe there's a room where people who are in New York, to save you money, can be in the room, because somehow a conference call is not as effective as face-

to-face dialogue, and money seems to be an issue.

DR. WARD: That's a great suggestion that we should go ahead and plan a face-to-face meeting in -- well, it's January or February, whatever is most feasible, in addition to a telephone meeting.

DR. MIDDENDORF: My suggestion would be that if you want to have a telephone meeting, we do that maybe in mid-January so you can get the Federal Register notice up and out. With the holidays coming up things tend to get slid a little bit. And then plan for something pos-- face-to-face possibly in mid-February.

DR. WARD: Yeah, I think -- I mean I think the Committee would prefer not to wait that long, because we want to be able to have some continuity of thought. Are the two of you commenting specifically on the meetings, the meeting schedule, or... Okay.

DR. WEAVER: Just in terms of moving the research agenda along, I'm wondering if it's allowed for us to e-mail our top three suggestions for research priorities so that those could be compiled. We could look for

areas of commonality, and then conflicts could be addressed.

DR. ALDRICH: That's exactly my point.

DR. WARD: That sounds like a great idea to me. We'll have to see if it works with the FACA.

DR. MIDDENDORF: Okay, I think the answer to that is, in part, what we can do is you can identify areas of research and send it in an e-mail, but the information will need to be discussed publicly at an open meeting. Okay? And the other thing is that individuals should not be putting things on their list, things in which they have the potential for possibly getting research grants so that they would potentially benefit directly.

DR. WARD: Does anybody else feel is it silly for Emily to have to whisper in Paul's ear, 'cause is there --

DR. MIDDENDORF: Yeah, this is the way she wants to do it so that's not a problem. The point Emily was making to me is that the e-mails all need to be one-way. It's not a dialogue. So if you set up your list, you should send it to Liz. Liz can compile the list and then that list will be discussed at

the telephone meeting.

DR. WARD: So we have a proposal for the draft agenda for the telephone meeting, which is to discuss the exposures and the aftermath of 9/11, the list of chemicals of concern with respect to carcinogenicity, to discuss what types of cancer might be associated with those exposures and therefore on the suggested list, and then to move quickly to discuss the research.

Is there any other addition to the agenda or --

DR. MIDDENDORF: I do want to make the point that it's probably not appropriate for the Committee to assign tasks to the program, which is what it sounds like has been done -- or an attempt to do. That's not something that was in the Committee's purview, so we can't give the program required activities. So I guess what I'm saying is that if the information that's already been developed for the report of cancer, you can use that for -- to address your things about exposure, the things that you want to learn. You can go to the literature. But I don't know that we can go back to the program and say you need to do this for us for our next

meeting.
DR. MARKOWITZ: Can we request assistance?
DR. MIDDENDORF: We can request, but we can't expect it. And Liz was putting it on the agenda as something that was going to be coming, so I don't think we can promise that.
DR. WARD: I'm not sure how we can do that based on the information that you have. I mean I wasn't even -- I mean you basically gave us a list with the IARC and NTP classifications, and you gave us summary data on exposure measures. And I do think -- and we have information on the sites of carcinogenicity from IARC, so I don't think that's an extensive preparation task that we're talking about.
DR. MIDDENDORF: So what, in addition to what's in the report on cancer, would the Committee be requesting?
DR. WARD: John, did you want to speak?
DR. DEMENT: Well, you have the classifications listed. And I think in addition, listing the sites where the cancers were found to be increased or suspected to be increased based on the available data would be helpful. It's certainly -- and I wouldn't say do it for this

whole list. I think there's a smaller list of exposures that are actually discussed back in the paper and back in the document itself that would be appropriate to spend our time on. We can't deal with this whole list.

DR. MIDDENDORF: Okay. So if we were to extract those that were identified by IARC as categories one, 2-A and 2-B, and extract from the documentation of the IARC categorization the animal tests and epi tests that were done and identify what was found from those, is that what you're asking for?

DR. DEMENT: That's correct. I think we're looking for a little more direction. I started making my own list based on my recollections of some of the documents -- you know, sites that were found to be increased. I mean basically IARC has to make a decision, and the decision's generally based on either human data showing an increase or some animal data showing an increase, and so that's what we're looking for, those sites where the data show increase, either one, 2-A, 2-B.

DR. MIDDENDORF: We'll go ahead and put in that request to the program.

