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KRISTEN MAREE CLEARY - PUBLIC COMMENT
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WELCOME AND INTRODUCTION, MEETING LOGISTICS

DR. CARREÓN-VALENCIA: Well, it's 11 a.m. so please, let's get started. Good morning, everyone. 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, and the members of the public who are following these proceedings via live webcast.

About two weeks ago, we commemorated the 20th anniversary of the September 11th terrorist attacks. It is customary at these meetings to ask for a moment of silence to remember those that were killed during those attacks. We also remember those responders and survivors who have died in these past twenty years, as well as others who have died or suffered from terrorist attacks around the world.

[Moment of silence.]

Thank you. I want to make everybody aware that the World Trade Center Health Program STAC is subject to the rules and regulations of the Federal Advisory Committee Act or FACA, and one of those rules is to develop minutes of our meetings. So please be aware that the meeting is being recorded to produce the minutes, and that these minutes will be posted on the Committee's website in a few weeks.

Another FACA rule is regarding public comments. Members of the public can submit comments to the STAC to consider as it develops advice for the World Trade Center Health Program Administrator. One way is for members of the public to snail mail their comments to the NIOSH docket, and we did not receive any comments via mail. Another way is to provide online comments on the NIOSH docket on the regulations.gov website. And as of 10:55 a.m. this morning, we have received nine online comments. Members of the Committee have been asked to monitor the docket and to read the comments. This docket will close tomorrow, Wednesday, September 29th. Another way for members of the public to provide comments is to sign up to provide oral comments during the designated times for public comments. That is today at 11:30 a.m. Eastern Daylight Savings Time, and we have six commenters, who will have five minutes each to provide their comment. I will ask them to turn off their cameras right now and just turn them in when there is their time to talk. There will be also another public comment period time tomorrow at 10:15 am Eastern Daylight Savings Time, and we have also six other commenters who have signed to provide comments.

Also, under FACA rules, we need to do a roll call at the beginning of the

meeting and after each break. We do this to ensure that we have a quorum. As I call your name, members of the Committee, please unmute yourself and indicate your presence for the record and also if there are situations that would change your conflict-of-interest status since you last filled out your OGE-450 form. I also ask that if you have to leave at any point, please let me know when you leave and also, please let me know when you return. We need to make sure that we keep quorum, which for this committee is nine people. So, I'm going to start with our Chair, Liz Ward.

DR. WARD: Present, no changes.
DR. CARREÓN-VALENCIA: Sophie Balk.
DR. BALK: Hi, present, no changes.
DR. CARREÓN-VALENCIA: Thank you. Chandra Davis, I spoke with her this morning. She had a medical emergency and won't be able to join us today. Thomas Dydek.
DR. DYDEK: No changes.
DR. CARREÓN-VALENCIA: Mariama James.
MS. JAMES: Present, no changes.
DR. CARREÓN-VALENCIA: Anita Jose.
DR. JOSE: Present, no changes.
DR. CARREÓN-VALENCIA: Michael Larrañaga.
DR. LARRAÑAGA: Present, and no changes.
DR. CARREÓN-VALENCIA: Catherine McVay Hughes.
MS. MCVAY HUGHES: Present, changes.
DR. CARREÓN-VALENCIA: John Meyer.
DR. MEYER: Good morning, no changes.
DR. CARREÓN-VALENCIA: Debra Milek.
DR. MILEK: Present, no changes.
DR. CARREÓN-VALENCIA: Lawrence Mohr. I think he hasn't joined in yet. Nicholas Newman.
DR. NEWMAN: Present, no changes.
DR. CARREÓN-VALENCIA: Jason Ostrowe.
DR. OSTROWE: Present, no changes.
DR. CARREÓN-VALENCIA: Robin Sassman.
DR. SASSMAN: Present, no changes.
DR. CARREÓN-VALENCIA: Aarti Surti.
DR. SURTI: Present, no changes.
DR. CARREÓN-VALENCIA: Leigh Wilson.
DR. WILSON: Hi, I'm here. Present, no changes. Thank you.
DR. CARREÓN-VALENCIA: Okay. Thank you all. It looks like we have 14 members present, which is a quorum, and we are ready to start. But before I turn it over to Dr. Liz Ward, who is the Chair of the Committee, Mia Wallace has asked me to

ask all the committee members and NIOSH staff that are on the Zoom call to please do not sign off during lunch and break. Just turn your camera off, your mic off, or mute your microphone and if at all possible, please stay on Zoom. With that, the mic is yours, Liz. Thank you.

AGENDA AND ANNOUNCEMENTS

DR. WARD: Thank you, Tania, and thanks to Tania and the staff that has done wonderful preparations for this meeting. I think we have a lot of information that they've shared with us that will help us in our deliberations. I'd like to welcome the existing STAC members back to the Committee and there are very many new members, and I welcome them as well. We'll try to run an efficient meeting. I know we've all had a lot of Zoom experience so hopefully it won't be too difficult. But with that, I will turn over to Dr. Howard to give his opening remarks.

OPENING REMARKS AND CHARGE

DR. HOWARD: Thanks, Liz, and good morning and welcome to the 12th meeting of the Scientific/Technical Advisory Committee for the World Trade Center Health Program. I also want to thank each and every one of you for taking time from your busy schedules to participate in the Committee and to offer your advice about the charge to the Committee that I will get into here in a minute. Before that, I did want to also echo Liz's warm welcome our six returning members and a special welcome to our ten new members. Just thank you so very much for your service.

2021, as you know, marks the 20th anniversary of the September 11th terrorist attacks in New York City, in Arlington, Virginia, and near Shanksville, Pennsylvania. It also marks the 10th anniversary of the World Trade Center Health Program. As of September 26th, the Program has a total of 114,127 members. We have 82,289 responders and 31,838 survivor or community members.

9/11 research continues to advance our understanding of the effects of 9/11 exposures on responders and survivors. Dr. Travis Kubale will present an overview of the Program's research activities over the past ten years. I welcome the Committee's views about the Program's research directions.

In addition, I seek the Committee's views in another specific area. As you are aware, the World Trade Health Program currently covers all major types of cancer, except for uterine cancer. I welcome the Committee's

evaluation and recommendation on whether there is a causal association between 9/11 exposures and uterine cancer which would support adding uterine cancer to the list of World Trade Center-related health conditions.
To prepare you for your deliberations, Jessica Bilics will present an overview of the Program's policy and procedures for adding cancer conditions to the list. This particular policy and procedure governs the Administrator's evaluation of evidence supporting the potential addition of a type of cancer to the list of covered conditions by the Program.
Dr. Geoff Calvert will present a summary of the White Paper, which you all have, entitled "Scientific Considerations for Potential Addition of Uterine Cancer to the List of Covered Conditions by the World Trade Center Health Program" that I believe all of you received ahead of the meeting. This White Paper presents the scientific considerations regarding uterine cancer identified by the Program's Science Team. It also provides information on mechanisms of carcinogenicity for your deliberations.
Should the Committee's deliberations result in a recommendation to add uterine cancer to the list of covered conditions, I encourage you to supply any additional scientific evidence that you believe can serve as a reasonable basis for your recommendation.
Upon receiving your 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 regarding subject-matter experts well-suited to provide this potential peer review, and I appreciate those names very much.
So thank you again for service, and welcome to all the new members, and I wish you a great meeting. Thank you, Liz.

DR. WARD: Thank you, John. So Tania, it's now 11:12. I guess it's—the public comments are the next agenda item—

DR. CARREÓN-VALENCIA: Right.

DR. WARD: And it's not quite time for the public comments.

PUBLIC COMMENTS

DR. CARREÓN-VALENCIA: Right, although we have, I see some of the public commenters already in

the room, in the Zoom room. So I think we could start with them, or we could wait until the time. But let me see. Patricia Grande, you are scheduled to speak. Do you want to start now?

MS. GRANDE: Yes, I can (inaudible @ 00:12:43).

DR. CARREÓN-VALENCIA: Great. Could you turn your camera on?

MS. GRANDE: Okay.

DR. CARREÓN-VALENCIA: And you have five minutes.

MS. GRANDE: Okay, thank you. In the interests of efficiency, I wrote a statement that I'll read which I think will just make it easier to get through this. So my name is Patricia Grande and on September 11, 2001, at the time of the first attack, I was on the subway headed for an appointment uptown, which I—where I got on the subway at the World Trade Center stop. I came out of the train on 59th Street and Lexington Avenue and on that crystal clear day, was able to see the Trade Center with little puffs of white smoke coming from the North Tower. I came through those buildings every day with my husband from the PATH train from Newark on our way to work at Goldman Sachs. My office at the time was at 20 Broad Street, on the second floor.

I returned to that building to work on Monday, September 17th, to find that the air-conditioning was not working, not turned on, and the second-floor windows were open. We were provided with a large floor fan, but the smell and dust were inescapable both outside of course and, in the office, where the dust covered every surface. I continued working out of that office throughout the fall and into the winter, with the smell and dust constant reminders of the horrors of that day.

The two colleagues who were on my team in that office were both diagnosed with reproductive cancers: Pat, a woman, with breast cancer; and Rick, a man obviously, with testicular cancer. I was diagnosed with uterine cancer in April of 2011. Since my cancer was aggressive, I had a full hysterectomy two days after my diagnosis, followed by many months of both chemotherapy and radiation therapy at Mount Sinai.

Since I've been overweight for many years, I wanted to know if my cancer was related to that, and when I asked my doctor, he told me that the type of cells he'd found, which were serous papillary cells, were atypical for endometrial cancer, uterine cancer, and my cancer was not related to my weight. Then he told me to be sure to have regular checkups because serous papillary cells often, and I quote, "like to travel to the esophagus, stomach, and intestines". So, every time I get indigestion or an upset stomach, I am plagued with fearful thoughts that maybe my cancer is coming back.

I applied to the World Trade Center Health Program, was seen by a doctor at the William Street Clinic, where I spent a whole day undergoing tests. The doctor felt that mine was a rare cancer, but when she tried to enter it into the system, she wasn't able to. She called upon a colleague, who was also not able to enter it. Therefore I have not been able to receive follow-up care through the Program and also cannot apply to the VCF.

Mine was a cancer of the reproductive system and it's my belief that all male cancers—or all cancers of the male reproductive system—are approved by the Program, and this is pointed out by page 2 of the Scientific Considerations document produced by the Health Program's Scientific and Technical Advisory Committee for this meeting, which states that the only cancer not currently on the World Trade Center list of covered conditions is uterine cancer. So it is my sincere hope that this type of cancer will eventually also be approved. Thank you for your time.

DR. CARREÓN-VALENCIA: Thank you, Patricia. Next public speaker is Kimberly Vann. If you could feel free, Patricia, to leave the room and join the webcast. So our next speaker is Patricia—Kimberly Vann.

MS. VANN: Yes, good morning. Good morning.

DR. CARREÓN-VALENCIA: Good morning.

MS. VANN: I don't know if you can see me, but I'll begin now. My name is Kimberly Vann. I have been employed by the City of New York for over 28 years. During the 9/11 event, I was working for the New York City Police Department located at 1 Police Plaza, Ground Zero. My unit was a part of the Police Commissioner's office. I reported to work that day and was told to leave after reports of explosions were reported in the vicinity of the World Trade Center. My unit was ordered to return to work three days later at 1 Police Plaza. Our unit worked at 1 Police Plaza throughout the period from September 11th to the end of the year, intermittently at the Pier. The air and toxic fumes were pungent daily as we entered the building. Food was brought in, as we could not remain outside due to the conditions. It was a traumatic experience for all. I have been designated as a first responder since working for the Department at that time. My health was severely impacted by the aftermath of this major event that began on 9/11/2001.

In September of 2019, I was informed by my healthcare professional that I needed further testing for a medical issue I was having of a gynecological nature. My gynecologist began a regimen of steroids, which were to eliminate the symptom of heavy bleeding. This treatment proved ineffective after several weeks, and a different steroid prescription

introduced was not effective as well. After additional test results were completed, I was told I needed an outpatient procedure to facilitate my healing.

After the procedure was done, further testing revealed a large growth that was cancerous. My diagnosis was of a combined clear cell and endometrial cancer serous that was quite aggressive. At that point, I was scheduled for a radical hysterectomy in order to prevent cancer spread. After surgery, I received 6 rounds of chemotherapy and 26 rounds of radiation. My care team explained that this treatment was necessary as the aggressive cancer has little chance of recovery should it not be contained.

During the chemotherapy process, the Taxol infusion went through my left arm as the needle dislodged and resulted in a major infection. My physician told me I was lucky to not have lost the arm after several weeks of antibiotic treatment and a delay in treatment of chemo that took place during the beginning of the COVID-19 pandemic in 2020.

Side effects of this treatment include neuropathy, which continues currently. Radiation has proven to be not without side effects, resulting in different infections on a fairly regular basis.

I have changed healthcare institutions due to the pandemic. As a result, my current physician gave me an opportunity to participate in genetic testing to ensure that my family members know the extent of their need for getting tested for this reproductive cancer. No one on either side of my family has ever had this illness and, as a result of the genetic testing, there seems to be no link as to my family and this particular reproductive cancer. The World Trade Center Health Program was presented with the medical documentation of my treatment for the illness, and I was denied the claim as this cancer is not under the particular—is not under the World Trade Center cancers that are recognized. I was told that there was not enough research regarding this cancer to have the Program certify my case. This has happened to many others, as there are testaments before me and after me. And this level, at some point, needs significant further testing on the behalf of those that will come before and after me. My case is not an original one. However, I feel that in sharing this information with you, the reproductive cancer issue should be made more relevant. Thank you.

DR. CARREÓN-VALENCIA: Thank you very much, Kim. Before I announce our next public speaker, I would like to recognize that Dr. Lawrence Mohr has joined the Zoom call. So Larry, would you please, for the records, state that you are here and if there have been any changes since you last filed your OGE-450 form?

Larry, are you there?

DR. MOHR: Yes, can you hear me?

DR. CARREÓN-VALENCIA: Yes, we can hear you. Good morning and welcome.

DR. MOHR: Yes, I've been having trouble signing in. It's on my end not yours, I'm sure. What would you like for me to do?

DR. CARREÓN-VALENCIA: Just let me know, have there been any changes in your conflict of interest status since you last filed your OGE-450 a few weeks ago?

DR. MOHR: No. No.

DR. CARREÓN-VALENCIA: Okay. Thank you very much. We—

DR. MOHR: You're welcome. Thank you, Tania.

DR. CARREÓN-VALENCIA: Thank you. Well, with that, we have 15 members present for the meeting, and therefore we continue to have a quorum. So our next public speaker is Tammy Kaminski.

DR. KAMINSKI: Hello, can you see me? Hello?

DR. CARREÓN-VALENCIA: We can hear you.

DR. KAMINSKI: Oh, okay. You can hear me and—

DR. CARREÓN-VALENCIA: Yes, and we can see you.

DR. KAMINSKI: Oh, not, all right then. Okay. You can hear me and see me?

DR. CARREÓN-VALENCIA: Yes. Yes. We can hear you.

DR. KAMINSKI: Okay.

DR. WARD: I can't see her now. I could see her a second ago.

DR. KAMINSKI: Okay, hold on. Oh, goodness.

DR. CARREÓN-VALENCIA: There you go.

DR. KAMINSKI: Okay, we're ready?

DR. CARREÓN-VALENCIA: Yes, we are ready.

DR. KAMINSKI: Hello. My name is Dr. Tammy Kaminski, and I want to thank the STAC members for your time and your attention to the inclusion of uterine cancer to the World Trade Center Health Program list of covered conditions. I am a wellness chiropractor and I volunteered my services, as many did, on a weekly—on almost a weekly basis for nine months at Ground Zero. I had direct contact with the substances that were in the site on the men and women's clothing as I worked on them, as well as their shoes, and the ambient air around us. We were told that the toxins were at a very safe level and we did not have to worry about having future problems, which we know that is not true.

2015, I was diagnosed with Stage 3 uterine cancer. I was healthy. I really had no symptoms, and it was a shock. I'm somebody who lives a wellness lifestyle and it was devastating, as any cancer is. As I had pursued my care and treatment with surgery and additional treatments, it came to—I realized that it could have resulted from the toxins at Ground

Zero. So as we researched it, my doctors—and the timeframe of the type of cancer—it was apparent that the causative relationship was very strong. I have been on the Registry with the World Trade Health Program since the onset, and fortunately never needed it to that point. I'm in New Jersey, so I contacted the New Jersey division with Dr. Udasin and the wonderful staff down there, and we were surprised to find out that uterine cancer was not included. As the other speakers have mentioned, all the reproductive or other reproductive organs have been included.

Once I started feeling better, I made it my mission to pursue why it wasn't included and to see what I needed or what we needed to do to get it included. Part of that was collecting the data, which you've heard about, you'll have it there; and also to get involve—get my Congresswoman Mikie Sherrill involved too. Their office has been very helpful in this pursuit. I realized that the data might be small because there's not as many women that were—there weren't as many women that were either volunteering or firefighters or policewomen. It's just the ratio was different. And as far as collecting the data, if it's not on the list, it's going to be hard to collect the data because they're not being cared for.

So, of my friends and colleagues that worked there, volunteered there, the female colleagues, the majority of them have had cancer—breast, thyroid—and again, it just shows that women were greatly affected and not having uterine cancer on the list doesn't represent all of the women who have been affected by this illness.

I want to thank everybody who has helped along the way, and that we're at this point, and I am in support of all of the women and to have this included. I thank you, the STAC members, and I hope we have a positive and optimistic outcome. Thank you so much.

DR. CARREÓN-VALENCIA: Thank you very much. Our next public speaker is Kristen Maree Cleary.

MS. CLEARY: Hi, thank you. Unfortunately, my video does not appear to be working. It says that it's been stopped. So I'll just go ahead and speak. Okay, I'm going to try now. It's coming back. There we go. Hi. And I'd like to read something that I wrote. I'm speaking today on behalf of my mother, Haydee Cleary, who passed away from endometrial cancer after volunteering with the Salvation Army at the World Trade Center recovery site after September 11th. For several months, my mother and I worked side by side, serving food and providing support, in the large white tent that was nicknamed "The Taj". It was a profound experience to share with my mom, and we both felt privileged to be able to contribute to the recovery effort in our own small way. We could not have imagined the price that she would later pay.

In May 2007, only seven months after my father's death from colon cancer, my mother received a diagnosis of early Stage 1 endometrial cancer. She had a radical hysterectomy and we felt lucky and hopeful that she would be fine due to the early detection. However, 18 months later the cancer was back. Her doctors were mystified, given that the original cancer had not penetrated the uterine wall and thus should not have been able to spread after the hysterectomy. As he had during her original diagnosis, her oncologist pointed to her time at the World Trade Center site as a likely cause of her cancer, especially given its unpredictable and aggressive nature. We tried chemotherapy and radiation for a year, but she lost her fight on February 7, 2010, less than three years after her original diagnosis. In 2013, her name was added to the Responders Remembered Wall in Nesconset, Long Island.

I personally suffered asthma and fertility issues after my time at the World Trade Center site, including uterine fibroids and deterioration of my egg reserves, and that's when I decided to enroll in the World Trade Center Health Program. At the same time, I enquired about whether my mother would be entitled to recognition. I was shocked to find out that, while other reproductive cancers are covered, endometrial cancer is not. I cannot wrap my head around the fact that I was basically being told that, despite her sacrifices, my mother had simply contracted the wrong cancer. And I cannot stop thinking about all of the women who had also given so much of themselves to help after 9/11, and how it must feel for them to be told that their cancer does not count, that their heroism and their sacrifice does not count. And these women need our help, and if my mom was still with us, she would say the same thing. Excuse me, I'm sorry. Not only do these women need medical coverage, but they also need to be shown that their contribution matters, and that we all recognize what they've endured as a result of their efforts to help their country heal after the atrocities of 9/11.

My daughters never knew their grandparents, which is truly the greatest regret of my life. I keep my parents' spirits alive for them as best I can, but it'll never be the same. They'll never have the chance to spend holidays and birthdays together, or even just to sit together and read a book. Every year on September 11th, we visit a local memorial here in Tampa, which includes a plaque for the responders who've died. I remind my daughters that their grandmother is one of those people who made the ultimate sacrifice for her country, and I would love to be able to tell them that her country recognizes that fact too. Thank you for allowing me to share our story, and I know that the Committee will make the right

decision, so thank you.

DR. CARREÓN-VALENCIA: Thank you very much, Kristen. Our next public speaker is Rhonda Villamia.

MS. VILLAMIA: Okay, it says, “Unable to start video,” so I guess I’ll just—can you hear me?

DR. CARREÓN-VALENCIA: Yes, we can hear you. Can you start your (inaudible @ 00:32:13)?

MS. VILLAMIA: Oh, okay. I see, okay. Okay. Yes, thank you for this opportunity to share my thoughts. I have submitted a more detailed written comment, which I trust you will read. I was a volunteer with the Red Cross, Salvation Army and St. Paul’s Chapel for the nine-month relief effort. In these settings, the volunteers were predominantly women of all ages, including sibling pairs and mother-daughter teams. In 2009, I was invited to join the WTC Health Registry Community Advisory Board. After being involved in several 9/11 health-related activities, including trips to D.C. with the FealGood Foundation to lobby for the Zadroga Act, I became aware that reproductive abnormalities were being voiced by the majority of women I encountered. I also repeatedly heard that this data was not being noted in our monitoring and treatment programs, so it appeared these and other emerging conditions were not being tracked as they should have been. I noticed there were no female reproductive health questions on the Registry questionnaire, so I began advocating for that, and reaching out to volunteers, while Community Advisory Board member Kimberly Flynn did the same with survivors. We both heard anecdotal reports of early menopause, with some cases of sudden cessation of menses, fibroids, endometriosis and breast cancer. In addition, I heard reports of infertility, miscarriages and birth defects. I myself developed uterine fibroids, as did my sister, and I began menopausal symptoms at age 46. In the Wave 3 survey of 2011, the Registry added four female reproductive health questions: age at onset of period, current status of period, age when period stopped, and reason for period stopping. But in the Wave 4 survey of 2015, these questions were not included. Instead, the questions were about current pregnancy, mammograms, breast cancers, cancers in blood relatives, and the opportunity to note any other conditions or cancers not on the list.

It is gratifying that the World Trade Center Health Program has certified breast, ovarian and certain rare cancers such as vulva, vaginal and cervix-uteri, and I am here today in support of uterine and endometrial cancer being added to that list of certified conditions. I would request that further research be done on our 9/11-exposed women. While I do not know the number of disaster relief volunteers that served at the World

Trade Center site, the total number, I do know that aside from our local volunteers, there were continual two-week rotations from throughout the U.S. and Canada, particularly with the Red Cross and Salvation Army. In the nine-month relief period, with new volunteers responding every two weeks, there was a large number exposed to the toxins, and the majority of these were women. More studies must be done on the health of our 9/11-exposed women, perhaps including a study of pairs such as siblings, and mothers and daughters.

Before I conclude my comment, I'd like to mention other concerns. Though these may not be within the STAC's purview, I am noting them for consideration by the respective decision-making bodies involved.

The first has to do with mental health treatment being interrupted due to provider's claims being delayed or denied in payment. I have been without treatment since July 7th due to my provider's claims from September 2020 forward not being paid. At this crucial time of year, counting down to this milestone 9/11 anniversary, it was especially imperative I be under treatment for my PTSD, and mine is not an isolated case. I'd like to see this situation remedied so our 9/11 community can have the mental health treatment we need without interruptions.

I'd also ask the Program to consider covering urticaria as secondary to PTSD. Despite medical documentation linking it to my PTSD, my request for coverage has twice been denied.

Thirdly, I'd like to ask the Program to consider approving acupuncture as a maintenance treatment for chronic musculoskeletal conditions. Though it is currently approved as a complementary long-term plan of care for cancer patients, it is only approved for acute short-term use otherwise, similar to physical therapy and chiropractic care. I have greatly benefited from the acupuncture over these past six years. aside from my musculoskeletal issues, it has proven beneficial to my other World Trade Center-certified conditions, enabling me to see fewer specialists. This makes clinical sense for the patient and economic sense for the Program since it's less costly to see fewer specialists and be on fewer medications. Acupuncture has no side effect that would create secondary conditions that the Program would have to cover. I therefore graciously ask that the acupuncture be made available to us, at least to the degree Medicare is, at 20 visits per year.

And lastly, I entreat the World Trade Center Health Program and Registry to provide a venue by which representatives from the disaster relief volunteers may dialogue with the Program representatives, because we are a numerically significant portion of the 9/11 community, whose voice

is not being heard. I gratefully thank the STAC members for considering all I have shared in my comment.

DR. CARREÓN-VALENCIA: Thank you, Rhonda. We have one more member of the public that asked to speak publicly, Rachel Lidov, but she hasn't joined the call yet. So in the interest of time, we will continue with our agenda. She was scheduled to speak at 11:30 and when she joins, we could listen to her comment.

DR. WARD: Thank you, Tania. We'll then start with our next speaker, who is Jessica Bilics on policies—oh, I'm sorry. Our next speaker is Travis Kubale on the World Trade Center Research Update.

WTCHP RESEARCH UPDATE

DR. KUBALE: Good morning and welcome to the new and returning members of the Committee and thank you for this opportunity to provide a short research briefing. Next slide please, Mia.

Our mission is to investigate the health impacts and disabilities arising from the 9/11 attacks, and to optimize the World Trade Center responder and survivor care in the framework of a limited benefit program. For continuity, I will briefly today summarize the progress and the status of the listed research initiatives since the 2019 STAC meeting and provide updated resource information. Next slide please.

The first section that I'm going to report on is our initiative on—our multi-phase initiative of research review. Next slide please.

The overall goal of this multi-phase review initiative is to simply learn everything that we possibly can from published World Trade Center research about research gaps, needs, and directions. The first phase of the initiative started in 2017 and was reported to the STAC in 2019, and involved the identification, collection, cataloguing of all World Trade Center publications. And as you can see from the slide, there has been a remarkable amount of research conducted overall, and before the establishment of the Act.

The second phase that we're talking about today is a milestone review publication, an effort led by Drs. Albeliz Santiago-Colón and Doug Daniels. The review is co-authored by World Trade Center leadership staff and provides an overview of the Health Program's structure, research population, exposures of concern, the research portfolio including solicitations and award summaries, descriptions of the literature from 2001 to June of 2020, and future directions. Stakeholders can see the information upon which the programmatic research-to-care planning initiatives are based. Now the publication, collection and evaluation is an

ongoing effort, and that includes over 1,000 publications, about 370 of which were funded by the Program. Next slide please.

