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WORLD TRADE CENTER HEALTH PROGRAM

THIRTEENTH MEETING

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) MEETING

November 18, 2021

The verbatim transcript of the
Meeting of the Scientific/Technical Advisory Committee
held on November 18, 2021, 11:00 a.m.

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Thursday, November 18, 2021

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ADJOURN

PARTICIPANTS

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SOPHIE BALK, MD - MEMBER
JESSICA BILICS - POLICY COORDINATOR AND GOVERNMENTAL AFFAIRS LIAISON
GEOFFREY CALVERT, MD - SENIOR MEDICAL ADVISOR
TANIA CARREÓN-VALENCIA, PhD - DESIGNATED FEDERAL OFFICER
THOMAS DYDEK, PhD - MEMBER
JOHN HOWARD, MD - PROGRAM ADMINISTRATOR
MARIAMA JAMES - MEMBER
ANITA JOSE, PhD - MEMBER
MICHAEL LARRAÑAGA, PhD - MEMBER
CATHERINE MCVAY HUGHES - MEMBER
DEBRA MILEK, PhD – MEMBER
LAWRENCE MOHR, MD - MEMBER
JASON OSTROWE, PhD - MEMBER
ROBIN SASSMAN, MD - MEMBER
ELIZABETH WARD, PhD - COMMITTEE CHAIRPERSON
LEIGH WILSON, DO – MEMBER

KIMBERLY FLYNN - PUBLIC COMMENT
JENNIFER WADDLETON - PUBLIC COMMENT
MATTHEW MCCAULEY - PUBLIC COMMENT
ANNE-MARIE PRINCIPE - PUBLIC COMMENT
PIERA GREATHOUSE-COX - PUBLIC COMMENT
GARY SMILEY - PUBLIC COMMENT

WELCOME AND INTRODUCTION, MEETING LOGISTICS

DR. CARREÓN-VALENCIA: Good morning and welcome. My name is Tania Carreón-Valencia, and I am the Designated Federal Officer for the World Trade Center Health Program Scientific and Technical Advisory Committee. I would like to extend a warm welcome to our Committee, the NIOSH staff that is joining us, and also members of the public who are following this meeting via webcast.

As you know, it is customary in our meetings to ask for a moment of silence to remember the people that were killed during the terrorist attacks of September 11th, 2001. We also remember those responders and survivors who have died since then, as well as others who have died or suffered from terrorist attacks around the world.

[Moment of silence.]

Thank you very much. So, I want to remind you that the World Trade Center Health Program STAC is subject to the rules and regulations of the Federal Advisory Committee Act or FACA, and for that reason, we develop minutes of our meetings. So please be aware that the meeting is being recorded to produce the minutes that we will post on the Committee's website in a few weeks. I have asked the members of the Committee to refrain from commenting among themselves using the Zoom chat, but also note that the public chat is part of the public record, and it will be added to the minutes of the meeting. If a substantive point is raised in the chat, either Dr. Ward or I will bring it up during the discussion.

I also want to remind you about the FACA rule that relates to public comments. Members of the public can submit comments to the STAC to consider as it develops advice to the World Trade Center Health Program Administrator, and one way to do that is to send mail, by regular mail, comments to the docket. We didn't receive any snail mail comments this time. Another way is to provide online comment on the NIOSH docket on the regulations.gov website. And as of 10:55 a.m. this morning, we have received three online comments. Members of the Committee have been asked to monitor the docket and to read the comments. The docket will close today at midnight. The other way to sign up

to present at the meeting is during the designated times for public comments. Today that will happen at 1:30 p.m. Eastern Standard Time, and we have six commenters, who will have five minutes each to provide their comment. All comments will also be part of the public record.

Also, under FACA rules, we need to do a roll call at the beginning of the meeting and after each of the breaks, to ensure that we have a quorum. So, as I call your name, please unmute yourself and indicate your presence for the record, and also if there are any situations that have changed your conflict-of-interest status since you last filed your OGE 450 form. And also, I want to ask members of the Committee that if you have to leave at any point, please let me know when you leave and when you return because we need to make sure that we keep quorum, which for the STAC is nine members, one more than half of the members. So, I am going to start the roll call with our Chair, Liz Ward.

DR. WARD: Present, no changes in conflicts.
DR. CARREÓN-VALENCIA: Sophie Balk.
DR. BALK: Present, no changes.
DR. CARREÓN-VALENCIA: Chandra Davis told me she had a medical emergency and won't be able to join today. Thomas Dydek.
DR. DYDEK: Present, no changes.
DR. CARREÓN-VALENCIA: Mariama James. She may not have joined yet. Anita Jose.
DR. JOSE: Present, no conflicts.
DR. CARREÓN-VALENCIA: Michael Larrañaga.
DR. LARRAÑAGA: Present, no conflicts.
DR. CARREÓN-VALENCIA: Catherine McVay Hughes.
MS. MCVAY HUGHES: Present, no conflicts.
DR. CARREÓN-VALENCIA: Thank you. John Meyer told me he won't be able to join today. Debra Milek.
DR. MILEK: Present, no changes.
DR. CARREÓN-VALENCIA: Lawrence Mohr.
DR. MOHR: Present, no changes.
DR. CARREÓN-VALENCIA: Nick Newman won't be able to join either. Jason Ostrowe.
DR. OSTROWE: Present, no changes.
DR. CARREÓN-VALENCIA: Robin Sassman.
DR. SASSMAN: Present, no changes.

DR. CARREÓN-VALENCIA: Aarti Surti won't be able to join either. Leigh Wilson. She had joined earlier, and I think she was having trouble with her Zoom connection. Is she here now?

DR. WILSON: I'm here.

DR. CARREÓN-VALENCIA: Oh, there you go.

DR. WILSON: Hi, I'm here.

DR. CARREÓN-VALENCIA: Any changes on your OGE 450?

DR. WILSON: No, no, no. No changes, thanks.

DR. CARREÓN-VALENCIA: Okay. So, by my count, we have 11 members present, which is quorum, and so we are ready to start, and I turn it over to Dr. Ward. Liz, you are on mute.

AGENDA AND ANNOUNCEMENTS

DR. WARD: Good morning, everyone, and I join Tania in welcoming everyone to the meeting. Tania, I forgot to print out the agenda. Would you mind sharing it? You're on mute, sorry.

DR. CARREÓN-VALENCIA: Yes, I will share it with you—

DR. WARD: Thank you, I appreciate that, and I will print it out subsequently. I'm always afraid to go to different screens when I am doing a video call for fear that something untoward will happen.

Thank you so much. Well, great. The first topic is Agenda and Announcements, so here we have it. I don't think, I don't believe there are any announcements, and you can see the agenda on the screen, so I would like to turn the floor over to Dr. Howard for his opening remarks.

OPENING REMARKS

DR. HOWARD: Oh, thank you, Liz. Good morning, everyone, and welcome to the 13th meeting of the Scientific/Technical Advisory Committee for the World Trade Center Health Program. Once again, I want to thank each of you for your time and your advice to the Program. It's very much appreciated.

As you remember, in the previous meeting, you were charged to provide an evaluation and recommendation on whether there is a reasonable scientific basis to support adding uterine cancer to the list of World Trade Center-related health conditions. A workgroup of the Committee has developed a draft recommendation, and I'm

looking forward to your deliberations. I want to thank the members of the workgroup—Liz Ward, Sophie Balk, Michael Larrañaga, Nick Newman and Robin Sassman—for taking the lead in developing the draft recommendations that you're all going to talk about today. Before hearing from the workgroup, Jessica Bilics will present an overview of a revision to the policy and procedures for adding cancer conditions, and I want to thank the Committee members that pointed out that we were not quite as clear as we needed to be in the previous meeting. And the changes to this policy and procedures clarify the role of the World Trade Center Health Program in the application of Methods 1 through 3 versus the role of the STAC in Method 4, the review of information by the STAC. As I mentioned in our last meeting, upon receiving the Committee's recommendation, I will evaluate the Committee's advice and will take action not later than 90 days after receiving it. If I decide to propose adding the health condition to the list, I will publish a Notice of Proposed Rulemaking in the Federal Register and solicit public comments on the rulemaking. In addition, prior to issuing any final rule to add uterine cancer to the list, I will request an independent peer review from three subject matter experts of the scientific and technical evidence that would be the basis for issuing such a final rule. I welcome your suggestions, and I think we have some already, regarding the subject matter experts well-suited to provide the potential peer review, so thank you for that. Finally, I want to thank those members that will complete their terms on the Committee after today's meeting—Thomas Dydek, Catherine McVay Hughes, Nick Newman, Robin Sassman and Leigh Wilson. I want to personally thank you for your service to the Committee and to the members of the World Trade Center Health Program. You have all of our gratitude. And I just also wanted to add that it doesn't mean the end for you. We keep all of our former members in a file and feel that we can call on you again. So, I hope that you'll be responsive if we do. So, thank you again, and have a great meeting today. Back to you, Liz. I think you're on mute, Liz.

DR. WARD: I seem to be having a technically challenged day, sorry. I think our next presentation is from Jessica Bilics, who will be talking about

non-substantive changes in the policies and procedures for cancer-related World Trade Center conditions.

DR. CARREÓN-VALENCIA: Liz, before we move on, I see that Mariama James had joined the meeting.

DR. WARD: Excellent.

DR. CARREÓN-VALENCIA: Mariama, would you please acknowledge that you have joined and let us know if there have been any changes in your conflict-of-interest since you last filed your OGE 450 form.

MS. JAMES: Yes, I have joined. No, there have not been any changes, and I'm sorry about my lateness. I was just emailing you simultaneously that I don't know what's going on but it's not connecting. So, I'm glad that it finally opened. Happy to be here.

DR. CARREÓN-VALENCIA: Thank you so much for joining. And so, we have 12 members present. Thank you, and thanks, Jess, please—

UPDATED POLICY AND PROCEDURES FOR ADDING CANCER CONDITIONS

MS. BILICS: Can everyone see my presentation now?

DR. CARREÓN-VALENCIA: Yes.

MS. BILICS: Okay.

DR. CARREÓN-VALENCIA: It's not in presentation format though.

MS. BILICS: Better?

DR. CARREÓN-VALENCIA: Yes, thank you.

MS. BILICS: Okay, thank you. All right, so—

DR. CARREÓN-VALENCIA: Sorry, you went back to Edit mode.

MS. BILICS: In mine, it's still the slide show.

DR. CARREÓN-VALENCIA: It might be delayed then. Okay, go on, yes.

MS. BILICS: Okay. As Dr. Howard, Tania and Liz Ward mentioned, I'll be talking about the updates that we have made to the policy and procedures for the addition of cancers to the list of World Trade Center Program—sorry, the list of World Trade Center-related health conditions. And this should be a fairly short presentation, but I'll go through several different categories of the updates that we've made to the policy and procedures.

So, this here is just the screenshot of the policy and procedures. You can see the different dates that we have provided updates or revisions, including the updates for today's date as well as a note at the bottom here of what the update in general is, as Dr. Howard

mentioned, clarifying the different roles and expectations under Methods 1 through 3, and then Method 4 related to the STAC.
So, the first category of updates to the policy is the identification of peer-reviewed published epi studies. I'll talk a little bit in detail about that in the next slide. The second category of updates made was consistency throughout the document itself, as well as alignment to the non-cancer policy, which is basically the same policy but for the addition of a non-cancer condition, where we are talking here about cancer specifically. And then the third category, which Dr. Howard mentioned, the clarification of the four methods. The methods themselves have not changed but we're just providing some clarification, and then also the roles of the Program within those methods versus the role of the STAC.

DR. CARREÓN-VALENCIA: Jess?

MS. BILICS: Yes?

DR. CARREÓN-VALENCIA: Your slides are not changing. Would you like me to share them?

MS. BILICS: Oh sure, yes, because on my screen they're changing and everything. So sure, if you want to go ahead.

DR. CARREÓN-VALENCIA: Yes, let me do that then. Okay, so you tell me—

MS. BILICS: If you could go to the fourth slide, that would be great. Perfect, thank you.
So, this first category of updates made, as I mentioned, was the identification of studies. So, in the May 2019 policy and procedures, which is what we presented to the STAC back in late September, in the first step is that literature search where we identify studies of that type of cancer in the 9/11 population, and then the second group of studies is related to whether or not there is a causal association between a condition already on the list and that type of cancer. And then also, looking at the most recent classifications made by the World Health Organisation's International Agency for Research on Cancer (IARC) and NIH's National Toxicology Program (NTP), their Report on Carcinogens. And then the second step is the literature review. So actually, during that step, we were identifying which of those studies found in the lit search were peer-reviewed published epi studies, and then those were being further reviewed for quality and quantity. Next slide.

Okay, thank you. So, the only change we made here was actually the point at which we identify a peer-reviewed published epi study. So instead of identifying it after we've had that whole body of studies found during the search, we're actually just limiting the search to those types of studies those studies that are peer-reviewed, published and epi. So, we're not further limiting any types of studies. We're just doing it at the step beforehand. And then the lit review is the same. It still looks at both the studies found, it looks at any medical basis provided by the petitioner, and it looks at the information on the classifications related to the IARC and NTP, and cancer, carcinogens. So, as I mentioned, no change in the content of the review except for the point at which we identify those peer-reviewed published epi studies. Next slide. So, the second category of updates that the Program made to the policy and procedures relates to the consistency throughout the document itself as well as the alignments to the non-cancer policy. So we noticed as we reopened the policy and procedures for cancer is that we hadn't classified what body of evidence that the IARC carcinogens was in. So, we just clarified that it was their Monographs on the Identification of Carcinogenic Hazards to Humans. We added citations for that, as well as a citation for the NTP's Report on Carcinogens, which we did not have in the previous. So those are additional clarifications. And then we updated, because we had realized the Program had used by the term "information" and "evidence" throughout the policy and procedures, we updated all the references to be "information", with the exception of this clarification. This is a footnote that we added to the current, the November 2021, version and I'll read this here. "Information may be gathered by the Program in a search of the peer-reviewed published scientific literature of epidemiologic studies of 9/11 populations or supplied to the Administrator by a petitioner. The Program then evaluates the information to determine whether it meets the standard of scientific evidence necessary for the Administrator to make a determination. Scientific evidence is a subtype of information that supports, refutes, or has no impact on the determination whether an association exists between a specified exposure and a specific health effect."