DR. WARD: Okay then, so is there -- yes?
DR. QUINT: I just want to point out, for the animal evidence the sites won't mean very much because it's not concordant necessarily with the human sites, so it -- that would only be relevant for the epi data -- the sites.
DR. WARD: Yeah, group ones, you typically don't have some specific sites, but --
DR. QUINT: Yes.
DR. WARD: -- the data will be limited, but I think the group ones will be the most informative.
DR. TRASANDE: Can I also suggest that perhaps, and recognizing that the hour's very late, that we might want to focus the program's attention on a certain sub-list of chemicals of concern? I mean I could rattle off a list of ones that come to my mind, but -- and I've mentioned some of them, but -- and that may not be helpful as what others might do. I think -- PHs, dioxins, perfluorinateds, particulates are some that jump out as of concern to me. That's not a complete list, that's just off the top of my head -- silica, asbestos, benzene -- thank you -- one three butadiene would be on my list as

well. John, are you saying cesium? Diesel, sorry, diesel, thank you. Absolutely right. And we're doing this in extremely rapid fashion. I don't mean to push it that hard, but --

DR. WARD: Well, it is a good point because when I look at the -- I was thinking it would be pretty straightforward to look at the list and look for the ones and 2-As 'cause those will be the strongest ones, but then I noticed that diesel is not -- I mean I don't even see diesel on the list. Is it a 2 -- I don't remember if it's a 2-B, so I'm not sure -- so these were -- this list was based on things that were measured, but maybe some things -- I mean if diesel isn't specifically measured, it would not be on this list, so we may -- you know, we may have to look at the list and make sure that there are not things like that that aren't on it that need to be added.

DR. TRASANDE: I would also double check -- and we may need to do this informally -- that there aren't chemicals not on the list that were used as part of the cleanup or rescue or fire extinguishing efforts that aren't otherwise

mentioned in here. I think the list is complete, but I'm putting a 'think' there for a reason.

DR. WARD: Okay. Yes, Susan?

MS. SIDEL: All of the oil that was burning from, you know, those -- I forget how many hundred thousands of gallons, but there was all this oil that was being stored in the basement for OEM. You know, there's all that -- okay, diesel, sorry. All right. I mean that was a big...

DR. WARD: So I think that's -- you know, I don't know if there's a mechanism for this, but if we're using the list that was put together earlier as our basis, I think we're adding diesel, including the stuff produced from burning diesel fuel. And I imagine it's okay for the Committee -- if they look at this list on the plane home and see something missing, they can e-mail you and ask -- make that sugges-- or -- e-mail me and I'll make it to Paul to add.

MS. HUGHES: So in the World Trade Center, that's all, I just want to add plastics.

DR. WARD: Yeah. Susan?

MS. SIDEL: Yeah, because every floor of the World Trade Center site is basically an acre, and every acre had hundreds of computers, and think about the carpet on the floor, the boxing for the computers, so all that has to be included, too.

DR. WARD: So we're at 11:55. I think we've had some very productive discussions today and yesterday. I think we're worn out. So if anyone has any additional suggestions for the call-in agenda, send them to me. I'll convey them to Paul, Paul will work on setting up a time for the next telephone meeting and an in-person meeting, and we'll work on getting the agendas together and the Federal Register notices.

Okay, so we are going to need dates of availability from people. Paul, do you want to send out a poll with potential dates and then have people fill them in, or -- that might be the most efficient way.

DR. MIDDENDORF: Yeah, I just need to remind you that we need to look at availability of personnel to support the meeting. We have very limited support and they have other tasks as

well, so that will be one of the considerations. And for the face-to-face meeting will be the availability of the location, so the sooner you can get me dates, the sooner I can make some decisions.

DR. WARD: So you want people to send you dates when they're absolutely not available or dates when they are available?

DR. MIDDENDORF: Probably not available.

DR. WARD: Okay, not available. Okay.

MR. CASSIDY: What time of day?

DR. WARD: Well, I think for the phone conference -- well, I guess that's -- it was brought up that maybe we should have the meeting -- the face-to-face meeting at a time when working people can attend, so we did have the idea of maybe starting let's say at 2:00 in the afternoon, going into the evening, and then continuing the next day, so that's a possibility. But a telephone meeting, I would assume it'll be probably at least three hours.

DR. MIDDENDORF: Yeah, we would probably start in the afternoon to accommodate our west coast folks so they don't have to get up at 5:00 o'clock in the morning.

DR. WARD: Okay, so -- yes.
MR. CASSIDY: What's -- this is a silly question. What's the -- for the face-to-face meeting, why would we start in the afternoon? Why wouldn't we start 8:00 o'clock in the morning?
DR. WARD: The idea would be to have part of the meeting off regular work hours. I guess the other option would be to do it on a Saturday, but I doubt that that's feasible if we want to hold it in the federal building with all the staff support, so that was the only idea is to allow some time for the public to be here when they're --
MR. CASSIDY: When it's open to the public.
DR. WARD: Yeah, yeah.
MS. MEJIA: For the telephone meeting, are we precluded from meeting with some of the Committee members in one room to handle that telephone call? Can we do that?
DR. MIDDENDORF: Yes, you can do that.
DR. WARD: Thanks everyone. We'll bring the meeting to a close now, and I appreciate all of your participation and input, and I guess you are free to send me any suggestions via e-mail

and I will convey them to Paul. Thank you.

(Meeting adjourned at 11:57 a.m.)

CERTIFICATE OF COURT REPORTER

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I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of November 10, 2011; and it is a true and accurate transcript of the proceedings captioned herein.

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

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

STEVEN RAY GREEN, CCR, CVR-CM, PNSC

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