Research trends and findings: a couple of key points that we want to make. Aerodigestive outcomes and disorders were reported soon after the disaster and include lower airway diseases such as, or outcomes such as, asthma and bronchitis and GERD; upper airway outcomes such as rhinosinusitis and vocal cord dysfunction. Mental health, which is primarily PTSD but certainly includes anxiety and depression, were also reported early. Long-term effects include increased incidence of some cancers, specifically prostate, lymphoma and thyroid, obstructive sleep apnea, additional respiratory illnesses that include sarcoidosis, pulmonary fibrosis, and persistent lower respiratory symptoms. There is substantial overlap in the respiratory illnesses and mental health conditions. The conditions have persisted, although some specific symptoms such as cough have improved over time, with treatment. Next slide please.

Certainly, an initiative going forward is to look at trends related to potentially vulnerable populations. And what we're going to be doing is working to solicit and fund studies that identify at-risk populations, characterize burden, assess health equity, and inform care. Next slide please.

Research trends in new conditions, a couple of points to make as well is the cohort age is, as you all know, the surveillance activities periodically do uncover emerging conditions. Current interest includes, but is not limited to but includes, autoimmune diseases, cardiovascular disease, and issues associated with cognitive impairment. Where research, we believe, can make an impact—and we have to begin to move parts of the Program and resources—is to look at the impact and solicit, well, sorry, solicit funding to fund intervention studies that target various lifestyle risk factors that are associated with these age-related emerging conditions. And that we feel is a gap that we need to address. Now that's not to say that we're not going to continue to fund research that's aimed, of course, at exploring the linkages with World Trade Center exposures, but we do acknowledge the challenge. Many emerging conditions are common in populations unexposed by the disaster. The conditions represent broad categories of conditions. We can report that since 2019, we have conducted studies that examine specific types of autoimmune diseases. Many times, sufficient power is an issue. We are also looking and have established—this is related to biological plausibility, which is also often challenging—we are collaborating with NIOSH toxicologists currently to

review the existing risk of 9/11 agents that may help us in this area as well. Next slide please.

Our future directions, when we are discussing those, involve continuing to work to identify effective approaches to improve the overall healthcare and wellbeing of at-risk populations. We also want to increase our ability to utilize knowledge and trend information from both the research publications but also Program data, including enrollment and claims, to accurately identify gaps, needs and conditions that are emerging. We, of course, want to work too, and will work, on identification, prevention and mitigation strategies intended to reduce the adverse health effects among the enrollees. Next slide please.

The next section for the Committee, I want to bring your attention to some recently published World Trade Center staff publications and some of the things that we're putting into place as far as science blogs are concerned. Next slide.

I've given four examples here of recent publications, and they cover a variety of areas, and it gives you an idea of the Program, what we're looking at, and what we're thinking as far as the overall research efforts are concerned. There is one, the third bullet, and I think you all have heard about this, but I really want to pause and point out, there is a very nice commentary that was recently written by Doug Daniels, Tania Carreón-Valencia and Jessica Bilics, and it gives a lot of very useful, important information about the petition process and adding qualifying health conditions, that I think are important for the Committee. Next slide.

Another initiative since the 2019 meeting, thanks to Max Lum and Julie Tisdale, is that we are beginning, and have developed, what will become, we think, a very robust segue into science blogs. We have two that are up now. We are excited about this opportunity because it serves as a platform for stakeholder comment and input, and also we think it publicizes the important research and outcomes that are ongoing. We also want to move from this into the potential of offering medical CME presentations, and that's something that Max and the group are working on at this point in time. Next slide please.

I want to talk just briefly about the RAND review and particularly about the translational impacts of our Program and how we are evaluating and measuring that currently. Next slide please.

As you all know, we are funding—it's a four-year study to look at the translational impact of World Trade Center-related research. This project does a variety of things, but it's going to help us and is helping us identify progress and opportunities for setting future research goals. The final

report we anticipate will be through review and released in early 2022. And there will be a Federal Register Notice and this report will be available for broad review and comment.

I also have included here, as an interim—this is a RAND publication, and it describes the translational research framework that underpins a lot of the effort that is going into this multi-year initiative. Next slide.

I want to say, and bring the Committee up to date, on activities that are related to youth research, and specifically the development of a youth research cohort. Next slide please.

As the Committee is aware—next slide. Okay, as the Committee is aware, we were in the process, we have completed it, and it has—

DR. WARD: Excuse me, Travis. I'm sorry to break in, but our last public commenter has joined, and I didn't want that person to be discouraged and think she had lost the opportunity to speak.

DR. KUBALE: Oh okay, I can pause here. This is just fine, Liz.

DR. WARD: Okay, great, thank you.

DR. KUBALE: Sure. Glad to, sure.

DR. CARREÓN-VALENCIA: Okay, well, so our last commenter is Rachel Lidov. You have five minutes to provide your comment.

FURTHER PUBLIC COMMENT

MS. LIDOV: I've unmuted. Can you hear me?

DR. CARREÓN-VALENCIA: Yes, you—we can hear you.

MS. LIDOV: Okay, good. This is Rachel Lidov. I am Rachel Lidov, Concerned Stuyvesant Community. I am speaking on behalf of parents whose children were exposed to the WTC disaster. In 2001, I was a member of the Stuyvesant High School Parents' Association Political Action Committee, which later became Concerned Stuy. In 2002, I cofounded 9/11 Environmental Action. Both organizations worked with many groups to press for a science-based indoor cleanup. We then fought for healthcare and compensation for those affected. I have long been watching the deteriorating health of many WTC responders. While I fully understood the different exposure scenarios, I also knew that babies' and children's bodies were still developing and could be harmed by exposures. I have testified before to the STAC about the need for more research into the risk that these youngsters would develop similar and different WTC-related conditions. Similarly, if NIOSH had committed to fund research on the survivor population, which is half female, we would have had a better understanding of WTC impacts to women.

I am going to speak now about a downtown resident I met many years ago, Kathleen (inaudible @ 00:51:54). On the morning of September 11, 2001, Kathleen and her husband were in the Battery Park City apartment that they shared with their son, about 600 feet from the World Trade Center. Her husband cried out from the bedroom, which had a clear view of the Towers. They feared the worst when they heard the second plane come down the Hudson and turn east at their building just before it slammed into the South Tower. They grabbed their puppy, some essentials, and joined the pandemonium on the ground floor, exiting onto Battery Park Esplanade. Walking uptown, they reached the north intersection at Liberty Street and the Marina. There was a terrible rumbling noise; the earth shook. They dove to the ground as everything went black and silent. They were fully covered in the white ash. Someone yelled, “Run!” As they reached Canal Street, the second tower collapsed. They walked to Chelsea to get their son from school.

Thus began a long period of displacement. Like many others, they made several trips back home with an escort from the National Guard. They saw WTC dust had intruded well into their apartment. At the end of January of 2002, they moved back into their apartment. It was professionally cleaned at their insurer’s expense.

Kathleen wrote this in a statement that was to accompany her WTC application. “And now, the worst just happened to me. I was diagnosed with uterine cancer in the Spring of 2018. My form of uterine cancer is rare, and I have gone through rounds of chemo and radiation and needed 35 transfusions because I now had anemia. I had to be admitted to the emergency room five times and hospitalized. I had to have a full hysterectomy on May 14, 2018.” On New Year’s Eve 2019, she learned that her cancer was back, and in 2020 she was back for another round of heavy chemo and radiation. But, alas, in November she died from the complications of uterine cancer.

So now is the time to say very clearly that uterine cancer must now be included in the WTC Health Program’s list of certified conditions. It is an embarrassment to the WTC Health Program that this has not already happened. As I watched Dr. Udasin’s presentation on endocrine-disrupting chemicals in uterine cancer at a 20th anniversary conference, I was reminded of a meeting of the Stuyvesant PA nearly two decades ago in which a doctor, father to one of the students, warned us of the possible damage to our children’s reproductive systems by these chemicals released in the disaster. The inventory of 9/11 agents includes a long list of EDCs. It is urgent to increase funding for research so that 9/11

survivors can understand both their own risks and the risks to their children, the youngest of whom are now young adults. We know that EDCs can lead to spontaneous abortions, birth defects and cancers in the next generation. Leaving this population in the dark is totally irresponsible. Thank you.

DR. CARREÓN-VALENCIA: Thank you, Rachel.

WTCHP RESEARCH UPDATE

DR. WARD: Thank you and Travis, you may continue. Travis, we're not hearing you. Are you on mute?

DR. KUBALE: Sorry, now can you hear me, Liz? I think I'm off mute.

DR. WARD: That's good, you're off mute.

DR. KUBALE: Okay, thank you. To pick up where we left off, as you all are aware, the Committee is aware, we discussed it was—had been initiated, it was a feasibility study—looking at the possibility of using the New York City Department of Education student rosters to add to and form a youth, World Trade Center youth cohort. The Registry staff was very helpful, did an excellent job writing the protocol, securing IRB approval, coordinating the data liaison with the New York City Department of Education, and identifying and contracting with a tracing vendor and producing the final report, which is available to the Committee. And it also includes a very clear executive summary on what was done. Again, it was a sample of 1,000 students, both from exposed and non-exposed zones in lower Manhattan, extending over into Brooklyn. And there were multiple levels of tracing to locate the students that included batch tracing and also, each round was followed by mailing of informational brochures about the World Trade Center Program and research in particular. Next slide please.

The findings were interesting. There was sufficient, the data was sufficient, the rosters were sufficient for tracing and updating and finding the students. However, the problem was that recruitment interest in research was very low, and particularly low in the unexposed populations—population. So, what we are doing as next steps is that there is a contract solicitation that has been written—it will be posted this calendar year and awarded early next calendar year—which is specifically aimed at trying to help overcome and evaluate some of the issues related to the low recruitment potential so that we can build a youth cohort. And we're excited about this. We think that there are individual groups that have contacted us that are very interested in the

possibility of trying to find, locate and identifying individuals that can increase the number of individuals involved in youth, in this cohort.
Now, the other next step that we're taking is that we're also—and I'll talk about this in a bit—we have posted for the FY '22 round of research solicitations a separate survivor research solicitation, and I'll talk about that in just a minute. We also want to point out that youth research is ongoing. We just awarded, to researchers at Columbia in the 2021 round, a project to examine the long-term physical and mental health outcomes among World Trade Center youth. We also are conducting what's called a "scoping review", an assessment of World Trade Center youth research. To date, we've identified, as part of that review, 175 research publications related to World Trade Center youth. I think there may be 163 which are research publications that cover a wide variety of areas. I think 12 to 14 are technical reports and not actual research papers. But again, that's available to the community. Next slide.
I'm going to talk next slide a little bit about the research solicitations, and the one that was just completed, the 2021. This solicitation was probably one of the most competitive and successful that we've ever conducted. It resulted in a record 22 high-impact awards, including 4 funded, in a joint announcement/solicitation, with NIOSH and the National Institute on Aging. The primary project focus areas for these awards include World Trade Center youth, cancer, respiratory disease, and mental health, and also emerging conditions that include cognitive aging, vascular dysfunction and sleep apnea.
Another point that I want to make to the Committee following the 2019 meeting is that this 2021 solicitation included 14 new first-time research PIs. Since 2019, since our meeting, we've added a total of 18 new PIs to the portfolio, and 4 new research institutions. Next slide.
Just a little bit, we do have, and this was talked earlier about, posted for 2022 a solicitation for survivor-only research cooperative agreements. And you can see the dates of the posting, the receipt date, when they're due and when the review is (final or in awards @ 01:02:26). A couple of points that I want to make. These solicitations are broad in scope. So, what we're hoping to do is that areas where some of our stakeholders have been concerned about the lack of research with survivors or a vulnerable population within the survivor population, this scope is broad and will include any and all of those initiatives. We are worried—and I will tell you—that when we look at our capacity to generate survivor research applications, we're worried about that number being low, and getting lower. And we're hoping that this solicitation that's targeted just to this

population is going to help improve that. Next slide please.

Future directions that I just want to briefly point out for our solicitations, and we've made, I think, some substantial changes in our structure since the 2019 meeting in the way that we look at, over the five-year period, how we want to direct our solicitations. We are certainly going to do everything that we can to ensure that there is a steady stream of new institutions and particularly new young researchers that are coming into the portfolio. We are also going to begin to target our research solicitations in certain areas. Particularly, where you're going to see us target will be areas of translational research, and particularly research that's looking at lifestyle risk factor interventions. And of course, we're going to continue to develop collaborative solicitation with parts of the NIH. Next slide please.

I'm going to say just a little bit about some resource documents. We'll go this pretty quickly, but I wanted you all to have, particularly the new members, I wanted to make you aware of a couple of things. Next slide please.

This is just the overall, you know, listing of some of the Program resource documents. Next slide. Here there are a couple of things, if you're interested in looking at the specific scopes of the funding announcements that are posted for the next FY, these are included. The Research Compendium is one document where we have all of the research information, how we're spending the money, where it's spent, since the beginning of Zadroga, and that's an interactive document that's updated each year. I also point to the Health Registry, a variety of very useful, very good resources. They are, again, one of the primary sources of survivor research. And so, in that, people that are interested in that, I do want to call you attention to that resource as well. Next slide.

Now, on the FTP site, many of these documents that we've made available we've talked about, but there are a couple I just want to call your attention to.

The fourth board is a summary of research funding, and this is a short document, and we are providing those more frequently now than we were during the briefing that I gave in 2019. And they're targeted, and they provide answers to specific questions or concerns that people have about research, in this case research funding and awards.

We also have examples of dashboard descriptions, and the reasons that I put that in is that I want the Committee to see we are integrating our data, the data that is collected, for instance with the Office of Extramural Programs. So, we are watching very closely where we have institutional

capacity, where we are getting, you know, research projects, and the type of research projects and the areas that are covered, and where we need to, you know, focus and therefore where it's not quite as good. So there are a variety of things that we monitor about the Program and about the research, all aspects of research. It's ongoing, and it's, again, on dashboards and you can see examples of that.

Recent publications—this is, I made a typo here. It's actually January through August of 2021. We have now—when started, it's six years, about six and a half years from the start of the Program, we were receiving about two publications, new publications, research publications, a month. During this period, we've received seven and seven, which is between two and three a week. So we are happy about that, but it is certainly a challenge for us to keep up with all of this.

Next slide, and final. I want to take just a few minutes to thank our researchers, our stakeholders, and the Committee for your interest and your commitment to World Trade Center research. It is much appreciated by all of our staff, and I would like to also thank the research staff that has worked incredibly hard over the last year, with multiple COVID deployments. I'm proud of all of them, and certainly I want to thank Dr. Howard and Dr. Reissman for their support in ensuring that we have the resources to carry out the research mission. And with that, I turn it back, Liz, to you for comment.

DR. WARD: Thank you, Travis, and we've got about 20 minutes for questions and comments for Travis before our scheduled break for lunch. I would like to use the raised hand feature in Zoom, so you can raise your hand by going to "Reactions" and clicking the raised hand bar. Depending on how many people have their hands raised, I may go in order of the checkerboard, or I may just, you know, if it's only a few I'll just call them in order that I see them. So, if anyone has questions or comments for Travis, please raise your hand. And Tania will help me but okay, I'm going to go in order of the checkerboards because that's really the easiest thing to do. So Mariama?

MS. JAMES: Thank you. Good morning, Travis. My question is whether or not there are going to be any research studies on youth physical health impacts other than those of the respiratory category, because young people I know, especially as a mother of three of them, are complaining about a lot more than just the respiratory at this point.

DR. KUBALE: Well, thank you for the question, and we do agree that it's important to have the option for a wide variety of potential research projects looking at a variety of outcomes. So, we've written the solicitations specifically to

allow for that. Now, where it, I will admit, it gets a little difficult for us is if we don't get applications, we don't get applications. But I can tell you that we are committed to all areas of youth research, and the solicitation scope is specifically designed to accommodate that. So we have never, on an initial evaluation of whether a project is within scope, we've never had one that has not made it through to review. So, our issue becomes one of how we look at increasing capacity to accommodate some of these areas that stakeholders are concerned about.

MS. JAMES: So, when you say you don't—when you, if you don't get applications, you mean from physicians seeking to do a particular research project?

DR. KUBALE: Right, or researchers. So, if you're talking about—I want to make one thing very clear—so the outcomes that you're talking about are certainly covered in the scope of our solicitations. So, there is no reason—if we get an application, it will go through the review process. That I can guarantee you, period. There is no question about that. Now, with our solicitations, every year, we do, as you know, we open up for public comment and give stakeholders the chance to talk about areas of concern they have. Now, one of the things that we do with that information is that we go back and discuss with the OEP staff to make sure that there is nothing that has been suggested that may not be included in the scope of something that we've written. And so that feedback is very important for us in how we tailor, you know, the specific scope of any of the solicitations that we have for responders and survivors, either one.

DR. WARD: Larry? You're on mute, Larry.

DR. MOHR: Yes, I'm Larry Mohr. I'm a new member of the Committee, so please forgive me if my questions have been covered previously or elsewhere. I am interested in—interested in the scoping for childhood illnesses that you talked about, and the children who were exposed, or adolescents who were exposed on 9/11 are now adults. And I'm particularly interested to know what's been done or what's planning to be done about following children or adolescents who were exposed on 9/11/01 to date. For example, I know the students at Stuyvesant High School were exposed and evacuated during that time. So, could you very briefly give me an update on that, and is that involved in the scoping of the childhood illnesses that you told us about?

DR. KUBALE: Yes, so it's a good question, Larry, and there are sort of several parts. So, one of the things that we're trying to do is that we're trying to figure out, you know, through the contract mechanism that we talked about, first of all, are there individuals that were exposed as youth, that are now young adults, that need to be and aren't involved in the Program and in

the research. So that's one issue for us. And that's, you know, that's a—that presents some hurdles.

Now, the other thing that I want to point out, Larry, that sometimes gets missed is that we have a very robust population of individuals that were exposed as youth, under 18 years of age, within the Registry, and there is a tremendous amount of research that is supported, you know, by that cohort of individuals. Now, there have been some concerns about the small number. We've never though, and I want to make this very clear, and we've made this—these studies are available to the Committee—we've never had any issue with power, with the studies being too small to, where that's a problem. So, it is a robust population. The Registry has been able to re-consent over 95% of the original cohort of individuals. So, there is an aggressive effort that is going on there, and it is currently giving us the capability of funding research like the Columbia group in this current round of research.

So, we are always looking, Larry, at ways that we can improve, you know, but we want to make sure that we're doing is that we're not forgetting that there has been research that's been done and continues, and it will continue, and we hope that the solicitations will bring more of that in as well. I hope that answers your question.

DR. WARD: Thanks—

DR. MOHR: Yes, thank you very much.

DR. WARD: Yes, thanks, Travis. I just wanted to add that I'm guessing around five or six years ago, we actually had a STAC meeting and discussion that was really focused on children's research, and we developed recommendations for Dr. Howard. And one of the nice things about the World Trade Center process is that you can go back and look at the docket and look at that Letter of Recommendation. You can see presentations from the meetings. You can actually see the whole transcript of the meeting. So, I think if anyone is interested in the history of our discussions and recommendations on specific topics, that's a great resource. And Dr. Howard did consider it an important enough topic for us to address as a STAC in the past. Thank you. Catherine?

MS. MCVAY HUGHES: Yes, hi Travis. Since the other two members have focused on kids, I want to focus on gender. If you could just give us a breakdown, since we are charged today to deal with uterine cancer, the breakdown of studies that have been based on men versus women.

DR. KUBALE: Catherine, I'll have to get back to you on that. I don't have the specific numbers. I will tell you that it is, you know, a concern, something that we're looking at, you know, going forward. So as far as vulnerable

	populations are concerned, and certainly as far as the survivor solicitation, that's something that we really want to pay close attention to. But I'm sorry, I don't have accurate numbers for you just off the top of my head.
MS. MCVAY HUGHES:	Right, because that could probably—you know, it's 20 years later but it's like a gap, like the children and the age, and so I just want it to be noted. Thank you very much, Travis, for all you've done though.
DR. CARREÓN-VALENCIA:	Thank you (inaudible @ 01:18:31).
DR. KUBALE:	The other thing that I would tell you, and I again don't have the numbers, but as far as the scoping review and in that document—in that, sure.
DR. CARREÓN-VALENCIA:	If I can just comment briefly, the White Paper that we shared with the Committee and also the public—it's posted on the Committee's website—lists all the studies on uterine cancer that have been published for the World Trade Center Health Program population.
DR. KUBALE:	Yes.
MS. MCVAY HUGHES:	I guess I'm just, I think with, unfortunate September 11, 2001, it's not an isolated incident I suspect, and that I'm just trying to flag it under lessons learned that there is an equal focus on people of all ages and gender.
DR. KUBALE:	Yes, Catherine, thank you, and I would say just a couple of things. One is that, again, you know, it's the characteristics of the cohort. Certainly, the predominant population among the responders is men. However, with the Registry, one of the things in those studies I think, you know, you'll see is that where gender is concerned, the research that is done there and the follow-up does have, you know, more of a balance. I don't have those specific numbers but again, that's generally what I can say, at least at this point, Catherine. Sorry I don't have more.
DR. WARD:	Thank you, and Sophie, you have a comment?
DR. BALK:	Yes. A couple of things. Just thinking about the children exposed, the young children exposed, and is there a focus—now they're adults, and is there a focus on their pre-conception exposures and what happened to their offspring? I just have, that's one question that I have.
DR. KUBALE:	Sophie, do you want me to answer that, or do you want to—?
DR. BALK:	Yes, go ahead.
DR. KUBALE:	Okay. So yes, again, there are two things that I would say. There have not been, to my recollection, there have been, certainly among the Registry, there have been recent studies that have looked at certain reproductive outcomes. In general, the studies that were done in that area—and you can see from the document, the scoping document—a lot of those were done pre-Zadroga. Now, all of our, again, announcements in the scope include the potential to fund those types of studies. So, it's

there if we get the applications. We haven't got a lot of applications, and so that's, Sophie, where, you know, there's just still more work to do. But I want to assure you that those are issues that are legitimate and those are issues that, if we can get projects, they're in scope and we'll fund them.

DR. WARD: Mariama?

MS. JAMES: Just a point of clarification from one of Travis's earlier comments, and I apologize in advance for being so dense, but does "the Columbia Group" refer to Columbia University?

DR. KUBALE: I'm sorry, yes, it's Christina Hoven.

MS. JAMES: Okay.

DR. KUBALE: Yes. Yes, I'm sorry to not—I'm sorry.

MS. MCVAY HUGHES: Wait, so she's mental health, right, Christina Hoven?

DR. KUBALE: Well, she—Catherine, that's interesting. She has been. They have, it was interesting in this particular—and it's in the document file on the FTP site—they are expanding, and it is not, this particular application, which is longitudinal, does not include just mental health. And so, there is a change for that group, and a change in some of the individuals that they brought to the team, so.

DR. WARD: Nicholas?

DR. NEWMAN: Hello. I apologize, I'm in a room with—a shared room so I have to wear a mask. Travis, you'd said that you've been able to engage more, like, investigators as well as other institutions and I'm just wondering what's kind of the geographic distribution of that? Like I imagine that it was predominantly New York area researchers, but I wonder, like are there other groups that are starting to get involved? Because some of the questions, as an environment health researcher myself, different groups in different parts of the country have different interests and expertise, and that may help to close some of these gaps that you've been mentioning, so.

DR. KUBALE: Well, thank you, Nick, and we appreciate the comments and certainly your thoughts about the solicitations have been on our mind since the last meeting. What I would say to that is that we are improving the distribution, but the distribution, you're right, is still centered primarily around New York City, with some exceptions, and there are exceptions in this last call that you'll see in the documentation that we've provided. One of the ways that we are going to look at this going forward, and we had a team that looked at how do you, with solicitations, whether the types of platforms that you need to look at, that increase participation and the scope of the participation. And one of the things that was interesting that we found that we were pleasantly surprised with the R21s—and for

those of you that are not really familiar with these types of things, these are two-year developmental grants, but they don't require certain things like a lot of pre-information or supporting information and pre-research that goes into those applications, and so it is a very attractive platform for new researchers. And we had seen this in other parts of the country where the portfolio in that area dramatically increased, and we were happy with how that happened in ours.

Now, is there more that we can do? Yes, and I think that some of the T and K grants are, you know, an area where we want to go to support that, and we think that we can increase the geographic and the distribution as far as the PIs and the expertise is concerned that way. So it's a work in progress, but that's what we're looking at trying to do. I hope that addresses your question.

DR. WARD: Yes, so we're just about out of time. I just have one comment myself, Travis, which is that I was glad to hear that you had a joint funding announcement with the National Institute on Aging, and I do think that is one possibility as time goes forward, both by—both to expand the pool of funds available, and also maybe to bring in some researchers who wouldn't otherwise be looking for the World Trade Center funding (in that @ 01:26:28). So, I'm glad you are pursuing that, that avenue.

DR. KUBALE: Thank you, Liz. We absolutely are, and we'll continue to do that. Thank you and thank you to the Committee.

DR. WARD: Thank you. Well, we're at 12:26 so I think we should break for lunch and, as Tania has said earlier, don't leave the meeting, just turn your video and your mic off, because that way we won't have to bring you back in. So, and we will start promptly at 1:15. Anything else, Tania?

DR. CARREÓN-VALENCIA: Nothing else, thank you and see you back at 1:15.

DR. WARD: Thank you.

[Lunch.]

DR. CARREÓN-VALENCIA: It's 1:15 on my clock so we're ready to resume the Meeting of the World Trade Center Health Program Scientific and Technical Advisory Committee. I'm Tania Carreón-Valencia, Designated Federal Officer for this committee. I want to welcome everybody back, and I also want to welcome back the members of the public that are following via live webcast. I'd like to make you aware that there is the option to watch or have close captions of this meeting. There is a button on the lower right-hand side corner of the webcast that provides the option. Just click on the CC icon.