So we had realized, as I mentioned, that we were using both terms early on in the P&P, and we've now changed all those terms to "information", with the exception of where IARC and NTP uses "evidence" in their actual reports or monograph, and then also where this level of the difference of a higher bar for what is scientific evidence after the Program and Administrator have already made or done an assessment to determine a subtype of this information. Those later on in the policy and procedures still remain "evidence". But early on, we just made that consistency change to make all the references "information". Next slide.

So just continuing with consistency and alignment, there was a couple of citations to different sections in this policy and procedures itself which we realized hadn't been updated in earlier versions, so obviously we fixed those. And then we also realized that, to align it with the non-cancer P&P, we added the timeframes that are used for the rulemaking process. In the reauthorization that the Program went through in 2015, Congress added a requirement for there to be an independent peer review, and I know that the STAC has provided information about peer reviewers themselves. But we worked in a timeframe for that peer review into our policy and procedures for the non-cancers, and we're just making sure that it's here in the cancer policy as well. So the public comment period would be open for 45 days, and the peer reviewers' comments would be posted at 30 days so that the public has that additional 15 days to review the peer reviewer comments and be able to make public comment on those peer reviewer comments. So, we just made that clarification, which we had planned to do anyway but we wanted to have it clearly stated in the policy and procedures. Next slide.

So, the last category of updates, and this is sort of the most significant of the updates, is related to the Methods 1 through 4, and I just wanted to reiterate what the methods are. These are the same as what they were when I presented to you at the end of September. But just to review, Method 1 is the peer-reviewed published epi studies of the cancer in the 9/11-exposed population, and then it goes through a Bradford Hill assessment. Method 2 is the peer-reviewed published epi studies of a causal association

between a health condition already on the list and that cancer. Method 3 is looking at the toxins, the carcinogens that IARC and NTP have listed as being—having limited evidence or possible evidence of being carcinogenic in humans. And Method 4 is a review of the information provided by the Scientific/Technical Advisory Committee, you all. Next slide.

So, the changes that we made to the methods here was basically just making it more clear that Methods 1 to 3 was an act being taken by the Program itself. So, the Administrator would direct the Science Team to go through and do that scientific search, do the scientific review, look at all the peer-reviewed published epi studies in both the 9/11 population or the connection of a condition already on the list to the cancer, and then also Method 3 which is the review of the classifications of carcinogens in the IARC and NTP literature. And then clarifying, in Method 4, is that this is a STAC-related—this is where the STAC has its role—we added that it be clear that the STAC provide a recommendation. The May 2019 just asked for a reasonable basis, but we made it clear that we wanted a recommendation as well as the reasonable basis for that recommendation. And we added this footnote here, and it says, “The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Methods 1 through 3.” So that was some of the confusion that we had noticed existed when we had the meeting at the end of September was that it wasn’t clear that we weren’t asking the STAC to find evidence or information that we hadn’t found ourselves in Methods 1 through 3, or finding possible sources for where those might exist, but that the STAC may base their recommendation and basis on something other than what the Program had already found, or some other criteria. So, we wanted to make that clear.

And then we just clearly stated—and this has always been done, and to us it was something that was always going to be done but we just made it as clear as possible—stating that the Administrator would review all the findings from all four methods and make the determination about whether or not one or more of those methods was met, and then proceed as necessary with rulemaking or a determination not to add the condition.

So, I think that's my last slide. I think the next slide, Tania, is just the questions slide. I'm happy to take any questions about any of the updates or the policy and procedures in general. I think Tania provided a copy of the policy earlier.

DR. WARD: So, are there any questions in the group? I'll be looking for your hands on Zoom like I did last time. Mariama?

MS. JAMES: Not a question but I would just commend those who worked on this for the addition of that Method 4. I think that's tremendous, the amendments that were made to Method 4. And so, thank you, on behalf of the community at large.

MS. BILICS: Thank you.

DR. WARD: Any other comments or questions? I am not seeing anyone else with their hands raised. So, we are scheduled to discuss the updated policy and procedures through 11:50, and it's now 11:25. But I assume we don't want to move the agenda forward because members of the public may be dialing in at a specific time to hear the workgroup report, which is scheduled to begin at 1 o'clock. So, shall we take a break or is there another alternative that you'd like to do?

DR. CARREÓN-VALENCIA: Well, we can start with the—you can present the report, I think. Members of the public are joining via webcast, and we can continue in the afternoon—

DR. WARD: Okay.

DR. CARREÓN-VALENCIA: After the break, you can provide a summary of your presentation if that's okay with you, and then we then have the public comment at the scheduled time.

WORKGROUP REPORT

DR. WARD: Okay, that's fine. So, I am going to share my screen, I hope. Share screen. Okay, are you seeing my slides? Okay, good.

DR. CARREÓN-VALENCIA: Yes, I am seeing them.

DR. WARD: Great. So, you know, I think it's helpful to talk about the conclusions we came to at our last meeting. So, at our last meeting, the STAC discussed Dr. Howard's request for recommendations regarding uterine cancer, and we had a fairly wide-ranging discussion about what the STAC's beliefs were with regard to this, and also what types of evidence and what specific

evidence, and what types of data could be used to support the recommendation. And I think there was a broad consensus from the group that the STAC would like to recommend that uterine cancer be added, but also there was a very strong consensus that we needed to present a well-organized and reasonable rationale. So at the conclusion of the meeting, a workgroup was formed to actually flesh out a recommendation with regard to adding uterine cancer, and that workgroup has been meeting since the last meeting pretty much. And so now I'll take you through the slides, and what I'm trying to do is everyone should have had the opportunity to review the draft recommendation in the form of a letter to Dr. Howard with some additional supporting information that the workgroup drafted and approved. So, I will just take you through the highlights of that document now.

So first, just restating the Committee's charge was to evaluate and recommend whether there is a reasonable scientific basis to support adding uterine cancer to the list of World Trade Center-related health conditions. And I think—and indeed, maybe Jessica or Tania can comment on this—one of the reasons that the World Trade Center Program clarified its policies and procedures is we're really talking more about information at a reasonable basis than just scientific evidence. So, but this was the language that was used in the draft.

And I think one thing that's really important to note, especially for those members of the Committee who were new as of the last discussion, is there has been a long history that's preceded this specific recommendation, and in 2012, before the STAC made its initial recommendations regarding cancer, there was an extensive review about the exposures at the World Trade Center, and I think many people at our last meeting were speaking up about, well, where's the evidence regarding exposures or does the STAC really understand the nature of especially the community exposures, which had to do with a lot of recurrent exposure to the dusts when they were re-suspended. So, I did want to set the stage to say that, you know, as far as the nature of the exposures, the hazards related to the exposures, we're relying in large part on the original STAC document as well as we recognize that these

issues have been addressed by the Program, both in their draft and final rulemaking, and in subsequent rulemakings that they've made with regard to adding cancer conditions.

One addition we did was, in our current work, was to look at the literature regarding uterine cancer and endocrine disruptors, which was not—we did not really focus on endocrine disruptors when we did our last recommendations.

So, I just wanted to give a very high-level overview of the 2012 STAC's documentation on exposures. I don't think I need to read through this, but I think it's very clear that the STAC acknowledged that the exposures from the collapse of the World Trade Center were incredibly unique, you know, that responders had potentially very high exposures to very diverse constituents of the dust and fumes from the debris. We also acknowledged that exposures among community residents and those working and attending school in the area were significant and may have had potentially longer duration than those among responders. And we also concluded that there are many—there's much that's unknown about World Trade Center exposures. There's very limited direct exposure information, either at the area level or at the individual level, so we have to recognize that. Much is known but much is unknown. So, we have to be very clear, in making our recommendations, to acknowledge that we don't have all the information that one would like to have to make scientific judgments about the relationship between exposures and cancer conditions.

So, to summarize, what the 2012 World Trade Center Health Program STAC recommendations contained, and the context, so they were made in the context that at that point in time, no cancers were considered World Trade Center covered conditions, and there had only been on epidemiologic study published for FDNY firefighters. So, in our deliberations, which were very extensive, we recommended some criteria for deciding which cancers should be covered which, importantly, included using the IARC monographs as a source for identifying which cancer sites were associated with which exposures. We also made specific recommendations for the addition of specific cancers.

And I will say that, when you read through the rulemakings that have been made subsequent to 2012, and the 2012 rulemaking, it's quite striking how seriously Dr. Howard considered the STAC recommendations, and even as late as—in his subsequent rulemaking about specific cancer sites, he went back and looked at what the STAC said earlier. And so I am very grateful to Dr. Howard for all the serious consideration that he's given to the STAC recommendations in the past, and so I did want to bring forward one of the points in our original 2012 recommendation, which was that while the STAC ultimately decided to recommend specific criteria for adding cancers, and to recommend specific cancers, we had considerable debate about whether there was a rationale for just including all cancers. And it was, our debate on that was significant enough that we included a paragraph in our recommendations that outlined the—you know, why we thought it might be a reasonable choice to include all cancers, and I think that's important to look at in the current context.

So, after the STAC made its recommendation, and I've alluded to this before, the Administrator published a draft and final rulemaking where he outlined four methods, and those have been thoroughly reviewed several times, and also by Jessica. And these were really very much in line with the recommendations of the STAC for considerations for adding cancer health conditions.

So, one of the things I think that came out in our discussion at the last meeting that we wanted to make a strong point on in our written recommendations is the question of now that the context has really changed from the original STAC context, which was no cancer were covered and should we cover any or all cancers, we're now looking at a situation where every other type of cancer is covered. And we think a very key question in those deliberations is whether it's biologically plausible that uterine cancer would be the only type of cancer that's not related to 9/11 exposures. And, you know, I think it's very clear, and it was mentioned in the White Paper, but it was also covered in our recommendation, that there's no reason to believe, given what we know about endometrial—okay, so here's one very important clarification that I'm going to make.

When I was reviewing the literature, and when the workgroup was reviewing the literature, one of the things that we need to explain is that much of the literature that we reviewed related to uterine cancer related specifically to endometrial cancer. And that's because that is by far the most predominant subtype of cancer arising in the lining of the uterus. There's also a second type of relatively common cancer that arises in the uterus, which is uterine sarcomas, but those are already covered by the Program. So, when I say—when you see the "endometrial cancer" in my slides, we're not trying to pull out endometrial cancer from uterine cancer and saying we're only talking about endometrial cancer. Basically, we're talking about all types of uterine cancer but because we're, in many cases, quoting documents in the scientific literature, we wanted to use the endometrial cancer, which is how these studies are designating their results. So hopefully that's clear.

So, in any case—and some of this was covered in the White Paper—cancers have certain characteristic mutations and different—you know, they arise in different cancer types, but they also have much in common, and there's a lot more detail in the White Paper. But here we're just listing some of the key mutations that are present in endometrial cancer that are also commonly present in other cancer types, and that really suggests to us that the genetic mechanisms through which endometrial cancers arise are very similar to those that affect other cancers. In addition, I think it's important to recognize that cancer of the uterus is a hormonally related cancer—there are some very hormonally related risk factors—and that there are other cancers that are related to female reproductive hormones, and we're focusing on breast just as an example. So, we're focusing on breast and endometrial, not to say that for example ovarian cancer is not also hormonally related.

So, as I said, we're looking at some—we're looking at endometrial or uterine cancer as a hormonally related cancer, and because of that, there are some special considerations. So, and when epidemiological studies look at the risk of breast and endometrial cancer, what they often find is that the risks may vary depending on the age at exposure, and the stage of development at which the

exposure occurred. So, an important example of that which we quoted in our letter was the diethylstilbestrol, which was an endocrine disruptor that was given to pregnant women to prevent miscarriage, was later found to cause several reproductive cancers in children born to those women. And some of those cancer risks actually extend throughout the life of the offspring and now have been also found to affect the women who received the DES.

So, because endometrial cancer is related to hormonal factors, the presence of multiple endocrine-disruptive chemicals at the World Trade Center site is of special significance in evaluating the risks. So, as I mentioned, in our 2012 recommendations, we focused on several classes of World Trade Center exposures which had substantial evidence regarding cancer in animals then humans. However, we did not focus on endocrine-disrupting chemicals, so we have added a section to our letter that is a literature review regarding endocrine-disrupting chemicals, both some basic background knowledge about what they are and how they work, but also specifying which of those chemicals were present in World Trade Center dust.

So, first of all, we gave a formal definition of what an endocrine-disrupting chemical is. There are many out there, but this was the one that we found often cited by other papers. And I think there are several important things about being hormonally related. So, hormones regulate a lot of activities in the body, and the tissues in the body are very sensitive to even small amounts of hormones. In addition, hormones—endocrine systems and hormones have very specific effects, and one example that I think came to mind a lot when I was reviewing this literature is there is a drug called tamoxifen which is given to women both to prevent breast cancer and for treatment of breast cancer, and that same drug can decrease the risk of—can increase the risk of—endometrial cancer. And that's really what we're referring to when we say that endocrine systems, there can be varied tissue-, cell- and receptor-specific effects during the lifecycle. So, a very complex area of science. There's not a lot—it's really considered an area of science that's just really beginning to develop. There's a lot of complexity. But basically, there were a number of classes of chemical

exposures, and cadmium in addition, which is not listed here, that were present in substantial quantities at the World Trade Center site that are considered endocrine-disrupting chemicals, and some of them specifically are endocrine-disrupting for the reproductive system.

And this slide kind of summarizes many, several of the reasons why it's so difficult to study endocrine-disrupting chemicals and predict their effects. So, they're acting, their mechanism acts in various ways. They can affect the receptor for the hormone and the target tissue. They can increase hormone synthesis or increase or decrease hormone degradation. And as I kind of indicated before, the most sensitive endpoint or tissue really is—it may relate to a number of different endocrine-disrupting chemicals, not just to one. There's often a long time period between exposure and development of disease, and it's also been found that they can act at very low levels of exposure, causing an exposure response where the response may be higher at the lowest doses and the higher doses, and lowest in between. So again, we're not saying—we're basically saying that exposure to endocrine-disruptive chemicals can be very significant, and there is a wide range of effects, and it's hard to predict what they will be in a given case.