	Before we continue our meeting, I would like to make another roll call to make sure that we have quorum. So, members of the Committee, please unmute yourselves and let me know that you are here. Liz Ward.
DR. WARD:	Present.
DR. CARREÓN-VALENCIA:	Sophie Balk.
DR. BALK:	I'm here.
DR. CARREÓN-VALENCIA:	Chandra Davis is still not here. Thomas Dydek.
DR. DYDEK:	Present.
DR. CARREÓN-VALENCIA:	Mariama James.
MS. JAMES:	Present.
DR. CARREÓN-VALENCIA:	Anita Jose.
DR. JOSE:	Present.
DR. CARREÓN-VALENCIA:	Michael Larrañaga.
DR. LARRAÑAGA:	Present.
DR. CARREÓN-VALENCIA:	Catherine McVay Hughes.
MS. MCVAY HUGHES:	Present.
DR. CARREÓN-VALENCIA:	John Meyer.
DR. MEYER:	Here.
DR. CARREÓN-VALENCIA:	Debra Milek.
DR. MILEK:	Present.
DR. CARREÓN-VALENCIA:	Larry Mohr. You're on mute, Larry.
DR. MOHR:	Present, yes, got it.
DR. CARREÓN-VALENCIA:	Okay, thank you. Nick Newman. Nick, Nick talked to me earlier on. He is unable to join for a few minutes, so right now we don't have him joining the quorum.
DR. CARREÓN-VALENCIA:	Jason Ostrowe.
DR. OSTROWE:	Present.
DR. CARREÓN-VALENCIA:	Robin Sassman.
DR. SASSMAN:	Present.
DR. CARREÓN-VALENCIA:	Aarti Surti.
DR. SURTI:	Present.
DR. CARREÓN-VALENCIA:	And Leigh Wilson.
DR. WILSON:	There we go. I'm here, thanks.
DR. CARREÓN-VALENCIA:	Okay, great, thank you. So we have 14 members of the Committee and we have a quorum. And Liz, the mic is yours.
DR. WARD:	Thank you. So, we will turn now to a presentation by Jessica Bilics on policies and procedures for adding cancer conditions.

POLICY AND PROCEDURES FOR ADDING CANCER CONDITIONS

MS. BILICS: Good afternoon, can you hear me okay? Okay. I'm Jessica Bilics. I am the Policy Coordinator and Governmental Affairs Liaison for the World Trade Center Health Program. Next slide. So, I'm going to talk today about the policies and procedures related to adding a cancer condition to the list of World Trade Center health-related conditions.

The Zadroga Act, which is the appropriating and authorizing act for the World Trade Center Health Program, provided us a definition for a World Trade Center-related health condition. You can see here the definition. I'll just read part of it. "An illness or health condition for which exposure to airborne toxins, and any other hazard, or any other adverse condition…is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition." And for mental health conditions, "A mental health condition for which such attacks…is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition." These definitions are in the statute, as I mentioned, and are reiterated again in our regulations in Part 88.1. Next slide.

This list here is the list that is currently in our regulations as the list of World Trade Center-related health conditions. You can see the main categories of aerodigestive disorders, musculoskeletal disorders, mental health conditions, acute traumatic injuries, and cancers. I want to note that the musculoskeletal disorders is, by a provision in the Zadroga Act, is for responders in the New York City disaster area only, but we did, when we added the acute traumatic injuries, which I'll talk about a little bit more later, we did add acute traumatic injuries, and we added it for responders at any site as well as survivors in the New York site. Cancers, the majority of cancers were added back in 2012, and that was done via the petition process, which we'll cover in a minute as well. Next slide.

So the Zadroga Act identifies two pathways in which the Administrator can add a condition to the list of World Trade Center-related conditions. The Administrator can add a condition at his own discretion, or the process can be initiated through a petition, and the Program has to identify whether that petition is valid, and we'll talk about that in a little bit. However, both pathways, regardless, require rulemaking, and that is a Zadroga Act requirement as well. Next slide.

So the Program created a form years ago, and it's been renewed over the years, allowing interested parties to submit a submission to the Program requesting the addition of a health condition. You can see here

it asks for basic information about the submitting individual, a way of contacting them, and then it asks for the condition that is being requested, and then the page that's not shown here provides some space for them to provide what is called the "medical basis", and I'll get into that a little bit more in a slide or two. This form is not a requirement for submitting a request. However, it is there, available, if anybody would like to use it. We also get, you know, requests via email. They just need to be clear, with a contact name and information, request the condition, clear intent to petition. We also get hard copy letters to our offices as well. Next slide.

So, I'm going to go into a little bit of detail here about a couple of policies and procedures that the Program created. The first one talks about how the Program looks at submissions that we receive and determines whether or not they are valid petitions. The second one will look at the policies and procedures for what we consider when adding a cancer condition to the list, and the one that we won't cover today is parallel to the one for cancer but for noncancer conditions, so policies and procedures for adding a noncancer condition to the list. Next slide.

So, the Policy and Procedures for Handling Submissions and Petitions. As I mentioned before, this is how the Program decides whether or not what was submitted is a valid petition. The Policy Team evaluates the submission and determines whether or not it meets the criteria that's in the Program's regulations to be a valid petition. As I mentioned earlier, basically the submitter's name, contact information, a clear statement that they are petitioning—we assume anything that we received on that form is a clear intent to petition but if it's not on that form, the clear intent to petition—also a signature, and then also, as I mentioned, the medical basis. And the medical basis is where we see a lot of submissions that end up not being valid, and it's because they don't provide sufficient medical basis.

The middle slide here talks about what is considered medical basis that we've seen to date. So, a reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations; or a reference to a peer-reviewed, published, epidemiologic study about an association between a 9/11 agent—which I'll talk about in a little bit—and the requested health condition. So that one doesn't need to be in the 9/11-exposed population. And then the last bullet here is clinical case reports or series of the health conditions in World Trade Center responders or survivors.

We see a lot of submissions that are first-hand accounts of somebody's

experience on or in the months after 9/11 and then their medical history, or they're talking about people that they know or that have similar conditions and experiences to them, or on behalf of a group of people that have (the other @ 00:09:26) conditions. Without actual reference to scientific studies, those are not sufficient to be a valid petition. They do not provide sufficient medical basis.

After the decision is made about whether or not a submission is a valid petition, that decision will go back to the submitter in a written letter, and then we'll give an explanation about why it is or it is not valid. Next slide.

So, when we have a valid petition, or if the Administrator has decided at his own discretion to look into whether or not a certain cancer should be added to the list, the Administrator will ask the Program Science Team to lead a review of scientific literature, and this is a systematic literature review. It looks at peer-reviewed studies, epi studies in the 9/11-exposed populations. It looks at studies of a potential causal association between the requested cancer and a condition that's already on the list, so whether or not it's one of the aerodigestive conditions that's already on the list progresses into a cancer. And then it also looks at classifications in the World Health Organization's International Agency for Research on Cancer, which we call IARC, or the National Toxicology Program (NTP)'s report on carcinogens. And that's where we get into the 9/11 agents that I mentioned earlier, and that's basically the chemicals and toxins that were identified at the 9/11 site. Those are considered 9/11 agents, and those are what we're looking in IARC and NTP when we're doing the literature review there.

If medical basis was—assuming it was a valid petition, if medical basis was provided, and that doesn't come up in the literature search for some reason, that literature would also be considered at this point. Next slide.

So, the Program Science Team, when they do get the results of the systematic literature review, they will evaluate the literature for the quantity and quality. So, when they're looking at quality, they're looking mostly for limitations such as study size, study design, whether or not there was selection bias, recall error, healthy worker effect, and other confounders, so if other things such as family cancer history or pre-9/11 exposures were taken into consideration when doing the analysis of the study. So, then the Science Team will take their results from that evaluation and document that, and then discuss their findings of that evaluation with the Administrator. Next slide.

So once there's the discussion with the Administrator, the Administrator will decide whether or not the evidence that the Science Team have

through their evaluation provides a sufficient basis for a decision—or sorry, does not provide a sufficient basis for a decision, and if that's the case, then it's documented and archived. If the evaluation was done as the result of a valid petition, then the Program is required to publish in the Federal Register, which is the government newspaper, basically that determination and why it was determined not to be added. And then the petitioner is also notified in a follow-up letter in writing.

If the evidence has the potential to provide a basis, the Administrator may take two actions. He may take the action to direct the Science Team to do a further assessment of the scientific medical evidence; and he may also decide to go to the STAC for a recommendation. Next slide.

So when, in this further assessment, there are four methods that the Program looks at, and they are not a priority, so only one of them needs to be met.

The first method, which is sort of the gold standard of epidemiology, is whether or not there are studies in the 9/11 population, so scientific, peer-reviewed epi studies in the 9/11 population showing an increased risk of the requested cancer. Method 2 is whether or not there is a connection between a condition already on the list, so I mentioned earlier the possibility of an aerodigestive condition, and whether or not the presence of that condition has a higher risk of resulting or turning into a cancer condition. Method 3 is whether or not the findings from the 9/11 agents in the IARC or NTP classifications suggest that the agents are carcinogenic. And then Method 4 is whether or not the STAC provides a recommendation to add a cancer condition. So based on these review-and-explore methods—and I'll go into them in a little more detail in a second—the Science Team would, again, create a document of the results, and then that would be further discussed with the Administrator. Next slide.

So going into more detail here for Method 1, so when the Program looks at peer-reviewed, published epidemiologic studies of 9/11-exposed populations, the Program is looking at four of the Bradford Hill criteria, and the Bradford Hill criteria is a set of nine criteria that is a commonly used way of analyzing epi studies to look at causation. So, these are pretty standard in the world of public health and science, but the Program only looks at these four. They look at the strength of the association between the 9/11 exposure and the health condition. They look at the consistency across multiple studies. If there aren't multiple studies then it would provide higher weight to the strength of association. It also looks at the biological gradient or dose-response, which is basically if somebody

has a higher dose or higher exposure to a toxin, then they are more likely to have the condition. And then the fourth one is plausibility or coherence, so does the association make sense with the rest of the scientific and medical literature.

To date, none of the cancers that the Program currently covers on the list have been added under Method 1. There have been studies on cancer in the World Trade Center 9/11-exposed populations. However, they have not shown a consistent causal association either in the population or between the 9/11 agents and the various cancers. So, none were added under Method 1.

Method 2, next slide please. Method 2 is the relationship between a condition that's already on the list and then the cancer being requested. So, if somebody has—and this is the example that we always give, and it's actually the only cancer that was added under Method 2 to date—is the adenocarcinoma of the esophagus, and that is often a progression from GERD, from gastroesophageal reflux disease. So that is the only cancer added under Method 2. Next slide please.

Method 3 is where we see a lot of our cancers being added, or have been added. So, there's two criteria here that must be met under Method 3. The 9/11 agent must be on what is known as the Inventory of 9/11 Agents. This is a Program-identified list of conditions. I'll have another slide on that in a minute. And that agent must be on the NTP, the National Toxicology Program's, list of known to be a human carcinogen or is reasonably anticipated to be a human carcinogen, as well as on the IARC, the International Agency for Research on Cancer has determined it to be sufficient or has limited evidence that it is a cause of cancer. And the IARC entity actually connects to specific types of cancer, where NTP doesn't give certain sites or organs for the cancer. Next slide.

So, as I mentioned, several years ago, the Program created a list known as the Inventory of 9/11 Agents. It's on our website. The link there for it is at the bottom of the slide. I'll just quickly read this here. Chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in our Program's regs, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of those three sites. So, this is actually a really extensive list. The Program has a big table at that link, and there's almost 400 agents identified. So this is a

pretty comprehensive list. It's based on a lot of different literature from post the attacks that was (collected @ 00:19:16) in the days and months after 9/11. Next slide.

So, as I mentioned, Method 3 is pretty much where, well, is where the majority of the cancers we cover were added back in 2012. I won't read these all but I'll just pause here for a minute so people can take a look.

[Pause.]

And then next slide. And you can see this is where most of the cancers—we've got two full slides here of the cancers that, cancer types and categories, that were added under Method 3. So I'll pause here again for a few seconds.

[Pause.]

Next slide. So, Method 4, Method 4 is where the cancer can be added based on a recommendation from the STAC, and it has to—it can't just be a yes, we want to add it. There needs to be a reasonable basis provided from the STAC as well. The Program did add a number of cancers based on this method back in 2012. You can see here that includes skin cancer, breast cancer, eye and orbit cancer, thyroid cancer, and then two general categories known as the childhood cancers and the rare cancers. And childhood cancers we defined in our rulemaking as being a cancer that is diagnosed in somebody under the age of 20. And then also the rare cancers was defined as a cancer with an incidence rate of less than 15 cases per 100,000 per year of the U.S. population. And these, as I mentioned, were based on the recommendations from the STAC in the 2012 meetings about adding cancers to the list. Next slide.

So as I mentioned earlier, the Program does need to go through rulemaking to add any conditions. So, after an assessment, the Administrator can take these three actions here. he can publish a Notice of Proposed—or in the Federal Register, what's called a Notice of Proposed Rulemaking, and that basically identifies that the intent is to add this condition and then the reasons for adding that condition. If the assessment doesn't lead to a decision to add the condition, he can publish a determination that there is not sufficient evidence—or that there is sufficient evidence not to add it. Or the third action is that they could publish, or he could publish, a notice that there is insufficient evidence to add the cancer at this time. To date, our decisions not to add anything have fallen under that last bullet there, the insufficient evidence. And these are options to be taken whether or not the assessment was done at the request of the Administrator's discretion or as a result of the petition process. Next slide.

So, this is just a graphic here about the Notice of Proposed Rulemaking process. So, you start with the Notice of Proposed Rulemaking, the NPRM, and as I mentioned, that's where the Program would define what its intent is, and its reasoning for its intent. After it is published in the Federal Register, there is a period of comment, a period for public comment. It's at least 30 days. We also are required by the Zadroga Act, when it was reauthorized, we were required to do a peer review process. So, the Program identifies at least three peer reviewers, depending on the condition being requested, and we have sought requests from the public on identifying peer reviewers, as well as requests from the STAC on those peer reviewers. So, the public comment, we usually do 45 days and allow for the peer review to be that first 30 days, and then an additional 15 days for the public after so they could look at the peer review comments and have time to comment on those peer review comments as well as their thoughts on the NPRM as well. After the public comment period has closed, the Program is required to view and respond to all the public comments, as well as the peer reviewed assessments. And once, if the Program is still of the mind to add the condition, then the process would be to publish a final rule. The other option would be if, for some reason, the public comment or the peer review, or additional information that the Program identified during that time, suggested that it shouldn't be added, the Program could also publish a notice saying it decided not to add the condition. But if it leads to a final rule, the Program publishes a final rule in the Federal Register. It proposes the actual regulatory language, and the rule will become effective within, or after 30 days of publication. So, if we were to publish today, we wouldn't be able to cover, certify or treat somebody's cancer condition, you know, until 30 days after today. Obviously, that's just an example. Here, as I mentioned down at the bottom, the Program is required to have the peer review, and we do get input from the public and the STAC on that. Next slide.
So, I mentioned that the rule would become effective after 30 days of publication and, in addition, during that time, the Program would be working on implementation criteria. So, things to be considered specifically for cancer would be exposure criteria, so how long somebody needed to be exposed, to what type of exposures; whether or not a latency period is required for cancer, we have identified latency periods for different types of cancer, so basically how much time needs to pass between the person's exposure and their diagnosis. And so we would need to do that for any type of cancer added, as we've done for those that have been added. We would also need to decide whether or not the

Program required any additional documentation for what's called certification, such as the pathology report. And then also, if there's any recommendations from the U.S. Preventive Services Taskforce regarding regular screening for cancer that was added, the Program would take that into consideration and then recommend, based on those USPSTF, the Preventive Service Taskforce, recommendations whether or not the Program would cover and pay for that screening.

I believe that's my last slide, so next slide, Mia. Thank you.

DR. WARD: Thank you. So, we'll open the floor for questions or any comments for Jessica. I'm not seeing any hands yet.

MS. JAMES: I raised mine, but I don't see it.

DR. WARD: Oh, I see now.

MS. JAMES: It says that—okay.

DR. WARD: Yes, it's blending into the background.

MS. JAMES: I have two questions. So, the first is with regard to the latency periods, are there, have there been ever any changes to those, based on new information that comes in that you're realizing maybe that people are getting the particular cancer earlier than normal, as it relates specifically to this disaster?

MS. BILICS: So actually, in the last couple of years, the Program has done a full re-review of the literature regarding latency cancers. We are working on the final draft of that but as of right now, the Program has not found any additional scientific literature that suggests any of the latency periods that we have currently would be lowered.

MS. JAMES: And the second is with regard to the papers, so I'll apologize in advance, again, as a lay and new member of the Committee that it's possible that I misunderstood or misread something. But in reviewing the documents that we were provided with, you have—let me phrase it this way. Is non-invasive cervical cancer eligible for certification?

MS. BILICS: So, no, only invasive cervical cancer is eligible.

MS. JAMES: Okay, yes, and the scientific consideration document was, you know, seemed to say that it was not. And so that was really where I was confused and where my question came in, because I've heard a number of times today, and I think over the period, that the only cancer that's not covered is uterine cancer. So that would be incorrect really, right?

MS. BILICS: Yes, there are certain types of cervical cancer, like I said, that are not currently covered, and they basically don't meet the definition of a rare cancer. And sometimes we also see conditions that don't meet the definition of what a malignancy is. We don't see that as much, but we do have the non-invasive cervical cancer issue, but yes. As a whole

category, uterine cancer is a whole category that is not covered.

MS. JAMES: Okay. All of the male reproductive—I think somebody else mentioned this too—all of the male reproductive cancers or organs are covered. What is the difference there with the female reproductive cancers that they're not all covered?

MS. BILICS: So, yes. So actually, all the other male—and we see this, we do get a lot of people asking that question about, well, the male reproductive organs are covered, what's the difference? And the difference is that all the other male, all the male reproductive organs actually met one of the other criteria. So, they either were identified through the Method 3, which is where a carcinogen that's identified through NTP or IARC is connected to being a cancer or a cancer of a specific site. And so those were all added under Method 3. And then there are some that were added under rare cancer, so you see where, if there's a cancer that was identified, and it's not on the list identified by itself but would be covered under the definition of a rare cancer because it occurs in less than 15 cases of incidence per year of 100,000. So, the issue with uterine, and I don't know the most recent incidence rate, but I believe it was like 22 or 23, and that's the problem was that uterine cancer does not meet the definition of a rare cancer. And so that's why it has not been added. It doesn't meet the definition to be—or there is no scientific studies of it in the 9/11 population that have sufficient evidence for it to be added under Method 1. There are no risk factors that were identified, or sorry, there was no condition on the list currently covered that progresses into uterine cancer, which would be Method 2. And then, as I mentioned just a second ago, Method 3 doesn't identify uterine cancer being connected to any of the 9/11 agents. And then to the last option would be under the STAC recommendation of what we identified as a rare cancer previously in the 2012 STAC meetings, that definition, and unfortunately uterine cancer has a higher incidence rate at I think it was 22 or 23 last time I saw.

MS. JAMES: Thanks.

DR. WARD: Thank you. Anita?

DR. JOSE: Yes, actually just what you were saying ties into my question, which is in terms of Method 4, what sort of guidance or benchmark is there? So you had said you can't just say yes or no; you'd have to give a rationale. I imagine there's like a specific kind of guidance or a benchmark about what that rationale would require. Could you speak a little bit about that?

MS. BILICS: I think actually, I think maybe the next presentation from Dr. Calvert might give you some ideas of some considerations specific to uterine cancer that would be possible to be a basis for the STAC. And also, your Chair,

Liz Ward, was here in 2012 when we added all the cancers, so she's experienced in this. So, she'd probably—she or Dr. Calvert would probably be, as well as some input from Tania as the DFO, would probably be the best people to address that, either in the next presentation or when you start deliberation. Tania has a comment now.

DR. WARD: Go ahead, Tania.

DR. CARREÓN-VALENCIA: Actually, it doesn't relate to this. I just want to let the Committee know that Dr. Newman had joined the call now, the meeting.

DR. WARD: Thank you. Thomas?

DR. DYDEK: Yes. There seems to be a disconnect between the language in the law and the selection criteria for adding diseases, specifically I believe your slide showed that it doesn't necessarily have to have strong causation kinds of evidence but, as well, it can be something that aggravates or contributes to, which is a lower bar. So, can you comment on how those less stringent requirements in the language of the law affects the selection process?

MS. BILICS: So that criteria is very applicable in terms of the certification process as well. So that's where a determination needs to be made by the treating provider, and then a final decision by the Program about whether or not somebody has a specific 9/11 condition. So, we don't consider—we give this example a lot, where if somebody came in already with asthma and their asthma got aggravated after 9/11, the Program can cover it. Similarly, if somebody was a smoker prior to 9/11 and then developed lung cancer ten years after 9/11, the Program doesn't consider the contribution of the smoking prior to the 9/11. We take the individual as they come to the Program.

Where we do see some issues with the aggravation is—and we worked with the NCI, the National Cancer Institute at NIH, on this was that the science actually doesn't support that exposure like 9/11 would cause a cancer to be either recurring earlier or increase in intensity due to an exposure. So, we actually do not currently cover cancers that are identified as a recurrence unless they are considered a second primary. So, there's some CEER guidance talks about the length of time between an initial diagnosis of a breast cancer and then a later diagnosis of a breast cancer, and if that length of time has elapsed then it's considered a second primary, or if it's, you know, left breast versus right breast, it's considered a second primary. So, there are some cases with that, but in terms of adding to the list, we have stuck with the methodologies. We feel like they've been pretty lenient in terms of not requiring that it's—especially with the NTP and IARC, that thing, that something is a known

carcinogen, we've allowed it to be likely to be or suspected to be a carcinogen. So, the Program has made some, you know, more member-friendly decisions where there is not positive, 100% definitive data on a condition.

DR. DYDEK: Okay, thank you.

MS. BILICS: Thank you.

DR. WARD: So, if there are no further questions for Jessica at this time, we can move on to Geoff's presentation on "Scientific Considerations for Adding Uterine Cancer to the List". I'm sure Jessica will be hanging in for that part of the call, and so if there are any questions remaining that come up as a result of Geoff's presentation, I'm sure she can address them. So, Geoff, I think we're ready for you.

SCIENTIFIC CONSIDERATIONS FOR ADDING UTERINE CANCER TO THE LIST

DR. CALVERT: Okay. I want to see if I can share my screen. Can you see it?

DR. WARD: Yes.

DR. CALVERT: Okay. So, my name is Geoff Calvert. I'm Associate Director for Clinical Quality at the World Trade Center Health Program, and the title of my talk is "Scientific Considerations for Adding Uterine Cancer to the List of World Trade Center-Related Health Conditions".

So just as a reminder, so this summary is a summary of the White Paper that you were sent earlier. The title of the White Paper is the title of my presentation. and so this is an outline of what I'll be talking about. So, I'll provide a background for uterine cancer, briefly talk about the procedures for adding cancers, but actually, Jess just covered that brilliantly so I really can skip by that. Then we'll talk about uterine cancer, definition, types, and risk factors. We'll talk about previous considerations for uterine cancer by the World Trade Center Health Program. Then we'll review the evidence available regarding uterine cancer among 9/11-exposed populations. So, we'll look at the evidence for Method 1, Methods 1, 2 and 3. And then we'll look at, I'll review additional considerations including the mechanisms of endometrial cancer development, sex disparities and occupational cohort studies, observed associations between 9/11 agents and increased uterine cancer risk, and then finally discuss other cancers—so cancers other than uterine cancer that are causally associated with endocrine-disrupting chemicals that are also 9/11 agents.

So as background, as you've heard earlier, uterine cancer is the only cancer type not included in the World Trade Center Health Program list of

World Trade Center covered conditions, with a few exceptions that we heard about, for example noninvasive cervical cancer. There are some exceptions though. There's uterine sarcoma, which is a rare subtype of uterine cancer, and that's covered as a rare cancer, which we heard is, rare cancers are those cancers with a U.S. incidence rate of less than 15 cases per 100,000 population per year. In addition, we'll cover uterine cancers that arise from the use of tamoxifen that's used to treat a World Trade Center-certified cancer, so that would be covered as a medically associated condition. So, we'll cover medically associated conditions that arise as a result of treatment of a World Trade Center condition. And then we'll also cover uterine cancers that arise from estrogen-secreting tumors, which those are rare. Those are rare cancers but if one of those progresses to uterine cancer, we will cover that again as a MAC, as a medically associated condition.

Uterine cancer is often referred to as "endometrial cancer" since greater than 90% of all cases of uterine cancer occur in the endometrium. So technically, in the medical literature, you'll more typically see endometrial cancer and not uterine cancer when you're looking for research papers. Endometrial cancer is the fourth most common cancer in U.S. women. So, it's, the top three cancers are breast, lung/bronchus, colon/rectum, and then number four is uterine cancer. In 2021, it's expected that there will be almost 67,000 cases of uterine cancer diagnosed in the U.S., and almost 13,000 women are expected to die from the disease in the year 2021. Incidence peaks between the ages of 60 and 70, but it's not unusual for younger women, women less than 40, to develop uterine cancer.

Risk factors for uterine cancer include endometrial hyperplasia, so basically increased growth of the endometrial lining can progress to cancer. You can get uterine cancer from unopposed estrogen hormone therapy. You can also, as I mentioned earlier, you can get uterine cancer from tamoxifen, so selective estrogen receptor modulators can cause uterine cancer. Obesity is a cause of uterine cancer. And then there are certain factors that are protective, that will help people, prevent people from getting uterine cancer. And this, so with increasing numbers of pregnancies or increasing duration of lactation, that helps prevent uterine cancer. Hormonal contraceptives can help prevent uterine cancer. Physical activity, and also, paradoxically, smoking can help prevent uterine cancer.

So, uterine cancer has been previously considered by the Program. So, we've received eight submissions to date, to add uterine cancer. Seven of

these did not meet the requirements to qualify as a petition, but one submission did. It was received in 2019. But when the Program reviewed the available evidence, it determined that the evidence was insufficient to add uterine cancer to the list of covered conditions.

So, the most recent submission was one that was received last year, in 2020. It was submitted by several of the Clinical Centers of Excellence, and they requested that the World Trade Center Health Program consider the contributing role of endocrine-disrupting chemicals. And it was determined that that submission did not meet the requirements to qualify as a valid petition because it provided no new medical basis. And I just mentioned about what medical basis is required.

But nonetheless, as a result of that, following that review of that petition, the Administrator determined that the issues raised merited further consideration. And these issues included the contributing role of endocrine-disrupting chemicals and the fact that here is a low number of women included in study populations with exposures to 9/11 agents. So, the Administrator directed the World Trade Center Health Program Science Team, which includes Tania, myself and some of our colleagues, to review the available scientific evidence for endocrine-disrupting chemicals causing uterine cancer, and to determine if that scientific evidence has the potential to provide a basis for adding uterine cancer to the list.

So as Jess mentioned, there are four methods to assess the available evidence, and I don't think I need to go through this slide. So let me skip this slide since Jess just covered this in detail in that last slide. Sure.

So, for the methodology to do our review, we did a review and looked at the evidence for Methods 1, 2 and 3, and I'll be providing our findings in this presentation. we reviewed data from several databases, including NIOSHTIC, PubMed, Scopus, TOXLINE, and also the comprehensive World Trade Center Health Program's Bibliographic Database, which basically, to our knowledge, has all of the 9/11-related scientific papers that have been published. And so, as I mentioned, a summary of our findings will follow.

So, with Method 1, looking at the evidence using studies of 9/11-exposed populations, we identified nine relevant peer-reviewed published epidemiologic studies. Three of them were excluded. Two were excluded because they only included men, and one was excluded because it didn't provide a comparison population or any background rate. So really, we weren't able to make any determination from that study. And then kind of the punchline first before I go into detail about each of those studies. So

we concluded that these studies do not provide a sufficient basis to add uterine cancer to the list, for these reasons here: no consistent evidence of elevated uterine cancer incidence or mortality was identified among either the responders or the survivors; no study reported a dose-response relationship let alone found one; the study designs are susceptible to selection bias; and finally, only external comparisons were made. So typically, the 9/11 population is considered healthier than these external comparison groups, so it's not unusual then if you do a study and use an external comparison group, it's not unusual to see that the 9/11 population actually has a lower risk. It's better to compare higher-exposed versus lower-exposed 9/11 populations, so doing that dose-response relationship. And as I've mentioned, for uterine cancer, no studies have done that type of an analysis.

So, to go into detail, the most recent study that was published is a study of cancer incidence in World Trade Center responders. So, this is a study that actually combined three responder cohorts. So, this is a study that's been underway for several years, and this is one of the first reports of that combined cohort. So, they combined responders from the general responder cohort, from the Fire Department of New York, which is FDNY, and also from the World Trade Center Registry. And in that combined cohort, they had 9,151 women among the total of 57,000 participants. All were involved in rescue/recovery/cleanup efforts at Ground Zero. So, they compared observed cancer rates from expected cancer rates using data from 13 statewide cancer registries, which is pretty amazing. That's a lot of work to go to 13 different statewide cancer registries. And again, they used New York State data as the comparison population.

And so, their findings for uterine cancer for the years 2002-2015 was a standardized incidence ratio of 0.66 with a 95% confidence interval of 0.45-0.94 based on 31 cases. So, when your standardized incidence ratio is below 1, that indicates that the population that you're studying is actually protected as it reduced—and in this case, a statistically significant reduced risk—of uterine cancer. And as I mentioned, there were no dose-response analyses reported in this paper for uterine cancer.

So, the next study, again, looked at responders, and this study only looked at the responders who were part of the general responder cohort. And it's a prospective cohort cancer incidence study. It's an update of an earlier paper by Solan that was published in 2013. This paper included a little more than 4,000 women, again all responders, all involved in rescue/recovery/cleanup efforts. They linked to only six, but still, that's a

pretty significant lift to link with six statewide cancer registries. And their expected cancer rates are based on state-level data, so they used data from all six of those states to come up with their expected numbers.
So again, when they compared observed to expected uterine cancer, their incidence ratio, standardized incidence ratio was 0.82, but this one was not statistically significant and it was based on only 8 cases. And again, no dose-response analyses were reported for uterine cancer.
So, the next study is one, another cancer incidence study. This one involved participants of the World Trade Center Health Registry. So this, in this study, they reported findings from both responders as well as survivors. They used data from 11 state cancer registries. Expected data was based on the state of residence. And again, this is an update also of an earlier study, of Li *et al*.'s study from 2012. And actually, here I've got expected cancer rates are based on New York State data. So, unlike the earlier study, with this study, the women did not need to live in New York State on 9/11 to be included in this study. This study included 5,000 women who were involved in rescue/recovery and 18,000, almost 19,000 women who were survivors who were not involved in rescue/recovery.
And so, in this paper, findings were only reported for uterine cancers that were identified, diagnosed between 2007 and 2011. That earlier paper reported findings for the earlier time period, 2003-2007. But for both time periods, the findings were very similar. So, for rescue/recovery workers, the responders, you can see that the standardized incidence was 0.82, again less than 1, indicating protection, but it wasn't statistically significant. For survivors, it was a little bit above 1 so maybe, possibly a slightly increased risk but again, not statistically significant, which means that that could just be due to chance. So, for it to be statistically significant, the confidence interval has to exclude the number 1, and you can see both of those confidence intervals include the number 1 in that interval. So that means it's not statistically significant. And again, no dose-response analyses were reported for uterine cancer.
Now we're moving to mortality studies, so these are women who died of uterine cancer, and so this next report is a mortality study of the general responder cohort. It's a prospective cohort mortality study where they follow women over time. In this case, they followed a little more than 4,000 women, again, responders. Deaths were ascertained through the National Death Index, which is basically a census of all the deaths in the country. So, they looked at deaths through the year 2011. They only found 2 uterine cancer deaths, so this is a standardized mortality, was 0.65, again less than 1 suggesting that women responders have a

reduced risk for uterine cancer, but it was not statistically significant. But you can see that there is a wide interval there, suggesting that there's a lot of, just a lot of—because the sample size is so small, you don't, you really, there's no indication that there's an association.

And I should actually mention that uterine cancer, this is for female genital cancers. So, these authors didn't even report findings for uterine cancer separately. So female genital cancers would include cervical as well as uterine cancer.

And then another mortality study, this is a mortality study of the World Trade Center Registry. Again, a prospective mortality study. This one was published in 2018. It's an update of an earlier paper they published in 2011. Includes a little more than 6,000 women involved as responders, almost 40,000—21,000 women, almost 40,000 total but 21,000 women who were survivors. Again, the deaths were ascertained both through the New York City Vital Records and also from the National Death Index. In this study, what the authors did is they told the reader that they examined 119 minor categories of causes of death, one of which—one of those minor categories is uterine cancer. But in the paper, they only reported statistically significant results for these minor categories. And in this paper, they did not report results for uterine cancer, which leads the reader to believe that since they didn't report results for uterine cancer, the findings for uterine cancer were not statistically significantly increased.

But they did report results for all female genital cancers and again, this is where uterine—basically uterine and cervical cancer are combined. And you can see for responders, the standardized mortality is less than 1. It's not significant. For survivors, it's elevated, again mildly elevated, 1.17, meaning a possible 17% increase but again, that's not statistically significant. But it is, for survivors, it is based on 43 cancers—43 cases with uterine cancer, and again no dose-response analyses.

So that covers all of the 9/11-exposed—studies of exposed 9/11 subjects, and in conclusion, the nine relevant studies do not provide consistent evidence that uterine cancer incidence or mortality is elevated among World Trade Center responders and survivors. So, the requirements of Method 1 were not met because collectively, these studies do not demonstrate a potential to provide a basis for a decision to add uterine cancer to the list.

So next we went to Method 2, which we looked for a causal association between the cancer and a condition already on the list.

And so, estrogen-secreting tumors have been found to be associated

with endometrial cancer, but these estrogen-secreting tumors are very rare. So, one type is these granulosa cell tumors of the ovary, and so this is the most common type of estrogen-secreting tumor but even this one is very rare, of about 4 cases per million women. So earlier, we talked about in the Program, we consider a rare cancer as one that's 15 cases per 100,000 persons, so this is, you know, very rare. And the granulosa cell tumors only account for 4%-6% of all ovarian malignancies. So that's going to be rare to find endometrial cancer associated with these.

There're also adrenocortical cancers. Again, those are rare—0.7-2.0 cases per million population. The estrogen-secreting variety is even rarer, and so it's even rarer than the 0.7-2.0. Generally, if you have an estrogen-secreting adrenocortical cancer, it's going to produce breast tenderness or dysfunctional uterine bleeding. We can only find one case report that linked these estrogen-secreting adrenocortical cancers with uterine cancer, so just one case report.

So, in conclusion, for Method 2, estrogen-secreting tumors are rare, and so uterine cancer would only be covered only for members who had both uterine cancer and a certified estrogen-secreting tumor.

So then for Method 3, and as a review for Method 3, so to be covered under Method 3, both of these criteria have to be met. So, the agent has to be a 9/11 agent, so a chemical, physical, biological or other hazard has to be included in the inventory of 9/11 agents; and that agent has to be determined by NTP to be a known human carcinogen or reasonably anticipated to be a human carcinogen, and IARC has to determine that there is sufficient or limited evidence that the 9/11 agent causes that specific type of cancer. So, it's got to be an IARC Group 1, 2A or 2B for that specific cancer, so in this case for uterine cancer.

And then, so we reviewed the available evidence for endocrine-disrupting chemicals causing uterine cancer, and so the definition for endocrine-disrupting chemicals varies by the authoritative organization that issued the definition, but they're not identical but they're similar. So, I provided the World Trade Center—the World Health Organization, the WHO's definition here, which, "An endocrine disruptor is an exogenous substance or mixture that alters function or functions of the endocrine system and consequently causes adverse effects to an intact organism, its progeny, or (sub)populations."

So, these are the 9/11 agents that are considered endocrine-disrupting chemicals. So, dioxins, perfluoroalkyl and polyfluoroalkyl substances or PFAS chemicals, the phthalates, polybrominated diphenyl ethers, the polychlorinated biphenyls or PCBs, and cadmium. But none of these

EDCs, these endocrine-disrupting chemicals, have been found by IARC or EPA to cause uterine cancer. So that concludes for Method 3, that kind of rules out that method.

So, but there are additional considerations. So, per the Zadroga Act, the STAC may consider any scientific evidence it deems relevant to determining whether or not there is sufficient support for the addition of uterine cancer to the list. So, as a result, we have accumulated additional information that the STAC may wish to consider in its deliberations. So, I'm going to briefly cover that now.

So, one is the mechanisms of endometrial cancer development, and so when you review the mechanisms for endometrial cancer development, they're not unique. They're not really that much different from, or different at all, from the mechanisms that you find in other types of cancers. So, the mechanisms of Type I endometrial cancer don't markedly, as I mentioned, don't markedly differ from those at other cancer sites, and the Type I endometrial cancer accounts for 80% of all endometrial cancers. The mechanisms for Type II are not as well-known, so we can't say all that about the Type II endometrial cancers.

So, for example, gene mutations found in Type I include those in PTEN, β-catenin and K-ras genes. So PTEN inactivation is found in endometrial cancer, but it's also found in malign ant melanoma, brain tumors, and ovarian, thyroid, breast and prostate cancers. β-catenin and K-ras mutations are also found in various other human cancers in addition to endometrial cancer.

The next bullet talks about mutations in Type II endometrial cancer. So, we know a little bit about Type II, and these are thought linked to oncogene HER-2 or the neu and tumor suppressor gene p53. So, the HER-2/neu gene mutations are also found in breast and ovarian cancers, and p53 gene mutations are found—are a frequent, frequent mutation in human cancer.

And then you have your microRNAs, which are short noncoding RNAs that regulate gene expression. And so, if you have suppression of that activity, that can lead to cancer promotion or initiation. So, the microRNAs inhibit DNA methylation in cancers and are referred to as tumor suppressor—or those that inhibit DNA methylation are referred to as tumor suppressor microRNAs. So, you have miR-152 is a tumor suppression microRNA in endometrial cancer, and if the activity of that is suppressed then you have, you see that more in endometrial cancer. Likewise, you see similar suppression in other types of cancer, including acute lymphoblastic leukemia, gastrointestinal cancer, and

cholangiocarcinoma.

Then there is the issue of sex disparities in occupational cohort studies. So, many epidemiologic studies of endocrine-disrupting chemicals involve occupational cohorts. And in these cohorts, typically, there's few or no women. So female is, quote/unquote, a “rare gender” in occupational epidemiologic studies. And because many of these studies don’t, didn’t include women or included low numbers of women, perhaps this could explain the paucity of uterine cancer findings that would support adding uterine cancer to the covered condition list.

So, for an example, asbestos. So, as you know, asbestos is a well-known carcinogen. Many studies have been published. If you look at the IARC review of asbestos, they’ve got about 350 publications reviewing toxicity of asbestos. We can only find 4 that reported risk of uterine cancer in women. So that’s some evidence that, you know, you don’t see a whole lot of studies of women in these occupational cohort studies. And even these 4 studies, not all of them were occupational studies. So out of the 4, 2 actually found significantly elevated risks, and these were asbestos-exposed workers. One found a not significantly elevated risk. It involved a cohort of female residents of an isolated asbestos mining town, and it’s asbestos workers. One found a non-significantly reduced risk, and those were wives of asbestos workers. So, but it should be noted that out of these 4 studies, only 1 clearly reported risks for uterine cancer. For the other 3, it appears they lumped uterine and cervical cancer together.

So I’m going to talk about these four studies in a little more depth, but IARC’s conclusion for asbestos is it is carcinogenic to humans, and it’s based on sufficient evidence for, in humans, for mesothelioma, cancers of the lung, larynx, ovary, pharynx, stomach, and colorectum. So, in IARC’s review, they made no mention of uterine cancer or even of cervical cancer.

So, the first study involving asbestos was a study of, a cohort study of Italian asbestos cement workers. So, it was a cohort that included 777 women who were employed between 1950 and 1986. The plant closed in 1986. They calculated standardized mortality ratios, so they looked at death, uterine cancer deaths. And again, it’s not clear if they included cervical cancer in their outcome. They compared the observed death rates with the region of Italy called Piedmont, and they restricted their analyses to deaths that occurred between the years 1965 and 2003.

So, in this table, I’ve got, in the first column, employment duration; second column, observed number of uterine cancer cases; expected number of uterine cancer cases; and then the standardized mortality

ratio, and 95% confidence interval. And you can see at the bottom, in the bold, you can see the total is significantly elevated, at 2.57. So basically, over twofold elevated risk for uterine cancer and possibly cervical cancer combined. And the authors do note that typically, you like to see a monotonic—meaning as duration of employment increases, your risk should increase, but you don't see that monotonic, that continuous increase. It kind of bounces around. So, the authors called that "unstable". But nonetheless, you do have the total there is statistically significant.

Then there was another study of, a cohort mortality study. These are women, Italian women who were compensated for asbestosis. So, these are all women who had asbestosis. And out of the 631 women with asbestosis, 277 of them died. This was a difficult study since they had to peruse records, registers, office records, in town all over Italy looking to determine if people were alive or dead, so just a very labor-intensive study. They calculated standardized mortality ratios, and used national rates for comparison, and so they restricted the analyses only to deaths that occurred between 1980 and 1997.

And again here, for these women who had asbestosis, they found that they had an increased risk of dying of uterine cancer. So again, a 2.56 risk of dying of uterine cancer, similar to that previous study we looked at, and this is based on 7 cases of uterine cancer deaths.

So, the next study is one that took place in Australia, in a remote town called Wittenoom. I'm not even sure if this town still exists. They describe it as an isolated mining town, where the living and working conditions were hard. The population was largely transient, with a low socioeconomic status. So, in this study, they did actually two types of study. They did a cancer incidence study, and they also did a case-control study. Cancer incidence study, they looked at, they used the background rates for Western Australia, and obtained incident cancer cases from the Western Australian Cancer Registry for the years 1982 to 2006. And then they also did a nested case-control design where cases were identified from 1960 to 2006 and compared them to other women in this population.

So, the cancer incidence, the standardized incidence ratio you can see is 1.23, 95% confidence interval; it's not statistically significant since it includes 1 in the interval, and it's based on 13 cases.

The nested case-control study, so it—they looked at a number of different when they did this nested case-control study. So they looked at, and they found that they didn't find any significantly elevated risks, but they did find

some non-significantly increased risks for intensity of exposure, but they never defined how—they never defined intensity, so it's not clear how that was measured. Its ratio was 2.3. And if they lived with an asbestos worker, that was also increased risk for uterine cancer. But they also found decreasing risks, low risks, risks below 1, for other risk factors including increasing age at first exposure, and duration of exposure. So as your duration of exposure increased, the odds ratios were actually below 1 for any duration of exposure greater than one year. And also, odds ratios were significantly below null for increasing time since first exposure, washed dishes, or was a former asbestos worker. So again, odds ratios below 1.

And then the last study, this is a study of, a mortality study among wives of workers in the asbestos cement industry in Italy. This is a study of the same plant as the earlier paper I described, the Magnani *et al*., 2007 paper. That was the first paper, first asbestos paper that I summarized. In this paper, the cohort included 1,740 women with domestic exposure, and 777 women who were blue-collar workers employed between 1950 and 1986. So, the vital status was ascertained through the registrar's office, again very labor-intensive, looking through registrar's offices records in towns all over this part of Italy. Calculated SMRs, again, the comparison rates were Piedmont regional rates from the region of Piedmont in Italy. Analyses were restricted to deaths that occurred between 1965 and 1988, and as you can see, there was a non-significantly reduced risk for uterine cancer among these asbestos-exposed women, based on only five cases. No dose-response analyses were reported for uterine cancer.

So then moving on to dioxin, tetrachlorodibenzo-p-dioxin, TCDD, the most toxic congener of dioxin, so we identified two papers that looked at dioxin.

So, one was a study of Seveso, Italy residents where there was an accident in 1976, an explosion took place at the factory, contaminated the region around that factory. And so, there were studies done that compared people who lived in different zones based on the proximity to where the explosion occurred. So, the highest exposed individuals were those in zone—the high exposure zone that we'll call here. I think that was actually called "Zone A". Then there were people in the medium-level zone, 4,821, and 31,643 in the low-level zone. And then in the unexposed zone, there were almost 182,000 individuals. So, they calculated age, sex, period-adjusted rate ratios, so this is an incidence study. Cancer incidence cases were ascertained through a 120-hospital network of the

Lombardy region of Italy between 1977 and 1996. And so, the risks here are for the different exposure areas based on where you lived at the time of the explosion. So, the highest risk was, for uterine cancer, was in the high exposure zone, so the area closest to that plant that exploded, but the relative risk was 1.24, not significantly elevated but it was elevated, based on only one case. In the medium zone, it was, the risk was below 1 at 0.6, and that's significantly reduced risk though, based on 3 cases. And again, the low exposure, again below 1, not statistically significantly below 1 though, based on 27 cases.

The other dioxin paper that we found was from Kogevinas. That was published in 1997. It's an international cohort study, a retrospective mortality study of 22,000 male and female workers. They didn't break out the number of female workers. But these are all individuals who were exposed to phenoxy herbicides, chlorophenols, and dioxins, basically in the production of these chemicals that were contaminated with dioxin from across 12 countries. They reconstructed job exposure matrices using job records, company exposure questionnaires, as well as serum and adipose tissue dioxin levels. The follow-up period for each of these cohorts differed but overall, it extended from 1939 to 1992. And uterine cancer was elevated in this group—SMR of 3.41—but again, a wide confidence interval that included 1 so it wasn't statistically significant and was based on just 3 cases.

Then if you look at PCBs, there's a few studies that we identified that we found some relationship with uterine cancer. The first one is a paper from Donat-Vargas published in 2016, involving a Swedish—that was a Swedish mammography cohort study looking at dietary, so dietary PCB exposure. They had almost 37,000 cancer-free women at baseline, took a dietary history and based on that history, ascertained what their PCB exposure was, and identified, then prospectively identified incident cancer cases through linkage to the Swedish Cancer Registry through 2012. So, they did find that endometrial cancer risk was highest in the tertile of PCB exposure, so an adjusted relative risk of 1.21, again not statistically significant. And the test for trend was 0.54, so not a significant trend of increasing exposure with increasing risk.

Then we have the study from Ruder, which this is a paper that we recently identified and is not included in the White Paper, so we need to update the White Paper to include this study. This is a study from NIOSH. It was a retrospective mortality study of almost 25,000 workers, almost half of which—or actually over half of which—were women, who were exposed to PCBs at electrical capacitor manufacturing plants located in

Indiana, Massachusetts and New York. Mortality was followed through 2008. Now, for the entire cohort, the SMR for uterine cancer was 1.07, and they stratified it based on short-term workers and long-term workers. I don't have how they define "long-term worker". But you can see that the vast majority of cases were among long-term workers, and the risk was elevated but not statistically significantly elevated, at 1.18. They also did a dose-response using job exposure matrices to calculate cumulative PCB exposure, and did find a trend, a statistically significant trend, of increasing dose leading to increasing risk for uterine cancer. The standardized rate ratio at the highest exposure was not significant but nonetheless, you do have that statistically significant trend indicating that increased PCB exposure is related to increased uterine cancer risk.

And then we have, finally, this is the last one I'll be talking about in depth, is cadmium. So, we have two papers that looked at urinary cadmium, the relationship between urinary cadmium and risk for uterine cancer. And actually, these two papers are also papers that we recently identified, are not found in the White Paper, but we'll update the White Paper to include these two cancers—or two studies.

So one, the first study was published in 2012. It's a prospective cohort mortality study of NHANES data. So, these are individuals who participated in NHANES, which is the National Health and Nutrition Examination Survey. It's conducted by the CDC. It's a nationally representative survey. Basically, every two years, they release new data. So, these are data of individuals who participated between 1988 and 1994. It included 10,636 women who were cancer-free at the time that they were interviewed as part, for NHANES. And as part of that exam, the subjects provided a urine sample where cadmium was measured, and then they followed these people over time, up through 2006, via the National Death Index. They found that the adjusted hazard ratio for a doubling of your urinary cadmium basically increased your risk of uterine cancer by 50%. That was statistically significant, based on 7 cases of uterine cancer. They also looked at, divided the subjects into quartiles, and compared the highest quartile with the bottom three quartiles. And when they did the analysis that way, they did not find a significantly elevated risk. It was just at 1.03; not significant. So, there were only 3 cases in the highest quartile versus 4 cases in the other three quartiles so again, a total of 7 cases identified in that study.

And the other study that was published in 2017, it's not quite as strong. It's a case-control study looking at, where they identified cases from cancer registries in three states—Arkansas, Iowa, and Missouri. They

identified 631 incident uterine cancer cases diagnosed between 2010 and 2012. They age-matched them to 879 controls who were identified via voter registration records, and then they measured cadmium in the urine, but it's not clear how many subjects actually provided urine, or when the urine—when the, how soon after the cancer was the urine collected, and when was it measured. So, there's a lot of questions in this study, but nonetheless, it did find that, similar to the previous study, the Adams study, that the adjusted odds ratio for when you double the amount of cadmium in the urine, there is a significant elevation in uterine cancer risk. So, the odds ratio was 1.22, statistically significantly elevated.

And then there's one other study that looked at cadmium, and again this is just previous to—similar to one of the PCB studies where they took a diet history of women in Sweden, this time took a dietary history and extracted, ascertained the amount of cadmium that they may have consumed. This study included a little more than 30,000 postmenopausal women who were cancer-free at baseline. It did a food frequency questionnaire at baseline and in 1997, so ten years apart. They then linked the population to the Swedish Cancer Registry, and they did find that endometrial cancer risk was elevated in the highest tertile of the baseline dietary cadmium consumption, with a relative risk of 1.39, statistically significant, and also a trend of increasing risk of uterine cancer with increasing dietary cadmium consumption.

So, then I just wanted to close out with, these are other—these are endocrine-disrupting chemicals that are included in the Inventory of 9/11 Agents. So, I've got the chemical, the agent, these are all either IARC Group 1 or Group 2B. I've got the cancers that IARC has determined the chemical causes, but you can see that in none of these will you find uterine cancer.

I want to call your attention to TCDD, where IARC basically says that for TCDD, it's related to, causal for all cancer sites combined, for lung, soft tissue sarcoma, and non-Hodgkin lymphoma. But it should be noted that IARC does not interpret that "all cancer sites combined" means that every cancer may be caused by dioxin. It's more that probably, since lung cancer is so common, lung cancer is probably driving the finding for all cancer sites combined.

So, I'll just give you like a few seconds to study this slide. It's basically, I think, my last slide.

So, this is actually my slide. So, the Administrator is seeking a recommendation from the STAC regarding whether there is a reasonable basis for adding uterine cancer to the list of World Trade Center-related

health conditions. So, with that, I'll open it up to questions.

DR. WARD: Thank you, Geoff. So, we only have about five minutes left to our scheduled break, which is great because I wanted to give the Committee of where I think we should be going. So, I was thinking at first, we should open, as Geoff said, the floor to questions for Geoff. But then if we have time before the close of the day today, I'd like to open the floor for as many Committee members as possible to kind of express their perspectives on the Administrator's question, and if they have any specific thoughts about the scientific rationale, to share those as well. That will prepare us—that will put us in, I think, a good position to plan our agenda for tomorrow, which starts off with me giving a recap of today's discussion. So, I think we have five minutes if anybody wants to start with a question. I see Mariama's hand up.

MS. JAMES: Hi, I had three actually, so I don't know if we have time. But the first is really more of a clarification. As I was sitting here listening to the gentleman speak about hormones, basically, and you know, as a female—and the toxins—my first thought was, well, it sounds like we're talking about the endocrine system. So I had a question from them, and then we made it to Method 3 where, and in fact it'd come up. And so, I just want to make sure I understand. The reason Method 3 can't be applied is basically because there's no precedent for it, right? Is that correct?

DR. CALVERT: So, the reason that we can't use Method 3 is because you have to, at least IARC has to determine that a 9/11 agent causes uterine cancer. So, to our knowledge, our review, IARC has not determined that any 9/11 agents cause uterine cancer.

MS. JAMES: But from the perspective, if we're talking about the female reproductive system, we're talking about the endocrine system essentially, and if we—if there are known endocrine disruptors present, why couldn't it be applied?

DR. CALVERT: Well, let me go back to—back to my slide.

MS. JAMES: I'm sorry.

DR. CALVERT: So, let's see if I can get back to that slide. So, this is, for Method 3, you have to meet these criteria. So, you have to have a chemical, basically a 9/11 agent that's on our list of 9/11 agents, and that 9/11 agent has to be a known human carcinogen according to NTP. And then, but here—this is kind of the key—IARC has to determine that that agent causes uterine cancer.

MS. JAMES: I see, okay.

DR. CALVERT: And so, yes, IARC has not determined that any of the agents on the 9/11

caused uterine cancer. So that's why we can't use Method 3.

MS. JAMES: That clears that up. Okay, and with regard to the Italian building, was the size and materials with which that building was made, developed, comparable to those at the Trade Center? Or does that even matter?

DR. CALVERT: So, are you talking about the Seveso in Italy, the explosion?

MS. JAMES: Yes. Yes.

DR. CALVERT: So that was—that was, if I recall correctly, that was a plant that was actually manufacturing herbicides, and certain types of herbicides like Agent Orange. So, they weren't manufacturing Agent Orange but the same kind of chemicals that are in Agent Orange, they were making at that plant. It exploded and it caused just a large area to be contaminated with this dioxin, this dioxin-contaminated mixture of herbicides. So, you know, dioxin is a 9/11 agent so at this, you know, this was not like an office tower like the World Trade Center building. This was a factory that was making herbicides.

MS. JAMES: So, would we make—would it make sense to think of it from a perspective of maybe what occurred at the Trade Center was like ten times worse, you know, magnified, versus what happened, occurred here?