Another reason that the workgroup—that was discussed at our last meeting and that the workgroup feels is important to understand is that while there have not been increases in uterine cancer risk observed in the studies of World Trade Center-exposed cohorts to date, there are many reasons why those studies are not now, and will probably never be, definitive with regard to uterine cancer. One is that even though the incidence rate of uterine cancer exceeds the threshold of 15 per 100,000 annual cases per year, it exceeds the threshold for rare cancers, because there are relatively small numbers of women in the World Trade Center cohorts, similar statistical power constraints pertain to uterine cancer. Small numbers of women in the cohorts and small numbers of observed and expected cancers really limit the ability of studies to evaluate exposure response, or to conduct relevant analyses by cancer subtype, menopausal status, age at exposure, age at diagnosis, and other factors that really are important for these risks

associated with WTC exposures and hormonally responsive cancers such as uterine cancer. We also recognize that many women in the cohorts under study are only now reaching the age at which peak incidence of uterine cancer occurs in the population, and that there is a possibility that survivors who were exposed early in life may experience increased risk of uterine cancers later because of the factors that I've discussed before about how exposures early in life may have long-term effects.

So, the STAC also recognized in our discussions last time that, although the IARC database is kind of the best available database, that makes conclusions about carcinogenicity of exposures at the World Trade Center site and also about which cancer sites are likely to be affected, that database is largely reliant on studies of industrial cohorts, which are primarily men. And so, you really can't use—that is just not a reliable database for understanding the risks of cancers that occur primarily in women associated with carcinogen exposures.

And during our deliberations last time and in our workgroup, we also talked about some issues that are kind of important and separate from the scientific evidence base, and we also reviewed, as I said, previous decisions made by the Administrator. And in those decisions, he has often articulated the importance of balancing the degree of certainty regarding cancer associations with the importance of providing timely services to affected responders and survivors. And I think, while the STAC recognizes that the World Trade Center Health Program has been very diligent in their deliberations in applying Methods 1, 2 and 3 fairly and appropriately in adding new cancer conditions, it's really, the current situation was really unforeseen in that by applying those methods appropriately, we now find that only one cancer is not—one type of cancer is not covered. And the STAC really does recognize the many comments from affected survivors, responders, healthcare providers from the World Trade Center Health Program including some panel members, who really view, in the current context, there is just a widespread perception that the coverage of all types of cancer except uterine cancer as a World Trade Center-related health condition is illogical and unfair

and may cause tangible harm. Again, the STAC recognizes that it is not—we don't believe it is illogical and unfair. We understand how it's arisen. But we also recognize that from the perspective of those who have not been following the details of this process, it can be perceived as illogical and unfair. And we also recognize the very strong support for inclusion of uterine cancer as a World Trade Center-related health condition among World Trade Center Health Program directors and providers.

We do think that there is potential harm in not covering uterine cancer, and that one such harm is that women who develop this cancer may experience poor health outcomes, and there really has been recent evidence that responders and survivors who are covered by the Program do have better survival than those who are not. We also recognize that responders and survivors who have been diagnosed with uterine cancer have stated that the lack of coverage has really undermined their morale and quality of life in a negative way, that it's affected them in a negative way.

And we also noted that, as far as we could tell, inclusion of uterine cancer—that currently, uterine cancer is not included in the World Trade Center Environmental Health Center Pan-Cancer Database, which we believe is a very important database for understanding the potential cancer effects of World Trade Center exposure on survivors, and we do believe that including uterine cancer will enable better—further study into these issues of uterine cancer in general, and also the less common subtypes.

So, we drafted, we created a draft summary recommendation for our—in conclusion, at the end of our letter, which is then followed by the supporting documentation. So our recommendation for the wording of the STAC recommendation is: "In view of the strong rationale for adding all types of uterine cancer to the list of World Trade Center-related cancers and the potential benefits to affected World Trade Center responders, World Trade Center survivors, and providers caring for these patients, we recommend that all types of uterine cancer be added to the list of World Trade Center-related conditions, and urge the Administrator to make all feasible efforts to do so as quickly as policies and procedures allow."

So, Tania and I talked yesterday about the best way to frame the

discussion, and I think we should first kind of discuss—use the slide show as a basis and see if there's any major questions or comments about the recommendations. Then we would like to go through the letter and the supporting documentation in detail, and make sure that—and see if there are any—so the first purpose will be, we want to make sure that the draft of our overall recommendation is clear and acceptable to all the members of the Committee, and then we will vote on it. And secondly, we want to make sure that all the members of the Committee are in agreement with the letter and the new part of the supporting documentation regarding endocrine disruptors. And then we will vote on the—then the Committee will vote on whether they want to accept the draft recommendation as the final recommendation. So, Tania, anything to add about how to proceed?

DR. CARREÓN-VALENCIA: No. That was great.

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DR. WARD: Okay, so let's see. I'm thinking—I will stop sharing my screen for now so I can see hands, and then I will go back and share, if necessary, to go back to specific points. And I'll slide my slide show over to the other screen so that I can see it as well as everyone on the video. So, Anita, I see your hand.

DR. JOSE: Yes, I don't have any questions. I just did want to take a moment to acknowledge the hard work that the folks that worked on this did. I am thinking back to what we talked about in September, and the questions and the thoughts that I had, and I saw them all included in there, and I know that was just a lot of information to sort of work on compiling together, and I just wanted to thank you for that because I—and the entire team, because I know that was a lot.

DR. WARD: Thank you and—

DR. JOSE: And sorry, I do think, from my perspective, it accurately represents a lot of the conversation that we had last time.

DR. WARD: Thank you, and I will say that the discussion really—we really tried to capture as much of the main points of the discussion as we could, because we thought it was very valuable. But thank you for that. I'm sure the entire workgroup appreciates those comments.

I'm looking on the screen. Does anyone else have their hand up? So maybe if there's no general comments, we should look at the draft of the—well, let's maybe think about pulling up the actual letter, and I think Geoff is prepared with the—Geoff Calvert—is prepared with the letter so that he can make any revisions that the Committee would like. And then we'll go back, after we discuss the details of the letter, we'll go back and show the screen of the full recommendation.

DR. CALVERT: Okay, let me call up the letter. Okay, can you see it?

DR. WARD: Yes. So, it's a real compromise between the size of the print and the ability to look page by page. So, I guess what we can do is ask is there any comment on—we do have the page numbers and the line number numbered on each page, so maybe we can just go page by page and see if there's any recommendations for changes on the first page, and if you would just refer to the line number, Geoff can scroll to that line. And I am looking at Geoff's letter now so I can't see hands. Tania, is it possible that you can look at the screen for hands and tell us if anybody has their hand up?

DR. CARREÓN-VALENCIA: Yes, I can do that.

DR. WARD: Thank you, I appreciate it.

DR. CARREÓN-VALENCIA: One thing I want to mention, Liz, on line 24 where you have the recommendation, remember you added "all types of uterine cancer" to the recommendation on the—

DR. WARD: Okay. Yes.

DR. CARREÓN-VALENCIA: On the slide but it's not in the letter.

DR. WARD: Okay, excellent. So, we will make that change. And we'll make that change everywhere it occurs? Well, we'll, yes, let's—we can keep going and look where it occurs.

DR. CARREÓN-VALENCIA: Okay—

DR. WARD: Thank you.

DR. CARREÓN-VALENCIA: And Jason has his hand up.

DR. WARD: Jason, please go ahead.

DR. OSTROWE: I'm just looking at line 22 and I'm just wondering if the words "personal experiences" maybe should be changed to "professional experiences".

DR. WARD: I can tell you the reason it says "personal experiences", and I think we could easily add "personal and professional experiences, I

think throughout the history of the STAC, including at our last STAC meeting, there have always been representatives of survivors and responders. And in many cases, their explaining the nature of the exposures that occurred in the aftermath of the attack, or as a member of the community, has really provided very important insights to the STAC, especially with regard to the nature of exposures. So, I would suggest not getting rid of "personal" but saying "personal and professional experiences" as a revision? Is that acceptable, Jason?

DR. OSTROWE: Yes, certainly and I think when you think about the idea of it being based off of a reasonable scientific evidence or reasonable scientific basis, I think that probably is considering, I think something like ten out of the—ten of the numbers of the Committee here have a background in medicine, "professional" just to me is—

DR. WARD: Yes.

DR. OSTROWE: Is more to what it is that we're trying to do.

DR. WARD: Yes, great, thank you.

DR. CARREÓN-VALENCIA: So Mariama has her hand up.

DR. WARD: Mariama.

MS. JAMES: Line 25, the word "on" is redundant. It says, "This conclusion is based on largely on…"

DR. WARD: Thank you. So, take, get rid of that first "on". Excellent. And I am seeing that—okay, does anyone have their hand raised now?

DR. CARREÓN-VALENCIA: No.

DR. WARD: Okay. So, I guess that means we can move on to page 2. Does anybody need to look at the bottom part of page 1 on the screen before we move on? I was assuming that most of you would have looked already but yes, let's stay on this for a minute so we can see.

DR. CARREÓN-VALENCIA: I just want to also mention that this document was shared on the website, on the Committee's website, so the public has also been able to take a look at it. That's the—

DR. WARD: Thank you.

DR. CARREÓN-VALENCIA: Anita has her hand up.

DR. WARD: Anita.

DR. JOSE: Yes, just, I think, to a point earlier about reflecting all types of

uterine cancer, on line 32 it says, "…one type of cancer, uterine cancer, is not considered..." So I'm not sure how we should update that but I want to acknowledge it so it's consistent with what was said earlier.

DR. WARD: Yes, Tania, do you have a recommendation for how that should be phrased? It's just English-wise it's a little tricky because we're saying "one type of cancer, uterine cancer," or could we say one type of cancer, all types of uterine cancer, even though it doesn't sound great? So Geoff, only one type?

DR. CALVERT: Yes, I kind of like how it is right now but I'm just your scribe, so however you guys want it.

DR. WARD: Okay, why don't we take out "only"—

MS. JAMES: Maybe you could say, "one type of cancer, uterine cancer in all forms" or "in all variations".

DR. WARD: Or possibly just one cancer, all types—one, yes. "One cancer type"?

MS. JAMES: Or all types of the one uterine cancer, I don't know, that sounds a little funky too.

DR. WARD: How about "only all types of uterine cancer"? Are. "All types of uterine cancer are not considered."

PARTICIPANT: Could it also be maybe "only one group of cancers" or something like that? I don't know if that…

DR. WARD: Only—how about "uterine cancer (all types)"?

DR. CALVERT: Sorry.

DR. WARD: Only uterine cancers. I think that's good. I mean, there's a slight technical detail in that uterine sarcoma is a World Trade Center-related condition and it is a uterine cancer, but if the Program can live with that ambiguity, I think we can live with that ambiguity. Okay, yes.

DR. CARREÓN-VALENCIA: There are two comments on the chat from Thomas Dydek, if you can make the comments too orally.

DR. DYDEK: Well, yes, and this might be a little premature in the discussion. It may fit better at the very end of the document. But there's at least one study that has shown uterine cancer statistically significantly associated with asbestos exposure, and I put that reference in the chat. Also, I think we should mention something about the long latency period if asbestos is, in fact, a causative factor, that could

explain why we haven't seen uterine cancer showing up in the cohorts of the first responders or the survivors.

DR. WARD: Right, and actually, the workgroup, there was quite a bit of discussion about asbestos in our last meeting. And asbestos was one of the agents that was reviewed in the White Paper, and I believe that the study and studies that you're citing were reviewed in the White Paper, and the trouble with those studies is that they include both cancer of the body of the uterus and cancer of the cervix. And so those studies were not considered by the Program or by the workgroup as definitive. The other discussion that we had at the workgroup was the potential perineal route of exposure to asbestos due to the bathrooms and toilet tissue being contaminated, and we did have a discussion about whether to bring that into our recommendations and, in the end, decided not to—in part because there has been a really large epidemiologic study looking at endometrial cancer and talc use, with the hypothesis that talc is contaminated with asbestos, and that very large, pretty definitive pooled study did not find any association. So, at the end of the day, we felt that the asbestos evidence was not strong, and since this will be going to a scientific peer review committee, we felt like we didn't want to put anything in that we felt was not good, strong evidence because it's just creating difficulties in the peer review. So, we did take that discussion really seriously, and discussed it quite a bit, and made a decision not to include asbestos in this report. And we also felt that we had made some very strong points to the report and did not need to include asbestos to make the case stronger; in fact, it might make it weaker.

DR. DYDEK: Okay, yes, as long as you've considered it, that's fine.

DR. WARD: Good.

MS. MCVAY HUGHES: Hi, I have a question here while we're here. First of all, I want to thank everybody, specifically the working group, on the amazing research and putting all this together in a very logical, scientific format. On line 33, "…considered a World Trade Center…", did you want to add "cancer condition" because not all World Trade Center conditions are cancer.

DR. WARD: Is that okay, Tania? Is that okay with the program? Okay, that

sounds good.

MS. MCVAY HUGHES: Thanks.

DR. CALVERT: Can you repeat that, where that—

DR. WARD: On line 33.

DR. CALVERT: Right.

DR. WARD: Put “cancer” before “condition”. World Trade Center-related cancer condition.

DR. CALVERT: Thank you.

DR. WARD: You’re welcome.

MS. MCVAY HUGHES: Yes, because some of the conditions were other ones, it could have been lung or respiratory. So, thank you.

DR. CALVERT: Right, and I think that was how the original version of this letter—I think before, earlier in the sentence, it talked about “among all cancers, only uterine”. So yes, I agree. Thank you.

DR. WARD: Catherine, your hand is still up. Did you want to—no? I’ve figured out that I can see the hands, Tania.

DR. CARREÓN-VALENCIA: Okay.

DR. WARD: So, I’m looking at it on my second screen. So, I think we’re ready to move on to the second page. Okay, so we’ll be looking at the top of the second page. Are there any comments or requested changes in the lines that we can see now? Not seeing any hands so I guess, Geoff, you can scroll down.

DR. CARREÓN-VALENCIA: Geoff, can you go up? Sorry. I just saw something on line 6, “to include all types of…”

DR. WARD: All types, thank you. And then I see Catherine’s hand up and Mariama’s hand up, so Catherine first.