DR. CALVERT: I would guess, you know, they have measured dioxin levels in people who were affected by this Seveso explosion, and dioxin levels have been measured like in the, boy, if I recall correctly, thousands of parts per trillion. Very, very high. I think with the World Trade Center, I'm not sure I've even seen any reports of dioxin levels more than like maybe 50?

MS. JAMES: Interesting, okay.

DR. CALVERT: So yes, the dioxin levels weren't as high at the World Trade Center as they are at this plant.

MS. JAMES: And lastly, considering that the Health Program doesn't really do cancer screenings, one of your last slides was cadmium, was it?

DR. CALVERT: Yes. Cadmium.

MS. JAMES: Are there any people in the Program that you know of, or that have been examined in any of the research projects, that got—you know, got a urine screening and this was found? Anybody in the Program, that cadmium was found in their urine? Because I don't remember ever giving urine when I go to a monitoring visit or something, for example.

DR. CALVERT: Yes. I would—because the cadmium wouldn't stay in your body if it was from 9/11, a 9/11 exposure.

MS. JAMES: That makes sense too, okay.

DR. CALVERT: It typically wouldn't—so you would have had to have grabbed that urine or measured it in the blood pretty quickly.

MS. JAMES: Okay, that makes sense.
DR. CALVERT: So, they did, they have measured that people were exposed to cadmium but I'm not—there probably are studies that looked at body burdens of cadmium. I'm not sure what they are—
MS. JAMES: There's no way to, like, screen for it now, basically.
DR. CALVERT: Not now, no.
MS. JAMES: Okay.
DR. CALVERT: But you know, we do, the Program does screen for cancers that are recommended, where the screening is recommended by the U.S. Preventive Services Taskforce. So, we do—but uterine cancer is not a type of cancer that's recommended to be screened for.
MS. JAMES: I see.
DR. CALVERT: Nonetheless, if a patient came to a monitoring exam complaining of symptoms of uterine cancer, we would, the Program would get that woman worked up to see if she had it.
MS. JAMES: Thank you.
DR. CALVERT: You're welcome.
DR. WARD: Thanks. So, I think we should take our break at the scheduled time. It's 2:46. So we come back around 3:01. And I'm reminding everybody not to leave the meeting, just to mute and stop your video as you step away. Thank you.

[Break.]

DR. CARREÓN-VALENCIA: I also want to welcome, once again, the members of the public that are following this meeting. We will do one more roll call to make sure that we have a quorum. Liz, are you in?
DR. WARD: I am here.
DR. CARREÓN-VALENCIA: Sophie Balk. We'll get back to her. Chandra Davis? No, she is not here. Thomas Dydek.
DR. DYDEK: Present.
DR. CARREÓN-VALENCIA: Thank you. Mariama James.
MS. JAMES: Present.
DR. CARREÓN-VALENCIA: Anita Jose.
DR. JOSE: Here.
DR. CARREÓN-VALENCIA: Michael Larrañaga.
DR. LARRAÑAGA: Present.
DR. CARREÓN-VALENCIA: Catherine McVay Hughes.
MS. MCVAY HUGHES: Present.
DR. CARREÓN-VALENCIA: John Meyer.

DR. MEYER: Yes.
DR. CARREÓN-VALENCIA: Debra Milek.
DR. MILEK: Present.
DR. CARREÓN-VALENCIA: Lawrence Mohr.
DR. MOHR: Present.
DR. CARREÓN-VALENCIA: Nick Newman. Jason Ostrowe.
DR. OSTROWE: Present.
DR. CARREÓN-VALENCIA: Robin Sassman.
DR. SASSMAN: Present.
DR. CARREÓN-VALENCIA: Aarti Surti.
DR. SURTI: Present.
DR. CARREÓN-VALENCIA: Leigh Wilson.
DR. WILSON: Present.
DR. CARREÓN-VALENCIA: Sophie Balk, are you with us?
DR. BALK: Present, yes. Yes.
DR. CARREÓN-VALENCIA: Great, thank you. So, we have 14 members present. We have a quorum. Thanks, Liz. You can continue.
DR. WARD: Thank you, Tania. Our next speaker is John.

STAC DELIBERATIONS

DR. MEYER: Sorry, yes. (Inaudible @ 00:01:50) question. So, one comment, one question for Geoff. It goes into kind of the general problems of risk estimates and SMRs with the World Trade Center studies that we do see, and I'm not sure you can give us this information, but it might be useful to have it perhaps for tomorrow, is how do these risk estimates compare to other cancers that are accepted under the World Trade Center, particularly in the responder cohort? We've seen numbers but we've got kind of a narrow range of studies on uterine cancer. What I don't see, you know, my understanding is sort of the risk estimates for only a few cancers have been sort of maintained above fairly high levels, perhaps thyroid and—thyroid, prostate cancer, and the like. So perhaps, I don't know if you have a ready answer to this or maybe it entails some other looking, but how do these risk estimates, given that we're probably looking at a healthy worker effect or something related to that in the responder group, compare to other risk estimates which are also probably less than 1 given the healthy worker effect in these populations, and yet we have them as distinctly recognized World Trade cancers?
DR. CALVERT: Thanks, John. Yes, you're right. With the—recall that the studies that looked at uterine cancer only compared their findings to the external

population, and if I recall correctly, when you look at, compare pretty much, I think all the other cancers, I don't know if there's even any cancer that was significantly elevated when you compare it to the external population. I could be wrong; don't quote me on that. But it's more when we compare the higher-exposed with the lower-exposed. That's where we, that's where you see the elevations, and that's where you see like the elevated prostate cancer, elevated thyroid cancer, non-Hodgkin's lymphoma, malignant melanoma. So those are some of the cancers that are elevated in the World Trade Center population. So, in those studies, they haven't found that every cancer that we cover is elevated in 9/11 populations. So it was, as Jess explained in her lecture, a lot of the cancers that we cover, we cover because of Method 3.

DR. MEYER: Yes, yes.

DR. CALVERT: Basically, IARC recognizes them as carcinogenic for those cancers.

DR. MEYER: Yes, so I think because we've got so few cancers really compared to the mass that get covered, I think it maybe behooves us to—I'm not saying your work wasn't good there—but to remember that most of those, almost, very few meet criteria 1 I expect, if you'd agree with that there. So that's a, just a point I want to make there, and maybe we should look at some of the other things that we cover.

And just one comment. I know we're sort of used to speaking in—we speak in kind of code or shorthand and the like there, but I just want to, as we go on with our deliberations, and perhaps write—you know, writing a position paper, I want to avoid the use of the word "protective" for things that show SMRs or risk below 1. And I think that got brought out when—somewhere along the line, I think as shorthand, you referred to smoking as "protective" and absent doing an RCT of uterine cancer and smoking, we can't really genuinely refer to that. But I think it also, it does our communication with the outside world and population a disservice if we do that and don't better interpret that than the shorthand of "protective". That's just my, you know, just one of my rants there and I'll leave it alone from there.

DR. CALVERT: No. Yes, my bad, right? You're right. You're totally right. I fully agree. And even the evidence, if you really investigate it, it's not that as strong as the other things like lactation, increasing number of pregnancies. But yes, we don't want to be sending that message that people can prevent uterine cancer by smoking. Yes. Right. Yes, we don't want to use that word "protective", you're right. Thank you. Thanks, thanks for bringing that up.

DR. WARD: Thanks. Debra?

DR. MILEK: I wanted to raise the issue of pathology. Our two earlier guest speakers

both mentioned types of uterine cancer that are not the most common cancer, which is adenocarcinoma. And the clear cell cancer I believe is even less common than uterine sarcoma. So, I'm wondering if—and I think I know the answer—if any of the studies have actually looked at the pathological type of uterine cancer as opposed to the bucket of uterine cancer.

DR. CALVERT: I don't recall seeing any studies that looked at anything but the broad bucket of uterine cancer. So, all the studies that I reported, and even as I mentioned, some of the studies combined cervical with uterine, so even too broad of a bucket. But yes, no studies that I recall broke it out by subtype.

DR. MILEK: I'm wondering if the World Trade Center-exposed uterine cancer is a perhaps more uncommon and more aggressive type of cancer that is being diluted as we look at just uterine cancer, which predominantly is adenocarcinoma. Just a thought.

DR. CALVERT: There's no, yes, no evidence of that. So, the studies that I reported, none of them found significantly elevated risks and, if anything, they were very low risks, below 1. Again, the problem being that—it would have been nice if they did some internal comparisons, so comparing a lower-exposed with a higher-exposed group, as many other studies have done with cancers and other World Trade Center outcomes.

DR. MILEK: Thank you.

DR. CALVERT: Thank you.

DR. WARD: Thanks. So, I don't see any other hands up with questions, and I don't mean to say you can't ask questions later but I just want to get the obvious questions out of the way so that, you know, we can really open the floor for people to either make comments on their thoughts or to ask questions. Tania?

DR. CARREÓN-VALENCIA: I just want to let you know that Dr. Newman is back in Zoom.

DR. WARD: Thank you. Debra, your hand is still up. Did you have—?

DR. MILEK: No, I'm sorry.

DR. WARD: Okay. It's okay. Okay, Jason?

DR. OSTROWE: Thank you. Thank you for the presentation, Geoff. Hopefully you can maybe clarify some of this for me. I want to make sure I have my details correct. When you were discussing the relationship between asbestos and uterine cancer, there was one study that you had cited that differentiated between direct and indirect exposure, and if I recall correctly, there were statistically significant differences between those two groups as it relates to asbestos exposure and incidences of uterine cancer. So, if that is in fact correct, wouldn't that suggest that survivors

and responders, female survivors and responders to the World Trade Center, all who were directly exposed, would be more likely to have been exposed to asbestos and therefore more likely to develop uterine cancer? I'm wondering if you can just maybe talk a little bit about that.

DR. CALVERT: So, I summarized four papers that looked at asbestos and uterine cancer risk. So, in two of those studies, they found significantly elevated risks for uterine cancer. The problem with those two studies though is that they combined uterine and cervical cancer. So, the one, there was only one study that clearly examined uterine cancer separately, and that study did find an elevated risk for uterine cancer from asbestos exposure, but it wasn't statistically significant. Then there was that fourth study which, probably the weakest of the studies, which did not find—found that the risk was below 1, so, but again that was non-significantly below 1. And three of those studies were in Italy. The one that was statistically significant that only led to uterine cancer, that was from Australia. Does that answer your question, Jason? Sorry.

DR. OSTROWE: I'm going to go back and take a look at the White Paper so I can parse out the detail.

DR. CALVERT: Okay, yes. Yes, all those papers are in the White Paper, described.

DR. WARD: Thomas?

DR. DYDEK: Yes, I've got a follow-up question about asbestos. Would it even be possible to contact the Italian researchers and try to disengage the two types of cancers?

DR. CALVERT: Well, yes, anything's possible. Those studies, I think, you know, I think they—I want to say they're about ten years old.

DR. DYDEK: Yes.

DR. CALVERT: But I think at least the Magnani, I think that individual I think is still active. That might be possible. Whether they would respond, not sure. But yes, good question.

DR. DYDEK: I'm thinking if asbestos were a causative factor. Just because you haven't seen anything in the WTC group may be a consequence of the latency period, which could be as much as 40 years. So just because you haven't seen anything, or I think there were two cases I believe in the WTC group, but there could be more as we go forward. I guess you can't have a crystal ball. But of those two cases, if there were two, I assume they both had hysterectomies, do you know?

DR. CALVERT: That information is not reported in those papers. They generally, these epi studies don't describe how—what type of treatment these individuals received. But there are actually, like in the most recent study from 2021, the combined cohort of all the responders, they had 31 cases of uterine

cancer.

DR. DYDEK: Okay. I'm wondering if those tissues were retained, if it's possible or ethical to look for asbestos bodies in those tissues.

DR. CALVERT: That would be a fair amount of work. We would have to go back to the women or the next of kin to get permission to try to access those tissues, and then if they agreed, if we could reach, contact them, and they agreed, then we'd have to see if even the tissues were preserved anywhere. So that's not even a guarantee. So that would be, typically when you do those types of studies, it's done more prospectively. You know, you'd know at day one that you want to collect these samples. So, when your subjects develop these cancers, you're in touch with the pathologist, asking them, hey, can you save a sample for us because we want to study it? So, you know, these are cancers that were diagnosed, what, back in 2016 and earlier if I'm not mistaken. So it would be, yes, that would be—and you know, and even if we got those, I'm not sure, what would you look for? How would they—would you look for; see how they were different from a group not exposed to the terrorist attack? It's, yes, it would be, that would be complicated.

DR. DYDEK: Yes. I am struck by the somewhat similarity between this situation and the talcum powder containing asbestos that's been studied, and they have elucidated a mechanism by which perineal application of talcum powder which probably contained asbestos, those particles can migrate through the uterus to the ovaries. So, it's passing through the uterus anyway. So, I remember one of the public comments was the toilet paper in the porta-potties had dust on it, and that would be a similar type of application to talcum powder used for feminine hygiene. So, this is all kind of conjecture but I'm throwing it all out to the group.

DR. CALVERT: Yes, thanks for sharing that. Very interesting.

DR. WARD: Nicholas?

DR. NEWMAN: Oh hi, I wasn't expecting you to pick up that fast. Well, I was just struck by the last little bit of the conversation here. I mean, I've been peripherally involved in another worker and community cohort related to Department of Energy, like uranium, the processing plant, and you know, I think the comments about latency period is definitely reasonable, as like that cohort, the exposure really ended in the late Eighties/early Nineties, and now there's a blip in the cancer incidence.

And then with regards to the tissue samples, that's something that's been stored along the way for this particular study, so it might be something to consider as, you know, as part of like the ongoing, like, design of what's going on. Like as these cases are coming, that maybe there's some

prospective thought about storing that or saving it or something. But I don't know what the mechanism would be. I mean, the study I'm talking about was, you know, funded initially through—by the large settlement. But then—a legal settlement—but has been now sustained through a bunch of NIH-funded studies. So, I mean, I think some of the questions that are brought up really have more of a research twist to them and not—you know what I mean? So, it might be worthwhile just thinking about that as recommendations come out for the future of the cohort.

DR. WARD: Thank you. I had exactly the same thought. I think there even is a funded project to collect biological—or to collect tissue from cancers that were diagnosed, but I could be wrong. Maybe that's a question that could come up tomorrow when we talk about research recommendations, and maybe Travis can shed some light on that.

I did want to say that, you know, one of the things that struck me when I first started thinking about this is that when we first came out with these recommendations, and the Administrator wrote the rulemaking regarding which cancer sites should be covered, you know, it was in a very different era. I mean we were really, there was much less epidemiology. We were really trying to, you know, think about what sorts of evidence we could use to—at that time, we really didn't consider should we consider—should we recommend that all cancers be covered. We were really looking at it more as a focus of how can we differentiate those cancers that should be covered versus those that perhaps the evidence wasn't as strong. I think now we're looking at it, you know, it's almost like the situation has completely flipped in my mind, and so I'm more thinking along the lines of, you know, is there any possibility that we believe that there could be a causal association between 9/11 exposures and every other cancer, but not with uterine cancer. So, in a way, I think when you're looking at biological plausibility, I mean, I think we all recognize the limitations of the epidemiologic studies. I think we just don't have enough studies of women. We have low power. I think some of the studies that Geoff cited were really about, you know, some suggest—even though IARC has not designated uterine cancer as associated with some of the World Trade Center exposures, there is some positive evidence that exists. But I think maybe the significance of one of those slides that Geoff showed might not have been apparent to all the members of the Committee.

So, one of the reasons he showed the graph which was looking at mechanisms of cancer is that, you know, we do—there is a whole body of science looking at how exogenous exposures cause cancer. And really,

you know, there are very many similarities between how exposures cause other forms of cancer, and how exogenous exposures cause endometrial cancer. So, I think that slide was pretty dense for most people to interpret. Even I, as a cancer epidemiologist, could not have explained all of those things. But I think that is the significance of that slide, and I just wanted to make sure everyone understood that.

You know, another thing that stood out to me as we were listening to the presentations is that Jessica mentioned that one of the criteria for evaluating studies where there is epi evidence is plausibility and coherence with known facts about the biology of the health conditions. So, I think, in a way, that's maybe a good context for us to consider in relation to uterine cancer is the plausibility and coherence of the biology of endometrial cancer with the biology of other cancers that we now consider to be World Trade Center-related.

I did want to, before I stop talking, thank, really thank Geoff and Tania and all the members of the Science Team for the incredibly thorough and thoughtful review. I don't think we could have had a meaningful deliberation on this matter without that very careful, detailed scientific presentation, and the major efforts to make it clear and succinct, and sharing the White Paper. So, I think before we—you know, I wanted to say that before we got caught up in anything else, because it really was an extraordinary effort.

Robin?

DR. SASSMAN: Thanks, Liz. I'd like to just echo what you just said about the information and the White Paper. Very thorough, and you know, I think it can be a difficult thing to try to explain to maybe non-scientific people, but I think they did a really good job.

And the thing that struck me, and I've read this paper two or three times now since we got it, and a couple of things that came out initially was just the—we talked about the epidemiologic, I guess, weakness in that there was a rare female cohort. I mean, it was very small, and so it doesn't really help to bolster any, you know, anything from the epidemiological standpoint. But I just keep going back to pages 27 and 28 of the White Paper in terms of the mechanism of endometrial cancer development. And I just, it's just hard to ignore the similarities in terms of how endometrial cancer develops and the similarities to other cancers. So, I guess I would just encourage all of us to maybe, obviously reread the whole paper, but really look at that closely, because I think it's something that needs to be thought about and considered as we deliberate.

DR. WARD: Thank you. I'm not seeing any other hands raised, but it would be great at

this point if people could just share their thoughts on the matter, you know, what issues are you thinking about, what issues are you—would it be worthwhile for the STAC to consider as we proceed with our deliberations. Catherine?

MS. MCVAY HUGHES: Hi, yes. I just wanted to remind, for the people who weren't here during 9/11 or the first year or so, that there was many, many, many different compounds, and one of the topics that was discussed extensively at prior World Trade Center STAC meetings was the impact of multiple compounds, not just looking at one isolated one, whether it's dioxin or PCB—you know, or cadmium. So, I just wanted to put that on the table, because that was, you know, a sticky topic. And there were fires that went on and flareups that went on for months. I remember seeing them from my apartment even in March of 2002, outside our window.

So, the second thing I wanted to mention was there was a document, it might have been one of the nine comments. It was submitted by three different—six different doctors that had worked extensively on World Trade Center health, and I wanted to know what others thought about it, particularly the page 2. It included Reibman and (Maloney @ 00:27:24) and Harris, Graber, Crowley and (Udasin @ 00:27:28). So, I just wanted to put that document into the discussion. Thank you.

DR. WARD: Would it be helpful to show that document on the screen in case anyone has not had a chance to look at it?

MS. MCVAY: I think that would be helpful.

DR. WARD: I also found it really, a really useful document.

DR. CARREÓN-VALENCIA: I'll look for it and I'll share it.

DR. WARD: Okay. Yes, and one of the things—it kind of relates to what you said, but I don't know. It seems like there are not a lot of cancer specialists or cancer epidemiologists on the team, but if there are people who are, please speak up. But one of the things I was thinking about, and this goes back to research I did when I was at NIOSH, is that you know, in the epi studies that Geoff has cited, which is the entire body of evidence really, no one really is taking into account what PCB congeners are present in the different exposure circumstances. And I actually did a study looking at specific PCB congeners and one of the things I remember from that time period is some of those congeners are considered to be estrogenic and some of them are considered to be anti-estrogenic. So, you know, you really—and it gets back to a lot of our discussions in relation to the first determining issue. And you know, we know so little about the nature of the exposure. So, and for different women or different people, there may have been different PCBs, different

TCDD congeners present, different mixtures of estrogenic and anti-estrogenic compounds. So, we can only go so far. The literature on endometrial cancer and exogenous exposures is extremely limited. And even beyond that, you have to recognize the complexity of these exposures and the complexity of endocrine disruptors in general in relation to cancer.

So, thanks, Tania. I see we have that up on the screen now. So, we can take a minute to read through it.

[Pause.]

DR. CARREÓN-VALENCIA: Let me know when you need me to move it down.

DR. WARD: I'm ready. Okay, yes, I think that second part, why uterine cancer should be a WTC-related, certified condition is probably what we want to focus on.

[Pause.]

Okay, has everyone had an opportunity to read it? Let's go back to the screen with everyone's faces so we know if anybody has their hands raised. Catherine, is your hand still raised, or did you mean to leave it up? Okay.

Okay, this is an incredibly quiet group, so maybe what we can do is just go around the table. Oh, Nicholas, hi. You've got your hand up. Good.

DR. NEWMAN: So, I mean, when I originally read this too, I was kind of struck by the fact that it seemed like this has been kind of singled out as a cancer not to be included, and I couldn't quite understand, like, because a lot of things, we don't know the whole cause of them, you know. And so, if you think of just, mechanistically, it's not implausible that something that affects gene expression and influences prostate, breast, and thyroid cancer, which are already on the list, that it wouldn't, like you know, that endometrial cancer is somehow special or different and that's why it shouldn't be there.

I guess one of the things maybe—and this speaks to my ignorance about the, you know, the issue because I'm not a cancer epidemiologist. I study mostly air pollution. One of the things that I wonder is what is the potential for a kind of latency period, or perhaps, you know, if most of these occur like after menopause, Type I cancers, how many people are in that group now, and would you be able to—are there just not even enough to be able to see the signal yet but the signal is going to be a lot stronger later? That was all.

DR. WARD: Geoff, did you want to comment on that, or Tania?

DR. CALVERT: So, thanks for that, Nick. So, as I recall, the average population in the World Trade Center is roughly like in the low sixties, maybe late fifties. And as I mentioned, the incidence for uterine cancer is highest in the 60-

70 age range of women. So yes, probably the mean/median ages, we're starting to enter the high-risk period. So yes, to an—but in regarding the latency, I'm not sure what the latency would be for uterine cancer, but I would think—well, it's been 20 years since 9/11 so we may have, that may not be an issue any longer. But again, the studies would be, the studies that have been done to date had much lower latencies, so I think that the most recent one were, included cancers diagnosed up to the year 2015, and a lot of them were diagnosed a lot earlier than that. So yes, odds are we don't have—even if there is a true risk there—we may not have sufficient latency at this time to see it.

DR. NEWMAN: All right, thanks.

DR. CARREÓN-VALENCIA: So, the other issue is power. The studies that we review are predominantly male. So, most of them include very, the percentage of women in each of these cohorts, it's small, which would have an effect on just observing an association here.

DR. WARD: Thank you. Sophie?

DR. BALK: So just to pick up—sorry. Just to pick up on what others have said, to me, the issue of excluding uterine cancer, it fails a logic test. Like, why would uterine cancer be different than all the other cancers? It doesn't make sense to me. I know we have incomplete data. We were, we did hear some data about asbestos and cadmium and the positive, statistically significant relationship with uterine cancer if I recall correctly, so we do have some data, but we have incomplete data. I think in pediatrics, we often make decisions that are protective in the face of incomplete data, and this may be one of these situations. I particularly worry about the children who were exposed. Latency period we know with endocrine disruptors is (inaudible @ 00:37:02), sometimes a lower dose has a bigger response than a higher dose. So, I wonder what will happen to the kids that were living in the area or going to school. But I guess my main point is that the logic doesn't make sense. It doesn't make sense to exclude this cancer.

DR. WARD: Anyone else?

MS. JAMES: Yes, I raised my hand and I see—

DR. WARD: I'm sorry. Your bookcase is the exact same color as your hand.

MS. JAMES: It's (totally @ 00:37:41) on the wall now. I'm also in agreement with the fact that it's nonsensical for uterine cancer, especially if we all seem to be on the same page that it's plausible and even perhaps likely that it is related and connected, that this is the one cancer that is not covered. And more to what Sophie was saying, you know, I've said this many, many times, that we cannot base, like, developmental things with the

children on 40-year-old men, and this—which is what we've done, you know, the whole time, with all due respect to the first responders. You know, I absolutely have the most respect for them. But we cannot determine the outcomes for children based on 40-year-old men or 50-year-old men or whatever it is. And the same is true for women, you know, and if there are not enough women that are examples, but we do have enough examples and enough common sense to tell us that something is extremely likely, I think it only makes sense that it should be added.

DR. WARD: Thank you. Anita, I'm sorry. I didn't see your hand either. It's the brown bulletin board. But go ahead.

DR. JOSE: That's okay, no problem. You know, I just, I don't have any—I just wanted to sort of echo some of the things that have been said before. I'm not an expert in cancer but, so I think some of the more technical stuff I'm kind of learning as I go, but the major sort of thoughts that I had when I read this was really about sort of the power to detect the difference when some of, many of these samples have not very many women in it. I took a look at, you know, a CDC website that talked about the number of first responders and survivors that were women. I think the overall sample, about one-fifth of them are women, and I'm not sure how many of them are included in these studies or consented to them. So, I agree with the power issue, and the other thing that I think was already brought up but was on the forefront of my mind is the age issue. So, it looks like the majority of members of the World Trade Center Health Program are 55-64, so they're just entering this period of highest risk, and I kind of think that maybe there's an opportunity here to sort of get in front of a potential significant elevation of the rates of uterine cancer.

DR. WARD: Thank you. Sophie, is your hand up?

DR. BALK: No.

DR. WARD: Okay. It looks like it is on my screen, so just checking. Aarti?

DR. SURTI: Hi. I just wanted to thank everyone for summarizing the scientific data. It was very easy to digest and was helpful in advance of this meeting. I think my reflection on reading the White Paper is that, you know, the representation of women in these studies has been quite small, and the rigor that's expected of Methods 1, 2 seems at odds with maybe just the lack of sample size, or rigor with some of the definitions around reproductive cancers and the pathology of uterine cancers. And I do believe that there's a plausibility that there's relationships between the exposures and potential development of uterine cancer much later on in life, especially for folks who may even be in the younger cohort, who we

may not know if the consequences of their exposures are perhaps in like 20, 30, 40 years.

DR. WARD: Thank you. Michael? I think you might be on mute, Michael.

DR. LARRAÑAGA: Thank you. Thank you. So, I'm new to the Committee and this is my first meeting. One thing that I'm kind of struggling with internally is, based on my review of the White Paper and the presentations, and my understanding, there seems to be limited evidence of a causal relationship, but there does appear to be some evidence of an association. And so, as members of the STAC, how are we to resolve that if we're asked to opine on a causal relationship?

DR. WARD: So, I'm wondering if Jessica or Tania would like to tackle that question, or Geoff. I was thinking we could pull up the slide again where you talk about whether it aggregate—yes, aggravates or, you know—Tania, Tania's nodding as if she knows what I'm talking about. Tania, you're on mute.