MS. MCVAY HUGHES: Yes. So, I just wanted to make sure you saw on line 34, page 2, it refers to World Trade Center dust but there was World Trade Center dust and smoke. Remember there were fires—

DR. WARD: Right.

MS. MCVAY HUGHES: That lasted for months.

DR. WARD: Right.

MS. MCVAY HUGHES: So, I don’t know if there are other places that need that reference as well. Thank you.

DR. WARD: Yes, I think we tried, in my slides at least, we either use “dust or smoke” or we just use “exposures” because somebody pointed out that there's also vapor, or you know. But I’m fine with either “dust

and smoke". We've used that a lot in the past, so I think that's fine. And Mariama?

MS. JAMES: I too was going to comment on the absence of smoke.

DR. WARD: Thank you. Okay. Okay, so now we're on lines—we scrolled down to lines 24-37. Were there any other comments on the earlier part?

DR. CALVERT: Do you want me to search for uterine cancer so that we can kind of hit that "all types" here all—so that we don't miss it for—

DR. WARD: That would be fine, yes.

DR. CALVERT: Okay.

DR. WARD: That probably would save time. And we may have to, you know, work the wording a little bit so it sounds appropriate, but—

DR. CARREÓN-VALENCIA: So, do you think it's like a good time, maybe Liz, to stop—

DR. WARD: Ah, good.

DR. CARREÓN-VALENCIA: And have the lunch break while Geoff does that—

DR. WARD: Excellent.

DR. CARREÓN-VALENCIA: And we can reconvene at 1:00 and continue. If all members, all the members of the public that will providing public comments have joined by 1:00, we could listen to them, or have them do, present and copy you at 1:30 as scheduled on the agenda if that sounds good to everybody.

DR. WARD: Sure. And you want to remind everybody not to log out, just to put themselves on mute? Okay. Thank you all. We'll see you again at 1 o'clock.

DR. CARREÓN-VALENCIA: Thank you.

[Lunch.]

DR. WARD: It looks like it's 1:00 now. And I'll turn it over to Tania to get a roll call of who's come back.

DR. CARREÓN-VALENCIA: Yes, thank you; thanks, Liz. And let me start the roll call again. Liz Ward.

DR. WARD: Here.

DR. CARREÓN-VALENCIA: Sophie Balk.

DR. BALK: Here.

DR. CARREÓN-VALENCIA: Chandra is not here, Chandra Davis. Thomas Dydek.

DR. DYDEK: I'm here.

DR. CARREÓN-VALENCIA: Thank you. Mariama James.

MS. JAMES: Here.

DR. CARREÓN-VALENCIA: Thanks. Anita Jose.
DR. JOSE: Here.
DR. CARREÓN-VALENCIA: I see you. Michael Larrañaga.
DR. LARRAÑAGA: Present.
DR. CARREÓN-VALENCIA: Thank you. Catherine McVay Hughes.
MS. MCVAY HUGHES: Present.
DR. CARREÓN-VALENCIA: Thanks. John Meyer is not here. Debra Milek.
DR. MILEK: Present.
DR. CARREÓN-VALENCIA: Larry is not here. Lawrence Mohr.
DR. MOHR: I'm here.
DR. CARREÓN-VALENCIA: Thank you, Larry. Nick Newman is not here. Jason Ostrowe.
DR. OSTROWE: Here.
DR. CARREÓN-VALENCIA: Robin Sassman.
DR. SASSMAN: Present, present.
DR. CARREÓN-VALENCIA: Aarti is not here, Aarti Surti. Leigh Wilson.
DR. WILSON: I'm here.
DR. CARREÓN-VALENCIA: Thank you. So we have 12 members present and a quorum. Thanks, Liz.

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DR. WARD: Great. So I think we'll continue where we left off and have the public comments at 1:30. So, Geoff, would you mind pulling up the document again?
DR. CALVERT: Sure. So, I turned on Track Changes so we'll have a record and we can reverse anything that I type in, easily reverse.
DR. WARD: Great.
DR. CALVERT: So, I think we were on page 2? And I did make this one edit in the footnote with "types of," if that's okay.
DR. WARD: We're not seeing your screen yet.
DR. CALVERT: Oh.
DR. WARD: At least I'm not seeing your screen yet.
DR. CALVERT: I'm sorry, yes.
DR. WARD: That's okay.
DR. CALVERT: Okay, how about now?
DR. WARD: Yes, now we got it.
DR. CALVERT: So, yes, in the footnote at the bottom of page 2, I added this "types of uterine cancer," if that's okay.

DR. WARD: Sure, good. And you were going to do a search and do that throughout, but you'll call our attention to it where it was done?
DR. CALVERT: Yes, and I only did it where you refer to adding the cancer, uterine cancer.
DR. WARD: Okay.
DR. CALVERT: Because other spots you talk about uterine findings in certain studies.
DR. WARD: Yes.
DR. CALVERT: So, it just didn't seem appropriate to—
DR. WARD: Good, good.
DR. CALVERT: Okay. So, I only changed it maybe in four or five instances. We can either cover those now or wait until we get to those spots, but it's more toward the end of the letter.
DR. WARD: Yes, I think we can wait until we get to those spots because it's clear and we'll see it the Track Changes.
DR. CALVERT: Yes.
DR. WARD: Okay. So were there any other comments on page 2?
DR. CARREÓN-VALENCIA: Yes, could you zoom a little on the screen?
DR. CALVERT: Zoom in or zoom out?
DR. CARREÓN-VALENCIA: Make it bigger.
DR. CALVERT: Make it even bigger?
DR. CARREÓN-VALENCIA: Wider.
DR. CALVERT: Okay. How's that? Is that too big? Or bigger, you want—
DR. CARREÓN-VALENCIA: That's perfect, yes.
DR. CALVERT: That's good? Okay.
DR. CARREÓN-VALENCIA: Thank you.
DR. CALVERT: You're welcome.
DR. WARD: Okay. If there are no more comments on page 2, we'll go to the top of page 3. So, does anyone have any comments or suggested changes on the lines that we can see? Mariama?
MS. JAMES: Oh, yes, I noted during the break on page 1 we referred to the "World Trade Center site and in surrounding communities," "World Trade Center site and in surrounding communities." And then on page 3, line 7 and a couple of other places that I can wait until we get there, it just says "World Trade Center site." And it's probably important that we continue to say "surrounding communities," and maybe even, to be more specific about those surrounding

communities in that we're talking about affected areas in Lower Manhattan and in some Brooklyn neighborhoods. I don't know if people in Brooklyn would readily recognize themselves as members of surrounding communities.

DR. CALVERT: So where on page 3 did you want to propose the—

MS. JAMES: It's page 3, line 7, and then again page 3, line 32, and then in some other places that I can wait until we get up to those pages.

DR. CALVERT: So, are people comfortable with the edit on line 7?

DR. WARD: I am; this is Liz. Jason, you have your hand up?

DR. OSTROWE: Yes, yes, I do. Thank you for bringing that up, Mariama, because it just occurred to me, what about the Staten Island landfill? Responders were exposed there as well.

MS. JAMES: Right. So, we may want to be more specific and mention the neighborhoods in Brooklyn and mention the Staten Island landfill as well.

MS. MCVAY HUGHES: Or the morgue.

DR. OSTROWE: Is there a term that we can use that encompasses all of those instead of having them broken down piece by—like maybe World Trade Center affected areas? I'm just throwing it out there instead of having it repeated over and over again in the document.

MS. MCVAY HUGHES: I also want to add morgues because I think the people who worked with the morgues were impacted as well.

DR. WARD: Catherine, what did you say? I didn't get the words.

MS. MCVAY HUGHES: I think the people who worked in the morgues also—

DR. WARD: Morgues, okay.

MS. MCVAY HUGHES: —were impacted, so I don't know how you'd want to use the word "communities."

DR. WARD: Well, one suggestion I have—which may not fit with everybody's view—is that maybe early on the document we kind of—I mean at this point, in my mind at least, what we're referring to is the recommendations that apply to responders and survivors, with survivors as defined by the World Trade Center Health Program. So maybe the first time we use this phrase, we could say "World Trade Center sites and in surrounding communities," but then put a footnote that clearly links it to the World Trade Center Health Program definition of responders and survivors.

MS. JAMES: That makes sense. So, the first time was on page 1.

DR. CALVERT: Yes, I think that's a great suggestion and I agree with it.
MS. MCVAY HUGHES: I second that.
DR. WARD: So is there someone from the program who can give Geoff—yes, you found it, Geoff.
DR. CALVERT: Is this where you want the footnote?
DR. WARD: I think so. Wait, no—
DR. CALVERT: Because it's part of a quote—yes.
DR. WARD: Okay, so we don't want it as part of a quote.
DR. CALVERT: So the next time is I think on page 3 is where you—
DR. WARD: Okay, well, maybe we can put the footnote on page 3 then.
DR. CALVERT: Okay.
DR. WARD: And then does somebody at the Program have the text for the footnote, or should we come back to that? I mean we could say something very simple like "As defined by the World Trade Center Health Program."
MS. HOWELL: Liz, can you hear me? I think it's the "NYC Disaster Area," I believe is the terminology in the World Trade Center Health Program. I may be wrong. Geoff, do you know?
DR. CALVERT: Well, yes, there's a—go ahead.
MS. BILICS: The New York City Disaster Area is specific just to survivors. Emily and I can check through our regulatory definitions to see if there's something better to use. But right now, we might just want to say "and other affected areas," or "other exposure areas."
DR. WARD: So you're recommending that we change it to "World Trade Center site and affected exposure—other exposure areas"?
MS. BILICS: "Other exposure areas," yes, I would say that for now and then I'll confer with Emily offline, and we'll see if there's something better that we think would work.
DR. WARD: Okay. Is that agreeable to everybody? Okay, so we'll have to go through—oh, Michael, go ahead.
DR. LARRAÑAGA: Thanks, Liz. Something just occurred to me; by talking about the World Trade Center site, are we excluding Shanksville, Pennsylvania and the Pentagon when we do that?
DR. WARD: Yes, I think that's another footnote. And I had planned to mention that earlier. So, in our recommendations we're mostly referring to the World Trade Center site because that's where most of the documentation about exposures is there. I do recognize that—I

	think the World Trade Center Health Program now refers to 9/11-related health conditions rather than specifically World Trade Center-related conditions. We want everybody to be consistent with the Program's current definitions, which would include the Pentagon and Shanksville, Pennsylvania group. So, do you think we need a footnote to that effect somewhere? But as I said, we've historically only talked about the exposures at the World Trade Center site because the exposures at the other sites were not as well documented, but we recognize that the program has made a decision that responders at all sites are covered.
DR. LARRAÑAGA:	I just want to make sure we don't lose sight of that, thank you.
DR. WARD:	Yes.
DR. LARRAÑAGA:	I don't know the answer, but—
DR. WARD:	I believe that the sentiment of the STAC is that saying it's a World Trade Center-related health condition will also mean that it's a 9/11-related health condition.
DR. LARRAÑAGA:	Okay, thank you.
DR. WARD:	But we could consider a footnote to that effect as well.
DR. CALVERT:	And I think when we get this footnote too from Jess that will include Shanksville and the Pentagon.
DR. WARD:	Excellent, perfect, okay, take care of two birds with one footnote. Okay, excellent. Good, any other comments? I guess we can scroll down a little bit. Are there any other comments? Okay, let's keep going. Okay, keep going. I'm not seeing any hands. Is everybody caught up or do you need a few more minutes? Oh, Sophie? Sophie, you have your hand up?
DR. BALK:	Yes.
DR. WARD:	Thank you.
DR. BALK:	Can you just go back to the last page, the last paragraph? Increases in uterine cancer risk? Isn't it uterine cancer?
DR. CALVERT:	What line?
DR. BALK:	Thirty-three.
DR. CALVERT:	Thirty-three.
DR. BALK:	Is it uterine cancer risk or uterine cancer, or both?
DR. WARD:	I would see we haven't seen either increases in incidence rates or—yes, in the studies I think we're alluding to, we're looking at the incidence rate of uterine cancer in relation the incidence rate in

	the referent population, which is usually like the residents of New York State or New York City. So, I think risk is appropriate. We could say uterine cancer incidence or risk, because I think we're primarily talking about incidence studies rather than mortality studies.
DR. BALK:	If you think that's accurate, that's good; whatever you think.
DR. WARD:	Yes, I think that's accurate.
DR. BALK:	Okay.
DR. CALVERT:	The next page?
DR. WARD:	Yes, scroll down. Oh, Sophie, is your hand still up? Or did you want to speak again?
DR. BALK:	No, let me get rid of that.
DR. WARD:	Okay. Thank you. Okay, seeing no hands, I guess we can scroll down.
DR. CALVERT:	So, here's one of the "all types."
DR. WARD:	Okay, I guess we can scroll down to the next—final page of the letter. So, the next-to-the-last paragraph should be exactly the same as the last conclusion slide in my presentation. So, this would be the language that we would vote on for our overall recommendation. So, I'm not seeing any hands raised. We'll get back to making motions and voting momentarily, but I wanted to go through that. The first section of the supporting documentation is straight out of the previous STAC report, so I don't think we can edit it. But the second section where we talk about the endocrine disruptors, we could look at together as the Committee. Some of the material in that is pretty technical and I can't say that it's an authoritative and encyclopedic document, but we tried our best to do the best with the time we had and the information we had to give a reasonable summary. So, Geoff, could you scroll down to where the second part of the supporting documents begins?
DR. CALVERT:	So not Attachment 1?
DR. WARD:	Well, it's in Attachment 1, but it's the second part. Okay, this is where we want to start. Because the earlier part was information that was already submitted by the STAC in 2012 and we really can't change it. Okay, so let's scroll back the beginning of this section. Oh, okay, Number 2?

DR. WARD: Yes, here we are. So, we're looking for hands if anybody has any comments or questions. Mariama?

MS. JAMES: In the final paragraph on page 4—

DR. CALVERT: On page 4?

MS. JAMES: —it talks about uterine cancers not being in the World Trade Center database. But they're not in the database because they can't be certified.

DR. WARD: Yes, that's what we're saying.

MS. JAMES: Oh, okay.

DR. WARD: Yes, so because they can't be certified they're not in the database, which kind of is a potential harm of them not being certified, but it's also a potential benefit of certifying them so that—

MS. JAMES: Right, okay.

DR. WARD: —help us—yes.

DR. CALVERT: Okay, I'll go back to—

DR. WARD: Page 8, I think.

DR. CALVERT: —that attachment?

DR. WARD: Yes.

DR. CALVERT: Here we go.

DR. WARD: Okay. Just want to give people a minute to look at this.

DR. CARREÓN-VALENCIA: Mariama, you still have your hand up.

DR. WARD: Okay, we're ready to move on to the next page. I don't see any comments, so I guess we can scroll down. I will say the workgroup did spend a fair bit of time on this together. The papers were not always the easiest to understand and so we struggled a little bit to make it as clear as possible and make sure we were summarizing information correctly. Even though it's kind of technical and we're not discussing it here, it is something that the workgroup did work on together in our calls to make sure it was as clear and accurate as possible. Okay, we can scroll down. Okay, I think we're close to the end of it, but we can scroll down. Okay, so that's it. So, I guess we can take—does anybody have any general—let's see; what time is it? Oh, it's 1:21. Tania, do you want to proceed to votes before the public comment or wait until after the public comment?

DR. CARREÓN-VALENCIA: I think we should wait for the public comments; however, I don't see that all the people that are going to provide public comments have joined yet.

DR. WARD: So, we'll just wait—

DR. CARREÓN-VALENCIA: I want to wait to give those public commenters the opportunity to share their views before you take the vote.

DR. WARD: Yes, I agree, yes.

DR. CALVERT: Should I stop sharing?

DR. CARREÓN-VALENCIA: No, I think give the Committee a little more time to look at this.

DR. WARD: Yes, I mean obviously we're not going to keep scrolling through, but if you have the written version of your report available or if you have it online in another screen, please feel free to continue to look at it. And if you see anything that you would like to recommend changing, we'll continue to take comments.

MS. BILICS: Yes, Liz, this is Jess. I just wanted to follow up on a term that might be used for referring to all the sites. So, the policy that I was thinking of that did a good job at explaining all of the New York exposure areas is our certification policy that has exposure tiers and timeframes. However, it does have separate footnotes: one for New York area, one for Pentagon, and one for Shanksville. So, Emily and I spoke and we think that may be the best language to use as a collective comprehensive term would be "locations covered by the World Trade Center Health Program."

DR. WARD: Okay. That sounds good to me.

DR. CALVERT: Does that look right?

DR. WARD: Did we want that in the main text, or did we want that in the footnote?

MS. BILICS: I will leave that up to the STAC. For the program, I'm not sure that matters where you put it, but however you want to present the data is fine with us.

DR. WARD: I mean my only concern about putting it in the main body—and I don’t think it's a big deal, but obviously we didn’t review data from all the locations. We reviewed data from the World Trade Center site and surrounding communities primarily. I mean there probably is some data from other sites. So, I think putting it in the footnote is probably the best.

DR. CALVERT: Okay, and then change this back.

DR. WARD: We could just say "World Trade Center sites and other exposure areas." That would be fine. And then have the footnote.

DR. CALVERT: And then the footnote reads this?

DR. WARD: Yes, is that agreeable to everybody? Mariama, you have your hand up?

MS. JAMES: Yes. So just wanted to make a distinction and point out a couple of other places where it was. So, on page 7, line 2, it's there but appears to—I mean reads correctly to me, although it's there, because that is more specifically just referring responders like on the Pile as opposed to the rest of us. So, you may want to leave it there, but it also comes up, that language of the "World Trade Center site" on page 8, line 2, and page 9, Lines 6 and 20.

DR. WARD: So, we want to change that wording everywhere to the way it was stated?

MS. JAMES: Perhaps with the exception of page 7, line 2, where it appears to be talking about responders specifically.

DR. WARD: Okay.

DR. CALVERT: Okay, so this is page 7, I don't see it on line 2.

MS. JAMES: Uh-oh, did I write down the wrong page?

DR. CALVERT: But in the other, let me just highlight—

DR. WARD: You know what could be happening, Geoff, as you're making revisions—

MS. JAMES: Page 8, line 2. Maybe page 8, line 2.

DR. CALVERT: Yes.

DR. WARD: No, I think, Geoff, what's happening is maybe your line numbers are changing as you make revisions.

DR. CALVERT: We can search for—let's see; this is page 9.

MS. JAMES: Yes, there it is on page 9, line 20.

DR. CALVERT: And it's page 8—let's see; this is page 7—oh, it's line 9?

MS. JAMES: Okay.

DR. WARD: Yes.

DR. CALVERT: But this is a quote, it looks like?

DR. WARD: Yes, we can't change it there.

MS. JAMES: Oh, okay.

DR. WARD: Because that's the direct quote from the original document.

MS. JAMES: Okay, okay.

DR. WARD: And that one is referring specifically to responders, as you said. So, I think that one's okay, but there were a couple of other places where we recommended changing it. So, like that would be one at the—

DR. CALVERT: Like this one here?
MS. JAMES: Mm-hmm.
DR. WARD: Yes.
DR. CALVERT: All right. Let me find... So, this is the language that we'll use?
DR. WARD: "World Trade Center site and other exposure areas," yes.
DR. CALVERT: Okay. So, change it here?
DR. WARD: See, that's where it gets tricky. I'm just not totally sure because...
DR. CALVERT: Oh, because you'd have to look at this Reference 13?
DR. WARD: Well, yes. I mean most of these references now are pertaining to samples collected either at the site or there are the studies of the window films in the community—
MS. JAMES: So maybe there it should stay. We also have in the line just above it, line 13, it's referring only to World Trade Center dust again. We may want to add the smoke there.
DR. WARD: Okay. And we could just change "World Trade Center site" to "World Trade Center sites," make it plural. And maybe that's a little bit more encompassing.
DR. CALVERT: And then here, do you want to change it?
DR. WARD: We could just say "sites" maybe. Yes.
DR. CALVERT: Oh, "sites," okay. Which one?
DR. WARD: Well, and keep the other exposure areas, I guess.
DR. CALVERT: Okay.
DR. WARD: And then we'd have the footnote "Locations covered by the WTC Health Program site." I think it's clear enough. I mean I think it's a little bit of a gray area, but I think we've made it clear enough that we're referring to all of the sites, basically, even though some of the studies were specifically at the World Trade Center site and others were done in the community.
DR. CALVERT: So, I'll look for other places where we talk about sites. So, this the quote past that, okay. So here we could change it. Is that okay?
DR. WARD: I think that's okay. I mean from a pure science point of view, I'm tempted to just go with "World Trade Center sites." But, again, we mean that to include the community. So maybe this is the best we can do because we do want to make sure that we're not just excluding it to the area immediately around the collapse of the building. We're encompassing all of the areas that are designated, in which people exposed were designated as survivors. I think it's

good. And maybe if the peer reviewers will raise a question about it. But DJ?

DR. MILEK: Debra.

DR. WARD: Debra, thank you, sorry.

DR. MILEK: That's okay, that's okay; I realize what it says. For me, on page 3, line 8, when it talks about "In supporting documents to the 2012 STAC," it kind of loses momentum for me as far as the endocrine disruptors go. And it seems like it would be better to pull out those sentences beginning with line 8 and then ending at maybe line 18 and inserting that page 2 after line 31. I know that's a lot to move. And that's the flow for me.

DR. WARD: Okay, let's take a look at it and see if everyone agrees.

DR. CALVERT: Did I capture the sentences that should be moved?

DR. MILEK: Yes.

DR. CALVERT: Okay. And so, move them to here?

DR. MILEK: I would say let's see if people agree. This is the flow for me. It lumps the endocrine disruptor momentum by having that inserted there rather than earlier.

DR. WARD: I think that's good. I mean for me it's good. I think that we would need to make a slight revision in the sentence that follows.

DR. MILEK: I agree.

DR. CALVERT: It looks like my screen got locked here. Does anybody know how to unlock it?

DR. CARREÓN-VALENCIA: Jess? No.

DR. CALVERT: So I'll stop sharing and see if that helps.

DR. WARD: Yes, stop and start again I think would be good.

DR. CARREÓN-VALENCIA: It's 1:33.

DR. WARD: Oh, let's do the comments and we can figure out Geoff's problem. Okay, I'll now turn the chair back to Tania for the public comments.

PUBLIC COMMENTS

DR. CARREÓN-VALENCIA: Thank you, Liz. And as we said earlier, we have six people that have requested to provide public comments. So, when I announce your name, please unmute yourself and turn your camera on. You will have—I'm sorry, what was it? Okay, you will have—commenters will have up to five minutes to provide comment. And

you all received a copy of the redaction policy for public comments, so I hope you took time to read it.

Well, our first public commenter is Kimberly Flynn.

MS. FLYNN: Good afternoon. I'm Kimberly Flynn and I make these comments on behalf of the World Trade Center Health Program Survivors Steering Committee. I'm going to submit a more complete set of written comments. In the interest of time, I'm editing as I go.

So, the question that women survivors and responders have been asking themselves, especially those who have been diagnosed with uterine cancer, is how is it that for nearly a decade after the 2012 edition of more than 50 cancers, uterine has been the only cancer not added by the Program? The WTCHP Science Team provided an answer. Occupational cohorts which are the main basis of the research literature linking environmental exposures to cancers are overwhelmingly male. The same is true of the responder cohorts receiving the lion's share of research support from the World Trade Center Health Program.

So, who is left unstudied? Mariama James answered at the last meeting, "You cannot know how 9/11 exposures are impacting women and children by studying only 50-year-old men." Because under the Zadroga Act the WTCHP relies on research for adding new conditions for care, research inequities translate into care inequities. Uterine cancer is today's example, but there are more. Survivors have long raised this issue with the Program. We know that there are scientific complexities around research design, but the Program has run a research-funding process where survivor proposals which are for studies of the disease population of civilians are placed at a disadvantage. With each funding cycle, survivor proposals are denied funding because they plan to study a so-called "self-referred population." This has serious consequences for survivors. Unlike responders, survivors do not have a screening program so the Program punts to the WTC Health Registry to conduct surveillance for emerging conditions and survivors.

The STAC has heard why this is problematical in discussions of the Registry's small and disproportionately affluent child cohort, but there are other ways that the Registry's surveillance is partial

and flawed. I can deal with that in written comments. However, as the STAC workgroup has crucially noticed, the survivor program is developing other approaches that promise to yield useful information. First example: the WTC EHC's Pan-Cancer Database. The Pan-Cancer Database includes patient demographics and exposure information, site-specific cancer characteristics, cancer molecular profiling, and biomarker information. One preliminary study led by Dr. Alan Arslan found considerable differences in breast cancer characteristics and distribution of breast cancer intrinsic subtypes in the WTC-exposed civilian population compared to that of the general population.

This is important because of the relevance of molecular subtype to breast cancer prognosis and treatment options. The studies using this database may well have significant translational import yielding molecular information that could guide targeted treatments, including for endometrial cancer but which current options are often radical. Studies could yield epidemiological information. Will epigenetic analysis of these cancers show a WTC fingerprint, as Dr. Arslan's findings hint? Further, such studies may shed light on links between cancers and environmental exposures beyond WTC. This resource and the studies based on it need research support. With respect to children, the STAC recognizes that the developmental age at which exposures occur is critical to the effects of EDCs across the lifecycle.

The workgroup cited Dr. Leo Trasande's study, finding that blood levels of EDCs dioxin and furan were significantly higher in WTC-exposed adolescents than a control group. Further, it is critical to investigate a range of endocrine-related conditions, including metabolic syndrome, PCOS, endometriosis, infertility, and cancer, as those with children on 9/11 enter their 30s and 40s. The SSC continues to call for assembling a representative cohort so that longitudinal surveillance of emerging reproductive health problems, among others, can get underway. Better late than never. At the last STAC meeting, Associate Research Director Travis Kubale stated that "Research is needed to better identify at-

risk populations, characterize burden, assess health equity, and inform care." We would agree. But we don't need research to tell us that there is health inequity. We need research to rectify the existing health inequities. We should start with women who make up half the survivor population and the 35,000 people exposed to WTC as children.

We believe the STAC is an important venue for discussion of health inequity with respect to the WTC affected population and, crucially, the unintended but ongoing research inequity that has helped to drive it. We now call for the next STAC meeting to engage the equity analysis that the Program is proposing. The affected community has often benefited from the public dialog between experts and stakeholders that happens at STAC meetings, and we are confident that we will do so again. Thank you.

DR. CARREÓN-VALENCIA: Thank you, Kimberly. The next speaker is Jennifer Waddleton.

MS. WADDLETON: Can you hear me now?

DR. CARREÓN-VALENCIA: Yes.

MS. WADDLETON: Okay, can you see me?

DR. WARD: I can see you.

MS. WADDLETON: Okay, I wasn't sure; I'm not seeing it on this end. Okay, thank you for letting me speak today. I really appreciate it. I want to thank the person who spoke before me because she's stellar in what she was saying. I'm going to try to get through this without crying, but a wise woman once said—can you still hear me?

DR. WARD: Yes.

MS. WADDLETON: "Speak even if your voice shakes." So that's where I am today. I represent several Facebook groups, one of which is the LHI Complaint Group on Facebook. We have close to 200 members and the lack of care through LHI is indescribable. It's inconsistent. There's lack of continuity. Some people are getting chest x-rays, some people are not. I believe that's one of the criteria that we fall under, that that's supposed to be in your yearly examination. I don't even know if you folks can even fix what's going on, but no one's listening. We've done interviews. We've written congressmen. We've written congresswomen. No one is listening. We don't even know what is eligible treatment. I personally have

never received a handbook for this of what I'm supposed to submit and not submit.