DR. CARREÓN-VALENCIA: Yes, sorry. Yes, maybe Jess, could you pull your slides?

MS. BILICS: Yes, hold on one second.

DR. LARRAÑAGA: I think it's one of the first couple of slides.

[Pause.]

DR. WARD: If we can't show it, maybe somebody could just read it, just to refresh our memory. Or just talk in general about how—

MS. BILICS: I'm showing it from my end. I don't know if Mia needs to show it, if Mia can pull up my slides again. On my computer it's showing that I'm sharing it, so I don't know if Mia needs to—

DR. WARD: Yes, so we're not seeing—

MS. WALLACE: Stop sharing and share back again, Jess.

MS. BILICS: Okay.

MS. WALLACE: Because it's frozen.

MS. BILICS: You want me to try my slides again or are you going to try, Mia?

MS. WALLACE: Yes, do it on your end again.

MS. BILICS: Okay.

MS. WALLACE: Now that you have it up. Do you have two screens?

MS. BILICS: No, I have one large screen.

MS. WALLACE: Because we just see your files.

MS. BILICS: Okay. Are you still just seeing files?

MS. WALLACE: No, we can see your screen. We can see the presentation.

MS. BILICS: Okay.

DR. WARD: So I think, you know, when I read this slide, and thinking about the various criteria that the Administrator has set forth, I don't think that there—I mean, interviewing the—I don't think that what, you know, the

Administrator is requiring that there be—and please correct me if I'm wrong, anybody from the Science Team—the requirement is not that we think there's sufficient evidence for a causal association, but rather that we think it's substantially likely to be a significant factor. And you know, I think that, you know, that is the sense of how the World Trade Center-related health conditions are defined. Tania, yes.

DR. CARREÓN-VALENCIA: Yes, that's correct.

DR. WARD: Yes. Okay. Can we go back to the screen with the participants? So, has that issue been sufficiently addressed, because I think it's a really important one? Does anyone have any further comments on that?

MS. BILICS: So, this is Jess Bilics again. I just want to comment that I know that Tom Dydek asked a little, Thomas Dydek asked about this earlier when, after I presented, and I talked about how that definition is mostly used and the statutory language comes from the section on the certifications. So that is really how the Program is required, and the physicians that are treating the members, are required to make the connection between an individual's exposures and the condition. And Dr. Howard came down to my office after I presented and pointed out that in terms of actual criteria for adding to the list itself, the law is pretty silent on what criteria the Administrator is to use for adding to the list. So, you know, while we provide that definition as being helpful for how the Program makes decisions in terms of treating people, there is a distinction between, you know, that definition for purposes of certification and then the inclusion of a condition on the list.

DR. WARD: Thank you, Jess, for that really important clarification. I appreciate it. And I do remember now, going back to the very first meetings, that we struggled a lot with the lack of specificity for what the criteria the STAC—you know, what criteria should be used for making that determination. So that is certainly a difficult issue for us. Larry? I think you're on mute.

DR. MOHR: Yes, there we go. Yes. In thinking about this, first of all, I don't think we can use an estrogen receptor thesis for either rejecting or adding uterine cancer, because the complex mixture of materials that people were exposed to, I think make that really impossible. As you alluded, Liz, some are estrogenic; some are anti-estrogenic. People may have been exposed to different things in different quantities at different times. I don't think that that's a reasonable way to look at this, and certainly not a reasonable way to exclude uterine cancer.

However, as I think it was Michael pointed out, there does appear to be an association, and so as I read the criteria for including it, you know, it really boils down to whether it is more likely or not that the uterine cancer

experienced by these women was related to or associated with the World Trade Center exposure. And there are two things that, to my mind—and again, this is more intuitive than scientifically rigorous—but the exposure to cadmium, which we know has a direct relationship to the pathogenesis of endometrial cancer, and as one commenter mentioned, and Thomas brought this up before, the association or the possibility of dust being on the tissue, the toilet tissue that women used in the porta-potty. And I think, as he pointed out, that's very analogous to the mechanism of endometrial cancer related to asbestos exposure via talc contamination. So, as I look at things in terms of being more likely than not, I think the plausibility of uterine cancer being related to World Trade Center dust exposure I think is significant, and more likely than not would indicate to me adding this to the list of World Trade Center-related cancers. And again, that's more of a deductive reasoning approach rather than a scientifically rigorous epidemiological approach. But I do think, in this case, it's very appropriate.

DR. WARD: Thank you. Thomas?

DR. DYDEK: Just as a matter of completeness, we've been saying quite a few times that uterine cancer is the only cancer not on the list, and I remember one of the slides said there were 24 listed carcinogens, although some are groups. So I'm wondering, for example brain cancer or bone cancer, would those be in the rare cancer group or is it really true that uterine cancer is the only cancer of any time that's not on the list?

MS. BILICS: Brain and bone cancer are both covered cancers. This is Jess again. And uterine cancer, the larger category, is the only one, with the exception that Geoff made earlier about the sarcomas being covered, other uterine sarcomas. There are Type II cancers, you know, that are not based on definition and malignancy, and I don't know if, you know, Geoff would probably be a better person to speak to the science behind that. But so, there are individual types of cancers that based on the definition of malignancy don't meet the definition of what is considered a cancer. But as a category itself, uterine is the only one that is not covered.

DR. DYDEK: Okay, thank you.

MS. BILICS: Yes.

DR. WARD: Michael?

DR. LARRAÑAGA: Yes, thank you. So, the reason I asked the previous question is because in the White Paper, in section 4, it says, "The Administrator has requested a STAC recommendation regarding whether 9/11 exposures have a causal association with uterine cancer." And you know—

DR. WARD: Yes.

DR. LARRAÑAGA: I want to make sure that I understand what we're charged with in this deliberation. That way I know what I'm supposed to do versus doing something I'm not supposed to do or that wasn't asked.

DR. WARD: Thank you. That's a really helpful clarification because it's something that I completely missed. I mean, my interpretation would be that he's not asking for us to try to satisfy the Bradford Hill criteria for causality, but some of the phrases that people have been using such as "plausible" or even "likely" or "more likely than not" are probably what he would be looking for, with a scientific rationale, not just, you know, if the Committee would like to give that recommendation, then I think it will be our task tomorrow to come up with what are the key points that we're basing our recommendation on. Is that agreeable to Tania and Jessica and Geoff? Yes.

DR. CARREÓN-VALENCIA: Yes.

DR. WARD: Okay, Tania, I'm looking for hands. If anybody is raising their hand that I'm not seeing, let me know. I guess it's 3:56 and we were planning to break at 4:00. So, I think I have a pretty good sense of, we have a pretty good sense of the perspective of those people who have spoken, and we'll be in a good position to do the—to discuss tomorrow how the group wants to proceed. Are there any final comments for today?

DR. CARREÓN-VALENCIA: Well, if the meeting doesn't have any further comments, Liz, I want to thank you for keeping us on track and thank everybody on the Committee for a very helpful discussion. I'm looking forward to Day 2 of our meeting tomorrow, starting promptly at 11 a.m. Eastern Daylight Savings Time.

DR. WARD: Thank you. Thanks, everyone, for your participation.

[Adjourn.]

INTRODUCTION

DR. CARREÓN-VALENCIA: 11 a.m. so let's get started. Good morning. Today is Day 2 of the World Trade Center Health Program Scientific and Technical Advisory Committee Meeting. I'm Tania Carreón-Valencia, the Designated Federal Officer for the Committee, and I would like to welcome the members of our Committee, the NIOSH staff, and the members of the public that are watching this webcast.

Yesterday we had a great meeting, and several interesting points and questions were raised. But before I address some of those, I want to make all aware that the Committee members have been instructed not to have private Zoom chats that involve the topics under discussion. Zoom

chat is part of the public record and any chat comments will be added to the minutes of the meeting. If a substantive point is raised in a chat, Dr. Ward or I will bring it up during the discussion.
I also want to inform you that as of 10:55 a.m., no new comments have been added to the docket on regulations.gov so there are still nine comments. We will have another public comment period at 12:10 p.m. Eastern Daylight Savings Time and six persons have signed up to provide comment. So, I will do another roll call to ensure that we have a quorum. Liz Ward.

DR. WARD: Present.
DR. CARREÓN-VALENCIA: Sophie Balk.
DR. BALK: Present.
DR. CARREÓN-VALENCIA: Chandra Davis still has a medical emergency and won't be able to join us. Thomas Dydek.
DR. DYDEK: Present.
DR. CARREÓN-VALENCIA: Mariama James.
MS. JAMES: Present.
DR. CARREÓN-VALENCIA: Anita Jose.
DR. JOSE: Present.
DR. CARREÓN-VALENCIA: Thank you. Michael Larrañaga.
DR. LARRAÑAGA: Present.
DR. CARREÓN-VALENCIA: Catherine McVay Hughes.
MS. MCVAY HUGHES: Present.
DR. CARREÓN-VALENCIA: John Meyer.
DR. MEYER: Present.
DR. CARREÓN-VALENCIA: Debra Milek.
DR. MILEK: Present.
DR. CARREÓN-VALENCIA: Lawrence Mohr. Lawrence also communicated with me this morning. He also had a medical emergency and won't be able to join us. I sent both Larry and Chandra our regards on behalf of the whole Committee. Larry also had some opinions regarding the proceedings, and I will share them with you during the deliberations. Nick Newman?
MR. NEWMAN: Present.
DR. CARREÓN-VALENCIA: Jason Ostrowe.
DR. OSTROWE: Present.
DR. CARREÓN-VALENCIA: Robin Sassman.
DR. SASSMAN: Present.
DR. CARREÓN-VALENCIA: Aarti Surti.
DR. SURTI: Present.
DR. CARREÓN-VALENCIA: Leigh Wilson.

DR. WILSON: Present.

DR. CARREÓN-VALENCIA: Okay, so we have 14 members present, which is a quorum. And before we start, I want to bring up the discussion you all had yesterday. Jessica Bilics presented the four methods by which a cancer condition can be added to the list of World Trade Center-related health conditions. The Science Team followed Methods 1 to 3 and conducted a thorough review and evaluation of the evidence. We were not able to add uterine cancer to the list following these three methods.

So, the Administrator is asking you, by following Method 4, to provide that recommendation, and he has provided clarification of his charge. The Administrator will welcome the Committee's 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 copy of the Administrator's opening remarks with this clarification was sent to the Committee yesterday and will be posted on the Committee's website.

In addition, Jessica and Geoff Calvert will be available today during this meeting as much as possible to answer any questions you may have. And with that, I will ask Liz to provide a recap of yesterday's discussion and in your deliberations.

RECAP FROM FIRST DAY DELIBERATIONS

DR. WARD: Thank you, Tania. I'd like to try to share my screen if I can. Are you all seeing a PowerPoint presentation?

DR. CARREÓN-VALENCIA: Not yet.

DR. WARD: Not yet, okay. I obviously did not do it right. Okay, share.

DR. CARREÓN-VALENCIA: Yes, it started showing.

DR. WARD: Okay, so you're seeing the PowerPoint?

DR. CARREÓN-VALENCIA: No, we see your—yes, we see the PowerPoint now.

DR. WARD: Okay, you see it now. Okay, so I actually spent a fair bit of time this morning trying to synthesize all the comments that people made yesterday, along with the public input. And I tried to do that in a way that could also be used to help us frame the scientific rationale. So, what I thought I would do is go through this slideshow and discuss the major points and then we can go back and see if there's anything I got wrong, if there's anything we missed. I left certainly room for conclusions. But I thought it would be good to just go through this slide by slide and make sure we're all on the same page.

So, I think the first thing that it's reasonable for us to point out is that we

recognize that the Program staff has done a very thorough review of the evidence for adding uterine cancer and that they've done that according to established policies and procedures. And they've made the conclusion that uterine cancer would not be eligible based on Methods 1, 2, and 3. And we do not have any disagreement with the work that they have done. So really our charge today is to deliberate and make a recommendation as to whether we believe there's a reasonable scientific rationale for adding uterine cancer based on Method 4. And the consensus that I heard yesterday was that at least most of the Committee members who spoke were in favor of doing that, but we were a little bit struggling with how we could bring the scientific evidence together to support that recommendation.

So, in part because I was involved with the initial recommendation in 2012 from the STAC to add certain cancers to World Trade Center-related conditions, I thought it would be good to go back and review our recommendations at that time. And these recommendations were really made based on a six-month, very intensive process involving meetings and writing and drafts.

And they do contain a lot more perspective than just the final recommendations. I also think many of us tried to say yesterday that given the fact that now every other cancer is covered, how can we frame the discussion on whether it makes sense that only uterine cancer is not covered? So, I thought one way to address this—and there may be better ways that you guys have—is that we believe there's a lack of biological plausibility that uterine cancer is the only cancer not related to World Trade Center exposures.

And finally, I think that it is important to mention that while the Program did a very good, very extensive review of the literature related to WTC exposures and uterine cancer, and while none of those substances really raised it to the level of conclusive, we do think that there is some positive evidence and we thought it would be worthwhile to summarize the positive evidence for the Administrator's consideration. I think a lot of this I already said.

So, I think what I'm doing here is I'm going back and talking about some of the themes that were in the 2012 recommendation that I think are still pertinent today do our deliberation. So, in the 2012 deliberation there was an extensive discussion of the lack of general exposure data and also the incredible diversity of exposures that people may have had depending on where they were, what their role was. Even on the pile itself, there were fires burning in some areas more so than others. And so that, I think, is a

limitation that we always have to bear in mind when we consider the results of the epidemiologic studies of World Trade Center populations, the really severe limitations with respect to exposure data.

Other limitations of the existing cohorts included surveillance bias, limited sample size, selection bias, and unlimited follow-up and periods of latency. And although in 2012 we really had only one epidemiologic study that had been published, and we knew that much more data would be forthcoming and should be considered, we also recognized that those studies were not likely to be able to resolve some of the major limitations of the studies of the World Trade Center cohorts.

Although we did not specifically mention it in the 2012 recommendations, it's very clear and it was discussed yesterday that studies of cancer of the breast and female reproductive organs in World Trade Center populations are particularly limited because of the small numbers of women in the cohorts, especially in the responder cohorts. And I think one point we could make, if we all agree, is that although the incidence of uterine cancer in the general population does not meet the critical for rare cancer, the rationale that we used in the 2012 report that rare cancers should be included due to the limited statistical power of World Trade Center-related studies to detect increases in those cancers does apply to uterine cancer because of the small numbers of women in the cohorts. And then this kind of elaborates on that point further. But it also states—and this was brought up by a number of people yesterday—that the small number of cases observed in studies today of the World Trade Center cohorts limit the ability to evaluate exposure response, and I think none of the studies really looked at exposure response for uterine cancer. And also, to conduct relevant studies by histologic type, age at exposure, age at onset, and other factors specifically related to uterine cancer that might be very important in establishing a causal relationship. In addition, the point was made that the majority of cohort members in the various cohorts are only now entering the age range where uterine cancer is common and that we are still unable to assess any risks that might occur after longer latency periods.

I think it was also noted, and it was mentioned in one of the presentations that the Program has set a really high bar in terms of using evidence from 9/11 studies to determine that a cancer is causally related to World Trade Center exposures. And I think Jessica said in her presentation yesterday that no cancers have been added under Method 1 to date. And that really does relate to a comment that was made yesterday about, well, it may be that the epidemiologic evidence for uterine cancer is as strong, or

stronger, than some of the cancers that we are now covering.

So, as we talked about and as Jessica and Geoff presented yesterday, most cancer sites that have been added to the list of World Trade Center-related conditions are based on Method 3 and also on the decision to include rare cancers, cancers with an overall incidence rate of 15 or fewer per 100,000. And it's really important to note that the foundation for Method 3 is the IARC Monographs program evaluations that identify cancer sites that are associated with specific carcinogens and, in this case, for specific World Trade Center-related exposures.

And the STAC did make that recommendation, but we also—and I won't read through this, but I'll give you a minute to read through it—we also recognize that that is really not the full story and that there are many exposures present in the World Trade Center dust that have not been adequately studied, but for which there's some animal evidence. They have been evaluated by IARC as likely to cause cancer, but there was not enough evidence from human studies to associate them with specific cancer sites, etc. So, again, while we think the approach that the STAC recommended and, to a large extent, the Administrator followed with respect to Method 3 is scientifically justified, it's really on the whole story. I think there are other considerations that need to come into play.

And I think one of the most important themes that has come out yesterday and that was also very well-articulated in the White Paper was that there is an inherit limitation in Method 3 with respect to cancers occurring primary or only in women in that most of the evidence for the carcinogenicity of these exposures to specific cancers sites, come from epidemiologic studies of highly-exposed industrial cohorts, most of which do not include women and, therefore, could not be informative in relation to uterine cancer.

I would say one of the very important themes that came across in the public comments, and I think was also reflected by some members of the STAC, is that uterine cancer is now the only cancer not covered by the World Trade Center Health Program. While we recognize that this has occurred through appropriate and proper use of policies and procedures for designating cancer sites as World Trade Center-related, affected members of the responder and survivor communities perceive this exclusion as illogical—I said "logical," that was a typo—but it's illogical and unfair.

And, again, trying to think of how we could possibly frame this in terms of developing a scientific rationale, my suggestion is that from the perspective of the STAC, we believe it's now relevant to consider the

plausibility and likelihood that World Trade Center exposures would be associated with every cancer site other than uterine cancer and, for this reason, we believe it is far more biologically plausible that uterine cancer is associated with WTC exposures than that it is not. And the foundation for that last comment really can be found in some of the very brief text that we included in the previous STAC recommendations. And everybody has access—that letter summarizing our recommendations is in the docket and we could also send a copy of it around to members so that they can see it.

But one of the things we talked about—and really, given the vast amount of knowledge about cancer mechanisms, we gave a very brief summary in the STAC recommendations from 2012, but basically the essence of it is that not much is known about the mechanisms through which exogenous exposures cause cancer, and many of these mechanisms are common across categories of carcinogens and cancer sites.

Secondly, we don't believe there's anything that's so biologically unique about uterine cancer to suggest that these common mechanisms associated with increased cancer risk with World Trade Center exposure agents would not apply to uterine cancer. In fact, as summarized very well by Dr. Calvert in the White Paper and in his presentation, there is substantial evidence that mechanisms of development of uterine cancer have much in common with the mechanisms of the development of other cancers.

Another very important point that has been made in the White Paper, was made in public comments, and was also discussed yesterday is that uterine cancers belong to a group of cancers whose incidence is strongly related to hormonal factors, including endogenous and exogenous estrogens, and could plausibly be affected by endocrine disruptors. The World Trade Center Health Program review has identified several World Trade Center exposures as endocrine disruptors and reviewed the literature regarding potential associations with uterine cancer.

The STAC generally agrees that the methodology and conclusions of the World Trade Center Health Program White Paper regarding associations between asbestos and World Trade Center agents identified as endocrine disruptors and uterine cancer based on the—while we basically agree with the conclusions of the STAC report, we also wanted to note that some of the relevant data that was presented yesterday and in the White Paper does support a potential association between these agents and risk of uterine cancer.

Then we did have a fair bit of discussion yesterday about asbestos and,

based on the STAC comments, I think that there is a—these would be the main points that I think we could present as a scientific rationale for the potential association with asbestos.

One is, as for most other agents, although there's an extensive body of literature related to asbestos and cancer and specific cancer sites have been identified as associated with exposure to asbestos, the information that is unique to women is extremely limited because it's mostly from industrial cohorts. Nonetheless, a few studies have found positive associations between asbestos exposure and uterine cancer.

Several people noted yesterday that asbestos is a recognized cause of ovarian cancer and there is evidence that asbestos in talcum powder applied to the perineal area may migrate through the genital tract to the ovaries and, by extension, through the uterus.

And it was also noted yesterday by responders and survivors that restrooms available to women at the rescue and recovery sites were often heavily contaminated with World Trade Center dust, including the toilet tissue women used. And that would provide a direct route of exposure to asbestos and other contaminants in World Trade Center dust to the female genital tract.

This is not to say that the female genital tract is not affected by exposures that come through inhalation. We know that it is, such as tobacco smoke and cervical cancer, but I think it adds to the biologic plausibility that, in addition, there is this rationale for a direct exposure to the female reproductive organs.

And at that point I kind of ran out of time and so didn't go through the endocrine disruptor agents, but I think if we want to present this as part of our rationale, we can pretty easily go back and summarize from Geoff's presentation the positive studies. And then I think we will need to draft together collectively—once we agree our recommendation to the Administrator and the scientific basis, we will collectively need to write a reasonable conclusion that brings it all together.

And I think some points that were made yesterday are appropriate to consider, like the mention that in pediatrics the principle of what's the most protective action or the most beneficial action to the population even in the face of limited data is often a principle by which decisions are made.

STAC DELIBERATIONS

DR. WARD: So, with that, I'd like to stop sharing my slides, if I can remember how to,

yes. And I'd like to open the floor for discussion and this how I would propose to proceed, that everyone gets a chance to speak and say what they want to say and then I'll try to take notes so that we can incorporate these issues into the text. And then subsequently, if there's general agreement that we've captured a lot of the important points in the PowerPoint slides, we can go back as a group and do wordsmithing to add the missing points and revise the existing points. Does that make sense to everyone? Tania, is that agreeable to you and everyone else? Okay, so why don't we just open the floor for discussion and comments and questions? Debra?

DR. MILEK: I'd like to add perhaps a closer look at the perfluoroalkyls. They have been detected in working populations and in the World Trade Center and are associated with an increase in cholesterol. And I think if we're considering endocrine cancer, an increase in cholesterol which is a precursor to androgens and estrogens should be considered as a potential risk factor.

DR. WARD: Okay.

DR. MILEK: And I agree with the various points you made, and excellent job summarizing.

DR. WARD: Thank you, thank you. I've taken note of that, and we'll see how we can include that point in the subsequent revisions of the points. Jason?

DR. OSTROWE: Just first wanted to say thank you for that really powerful and persuasive summary. The one thing that I was listening to that caught my attention was on slide 13 where one of the survivors talked about the contamination of the toilet paper. I'd also think that we could add, as somebody who was there and personally observed this, contaminated clothing that responders and survivors were wearing.

DR. WARD: Oh, yes.

DR. OSTROWE: So, I think that is something also that we could maybe put in there.

DR. WARD: Great. Anyone else? Oh, yes? I'm sorry, I'm forgetting your last name and it's not showing. I'm forgetting your first name, L. Wilson.

DR. WILSON: Leigh Wilson, hi, how are you?

DR. WARD: Thanks, good.

DR. WILSON: I didn't have too much to add yesterday, but a couple of things that I was thinking about. Yesterday we had somebody commenting on how the data collection with the IAMQ, which is the annual questionnaire, has historically not had much attention to women's issues. They haven't captured miscarriages and this kind of thing. So, one thing I was actually thinking about was potentially we may have lost a lot of women coming into capture uterine cancer diagnosis based on the fact that they've lost

interest in coming to the Program, feeling like women's health issues have typically not been addressed as they would hope. I mean I know we've discussed that potentially uterine cancer develops in older women, so maybe we're losing members who we would capture with this diagnosis because they stopped coming in.
And the other thing is people are constantly being added to the Program. Even though it's been 20 years, we still have responders and survivors who are coming in, so possibly we haven't seen an uptick in a disease that may or may not—obviously you don't know if there's an uptick in disease, but maybe those folks haven't enrolled yet or those conditions haven't been captured. It's just a thought.

DR. WARD: Yes, those are very good points and I think it might be important to talk about the—we kind of have two concepts, related to what you said. There's the World Trade Center Registry which has done the big questionnaire studies that include survivors. And I agree with you that there's some possibility that some women might have stopped participating because they felt there was not sufficient attention to women's reproductive health issues. On the other hand, it's my understanding that the cancer incidence in that study is in the enrollees whether they continue to participate in questionnaires or not is determined from linkage with cancer registries. So, I don't know to what extent cancers would be missed. It's a little bit complicated.

DR. WILSON: I mean, I'm not sure. Because I work in the World Trade Center Health Program and every year people come in and they report what diagnoses they have, so some of it is based on self-report and then it's verified with a cancer registry. But a lot of it is based on somebody comes in each year and says, "I have this diagnosis," and so on, then it becomes verified with the World Trade Center Health Registry and/or cancer registries. But I can definitely comment that I've had a number of women over the years—I've been there eight and a half years—a number of women who have actually stopped coming in because they feel like we have not given the proper attention to their specific needs. So, it's just a, you know, (inaudible @ 00:30:27) a potential, just a potential concern.

DR. WARD: Yes. Right.

DR. WILSON: Thank you.

DR. WARD: Thank you. Catherine?

MS. MCVAY HUGHES: Liz, you did an amazing job, like you always have chairing this Committee, synthesizing complex information, and getting, trying to get a consensus and raising issues. I just wanted to follow up on Jason's comment. Not only were the clothes contaminated with World Trade

Center dust, but I think they're bringing it home and doing the laundry as well. So that was just something I wanted to add just to continue that thought, thanks.

DR. WARD: Thank you. And we didn't mention it, but I think certainly there was potential for ingestion exposures. And a lot of that was kind of discussed in the first STAC recommendation regarding cancer. But yes, all those issues are important. Thomas?

DR. DYDEK: Yes, two general comments. In the charge that we've all seen, they mentioned various criteria from Bradford Hill. There are four, I think, that the Agency specifically concentrates on. But there are nine all together and one of the ones that's not in that group of four is analogy. And I think we've kind of been touching on that; that there are rare analogous types of cancer caused by agents in the World Trade Center dust. So, I think we can bring in some of the Bradford Hill criteria that are not specifically called out in the regulations and the approach that the CDC has taken. So that's one comment.

The other one I have is the study that has been quoted as not showing an association is the Australian study of asbestos exposure of women who either lived in a town where there was an asbestos processing—or I forget exactly what they were doing in Wittenoom, Australia. But the group of women who were actually workers at that plant and would have had exposures perhaps similar to the workers at the World Trade Center site, there were only two cases out of those women who worked there. So that's a very small number and not really high enough to make that a very strong argument against an association between asbestos exposure and uterine cancer. So those are my comments.

DR. WARD: Great, thank you. Sophie?

DR. BALK: Hi, good morning. I can't see myself on the screen. First of all, Liz, thank you for a beautiful summary of yesterday's events discussion. What I wanted to do was just raise an example of endocrine disruption that may be helpful in talking about the importance of latency periods and what happened to the offspring of women who were pregnant at the time. And that is the example of diethylstilbestrol that was taken by pregnant women maybe half a century ago. And it took a latency period of 20 years to see the effects in offspring. And that was a very rare cancer—clear cell adenocarcinoma of the vagina—in female offspring and other uterine abnormalities that affected fertility, anatomical abnormalities, but it took a whole latency period. And this is something that we may see, but it's not knowable yet. But the DES example may be helpful.

The other thing that I've been thinking about is, again, the exposures to

children who lived in the area or were going to school in the area and these small exposures to endocrine disruptors may have a very big effect in children who are growing and developing rapidly. And, again, this is not knowable until a certain amount of time passes. So, I hope those things may be helpful in our arguments.

DR. WARD: Great, thank you. Mariama?

MS. JAMES: Yes, again, your summary was incredible. I used the clapping emoji a couple of times for the reaction. Totally agree with Sophie. In fact, that is exactly why I had raised my hand is to add a little more to the conversation that we've been having about the lack of women's exposures and maybe some of the impacts that have happened on women. But to take that a little bit further, the children—female children, in particular, since we're talking about a female reproductive issue—that were born between September 11, 2001 and—what is it, March 2002—that's the period that falls into the eligibility for being covered under the Program. Those children will have lived all of their first developmental stages being exposed in the variety of ways that we've already discussed. So, whether it was actually on your clothes or, again, in the context of survivors, it was in your home, in all your furniture, possibly in your food. It just got in everything and was still able to be read by whatever meter scientists use to read that sort of thing, a year, two years later, I know from firsthand experience when they came to my house. So, these girls would have been constantly exposed, or exposed more than once, several times, over and over, over a period of maybe the first year or two of their lives. And what does that do maybe to the female reproductive system or to any development in the human body or the female human body.

And to bring in the conversation about the asbestos, I believe that the gentleman that gave that part of the presentation said that the data that he was using was ten years old. So that would mean that, at this point, it's the 20-year mark—that was ten years ago. Now we're at the 20-year mark, aligning with the anniversary, where asbestos begins to be seen or the impacts of asbestos on the human body and the asbestosis and those things, begin to be found, you know, if one is having it. So, think of these girls now, they are 20 years old at this point, you know. Again, firsthand knowledge, my own child will be 20 in October. So, I don't know if there's a way to note that we also need a lot more attention, research overall on the uterine cancer even after we say yea or nay to a recommendation. But regardless of that, there has to be more research not only on the women that we would presume to have been potentially

impacted by this—like first responders or general responders or even some of the more adult survivors—but specifically the adolescent survivors or the young-adult survivors. I think it's very important that we start paying some attention to them. Thank you.

DR. WARD: Yes, I think that is a general point that probably goes beyond the specific question of uterine cancer. But I did want to mention that the 2012 STAC recommendations did specifically make the recommendation which was adopted by the Administrator that along with rare cancers, any cancers occurring in children under the age of 20, which would include a good number of the children that were *in utero* or younger life, should be considered as World Trade Center-related conditions. So then once the survivors reach the age of 20, then the main list of World Trade Center-related cancers would come into play and that's where the inclusion of uterine cancer would be important for those children who ultimately develop that.

But we did, at least in making our initial recommendations, consider very seriously the issues that you raise about the potential exposures in early life and how they may have a different and more impactful result than exposures occurring later in life because of the developmental stage of the children. But I also think that the recommendation overall that research needs to continue and especially cancers in women and cancers that are rising related to exposures *in utero* in early life is a general recommendation that the STAC can also make. Nicholas?

DR. NEWMAN: Hello. Thank you, Liz, for your wonderful summary. I feel like at some level, it would be easier if we were the ethical advisory committee to the World Trade Center Health Program. But just to get us back to some of the science gaps—because my thought would be if we're going to recommend that this be added that we try to put as strong an underpinning under it as possible.

So, there's been some discussion about asbestos and dusts that were present at the site. And what's been cited basically is anecdotal reports of that. I mean I was looking at some publications around World Trade Center dusts that have already been published and a lot of it seems to be about like inhalation. So, I'm wondering—and this is a question maybe to Tania and Geoff, *et al*.—are you aware of any quantitation of these things we've just talked about on various items around clothing, etc., to create the scientific plausibility that this stuff could be tracked in or it could be on toilet tissue? I mean I've seen pictures of entire tea sets or whatever encased in dust. So, I think it would be helpful to put the science underpinning under this to say—do you hear what I'm trying to say, Liz?

DR. WARD: Yes, and I think that's an excellent point and I regret that I didn't think of it sooner. But we did a lot of that legwork when we made the 2012 recommendations, so we've got a multipage report. We had some really great experts on the Committee at that time, including John Dement who is one of the leading experts on asbestos. And so, the STAC did a really detailed review—and Catherine was there—of the evidence for all of the exposures. And I can't say that it captured everything, but I read through it last night and we did really talk in pretty much detail about what was the evidence for the level of inhalational exposure to asbestos.

We talked about what was present in bulk samples of the dust. And we also did give great consideration to what we would consider the qualitative descriptions of exposures that were given by members. We had extensive presentations at that time by responders and survivors who were directly affected, and we've reviewed a lot of photographic evidence.

So I think a lot of the evidence base that the STAC has as background for our deliberations this time are really pretty well-covered in the material in the 2012 recommendations, which was one of the reasons why I cited it as one of the three main streams of evidence that we would be using to document. So maybe Tania or Mia can forward that to the Committee so they can take a quick look at it during lunchbreak.

DR. NEWMAN: Not to cut in, but what I want to do is to try to make sure that we put as strong a basis to this so that the recommendation survives the peer review and doesn't just get bounced back.

DR. WARD: Yes. And one way to do that, I think, is where it's most relevant—like with the question of asbestos exposure—is to, in our recommendations, refer to and footnote the text from the original, from the 2012 recommendation, that would support the importance of asbestos as an exposure at the World Trade Center site.

So, I think it would be hard for us to go back and do another complete literature review, but I think a lot of what we're saying today we also said in that 2012 report, but we had a lot more time and great expertise on the Committee at that time to develop those recommendations. So, I think that is something that I came up this morning with as I was struggling is we can, I think, use and cite the recommendations of the 2012 report and the data that we presented, the evidence we presented in the 2012 report, as part of the background for the current recommendations.

And of course, if there's something else that we consider highly relevant that the earlier STAC recommendation didn't include that the Program is aware of, I think we can also include that. But I do think, thankfully, the

2012 report will be a real resource in terms of addressing some of the issues that you're raising. Thomas?

DR. DYDEK: Yes. One thing I'm kind of struggling with—and I think some of the other Committee members are as well—is the binary nature of our charge. Are we supposed to say either yes or no? But it's not that clear to actually be able to say yes or no. I think if we go strictly by is there strong science right now to support the association, we would have to say no. But there are reasons why we don't have that evidence. So, what would be your advice on is there a third option, like maybe? More research is always needed, of course, but I think especially in this case. So, what do you think about that?

DR. WARD: I think the Administrator is asking us to make a binary recommendation, but he's really saying that whatever recommendation we make we have to present a reasonable scientific rationale. So, if we, I think at this point there's no likelihood, from what people have said, that we're going to say no, right? So, if we say yes, then I think that what he's asking us to do is to present a reasonable scientific rationale for that recommendation. And I think that's what we're trying to do today.

I think some of the issues you're talking about really apply more to Method 1, and you know, Method 1 which, where you review the epidemiological evidence and use the Bradford Hill criteria to evaluate the strength of evidence for an association. And the Program's already done that, and I think we've concurred with their conclusion. And there was somewhere some text that really described all of the information that the Administrator hoped the STAC would bring to making their recommendations under Method 4. And it really did include things like personal experience of the STAC members. And I don't know if Tania or anyone can find that text, but really, we have the ability to draw on whatever scientific information we believe is reasonable and relevant to make our recommendation. We're not at all constrained by the Bradford Hill criteria or that were already considered under Method 1.

DR. DYDEK: Okay, thanks.

DR. WARD: John?

DR. MEYER: Oh, hi, just a couple of things I think to add to what's been already—and this probably goes back to your discussion with Nick a couple of segments ago, which is that I don't know necessarily—I will have to admit I don't what is covered because it wasn't on the STAC in 2012 but is covered with exposure. But I think in that, fundamentally you've got about a 10-year period of time in which exposure for the female GU tract has been much better described, and particularly around questions of

asbestos and talc and baby powder. So, I don't think you have to go back and reinvent your wheel from 2012.

I think you only need to look at exposures to particularly the general tract from there, but certainly it's described as in the—just to make a long story short is that much ovarian cancer actually has its origin in the fallopian tube rather than the ovarian serosa. And I have to go back and check this myself; there may actually be some exposure data with asbestos in the GU tract in women firefighters separate from the questions of talc.

So I don't think you'd necessarily need to reinvent the wheel, but I think there's probably—correct me if I'm wrong, Liz—probably in the intervening decade, there is a lot of exposure that's separate from things like respiratory exposure but that is distinctive to exposure in the GU tract, even in people who weren't using it as cosmetic or drying product, applying it to the general area, but to firefighters in particular who would have become exposed to that in the GU tract.

So that's just one comment, and certainly I can have a peek into that if there's any need to do that or assist you in that there, because I think I had to review it for some other cancer cases.

And then the second, and this is just a comment, we probably should just not even talk about Hill's criteria anymore because I think if we were to go back, this was I think some of my point to Geoff yesterday, which is to go back and look at that. First of all, Hill didn't intend it as a checklist for causation in the first place. So, there were suggestions when you didn't have an RCT to prove that something might be carcinogenic or not. And looking at the epi of some of the other cancers that we have, very few things are going to qualify.

So, I think I would just make a plea to just concentrate on 3 and 4 and leave Hill's criteria out alone because nothing we do is going to satisfy that. But it's just my two cents on the point there.

DR. WARD: Yes, and I think the point you made about additional evidence like regarding exposures to the urogenital tract in female firefighters would be relevant. I'm not familiar with that. I mean I did think it was really important to mention the talc and ovary associations. I'm not sure how much depth we need to go into in making these recommendations. I do think we need to cite some references. Again, our recommendations are really based in large part on very general principles, and I don't know if we need to go in depth into everything.

DR. MEYER: Okay.

DR. WARD: But I think if there is knowledge that's emerged in the last 10 years, which would include much of the knowledge about asbestos and talc and

ovarian cancer, I think we should mention it. So, anything anyone wants to contribute to that would be greatly appreciated.

DR. MEYER: Being new on the Committee, I don't know how much you need to bludgeon people with evidence versus just mention it.

DR. WARD: Yes, I don't think in this case we need to bludgeon, but I do think we need to make sure that we do a rigorous job, and we provide references for things which were not previously—I mean I think if something's in the White Paper, then we can refer to the White Paper. If we're bringing in evidence that's not in the White Paper, we should certainly provide references. And I also do think that the 2012 STAC recommendations, while they don't represent the view of the current members, were seriously considered by Dr. Howard and did form the basis for a framework that was actually adopted by the World Trade Center Health Program. So, I think citing those recommendations is a reasonable thing to do and will really save us a lot of time in terms of documentation on some of the issues. Good. Robin?

DR. SASSMAN: Yes, so I was just looking at the White Paper again and trying to think about how can we bolster our opinion? And as I mentioned yesterday, I think a really good point to bring out in terms of our stance is just going back to the mechanisms that were talked about in the White Paper. And one of the things that I think we can maybe point out specifically is about the gene mutations of the Type I endometrial cancer, which is the most common type, and the fact that the gene mutations that are found in endometrial cancer are also found in melanoma, brain tumors, ovarian cancer, thyroid and breast cancer, as well as prostate cancer, all of which those other cancers are already part of the Program. So, I think that would be one way to bolster our opinion in that stance since we of course can't rely upon the epidemiological studies to do so.

DR. WARD: Yes, I think that's great. And I did have a slide where I alluded to that, but I think if we could summarize, again, the text—I don't know if that's something you might be willing to consider drafting. It actually takes a little bit of time to go from the summary that was provided by Geoff into an even higher-level summary of how we view that evidence. So, if you would be willing to draft that, that would be really helpful.

DR. SASSMAN: Sure. Yes, I'd be happy to do that. And from what I understand from the White Paper, it's essentially based on footnote 57 which is the paper by Banno. So, I can certainly do that and send it to you.

DR. WARD: That would be terrific, thank you. I'm not seeing any more hands.

MS. JAMES: I put mine back up.

DR. WARD: Oh, your background again. Thank you, go ahead.

MS. JAMES: I felt that it was important to reiterate, at least for the purpose of these deliberations if not for the actual report so as not to be redundant in the efforts you guys have already made in 2012 or at any other time, that the dust was everywhere. I mean I don't know how else to say it. It wasn't just on our toilet paper, whatever. The dust was everywhere: residents, businesses. We cleaned up that dust ourselves, local workers, we cleaned up the dust. And we were actually advised to clean up the dust at several levels of government, well, from local all the way up to the feds that this was what we were supposed to do. And after we had cleaned everything up and thrown everything out, thrown furniture out and stuff like that, again, a year later I can tell you from lived experience, when our homes were tested again, we were told to throw out our furniture again, everything again. It was still present. So, it was definitely on our toilet paper and it was definitely on our clothes and it was in everything else if you were a survivor. And perhaps if you were a responder too, you took it home with you and it didn't just go away. I just felt that should be stressed again, at least for the purposes of the deliberations.

DR. WARD: Yes, I think so, and it was certainly very strongly stressed in the first STAC report. So, again, I'm thinking one way we can handle some of this is to actually have footnotes and refer back to the text of the earlier STAC report on that because, again, that was an incredibly important issue, and we did really try to emphasize it when we made the first set of recommendations. And, again, I think a lot of our deliberations and discussions when we made the first set of deliberations are relevant to our deliberations today. Catherine?

MS. MCVAY HUGHES: Hi, yes. I just wanted to—you know, Liz—I want to second what Mariama said. And so even though our apartment was cleaned, the next day there was so much dust in the air. It was suspended. It had to be cleaned again. And this is with the windows being closed. And then the dust would settle the next day. And we had a HEPA filter air purifier and we brought it in. It was a pretty large one. And usually, the filters are supposed to last for six months. It was filled in a couple days literally. It was totally packed and caked with dust. So just for the people who haven't attended all these meetings or heard all these stories, I just want to remind people. And then when you're told that you have to—you don't realize washing every single dish and cup in your cabinet, and was it done properly. So, I just wanted to put that out there as well as the other source.

And just to change the topic to something else that's related to this, I believe in another STAC meeting we had talked about the impact of sleep

on the endocrine system. Can someone—I don't know if you're expert on that. Because I was just trying to Google and there is something on this on the Internet. I'm not an expert here, but in the ncbi.nlm.nih.gov website, it's like "Our data demonstrated that poor sleep is common and detrimental to endometrial cancer survivors," and they go into it a little bit. So that might be something to research. I just want to throw that out there.

DR. WARD: Yes, I think one thing we did discuss early on in relation to breast cancer was evidence that there might be an increased risk of breast cancer associated with working at night or working long shifts, which would cause circadian rhythm disruption, and that was part of the rationale initially for covering breast cancer. I don't think we've talked about poor sleep. And I'm not sure it would be really helpful at this point to add that to our rationale, especially if it pertains to the health of people who've already been diagnosed with endometrial cancer.
So that's just my first reaction is that I don't think we need to bring in every bit of research. I think we need to focus on the things that we think we can make a strong argument about. Because I think there's enough of that and if we bring in too many things, it may detract from the major evidence that we're bringing forward. But if you find anything, Catherine, send it on and we can discuss it.

DR. CARREÓN-VALENCIA: Liz?

DR. WARD: Yes, Tania.

DR. CARREÓN-VALENCIA: Just for the record, I would like to share with the Committee the email and opinion of Larry Mohr regarding this issue.

DR. WARD: Thank you.

DR. CARREÓN-VALENCIA: So, he says, "With respect to uterine cancer, in my opinion, it makes no sense to cover ovarian cancer and perineal cancer and not cover uterine endometrial cancer. Therefore, I recommend that the Administrator appoint a panel of three experts to determine the rational scientific basis for including uterine endometrial cancer as a covered condition." Now, regarding the 2012 STAC report, it is available for all Committee members and the public on the Committee's website. And we will pull out the link and we'll show it to everybody after the break.

DR. WARD: Excellent. And what I'll do as we go through, what I was thinking I might do next when we're done with this morning's discussion is try to take the points that people have made and see where they might be addressed in the existing slides, or else suggest that we need a new slide. And then we can possibly start going through the slides and wordsmith our conclusions that would then be incorporated into our recommendation

report. I can also try to have the 2012 report open so that if there's—I don't think we need—I think if we just attach the 2012 report, that would be fine, but it's not going to really draw attention to the important points. But maybe we can collectively discuss which points in the 2012 report provide a really essential basis for some of the conclusions we're making here, such as the evidence for asbestos exposure. And then we can plan to include those in our document as footnotes, or other footnotes.
I think what we should strive for is that our main document is fairly succinct with appropriate scientific references, but that we also provide additional information that's readily available to the Administrator. Nick?

DR. NEWMAN: Yes, just a question and a point. The question: the letter that you wrote in 2012 that's on the website, it's like 51 pages long or something. Is that the report?

DR. WARD: Yes.

DR. NEWMAN: Okay, okay, because I pulled that up and I just wanted to make sure it was correct.

DR. WARD: That is it.

DR. NEWMAN: And I guess the other thing I wanted to say is, don't get me wrong, I'm not trying to play down the lived experience of the people who were in Manhattan and the dust and all this other stuff. It's just that I'm worried that a peer reviewer is going to be someone living in Idaho or something who's never had any experience with this, and we want to provide as—because I've sat on other review committees, you really just have to get it down to what facts are there. So, I just want to make sure that if this discussion that we have here about this lived experience with the dust and how pervasive it was and all this other stuff, if that's legitimate to be included as part of the STAC's comments or whatever, that's fine. I just want to make sure that if we're saying things that we put as much scientific underpinning under it as possible because the people reviewing it aren't going to have the necessary feedback of survivors and people who were at the scene and all this other stuff. So that's where I'm coming from. I feel like if we're going to make the argument, we want to make it as strong as possible so that it lives through what the next phases of this are.

DR. WARD: Great. And I agree and, like I say, I think a lot of that is already present in the earlier STAC report and that would be the most efficient way to cover the main points, but if there are additional points that we should cover and reference—and that report of course includes reference to the published literature on exposures, as well as a description of why we feel the qualitative information is also important.

But, Tania, I wanted to get the comment that you just read so that we can talk about how we want to proceed. The comment suggested that rather than try to conclude our evaluation and they shouldn't then report today, that we form a workgroup to take the process further. And I wondered if you wanted to talk a little bit about that option and we should get a sense from the Committee as to whether we feel, based on the White Paper and all of the discussions we've had today and possibly adding a few additional points that might—so actually one question I have is, I think we can come up with—I mean unless there's strong sentiment in the Committee that we need to have a workgroup to consider this further, we do have at least 90 days to get back to the Administrator. We don't have to give the Administrator an answer today.

My sense from what people were saying is that we could possibly form the basis for recommendation to the Administrator today, but I can't remember the processes in the past. So, do we have an option that we could discuss the major conclusions of our deliberations today, but have an opportunity to draft the fuller recommendation and share it with the other Committee members for comments and approval before we send the details to Dr. Howard?

DR. CARREÓN-VALENCIA: Yes, certainly you can do, either appoint or work in a committee or a subcommittee, discuss among yourselves, and then bring your recommendations to the full Committee for a meeting, following FACA procedures, or you can work among yourselves and submit a recommendation. And, yes, you have 90 days—that started yesterday—to provide your recommendations to the Administrator.

Before moving along, this is the time to start the public comment period or session. So, I was wondering if we could stop at this point, hear our six commenters, and then continue after the break.

DR. WARD: Perfect, yes.

DR. CARREÓN-VALENCIA: Great. Thank you.

PUBLIC COMMENTS

DR. CARREÓN-VALENCIA: As I said, we have six people that will be commenting. I'm going to ask those that will do so to unmute yourself and you will have five minutes to provide comment. The policy on redaction for public comments was shared with you and I hope if you haven't read it, that you do so.

So, our first commenter is Dr. Iris Udasin. And you have five minutes.

DR. UDASIN: So how come I can't start my video so that you can see me?

DR. CARREÓN-VALENCIA: I'm working on it.

DR. UDASIN: It says here, “You cannot start your video.”

DR. CARREÓN-VALENCIA: I’m working on it. Hold on, hold on, Iris, sorry.

MS. WALLACE: We can see you in the timer.

DR. UDASIN: Okay, it says I cannot start my video because the host has stopped it. But all right, if you tell me that I have my video, then—oh, no, now it told me I can start my video, wait. Oh, yes, there I am. Okay, thank you, so sorry about my lack of technical proficiency.

So last year Dr. Graber and I submitted a letter about why we felt that uterine endometrial cancer should be considered along with the other cancers World Trade-related. And we had all of the female investigators sign that letter and I believe that we submitted it. Additionally, I spoke in the 9/11 conference at Mount Sinai, and I believe we've uploaded those slides to you, which hopefully will give you some more references if there are any references that you haven't found.

So, the first thing that I want to say is that we have accepted the fact that there haven't been an excess of uterine cancers found in the 9/11 responders. We understand that. But what we want to say is that there is a great amount of medical literature about the fact that endocrine disruption can cause uterine cancer, ovarian cancer, testicular cancer, etc.

What you may or may not have considered is that there were actual biologic monitoring studies that were able to be performed that actually demonstrated that people found accumulated PFAs in mothers during pregnancy in cord blood, polychlorinated dibenzofurans were found in homes in various neighborhoods. And in the materials themselves, a fair number of PCBs, polychlorinated dioxins, and furans were found. So, this is very important in consideration of a mechanism to explain why uterine cancer can be related to 9/11, as opposed to analyzing individual whether or not there was truly an excess of uterine cancers.

Now, there's literature for a long time, even 50 years ago, about endocrine disruptors causing cancer and very clearly there's the DES literature. And I cite that in the materials I have provided for you. Articles from Linda Birnbaum show developmental and carcinogenic effects of related endocrine-disrupting chemicals and I’ve provided that as a reference for you in my slides that I submitted. A recent Medline study done in 2019, reviewing articles over a 23-year period and they were human studies that showed that the carcinogenic effects of endocrine disruptors are quite plausible.

So, where does that leave us in 9/11 and cancers? Right now, we're covering prostate cancer, breast cancer, ovarian cancer, testicular

cancer, vaginal cancer, penile cancer, but we're not covering uterine cancer. And while there are studies that have cited excesses of some of the cancers that I mentioned, they were not clear studies that cited excesses of all of the cancers that I've mentioned. And why uterine cancer should be singled out in that way does not make sense to me, and that's the reason why I got involved in this.

I want to say that I follow personally three patients that have this type of cancer and that's in the Rutgers responder program. I know that there are many other patients with this condition, and I'd like to see these patients have the same access to care and access to benefits as the patients with other solid tumors that we are seeing in the Program.

So, I thank you for your attention and I guess I did this within the correct amount of time. And again, please consider it as there are real people here that need to see real physicians, who may or may not have proper health insurance, and we want to take care of these brave people. And I thank you.

DR. CARREÓN-VALENCIA: Thank you very much, Iris. Our next speaker is Kathy Hanson.

MS. HANSON: Hi, thank you. I hope you can see my video. My name is Lauren Hanson McGrady. I am speaking on behalf of my mother, Kathleen Hanson. She has a severe hearing deficit so she asked if I would speak on her behalf today. So, I do have a letter that she has written:

"To whom it may concern and thank you so much for all of your time, my name is Kathleen Hanson. I am the widow of Detective Specialist Michael T. Hanson"—sorry—"who worked for the NYPD ESU Truck 1 in Manhattan. He did the rescue effort/recovery at Ground Zero from 9/11/2001 until May 2002, for 16-hour days searching for any possible victims, as well as doing recovery for the families. Michael also attended Mass every Sunday with Monsignor Romano assisting by giving out Communion."

"Mike was certified by the World Trade Center Health Program at Mount Sinai for respiratory illnesses, GERD, rhinitis, and sleep apnea. Mike started having neurotoxic symptoms in 2018 and was treated at Columbia under Dr. Neil Schneider. Starting in approximately March 2018, Mike quickly and rapidly declined from being totally ambulatory independently to walking with use of a cane, then a walker, and finally a wheelchair until he was bedbound and could not stand on his own. And because he lost the use of his arms and legs, we actually had to lift him ourselves. He passed away in October 2018 after this rapid, six-month health decline. He had just turned 60 in that June. There's actually no history of any neurological illnesses in his family as well."

"I had a private autopsy done and that found the metal antimony in his brain tissue. Antimony is known to be neurotoxic metal and antimony was known to be present at Ground Zero. Antimony destroys the myelin sheaths, eventually killing those affected neurologically. The diaphragm of the patient ceases to work so then respiratory arrest occurs."
"The day after Mike passed, I, Kathleen Hanson, lost his NYPD pension as well as his medical benefits since neurotoxic illnesses are not considered by NIOSH to be a certified Ground Zero illness. Mike has a good friend Sergeant John English of ESU who was also at Ground Zero the entire time with him. John now has end-stage Parkinson's disease. I also know of many others who have developed neuropathy, multiple sclerosis, Parkinson's, ALS, and other neurotoxic illnesses."
"We respectfully ask that NIOSH get neurological illnesses as a Ground Zero-certified illness for those brave men and woman who were at the World Trade Center recovery site and those around that have developed these horrible diseases and/or have passed from them. We can never, ever forget 9/11 and this attack on our country, killing thousands that day but are still continuing to kill 20 years later. Thank you so much for your time and attention."
I do apologize for the emotion as my dad was my hero, so please take care of those that are still here. Thank you.

DR. CARREÓN-VALENCIA: Thank you very much, Lauren. Our next speaker is Matthew Skiba.

MR. SKIBA: HI, guys, can you hear me all right?

DR. CARREÓN-VALENCIA: Yes.

MR. SKIBA: Awesome. So good afternoon, everyone. My name's Matthew Skiba. I'm the son of former New York State Police Captain David Skiba. First and foremost, I just wanted to give credit and applaud everyone here, the World Trade Center and the Victim Compensation Fund. When new data and information comes available, your adaptability, flexibility allows for the support of all those who have sacrificed and have suffered since September 2001.
I'm optimistic that uterine cancer will be added to the list of covered conditions, but today I wanted to discuss a separate issue that I believe needs more attention. The policy I want to talk about is titled "Minimum Latency and Types or Categories of Cancer". I'm sure the entire STAC Committee is familiar with this, but for those who are listening and are unfamiliar, "latency" can be defined as the amount of time that passes between exposure of cancer agents and diagnosis. The current policy states that all solid cancers need a minimum of four years to pass until a condition would be recognized, which means any patient diagnosed with

any type of solid cancer earlier than September 2005 would be ineligible for any benefit or recognition. Since this policy was last revised in 2015, more information has been published regarding latency.