This year I had cancer. I submitted my certification and because it was after the fact that my treatment was over, I'm no longer eligible for them to pay anything. My concern at the time was my cancer, not whether or not my paperwork got filed. Like I said, there's a lack of continuity as far as treatment goes, especially between the Centers of Excellence and the people who are outside the New York/New Jersey area who fall under LHI. There's no tracking. The people are being sent to clinics that do drug testing for workplaces. They're never seeing the same doctor. There's no way to track this information. We've also been told that this information that's being collected through LHI is not part of studies that go on through these Centers of Excellence. So, if you have a large group of people with autoimmune diseases outside of the Centers of Excellence, they're not being counted in the studies that are going on within Rutgers and the other hospital centers. There's no way that you can find the patterns if you're not including the entire population that was there that day.

There's a clear divide between men and women and New York and the people outside, who responded from outside of New York. It's felt every day within the 9/11 community and I'm just speaking to voice their concerns. There's an entire subsection of responders that wind the New Jersey waterfront that are not eligible for any treatment whatsoever. They've had cancers, PTSD, and autoimmune issues. But because they were not included in the circle, they are not covered under the World Trade Center Health Program, but they were exposed to the same toxic dust on survivors who came across through ferries and boats. I think this data needs to be collected and have them put into it. Autoimmune issues are a raging issue. I have a neighbor who is a retired New York City detective who also has autoimmune issues. I live in a very small neighborhood in Lehigh Acres, Florida. That's the middle of nowhere and yet we have two people. That's a pocket enough for there to be some issues. We don't understand where to get this information to see where anyone is regarding studies. I heard in 2016 that autoimmune would be covered within

two years. Here we are five years later. Copays for any drugs that might make a difference in my life are $500 a pop. This needs to be something that's reassessed and looked at.

I'm hoping I've gotten in as much as I possibly can. I'm hoping by putting you on notice that someone can get this information to the right people. I have a lot of people depending upon me. Like I said, I run a Facebook group for the LHI Complaint Group; New Jersey, 9/11 responders, and autoimmune diseases within 9/11 responders. I have several hundred people in that group alone that have autoimmune diseases. We keep being told that there's no link. The immune system is the powerhouse to the body. If you don't have a strong immune system, you can't fight off anything. I've been stuck in the house now since March of 2020, maybe outside of doctors' appointments and a quick trip to the store. But I'm basically a hostage because of the autoimmune issues that I know for a fact that were caused by my response that day.

My biggest concern right now is the folks in the LHI group. I had to switch out of LHI. I'm now in Rutgers. Not everybody is as fortunate as I am to be able to go to New Jersey to make this trip to have my yearly exam done. I still have family in the area that lets me stay with them. Not everybody's in my situation, but people are being ignored. The staff was rude to them on the phone. And they are so quick to dismiss anything that's not on their list. We need autoimmune to be put into certified conditions. Thank you for your time. And, like I said, the woman who spoke before me, she was amazing. Thank you.

DR. CARREÓN-VALENCIA: Thank you very much. Our next speaker is Matthew McCauley.

MR. MCCAULEY: Good afternoon and I'd like to thank the panel for giving the time to myself and the other speakers on this public comment, especially this addition session as it's nice to see that more speaking time was provided after the first STAC committee that was two months ago. I applaud the two speakers before me. I think one of the things that came up in their speech was the equity and the equity of these programs and how the STAC committee can continue to push forward the equity.

I'm a retired New York City police officer. I was a paramedic. I was a responder at Ground Zero. As many of you know, I am also an

attorney. I represent a lot of people who have become ill as a result of 9/11 illnesses. And I'm here to talk about the World Trade Center Health Program. I'm not here to talk about the Victims Compensation Fund or any aspect of that. It's purely the World Trade Center Health Program and the work that you do. On one side of it I will applaud every here and the rest of the program for the steps forward that have been made, especially in the recent past. There were delays that were fixed. There were things that have been taken care of. And now the process seems to be moving a little bit faster again, which is good. I know there's a volume that's there. However, there are strides that can be made.

First off, with respect to uterine cancer, I applaud all the work that everybody here has done today and in the past and over the months and years in the past. As Dr. Howard and Dr. Prezant and even back to Jim Melius know, this is one of the things we've always discussed was on one side of it was uterine cancer and it's nice to see that that's moving forward. There are many women out there who will benefit from this program, especially with lifelong medical care. And it is clear, based on what the World Trade Center Health Program doctors have said that this should be included. Now the time is for the STAC committee and for the Program to move it forward.

However, there are a couple of other issues with respect to cancer that I would like to see that the World Trade Center Health Program and the STAC take into consideration. Number one, and the second part that has always been a discussion with Dr. Melius—God bless him—Dr. Howard and even Dr. Prezant, was the latency rule. The latency rule is definitely there as a gatekeeping aspect of things, and I completely respect the gatekeeping functions that the World Trade Center has. However, it wasn't meant to be a complete wall to anything outside of a certain time period. And that's what it became.

We are now 20 years post-9/11. The science has moved so much farther. The latency rules that are there are almost 10 years old since when they were first written. Many clinicians will sit down and say that they have a belief that certain illnesses less than four years after 9/11 were caused by 9/11 exposures. That evidence-

based discussion should be permitted to be reviewed by the Health Program. They should take it case-by-case basis with certain things. There are evidence-based statements and doctors that are out there. This isn't about hiring an expert to go back and look at records. It's about treating physicians looking at their patients, knowing their patients, and oncologists being able to say that it's in their opinion that something was caused by the dust and the debris from Ground Zero, whether if it's a responder or a survivor, it doesn't matter. The Program should look at that aspect of things and look at the clinicians and what they have to say and not just stop at yes. The gatekeeping functions are necessary and those are fine to be there but please, I beg that you look at the evidence-based discussions that some doctors are willing to present, as many of them will say that a straight latency rule is just not appropriate.

The next aspect of cancers really came out in a recent study report which had to do with early surveillance. There are issues with early surveillance. Thank God it's there. However, with early surveillance comes issues of thyroid cancers—was common with thyroid cancers, with kidney cancers, and also seen in colon issues where the cell types have not quite matured to what is considered to be a malignancy. However, the thyroid needs to be removed, the kidney needs to be removed, and they have what's called a high-grade dysplasia. The treatments are almost exactly the same. They're caught early. And the Health Program should be able to provide benefits to these people. They should not be cut off just because it's not at a malignancy at that point. The physicians will all say that these issues would have become a cancer. So, if it would have become a cancer and it's caught early, then just because it's caught early shouldn't mean the Health Program shouldn't cover it.

So, I would ask that that be considered, that research be done to consider including these issues that if they had waited another month or another year would have become an illness that is covered by the Health Program. These people need this coverage for the rest of their life. The amount of money that somebody spends on thyroid medications for the rest of their life when it

comes to something is staggering, whether it's an early capture or if it's a thyroidectomy for a malignancy.

And the last part of it that I would like to address is technology. The Health Program has made many, many strides with respect to it; when comes to the OASIS system, when it comes to other things. I ask that you please embrace technology and go farther. Add more to it. It will bring the efficiency of the Program up. It will create issues where people would get in faster. I'll end in five seconds. I just ask that you please create a portal for the World Trade Center Health Program, especially at the early aspects of enrollment, so more people can get into this program that should be there. Thank you very much.

DR. CARREÓN-VALENCIA: Thank you very much. Our next presenter is Anne-Marie Principe. I hope I'm pronouncing it correctly. Let me check your screen. Thank you.

MS. PRINCIPE: Okay.

DR. CARREÓN-VALENCIA: And we can see you, thank you.

MS. PRINCIPE: Okay, good, thank you. Can you hear me very well?

DR. CARREÓN-VALENCIA: Yes, we can. Thank you.

MS. PRINCIPE: Okay. My name is Anne-Marie Principe. I had a small business on Greenwich Street just north of the World Trade Center. I'm a survivor and advocate. And I understand we're speaking today about certifying ovarian cancer, but sadly it is too late for my friend Ari Goodman who died of this disease one year ago. I've been part of the Bellevue program since its inception. I've spent the last 20 years battling various 9/11-related medical conditions, including a brain lesion, breast cancer, lung disease, rhinitis, sleep apnea, vocal cord paralysis, and peripheral neuropathy. Equally important, I'm one of the advocates alongside Matt McCauley who fought for the healthcare bills in the VCF. And I am grateful for our program, but we can do so much better.

There have been continuous issues with the way this Program is administered. Fiscal prudence and financial oversight appear to be nonexistent. The pharmacy management company does not bother to negotiate cost. Onboarding process for participants in the Program is extremely detailed and certification can be daunting, and it does not guarantee treatment. It takes months to

get an appointment and if we are treated outside of a World Trade Center of Excellence, it becomes a logistical nightmare. In theory, victims can go to outside practitioners for treatment, but physicians are no longer willing to sign up because they literally don't get for years. I've personally had bills for approved treatments that took more than two years to be paid. How could anyone wait two years to be paid? Would any of us? As a result, many of us are struggling to find practitioners who will take our insurance. Trying to get our medical treatments paid for is a full-time job. I spend hours on the phone every month trying to get my doctors paid while I should be focusing on my health.

We are still being treated according to the same protocols that were created 20 years ago. I'm routinely prescribed addictive narcotic drugs such as fentanyl, morphine, and oxycodone, substances that are as toxic as the dust I inhaled. Yet when I request far-less-expensive, holist remedies like IV vitamin drips or acupuncture, my requests are denied. When I was diagnosed with breast cancer in 2018, Sloan Kettering insisted on six months of chemo and a six-week course of radiation, which would have cost the Program over half-a-million dollars and it was approved by the Program.

However, I went for a second opinion to Dana-Farber and I was not covered but still I went on my own. I was given an Oncotype test that proved that chemo was not the best course of action for my cancer. As a result, together with my doctor, I chose natural and alternative treatments. My regimen includes large doses of vitamins, minerals, medical marijuana, meditation, hyperbaric oxygen, and cryotherapy. And although our Program would have paid over $500,000 for that expense, they refuse to cover the doctor that saved them that expense or the holistic treatments that cost less than 5% of what the Sloan treatment program would have cost. My functional medicine treatments are doing more than keeping me alive.

No one who sees me today would know that I have breast cancer. Why does the Program not cover treatment like acupuncture, hyperbaric oxygen, or nutritionists which will save money in the long run? Common sense dictates preventive care is far less

expensive than waiting to treat a condition that has already become catastrophic? If the Program would institute wellness programs, not only would we all be in better heal, but it would lower medical costs. There are numerous social media pages, including a complaint page, on World Trade issues where hundreds of us post about chronic problems. There is a lack of communication, unpaid bills, uncovered treatments, and a failure to certify numerous conditions that many of us share. If we can survive and put a vaccine forward in six months, why does it take us 20 years to certify our conditions?

Many survivors are experiencing mental health issues directly related to being denied the treatment they seek. My own enrollment was questioned when I tried to get mental health treatment and my daughter was denied mental healthcare, even though she's registered and certified. We were told her mental health issues are not really connected to 9/11. My daughter has had to watch me fight for my life through grave illnesses and she is sick from World Trade Center dust. How can you say that my family is not impacted by 9/11? How can PTSD still not be a certified condition? The dysfunction of this Program retraumatizes survivors by making them fight for their lives and their healthcare. This must change.

I have action items that I'd like to suggest. One is overhauling the current payment protocol to guarantee payment. Conserve the Program's assets by negotiating lower prescription drug costs. We should not be paying full rate for our prescriptions. And we should have a bunch of 9/11 survivors who have these conditions who work as an advisory board so that you fully understand what this is like for us. And as far as redacting my testimony, I will ask you not to do so. Please keep in mind that in order to get our legislation passed, all of us have exposed our medical conditions, our private, personal healthcare, so that this Program could come into place. I ask you not to redact one word of anything we've said. Thank you for listening and do not silence us by using HIPAA.

DR. CARREÓN-VALENCIA: Thank you. Our next speaker is Piera Greathouse-Cox. You have five minutes.

MS. GREATHOUSE-COX: Can you see and hear me all right?

DR. CARREÓN-VALENCIA: Yes.

MS. GREATHOUSE-COX: Okay, wonderful, I like it when technology works. This is good news. Hi everyone, thank you so much for providing me the opportunity to share my thoughts today. I will be consulting some of my notes, so apologies in advance for any lack of eye contact. My name is Piera Greathouse-Cox and I'm enrolled in the World Trade Center Health Program because I have stage IV adrenal cancer. Just a little bit of personal history: I was 16 years old and a senior in high school during the September 11th attacks. My father and I lived in an apartment on Broadway and Maiden Lane, which is about two blocks from Ground Zero, throughout the cleanup effort. In 2019 I was diagnosed with adrenal cancer and this year my cancer metastasized and became substantially more aggressive. My oncologist has given me a life expectancy determination of approximately one year. When I was approved for enrollment in the World Trade Center Health Program, I was extremely relieved to have access to the care offered by the Nationwide Provider Network. And I continue to be grateful for the Program's ongoing support.

I'm here to day to advocate for the inclusion of uterine cancer on the list of WTC-related health conditions so that women like me who are suffering from hormone-related cancers potentially caused by breathing high levels of endocrine-disrupting chemicals in WTC pollution, can receive the lifesaving treatment they need without incurring potentially devastating medical debts. It's my understanding that uterine cancer is the only type of cancer not yet covered as a WTC-related condition.

The most recent STAC report makes the following observation, which it would seem prudent to heed: "Mechanisms for carcinogenesis resulting from endogenous and exogenous exposures are similar for most cancer types. It is therefore highly implausible that uterine cancer would be the only cancer not related to WTC exposures." Uterine cancer only occurs in women and women are statistically underrepresented in past and current research cohorts, making it close to impossible to demonstrate a causal relationship between exposure and disease; that substantive numbers of women and individuals who are under 18

at the time of exposure are not being tracked by researchers to look for emerging illnesses likely means that some of us will lack access to care.

Good longitudinal data is required for empirically based eligibility requirements and effective treatments leading to positive health outcomes. With research on people exposed as children especially, we can identify long-term trends that may produce better screenings and early interventions for everyone. It's important that we start working now to determine if child survivors are developing cancer at much younger ages than the current science would predict. Data for more inclusive research on children, women, and diverse populations will create better care for all the responders and survivors whose health was harmed by the World Trade Center disaster.

In conclusion, I believe women diagnosed with uterine cancer should have access to the same excellent World Trade Center Health Program resources that I do. So, thank you again for the space to share my thoughts today. I know I didn't even use all of my time. Hopefully, it can be absorbed into the universe of this Zoom call. I'll end here, thank you.

DR. CARREÓN-VALENCIA: Thank you very much. And our last public commenter is Gary Smiley.

MR. SMILEY: Hi, good afternoon. First off, I'd like to thank the STAC committee for allowing us to speak. My name is Gary Smiley. I'm a retired rescue paramedic from the New York City Fire Department. I'm a collapse survivor of the North and South Towers. I currently work as the World Trade Center liaison for the New York City Fire Department's Uniformed Paramedics and Fire Inspectors Union and I'm also an advocate for the 9/11 community.

There are two issues that I'd like to raise that kind of echo the comments of my dear friends Matt, Anne, and Jennifer. The first issue would be the issue of autoimmune disease. Since I sit on the World Trade Center Medical Advisory and Steering Committee for the last six years, I've witnessed study after study after study and at the end of each study autoimmune disease is then shot down. Most recently prior to the pandemic, in 2018 I believe, they studied over 35,000 individuals and a little over 100 of them were

deemed to be "inclusive of the study but not enough to approve autoimmune disease." I mean I can speak here from a guy who's an athlete who, besides having seven illnesses that disable me from my job, have autoimmune disease and have diabetes from autoimmune exposure. I spend a lot of time with men and women that I advocate for that can't even stand on their feet because they have such pain from neuropathy and from different types of illnesses that fall into the array of autoimmune disease.

We're 20 years post-9/11. I think that we have to move forward. We have to take a critical jump forward and say, "This is caused by what we were all exposed to, either at the World Trade Center site, at the Pentagon, or at Shanksville." I'm not here to give you studies and stats and use fancy words. I'm the common guy that takes care of the common man and woman that responded to the events on 9/11. And I just think we deserve to treat these men and women appropriately and with the care that they deserve. I've spent hundreds of hours in Washington, D.C. storming the halls to make sure that the Zadroga Act was funded up until the Year 2090. And I believe that we have to take advantage of what we gave the World Trade Center Health Program and the steering committee in terms of monetary resources to use those funds to make sure that we cover every individual illness or disease that was related to our exposure.

The second thing I would like to comment on—and echoes a lot of what my friend Anne-Marie spoke about and the research aspect that Matt spoke about—and that is alternative therapies. I know dozens of members from the fire department, the police department, and the responder and survivor community that rely on alternative therapy and alternative research to both manage their conditions and also to keep themselves alive. Homeopathic remedies—acupuncture, massage therapy—these are all critical to the body's wellness and being and really need to be included. There is scientific evidence from multiple terrorist-attack survivors, from the World Trade Center to the Boston Marathon bombing to the Madrid train bombing, that these alternative therapies work on survivors of terrorist acts; just as we all are, we are all survivors of a terrorist attack.

In addition, I believe that the Program should look into and embrace alternative research studies. There are many programs available to World Trade Center members that, although not looked upon happily by the insurance community, are definitely lifesaving procedures and events; from body scans to cancer biomarker screenings that we use regularly in New York City, thankfully through grants that are provided by foundations and charities, which otherwise would not be affordable by the average first responder that is a World Trade Center first responder.
I mean I beg you guys. I mean I would be happy to sit down with you and show the results. I mean we just sent over 100 people to an imaging study that we just got a grant for. Do you know that 83% of them, we found heart disease related to 9/11 illnesses? It's not a stretch to say that all these things that we're finding in these men and women are related to their exposure.
I have about 20 seconds left. I'd like to thank you once again. I'll ask the same as I do Anne-Marie, my life is an open book. Please do not redact anything. You can keep my name. You can use my name, my address, anything that pertains to my healthcare. I give it to the World Trade Center Health Program for research and for the availability to the public. Thank you very much for allowing me to speak today. I appreciate all the work that you guys do.

DR. CARREÓN-VALENCIA: Thank you. And thank you to all our public commenters. I ask you that you please leave the Zoom room and continue following through the webcast. And, Liz, the mic is yours.

STAC DELIBERATIONS AND RECOMMENDATION

DR. WARD: Thank you, Tania. So, we will return to where we were before the public comment section, which is Geoff was sharing his screen and we were looking at it for post-rearrangement of the letter. And we'll go from there. Okay, so I think before we decide if we want to keep this in whole or in part, we need to look at the sentence that would come after the part that's moved to make sure it would flow logically. So, Geoff, if you could scroll up to where you moved those sentences from. Okay, so it is now reasonable "Because endometrial cancers are clearly related to hormonal factors, the presence of multiple endocrine-disrupting chemicals at the WTC

sites and other exposures areas is of special significance in evaluating risks associated with WTC exposures." So, we could leave it as it is and just take out the "in addition" and just say "there is evidence that"—or we can—I guess my one question is should we move up the list of endocrine disruptors? Should we move back the list of endocrine disruptors? I guess—well, let's see what other people think. I'm fine either way.

Yes, I think the one thing that we'd have to do is take out the "in addition" because that wouldn't be logical.

MS. MCVAY HUGHES: You think you want a paragraph right there, then?

DR. WARD: Okay, Geoff, can you scroll down? So maybe if we accept the move, we don't really even need to say—well, I guess it's okay. I'm a little concerned about the logical flow of putting it here. What do other people think?

DR. CARREÓN-VALENCIA: Sophie has her hand up.

DR. WARD: Yes, Sophie, thank you.

DR. BALK: Yes, I find it hard without seeing the whole thing, but I think it flowed better the original way. That's my opinion. But I find it very difficult because we're only seeing little pieces of it. I think what I'm looking at now is more like background and definitions of what you looked at. So, I would put it back up. But that's my opinion. But again—yes, not it's tiny.

DR. WARD: Okay, any other opinions?

You know what? I mean one possibility would be to just take the whole sentence about that enumerates all the classes of contents we talked about in the 2012 report, just take that out completely because that is kind of background.

MS. MCVAY HUGHES: Or use it as a footnote. Why eliminate it altogether?

DR. WARD: Okay, yes. I guess just because it breaks the flow a little bit.

DR. CARREÓN-VALENCIA: Mike has his hand up.

DR. WARD: I'm sorry, Mike, go ahead.

DR. LARRAÑAGA: Thank you. I was going to agree with—I think it was Robin or is it Sophie—on leaving it where it was originally. I'm hesitant to agree to it. This could be kind of a major change without really having the time to read through it and logically understand it.

DR. WARD: Okay, anyone else? Sophie?

DR. BALK: Yes, hi. I also would keep in the list that you want to make a

footnote. I just think it's important for people to know exactly what you're talking about. And it's a big list.

DR. WARD: Okay. Debra?

DR. MILEK: I agree with keeping the list in. I think that is an important piece.

DR. WARD: Okay. Sophie? Did you want to comment again?

DR. BALK: No.

DR. WARD: Well, it sounds like most people are in favor of keeping it as it was. And being that since the comment was in part editorial, that maybe we should keep it as it was just because people are concerned that they can't fully evaluate the change and I think the meaning. I mean the substance of what we're saying is there. Debra, are you agreeable to that?

DR. MILEK: Let's see. I think that it might have been helpful to allow us to do some wordsmithing before the actual meeting for the non-scientific content. For me, this was a flow issue. I get sidetracked from everything that seems to be endocrine disruptor and then to go back to everything else and then back to endocrine disruptor, that just lessened the power of it for me. But I mean if everybody else feels otherwise, then I don't have a disagreement.

DR. WARD: Okay, so I don't think we need to take a formal vote, but it sounds like most people are in favor of keeping it as it is. And next time around I guess we could think about what a process would be to try to incorporate comments in advance to the meeting. It is hard. I mean even working as a small workgroup it was pretty labor-intensive to keep iterating on different versions of the document. But I think this more a change in terms of editorial and flow. And since there isn't any real disagreement on the content, I think we can just leave it as it is.

Okay, so any other comments? I think that where we began was we had pretty much agreed on the text of the letter and the Part 2 of the supporting information. And we are at the point—Debra, did you have your hand up? I'm sorry, you're on mute.

DR. MILEK: I was going to make another comment for page 3—or a question. Beginning with line 28—I'm sorry, not 28—line 26, "young people who attended schools and childcare center as well as residents who were infants," do we want to say "in utero" preceding "infants"?

DR. WARD: I think that's fine. I think that would be a good change.

DR. MILEK: And then ending that sentence, "during the attack and aftermath"? Aftermath being several years of dust exposure, etcetera.

DR. WARD: Well, I'm good with that change. Any objections? Okay, Debra, your hand it still up. Did you have another one? Okay. Any other recommended changes before we go ahead and take a vote approving or disapproving the content of the letter and the supporting documents? If not, I'll go ahead and turn it over to Tania because I believe we'll want to take a roll-call vote.

DR. CARREÓN-VALENCIA: Yes, so if you all agree with the document as it is, I'm going to take a roll call. So please let me know if you agree or disagree, or with yea or nay. Okay? So Liz—

DR. OSTROWE: Before you do that, can I just ask a quick question?

DR. CARREÓN-VALENCIA: Oh, sorry.

DR. OSTROWE: Yes, it's quite all right. So, the vote, as I understand it, is to approve the content of the document but allow for further editorial changes as necessary?

DR. CARREÓN-VALENCIA: Yes, we need Liz to make a motion, and a second, before proceeding to the vote. Sorry about that.

DR. WARD: Okay, but before we do that, let's just say—I mean I don't know that we're going to—you were saying approving it with other editorial revisions as necessary. I think we need any important revisions to be stated now. I don't think there's a process for us to go back and say two days from now we're going to change this because the Committee is voting on it as it is. So if anybody's still uncomfortable—I mean I think it's also important to remember that the purpose of this letter is to provide advice to the World Trade Center Health Program and even if there are some minor editorial—or there's some minor editorial changes that one person or another person might feel would make it clearer, I think what we should be focusing on now is the substance of it and the clarity of it, but not really so much editorial changes at this point. Leigh, you want to speak?

DR. WILSON: Yes, I just had a quick question. Tania, I don't know if you know the answer to this. I believe somebody just recommended that we change coverage to include infants that were in utero. Do you know if the World Trade Center Health Program covers fetuses? I

	feel like I had this question once before and the World Trade Center Health Program doesn't actually cover fetuses. Do you know the answer? So, before we add it to this, I just want to make sure that that is—that now young adults are covered by the Program.
DR. CARREÓN-VALENCIA:	And Jessica, can you answer that?
MS. BILICS:	Sure. The Program will cover—will enroll somebody who was born within the exposure timeline for enrollment. So, if they were born and meet the hour duration requirements of being a survivor, we will cover them. But if they were not born in that time exposure, they will not be covered. So no, in that sense, we do not cover somebody that was only in utero throughout the whole statutory exposure time.
DR. WARD:	And can you remind us, what is the statutory exposure time?
MS. BILICS:	It goes through July 31st, 2002.
DR. WARD:	But isn't it virtually impossible that somebody would be born who was—I guess I'm trying to figure out what the—because people are in utero nine months, so who would be included and who would be excluded?
MS. BILICS:	So, they could be in utero through a period of that time, as long as they meet the certain hour requirements for being born and meeting those hours in the exposure are before July 31st, 2002. So, if they were born in May 2002 and lived in the exposure area, they likely meet those hour exposure criteria to meet the statutory definition of being a survivor.
DR. WARD:	Okay. Catherine?
MS. MCVAY HUGHES:	You can just go back to the first page, there are just two words are repeated in the first sentence of the first paragraph, I believe, on here, "To your request to the, to the," I think we've taken out that.
DR. WARD:	Yes, I see that now.
MS. MCVAY HUGHES:	Okay, thanks.
DR. WARD:	Thank you. Leigh, did you want to comment again? Leigh, we're seeing your hand moving in front of the screen, but I don't know if that means you want to comment.
DR. WILSON:	Oh, sorry. I was trying to undo my hand up. I didn't realize I didn't take it down. Thanks.
DR. WARD:	Okay, thank you. Sophie?

DR. BALK: Yes, so it's still not clear to me who's covered in utero and who's not. So, who's not covered?

MS. BILICS: So, the statute has a requirement that somebody at the most has to be in an exposure area for 30 days to be eligible as a survivor. So, 30 days between September 11th and July 31st, 2002. So, if they were born in May of 2002 and lived the rest of May 2002 through July 2002 in an exposure area, they could be enrolled as a survivor. None of their time in utero counts towards that. It's just the date of birth and the time from the date of birth to the end of the exposure period. Does that make sense?

DR. BALK: No, because—so you're not accounting for prenatal exposures?

MS. BILICS: Correct.

DR. BALK: You had to be born—

MS. BILICS: Correct, it'll be—

DR. BALK: But it could be a mom was exposed and she was pregnant in October, the baby's not covered, and then they go and get born somewhere else?

MS. BILICS: Correct, unless they were born and exposed and meet the statutory requirements for exposure in the covered area in the exposure timeframe, which goes through July 2002, the program cannot enroll them.

DR. BALK: So, am I correct that if you're pregnant in like October but you happen not to be born during the statutory period, happen not to be born in the area, like say you move upstate or something, then you're not covered?

MS. BILICS: Correct.

DR. BALK: That's interesting. It doesn't make sense, but—

MS. BILICS: There was no exposure in the exposure area, which is a statutory requirement.

DR. BALK: But the mom was exposed.

MS. BILICS: The mom would be covered.

DR. BALK: Yes, but the baby's not covered. I mean we're talking about in utero exposures.

DR. WARD: Well, I mean I don't—

DR. BALK: Maybe it's moot. It's just—

DR. WARD: Well, it's—no, I think it's good we had this discussion because it was something that I—it certainly had not occurred to me. But for

the purposes of this letter, I think it's okay in the context that we're saying it. Well, what we're saying is "these data raise concern for the young people who attended schools, as well as area residents who were—as well as"—we're saying "area residents who were in utero, infants, as well as"—if we wanted to make it less—I mean we could say "as well as those who were in utero, infants, children." I mean I guess what I'm saying is I think we can say "in utero" regardless of whether the Program covers those children. In this context we're just saying this raises concerns about it. It's not saying whether or not the Program covers it or should cover it. We're just saying it raises concerns.

DR. BALK: I agree with that. Just the rules don't make sense, but it's irrelevant for this letter.

DR. WARD: Debra?

DR. MILEK: I agree that it raises concerns. It also follows the discussion about DES and in-utero exposure. So, I don't know if it's creating its own problem down the line. Certainly, there's concern, but the conflict between concern and coverage should be considered.

DR. WARD: Mariama?

MS. JAMES: So as a lay person—and I may still be biased as a mother of one of these children, actually—I think it's implicit in the way that it's written that we're talking specifically about those who were in utero upon 9/11, not necessarily throughout the duration of the eligibility period. So, upon 9/11 you were in utero, if you were successfully born thereafter, you were born automatically—there's no way that you were not born within the period that is covered and are now a young adult that is considered a survivor. For example, like I said, I have a 20-year-old, she just turned 20 in October, she was born a month after 9/11, she was in utero and she is now a patient of the World Trade Center Health Program.

DR. WARD: Thank you, that's helpful to me. One struggles with the statutory definition in relation to what it means in terms of the people who were affected. So, I think that was a really helpful clarification. So, my sense—Debra?

DR. MILEK: Do we then need to eliminate "it's aftermath"? Because my thought was that that meant that the continual exposure to dust in that area was also problematic.

MS. MCVAY HUGHES: It was totally problematic. It wasn't limited to the day of September 11th. You could smell it inside our apartment months later.

DR. MILEK: Yes, exactly. All right, I guess that's the difference between concern and coverage.

DR. WARD: Right, and I kind of feel like we could just go ahead and say "concern" without necessarily worrying about the coverage because that's—unless the STAC comes back to us and says, "We would like your opinion on whether the statutory requirements for COVID coverage should change." We're pretty much giving our opinion on—the main purpose of this is to give our opinion on the specific question that we were asked and provide the scientific rationale and other basis for our opinions. So, Michael, you wanted to speak?

DR. LARRAÑAGA: Yes, thank you, Liz. I think we should leave the aftermath. That's just what I was going to add.

DR. WARD: Yes, I think in this context we need to have the aftermath because we're not just talking about in-utero people, we're talking about pretty much a large group of people of different ages. And if there is a concern or a distinction about the definition of "in utero," I think—I think we're all—I mean it sounds like those who have spoken are in agreement that the presence of these EDCs at the site raise concerns for the children who were in utero at the time of 9/11 and probably some concern for children who continued to have—or for infants who were in utero after 9/11, but whose mothers continued to be exposed to the dust. I think the STAC is in agreement with that and that that is what this expresses. Mariama, you have your hand up?

MS. JAMES: Yes, so now just a question I guess that's more procedural. Doesn't the STAC have like purview over eligibility? Like, couldn't we not discuss this maybe at length at a future meeting or is that not something that would be appropriate?

DR. WARD: Well, the way the STAC is set up, we basically are here to answer questions or give recommendations to Dr. Howard about the questions or the issues that he chooses to consult the STAC with. So, our main purpose is really to respond to Dr. Howard. That doesn't mean things can't come up in the course of discussion, but in terms of making a formal recommendation, we can only do that

if Dr. Howard asks for our recommendation on that topic. We're not empowered to decide our own agendas.

But I will say, again, what has impressed me so much in reading through the previous rulemakings is that Dr. Howard takes everything the STAC says, at least our written recommendations, very—he reviews them very carefully. And I think the members of the Health Program also pay attention to our discussions in the course of the meetings and it could be that this would cause some discussion within the Program and the Program might come back with a change or might at least consider the points that were made during this discussion internally.

Okay, so I guess we need a motion to approve—I think Tania said that I can make the motion to approve the letter and supplementary materials as drafted.

DR. CARREÓN-VALENCIA: Yes, Liz, before you move on to the motion, I just want to share with you Dr. Aarti Surti, who couldn't attend the meeting today, asked me to share a statement with you. I also want to remind members that per our bylaws there's no proxy vote, so you cannot vote for a member that is not present. However, we can share their thoughts.

So, she asked me to tell you that "I wanted to share my apologies to the group and public for not being able to attention the STAC meeting today. Based on the review of the public comments, as well as the draft of the working group report from November 10th, 2021, I am in agreement with the working group that uterine cancer should be included in the World Trade Center-related health conditions. Based on the historic inclusion criteria for other cancers from 2012, and the potential environmental exposures to World Trade Center first responders and survivors, I believe there is a scientific basis for the inclusion of uterine cancer in the listed of WTC health conditions. This inclusion has the potential to impact many first responders and survivors not only now, but also in the future. Thanks."

DR. WARD: Thanks, Tania. Mariama?

MS. JAMES: Yes, I just wanted to share with you from where I got the idea that we had I guess more of a voice in eligibility. Maybe this needs to be reworded or I'm just a doofus but let me read it to you. "The Act

	requires the Administrator to seek advice from the STAC with regard to determining eligibility criteria for responder and survivor membership in the Program." So that was where I got my thought.
DR. WARD:	Okay—go ahead.
MS. BILICS:	This is Jess. I was just going to say that the statute requires that if the Administrator were to modify the statutory eligibility criteria, the statute does require us to go to the STAC if the Program is suggesting that there would be a modification to the statutory eligibility criteria.
MS. JAMES:	Oh, okay, thank you.
MS. BILICS:	And so, when we had to create a lot of the eligibility criteria for both the Pentagon and Shanksville sites, we did go to the STAC and I think that was early 2012 that there were presentations about the exposures at both of those sites and I believe the STAC did a voice vote at that time in concurrence with what the Program was proposing. But, yes, the requirement is specific to modified eligibility criteria.
MS. JAMES:	Thanks.
DR. WARD:	Thank you for that clarification. So, I think I had made a motion that the Committee takes the vote to approve the text as drafted of the letter and the supporting documentation. And I need a second for that motion.
DR. LARRAÑAGA:	This is Mike, I'll second.
DR. WARD:	Thank you, and Tania?
DR. CARREÓN-VALENCIA:	Okay, so please let me know if you support or not the motion. Liz Ward?
DR. WARD:	Yes.
DR. CARREÓN-VALENCIA:	Sophie Balk?
DR. BALK:	Yes.
DR. CARREÓN-VALENCIA:	Chandra is not here. Thomas Dydek?
DR. DYDEK:	Yes.
DR. CARREÓN-VALENCIA:	Mariama James?
MS. JAMES:	Yes.
DR. CARREÓN-VALENCIA:	Anita Jose?
DR. JOSE:	Yes.
DR. CARREÓN-VALENCIA:	Michael Larrañaga?
DR. LARRAÑAGA:	Yes.

DR. CARREÓN-VALENCIA: Catherine McVay Hughes?
MS. MCVAY HUGHES: Yes.
DR. CARREÓN-VALENCIA: John Meyer is not here. Debra Milek?
DR. MILEK: Yes.
DR. CARREÓN-VALENCIA: Lawrence Mohr?
DR. MOHR: Yes.
DR. CARREÓN-VALENCIA: Nick Newman is not here. Jason Ostrowe?
DR. OSTROWE: Yes.
DR. CARREÓN-VALENCIA: Robin Sassman?
DR. SASSMAN: Yes.
DR. CARREÓN-VALENCIA: Aarti Surti is not here. Leigh Wilson?
DR. WILSON: Yes, thanks.
DR. CARREÓN-VALENCIA: Thank you. So, the yeas have it.
DR. WARD: Great. And I think we decided we should take a separate vote on that one concise paragraph that I summarized in my slide that is now up on the screen in the Word document. So, does anybody want to propose any changes to this or make a motion that the Committee vote to approve it?
MS. MCVAY HUGHES: I'd like to put a motion to the floor.
DR. WARD: Thank you. And do we have a second?
MS. JAMES: Second.
DR. WARD: Okay.
DR. CARREÓN-VALENCIA: So just for the record, can you say who made the motion and the second?
MS. MCVAY HUGHES: Yes, Catherine Hughes, motion.
DR. CARREÓN-VALENCIA: Okay.
MS. JAMES: Mariama James, second.
DR. CARREÓN-VALENCIA: Okay, great, thank you both. Okay, so let's count the votes again. Liz?
DR. WARD: Yes.
DR. CARREÓN-VALENCIA: Sophie?
DR. BALK: Yes.
DR. CARREÓN-VALENCIA: Chandra is not here. Tom?
DR. DYDEK: Yes.
DR. CARREÓN-VALENCIA: Mariama?
MS. JAMES: Yes.
DR. CARREÓN-VALENCIA: Anita?

DR. JOSE: Yes.
DR. CARREÓN-VALENCIA: Mike?
DR. LARRAÑAGA: Yes.
DR. CARREÓN-VALENCIA: Catherine?
MS. MCVAY HUGHES: Yes.
DR. CARREÓN-VALENCIA: John is not here. Debra?
DR. MILEK: Yes.
DR. CARREÓN-VALENCIA: Larry?
DR. MOHR: Yes.
DR. CARREÓN-VALENCIA: Okay, Nick is not here. Jason?
DR. OSTROWE: Yes.
DR. CARREÓN-VALENCIA: Robin?
DR. SASSMAN: Yes.
DR. CARREÓN-VALENCIA: Aarti is not here. Leigh?
DR. WILSON: Yes
DR. CARREÓN-VALENCIA: Okay, we have again a majority voting in favor of the motion. Thank you all.
DR. WARD: And thank you everybody for really great input. I think the letter has been—everything was improved by your input, so great job everyone.

RECOMMENDATIONS OF PEER REVIEWERS AND DISCUSSION

DR. WARD: Next, we wanted to talk about recommendations for peer reviewers. And, Tania, do you want to kick us off?
DR. CARREÓN-VALENCIA: Yes, absolutely. As Dr. Howard mentioned this morning, if he decided to propose adding uterine cancer to the list of World Trade Center-related health conditions. He will publish a Notice of Proposed Rulemaking, or NPRM, in the Federal Register. This NPRM will solicit comments from the public. Also, the Administrator will conduct an independent peer review of the Program's evaluation of scientific and technical evidence supporting the addition of uterine cancer. The peer reviewers will be asked to review the evaluation of the evidence for adding all types of uterine cancer to the list within the context of the policy and provide a brief written report.
So, Dr. Howard, as he mentioned this morning, would appreciate receiving suggestions of subject matter experts that can conduct

such peer review. We have already received some names and now I am opening this discussion and will take your suggestions.

DR. WARD: Sophie?

DR. BALK: Hi, so I want to suggest that a pediatrician be included and I specifically—I'm thinking about Dr. Maida Galvez at Mount Sinai. She's a pediatrician and environmental health expert and she's done a lot of work on endocrine disruptors. And adding a pediatrician would add a perspective of early-life exposures.

DR. WARD: Okay.

DR. CARREÓN-VALENCIA: Noted.

DR. WARD: I'm not seeing any other hands. I mean I don't know that you absolutely need a gynecologic oncologist, but that would be another area of expertise. I don't know of any gynecologic oncologists that also have expertise in environmental exposures, but I can take a look and see. But there is a subspecialty of gynecologic oncology that mainly treats these types of cancers.

DR. CARREÓN-VALENCIA: Okay. I took note of that.

DR. WARD: I'm not seeing any other hands.

DR. CARREÓN-VALENCIA: Well, if you have other recommendations, I have been taking them via email. So please send them to me. I can certainly add them to the list that we are building now.

DR. WARD: Great. And I will put that on my homework list for sure. I know there's a lot to keep up with in reviewing the main documents.

ADMINISTRATIVE ISSUES AND CLOSING REMARKS

DR. WARD: So, at the end what we have left is administrative issues and closing remarks. So, Tania, are there any administrative issues?

DR. CARREÓN-VALENCIA: No, I don't have any administrative issues. I definitely want to thank you, Liz, for sure for your leadership in leading us again to a very successful and effective meeting. I want to thank of course the workgroup for all the work you did and the Committee for—I know it took you a long time and many hours of work to get to the document you have. I'm also very thankful to Mia Wallace, Jessica Bilics, Geoff Calvert, the members of the Science Team, and many other people at NIOSH that have worked extensively to get us to this point. And I don't want to leave of course without thanking the members that will be leaving the Committee after

today's meeting. And so, Thomas Dydek, thank you so much. Leigh Wilson, Robin Sassman, Nick Newman who is not here, and I know I'm missing one other person.

DR. WARD: Catherine.

DR. CARREÓN-VALENCIA: Catherine, of course. Catherine, thank you so much for everything, for all your years of service to the Committee and of course everybody else. You will be receiving recognition from the Program and the Administrator. But thank you, again, for all your service and work on the Committee. And that's all for me, Liz, thank you.

DR. WARD: Yes, and I can't do anything but echo all of Tania's comments. I think it takes a village to come to making a recommendation like this. And I think we benefited greatly from the work of the staff in preparing the White Paper and all of the discussions and input and of course the workgroups. So, I really appreciate all of your support and we'll see what happens next. And I hope to see you all again soon. Thank you.

MS. MCVAY HUGHES: Thank you everybody, it's been an honor. Stay well, Happy Holidays.

DR. WARD: Catherine, I will personally miss you a lot.

MS. MCVAY HUGHES: Yes. Hopefully next time you guys can meet in person.

DR. WARD: That would be great.

DR. CARREÓN-VALENCIA: Yes. Thank you all. Have a good day.

DR. WARD: Thank you.

[Adjourn.]

GLOSSARY

DES	Diethylstilbestrol
EDC	Endocrine-disrupting chemical
EHC	World Trade Center Environmental Health Center
FACA	Federal Advisory Committee Act
FDNY	Fire Department of New York
IARC	International Agency for Research on Cancer
LHI	Logistics Health, Inc.
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
P&P	Policy and Procedures
PCOS	Polycystic ovary syndrome
PTSD	Post-Traumatic Stress Disorder
STAC	Scientific/Technical Advisory Committee
WTC	World Trade Center
WTCHP	World Trade Center Health Program

CERTIFICATION STATEMENT

I hereby certify that, to the best of my knowledge and ability, the foregoing transcript of the September 28 and 29, 2021, meeting of the World Trade Center Health Program Scientific/Technical Advisory Committee (STAC) is accurate and complete.

Elizabeth Ward

Elizabeth Ward, PhD
Chair, STAC