A study published in October 2020 by the International *Journal of Environmental Research and Public Health*, identifies itself as the first report on cancer characteristics of enrollees at the World Trade Center Environmental Health Center, which is a part of the World Trade Center Health Program. The study's 2,999 cancer diagnoses across 2,561 patients enrolled within the World Trade Center Health Program and the information reviewed is early-onset diagnosis for each type of cancer. The earliest case of breast cancer among World Trade Center Health Program patients was diagnosed 3.3 years after September 2001; earliest case of lung cancer was diagnosed 3.3 years after September 2001; earliest case of head-and-neck cancers among World Trade Center Health Program patients was diagnosed 3.6 years after September 2001; and the earliest case of prostate cancer among World Trade Center Health Program patients was diagnosed 3.9 years after 9/11.

Based on the currently used policies though, which states a minimum latency of four years, all these patients are ignored. The door is shut on their claims due to the sole fact that they developed cancer more rapidly than the arbitrary expectation of four years.

Among these patients that have been ignored and denied repetitively is my dad, David Skiba. At the time of 9/11, my dad was a 37-year-old, healthy trooper, with a seven- and a three-year-old at home. And according to the many affidavits we have from many of his coworkers and the New York State Police members, my dad was one of those that was most frequently assigned to the rescue-and-recovery details at Ground Zero. In January 2005, three years and four months after September 2001, my dad was diagnosed with lung cancer that metastasized in his brain. He battled this cancer for three years and ultimately passed away on February 19, 2008. He was 43 years old. He didn't get to see his 13-year-old daughter and his 10-year-old son grow up. He didn't get to enjoy retirement like most of his colleagues are now. And since the New York State Police have aligned with the World Trade Center Health Program policies, he's not recognized for his contributions to one of the most significant events in U.S. history. His death isn't considered a line-of-death duty. His face isn't on the Wall of Honor at the New York State Police Academy. But those who he worked alongside with down at Ground Zero are. Because he was diagnosed with cancer eight months

earlier than the arbitrary value of four years, that new studies suggest is already incorrect, I won't be able to bring my kids to the Wall of Honor and tell them all about their grandpa. This policy has left my mom Linda, my sister Nicole, my aunt Lisa, my grandparents Mattie and Lydia, and myself, and most importantly my dad, literally and figuratively in the dust. Within the Minimum Latency and Types or Categories of Cancer policy, the first method that is listed and to determine latency is direct observation. I believe that the study published by the *International Journal of Environmental Research and Public Health* satisfies this requirement. If any cancer is diagnosed earlier than four years, I believe the policy should be looked into and adjusted, whether the latency is decreased to three years like the study suggests, remains at four years but rather than shutting the door immediately on each claim, review on a case-by-case basis or eliminate it entirely.

It would bring justice to my family, my dad, and the many other families that are stuck in the same situation. So, thank you all for listening and allowing me this platform. I've covered everything I was hoping to, and I hope that these short five minutes generate some momentum and action into looking into a policy that conflicts with currently-available data and excludes heroes like Captain David Skiba. Thank you.

DR. CARREÓN-VALENCIA: Thank you, Matthew. Our next speaker is Michael Sweeney.

MR. SWEENEY: Hello, can you hear me?

DR. CARREÓN-VALENCIA: Yes, we can.

MR. SWEENEY: Okay, can you see me now?

DR. CARREÓN-VALENCIA: Yes, we can see you too.

MR. SWEENEY: Okay, I can't see myself, but I'll go ahead. My name is Michael Sweeney. I'm a retired detective, NYPD's Emergency Service Unit. I retired in 2008 after 20 years on the job. I was also a New York City MAC-certified paramedic for 26 years. I was at the World Trade Center before the North Tower collapsed. I was on Vesey and Church, and I had to run for my life. And I'm just lucky to be here. But since working the World Trade Center from September 11th until they closed it the site in May of 2002, I've been diagnosed and certified with rhinosinusitis and basal cell carcinoma twice in about four years. I go for my second Mohs procedure in two weeks. I'm constantly coughing, clearing my throat, and scars on my face is nothing compared to neurological diseases that my fellow officers and first responders and people in the area are facing.

My brother-in-law John English I'd like to talk about. John was a sergeant in the NYPD's Emergency Service Unit, and he worked constantly at the World Trade Center from 9/11 until it closed. John retired in 2003 and is

now suffering from Parkinson's disease. Unfortunately, John couldn't be with us today, but he did send me this letter telling about the diagnosis and how it all started with John. In April of 2014 he was working, he was driving the vehicle and his left hand was on the steering wheel. He noticed his pinky was slightly twitching while his left hand rested on the wheel. He says he didn't think anything of it much because he figured probably just overuse of the muscle, something like that. His symptoms continued unabated, but still were not causing him any problems in his daily activities.

In July of 2014 he was on vacation in South Carolina when he noticed his whole left hand was beginning to shake at rest but not all of the time. When he arrived home, he was sitting on the couch with his wife and she noticed his hand shaking. She asked him when this started, and he told her it started two months ago. She was also a paramedic, just for the record. She stated, "We're going to a neurologist." John went to a neurologist in December of 2014. A highly respected neuro fellow in his field conducted a neuro exam and on completion of the neuro exam, he told John his diagnosis was Parkinson's. John was devastated. He said, "I have no family history of any neurological diseases, no one in the family has Parkinson's." I asked him, "How could this have happened?" He told me that, in his opinion, since he worked at the World Trade Center Ground Zero site and since exposure to toxins is one of the primary causes of Parkinson's, that his work at the site was very likely the reason for his Parkinson's diagnosis. He said that this is his medical opinion, but that a study of first responders with neurological conditions should be undertaken.

Since then, John's condition requires that he takes medications like carbidopa, levodopa, rasagiline, and trihexyphenidyl in order to try to live a somewhat-normal life. He says, "My symptoms have progressed to my entire left arm shaking, my left leg shaking and foot-dragging at times, my left-sided facial twitch, and almost complete loss of fine motor skill with my left hand." He has met with several of the first responders from his days at Ground Zero with different types of neurological conditions. They all truly believe that they are afflicted with these conditions as a result of their work and their time at the World Trade Center during the rescue and recovery efforts.

It took a lot of fighting to get the Zadroga Act passed in order to cover illnesses that were materializing earlier on since September 11th and neurological conditions that have materialized since that day, although are not being covered. Some of the respiratory conditions that came later

are in fact covered and John is certified for one of these respiratory conditions. So, he totally believes, and we all believe, that it should be apparent that these illnesses are caused by the exposure at the World Trade Center site, Fresh Kills Landfill, and at the morgue.
In John's statement he says, "It's not for myself that I make this plea. It is for the families of the first responders who will have to deal with these diseases for the rest of their lives, taking care of and making funeral arrangements for their loved one. Also on a final note, I would like this panel to know that even if I knew this would be a consequence of responding to this terrorist attack, we would have gone in no matter what. We made a commitment to protect our fellow citizens when we took this job and will never turn away from it. I ask you to do the same."
We never forget. And "Never forget" is not a slogan to us. We live it every day. I appreciate you guys taking time to hear me out and I hope you'll please look into this because everything points to exposure of neurotoxins and the neuro diseases. Thank you very much and everybody have a great day, stay safe.

DR. CARREÓN-VALENCIA: Thank you very much. Our next speaker is Kimberly Flynn.

MS. FLYNN: Good afternoon. I make these comments on behalf of the WTC Health Program Survivor Steering Committee. We believe that the rationale presented by Dr. Udasin and the other investigators for adding uterine cancer is sufficient. They reason that many of the 800 recognized endocrine-disrupting chemicals are known constituents of WTC dust and smoke, that EDCs have been shown to impact reproductive health across the lifecycle, that the estrogenic action of many EDCs by dysregulation of microRNA expression and other mechanisms, is plausible evidence of a causal role in uterine cancer. Furthermore, none of the available studies factor in simultaneous exposures to multiple EDCs and other carcinogens, a scenario that played a key role in the 2012 cancer deliberation and was used to justify adding cancers that would not meet the high bar set for uterine cancer currently. We are between a rock and a hard place with this cancer, which is not rare enough to qualify under the rare cancer provision, yet not frequent enough to be detected in largely male study cohorts. The STAC should appreciate also that although the vast majority of studies glossed in the scientific considerations document were underpowered due to very small cohorts of women, it does appear that a collective trend can be seen across a number of these studies, suggesting increased uterine cancer among women exposed to EDCs, focusing exclusively on individual studies can obscure/affect trends that would be apparent in a forest plot.

For instance, the mortality of female workers in the Italian asbestos cement factory, did show a statistically significant access mortality of women from cancers of the uterine corpus and cervix combined. We have contacted the study authors to request the data specific to the uterine corpus. Since cervical cancers, though, make up less than a quarter of all uterine-related carcinomas, there is a good chance that the data from this study would show a link between asbestos exposure and uterine cancer. The analytical approach used throughout the considerations document of dismissing all studies whose 95% confidence interval includes an RR of 1.0 erases the opportunity to examine collective trends across multiple studies employed in metastudies such as the Cochrane reviews.

And now I want to widen out to the research issues which are also on this meeting agenda. A refrain in the scientific considerations document is, "Most studies have been conducted in occupational cohorts which included a small number of women or no women at all." This statement is mostly true of the entire WTCHP research portfolio, where 78% of research money funds studies of a responder cohort that is 86% male. While we would agree that the research budget is inadequate to address the full range of multisystem health impacts for all 9/11 populations, we do not accept the large disparity. Most glaring is the lack of support for research on how the WTC disaster affected women, who constitute 50% of survivors, and the health of more than 35,000 9/11-exposed children. Given that the WTCHP operates on a research-to-care model, research decisions have far-reaching implications. Research gaps become knowledge gaps which, in turn, become diagnostic and treatment gaps. This is bad science that translates into a denial of care. The SSC will be updating the STAC in writing on whether the Program has followed the STAC's 2026 recommendations on children's 9/11 research. The short answer is mostly not. And I also want to comment that there is no research being done now on reproductive health impacts to people exposed as children.

We are also calling on the STAC and the Program for a meeting in the next six months to start the conversation around health equity and the impact of unequal research. Finally, we call on the Program to review the diagnoses of the women who have come forward in this meeting, several of whom have been struggling for years to figure out whether their individual cancers are rare by the Program's definition. Obviously, we are calling for adding uterine cancer as an entire class, but these women are entitled to an immediate remedy, if there is one. Thank you very much for

your consideration.

DR. CARREÓN-VALENCIA: Thank you, Kimberly. And our last speaker is Donna Malkentzos.

MS. MALKENTZOS: Okay, coming over?

DR. CARREÓN-VALENCIA: We can hear you.

MS. MALKENTZOS: Hello?

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

MS. MALKENTZOS: Okay. First, I want to thank Ms. Hannah Silverman for giving me her five minutes. I was a first responder. I worked at all three sites, being Bellevue Hospital, World Trade area, and the landfill. I have clearly over 100 hours working, both of which were at the landfill, which I will describe later. I was first diagnosed with uterine cancer in 2013. I was 55 years old. I had a full hysterectomy. In 2014, I had 28 shots of radiation, and that's when I started to contact John Howard, trying to get my cancer approved under the World Trade. In 2016 I had gone to the hospital; I thought I had a hernia. Well, once they did the operation, it wasn't a hernia. I was diagnosed with metastatic carcinoma, favor ovarian, primary showing features of serous and clear cell carcinoma. Not having a clue what that is I then decided to go right to Sloan.

Sloan compared the slides with the original cancer, uterine cancer, said it was close and they can understand how they said it might be ovarian. I had six bouts of chemotherapy, again trying to get my cancer approved; sent letters with all the information to NIOSH, John Howard. Thinking that was it, in 2018 I started to have pain in my neck and my shoulder. I went to physical therapy, I went to Sloan, and they gave me some shots, didn't know what it was. In June of 2018 my CT scan came back, my cancer came back, and I was originally told in the liver and it was inoperable. Well, it wasn't in the liver. I had seen a fantastic surgeon from Sloan and fast-forward, I had another surgery, they wound up removing part of my diaphragm, and now I'm on hormonal therapy.

Okay, again, each and every time contacting John Howard's office trying to get the cancer approved. In the interim I found a couple of studies. Of course, I lost most of them, but one of which was about cadmium and cancer. It was written by a Catharine Paddock, PhD, August 11, 2017. And in that—and, again, this is information I have forwarded—in that it stated from a Professor Jane McElroy, "Endometrial cancer has been associated with estrogen exposure. Because cadmium mimics estrogen, it may lead to an increased growth of endometrium, contributing to increased risk of endometrial cancer."

Okay, after that I still had to do more research and in the *Journal of International Medical Research*, I came across—sorry for being a little

disorganized—okay, on Page 4 regarding my diaphragm—because I was trying to say maybe it's a rare cancer. And here it says "The most common location of distant metastasis from endometrial cancer is the lungs, bone, liver, and brain. Endometrial carcinoma rarely metastasizes to the diaphragm. Only two cases of endometrial carcinoma metastasizing to the diaphragm have been reported." So, with that I still was denied getting it.

Now, two points I want to make out. May 2nd of 2013 the PBA sent a letter to NIOSH requesting prostate cancer being approved. It was approved September of the same year, September 19th. I thought that was pretty quick. Now, in September of—I know my time is running out, I apologize—September 16th of 2019 I got a letter saying my cancer was certified. I was ecstatic. When I went for my yearly checkup with the World Trade, they said, "No, it was a mistake." Because I thought maybe they'd pay for my medication which was over $100 a month. And they said, "You're not certified." October 23rd of 2019 I got another letter with a list of all my certifications. That was the fourth one. November 29th of 2019 I got an award letter from VCF. February 21st of 2020 I basically got an "Oops you're not covered, we made a mistake," which to say the least was a little discouraging.

The last thing—and I'm so sorry I'm going over my time—is I just want you guys to know at the sites, especially the landfill, initially we had no protective gear for the first few weeks. The dust in the air—and I'm the one that made a comment about the porta-stands—was thick. We had maybe at times the white little mask. We ate outside. We had no tents. We drank outside. They did supply water—that was kept outside. So, you cannot tell me that the dust in the air did not come through us at some point, be it orally or anywhere else. Thank you so much. I'm so sorry I went over my time but thank you.

DR. CARREÓN-VALENCIA: Thank you, Donna. Liz?

DR. WARD: Sorry. That's great. So, I guess we should break for lunch and come back at 1:30. I was wondering, Tania, if you and maybe Dori and I could talk during the break? Okay.

[Lunch.]

STAC DELIBERATIONS AND DEVELOPMENT OF RECOMMENDATIONS

DR. CARREÓN-VALENCIA: Please, I think we should continue the meeting, thank you. Thank you all. Thank you to the Committee members for being here and, of course, the

members of the public that are following the webcast. I'm going to take another roll call to check on our quorum. Liz Ward.

DR. WARD: Sorry, here.
DR. CARREÓN-VALENCIA: Sophie.
DR. BALK: Here.
DR. CARREÓN-VALENCIA: Chandra is not here. Thomas.
DR. DYDEK: Present.
DR. CARREÓN-VALENCIA: Mariama.
MS. JAMES: Present.
DR. CARREÓN-VALENCIA: Anita.
DR. JOSE: Here.
DR. CARREÓN-VALENCIA: Michael.
DR. LARRAÑAGA: Present.
DR. CARREÓN-VALENCIA: Catherine.
MS. MCVAY HUGHES: Present.
DR. CARREÓN-VALENCIA: John.
DR. MEYER: Here.
DR. CARREÓN-VALENCIA: Debra.
DR. MILEK: Present.
DR. CARREÓN-VALENCIA: Larry is not here. Nick.
MR. NEWMAN: Present.
DR. CARREÓN-VALENCIA: Jason.
DR. OSTROWE: Here.
DR. CARREÓN-VALENCIA: Robin.
DR. SASSMAN: Present.
DR. CARREÓN-VALENCIA: Aarti.
DR. SURTI: Present.
DR. CARREÓN-VALENCIA: Leigh.
DR. WILSON: Present.
DR. CARREÓN-VALENCIA: Thank you very much. Before we move on, I want to share my screen briefly to show you and the members of the public where you can find that document that Liz was referring to, the report from the STAC 2012 meeting. Can you see my screen now?
DR. WARD: Yes.
DR. CARREÓN-VALENCIA: Okay. So, on the docket page—I'm sorry, because of the thing on the top, I can't read the link. But I hope you can see the link to the docket. It's NIOSH Docket Number 248. And it's on the NIOSH website. And if you go on Docket Number 248, you will see the first document is the letter from the Chair Dr. Ward to Dr. Howard. And that's the report she was referring to. But then you can see other documents that show the

preparatory work that took place that led to those letters to the Administrator and the recommendation, which we will also discuss how you will continue your deliberations to develop a report to Dr. Howard. So, I hope you all have a chance—I'm going to move up again so you can see the link to the website.

DR. WARD: And you can also just search under "World Trade Center Health Program STAC" and it will bring to that place as well.

DR. CARREÓN-VALENCIA: Right. And it's also on the Committee's website. A link to this, it's also on the Committee's website where information from every meeting is posted. At the end you will find a link at the bottom, of all the meetings you will find a link to this docket. So, thank you. And, Liz, you want to continue?

DR. WARD: Thank you. I had a consultation with some of the members of the Program over lunch because the procedures under which FACA have to operate are a little bit counterintuitive to me, so I think I inadvertently said something incorrect at the end of meeting. So, I wanted to clarify with them how we will be proceeding, both in terms of voting on the overall recommendation and then preparing the report.

So, I think the key thing that I misstated was I said that we could possibly work on the draft collaboratively through email. And then if we were really close to an agreement today, we could finalize the draft via email. But given the importance of having public record of all of our deliberations, we don't think that will be possible. We think the alternative process that would work with the FACA rules is that we do as much as we can today to agree on the content of the scientific rationale for our recommendation, but then we form a subcommittee to prepare a draft of that recommendation which would then come back to the full committee for review that would entail both having an open meeting of the subcommittee to discuss the proposed draft, and then an open meeting of the full committee to discuss the draft that the subcommittee provides. And both of those meetings would be published in the Federal Register, so there would be a time consideration. Tania, did you have anything to add about that?

DR. CARREÓN-VALENCIA: Yes. The meeting of the subcommittee does not necessarily need to follow all FACA rules and does not necessarily have to be an open meeting. But we will be consulting with the CDC FACA office to make sure that we are running this meeting appropriately. However, the meeting where the report and recommendations from the subcommittee are shared for a vote with the full committee, that needs to be an open meeting subject to all FACA rules. That means including a Federal Register Notice and an opportunity for public participation and comment.

So, I wanted to clarify that.

DR. WARD: Right. And the procedure, I want to allow adequate time for discussion before we take a vote on our recommendation as to whether or not to add uterine cancer. But the procedure for making a decision on that would be that a member of the Committee would make a motion and then it would be seconded and then a formal vote would be taken with each person's vote recorded.

So, one possible way to proceed is that we open the floor again to hearing any comments or questions that people would like to have resolved before they feel that they would be prepared to take a vote. Then if there is a sense that we should continue to a vote, someone can make a motion. If the vote is to approve, then we could go through the slides and make sure that—we have a person from NIOSH named Ann with us today and she actually can take notes as we go through the slides on matters that we would like to add or revise. Of course, if the recommendation would be no, we would have to provide a rationale for that recommendation and we would have to work on that subsequently as well, most likely.

And can Emily or Jess refresh our memory, because somebody brought it up today, so according to the procedures, it's my understanding that we would not really have the possibility of going back and saying there's insufficient evidence. Our options at this point are only to say we recommend, or we don't recommend. But once the matter is referred to the STAC—before it would refer something to the STAC, the Program would determine if there was insufficient evidence and that would be published in the Federal Register. I hope I haven't botched that too badly, but does anybody want to restate and clarify?

MS. BILICS: This is Jess. So, after there's been a referral to the STAC, the options available to the Administrator are to publish a Notice of Proposed Rulemaking or to publish a no to add the condition because of insufficient data, but because there is data that it is not an association between the condition. So, it's the option of doing an FRN that shows that there's insufficient evidence that goes away based on the Zadroga Act once the referral has been made to the STAC.

That doesn't mean that the Program couldn't consider it at a later time where there could be new scientific evidence, but since we've gone to the STAC already, the Administrator does not have the option to publish a Federal Register Notice of Insufficient Evidence after having gone to you all right now.

DR. WARD: Thank you. Yes, so I think there is a place for us to say that more

research is recommended, but it's not an option at this point to say we can't make a recommendation because there's insufficient evidence. Okay, so now that we've totally cleared up that confusing point, we can move on and get additional comments from the group. Catherine?

MS. MCVAY HUGHES: Yes, I just have one question of clarification. So, if this meeting concludes in a yes, does the subcommittee need to happen? Because it's already going to be reviewed by three other experts before John Howard makes a decision, right?

DR. WARD: No. If the Committee votes yes, then the charge to the Committee requires us to present a reasonable scientific rationale for our recommendation. And so, it's the task of the STAC to prepare that report, to make that recommendation similar to what we did in 2012, write a formal recommendation to Dr. Howard with what we consider the most relevant background information. Then once Dr. Howard receives our recommendation, then he makes the decision whether to proceed with the rulemaking, but before that there would be another period of public comment and then there would be a peer review by three experts. But what the three-expert peer reviewers would be looking at is the scientific rationale that the STAC has provided for the recommendation.

MS. MCVAY HUGHES: So, the earliest a decision could be made after today would be how many months from now?

DR. WARD: Jess, I think I'll turn these questions over to you.

MS. MCVAY HUGHES: Thanks.

MS. BILICS: So, if a decision were not to be made today and there were to be subcommittees, the Program would need to have another public meeting, which we need to provide at least two weeks' notice in the Federal Register for, so it needs to be announced. So, we would then announce it at least two weeks in advance, hold the meeting, hopefully there would be a vote one way or the other at that meeting, and then the Program would take back the information received, the recommendation received from the STAC.

If the decision was to publish a Notice of Proposed Rulemaking, the time period between once we get the STAC's recommendation and the publication of the Notice of Proposed Rulemaking is basically the amount of time it takes the Program to put together that document, the economic analysis and all the other requirements that are part of the rulemaking process and get it through clearance. So, we're talking probably at least a few months.

Once there is a published Notice of Proposed Rulemaking, there is at least a 30-day public comment period, but we extend it at least 15 days

after that to allow the public to see the peer reviews, peer reviewers' comments. And then once those 45 days have passed, there's a publication of a final rule or the determination to not add the condition based on the review of public comment or peer review. And if the decision is have a final rule to add it, there is a 30-day effective period. So, we are talking probably at least six months, even if everything is a yes, before anybody could be certified and covered for a condition. And Emily wanted me to point out too that the timeframe from the period we have, the dates that we get the recommendation from the STAC, is a 90-day window to add what are the actions in the Federal Register. So, we have three months to be able to write and clear a Notice of Proposed Rulemaking or a decision not to add based on evidence of that the condition is not related to 9/11 exposures.

DR. WARD: Tania?

DR. CARREÓN-VALENCIA: I also want to clarify that you could have a workgroup or a subcommittee. Workgroups are generally not subject to FACA rules, so you can work as a workgroup and then provide recommendation to the full committee, which abides to all the FACA rules: FRN, Notice of Public Meeting open to the public, etc. You could also have a subcommittee and that subcommittee follows all the FACA rules. So those subcommittee meetings don't need a full committee vote, but they will need to be open to the public and be announced on the FRN. And I understand it's confusing, but that's the way the law (works @ 00:15:39).

DR. WARD: Do one of those two categories have a designated maximum number of members? I think I remember three, but I could be just making that up.

DR. CARREÓN-VALENCIA: No, the three is the number of peer reviewers that is per the policy and procedures.

DR. WARD: Okay. Okay, got you. Okay, okay, so I guess—

DR. CARREÓN-VALENCIA: (Inaudible @ 00:15:58).

DR. WARD: So, what would be the pros and cons of—I think it's clear that we'll need to proceed with either a working group or a subcommittee. Would you like to talk about the pros and cons of either approach, and why we would do one or the other?

DR. CARREÓN-VALENCIA: Well, in terms of following the FACA rules, the Federal Register Notice needs to be prepared and needs to be published two weeks, at least two weeks in advance of a public meeting. So that adds time to the full meeting. And you know you have 90 days to prepare a recommendation to the Administrator. So that probably logistically is less viable—well, we can decide the merits of each one, but maybe the workgroup could be more efficient in terms of you work in a smaller group. It doesn't have to

	be three, it can be any number.
DR. WARD:	Okay, any size.
DR. CARREÓN-VALENCIA:	And then provide a working document and a recommendation that will be discussed by the full committee in another meeting that needs to be announced at least a week in advance in the Federal Register and open to the public.
DR. WARD:	Okay, I think it's coming clearer. I do recognize and I think it's the sense of the Committee that it's not our goal to drag this on and take the full 90 days to submit our recommendation if, in fact, the task can be completed more quickly. And I am certainly available and willing to do a lot of work preparing the draft that the workgroup will review. It is seeming to me now that a workgroup would be more appropriate than a subcommittee because there would be less delays possibly caused by Federal Register Notices. The one question I had for Jess, I think Jess when you started talking last time, you said if the Committee does not vote today. But the scenario that I think Tania and I were talking about at lunchtime is the possibility of taking a vote today and then based on that vote, proceeding to draft the scientific rationale. So is there any problem with doing that? Does anybody from the legal team have any concerns with that?
MS. BILICS:	(Inaudible @ 00:18:43) Emily, but I'm not aware of any legal. Go ahead, Emily.
MS. HOWELL:	Yes, sorry, this is Emily Howell from Office of the General Counsel. So, I would recommend that since there are still deliberations about the basis for any recommendation, that the vote today would be more along the lines of voting to form a workgroup and a vote that takes I guess the general direction of the full committee of the STAC for what they want the workgroup to be working on. And that may mean we believe that there is or is not a basis for this and we direct the workgroup to put together materials to support that. But the formal vote on whether or not to recommend to the Administrator that uterine cancer be added or not added to the list should really take place once that report has been deliberated upon by the full STAC so that you're voting not just on the outcome, but on the basis for that recommendation.
DR. WARD:	Yes, that makes sense to me. I think I'm finally more clear on the process. Thomas, you have your hand up?
DR. DYDEK:	Yes. Maybe I'm not so clear. But if we vote yes, it seems like one way would be to provide new scientific evidence that would support that, which I don't think we have. But can we vote yes and provide scientific evidence why the evidence for no is not so great?

DR. WARD: Well, I think you may be focusing on the phrase “new evidence,” which was part of Dr. Howard’s charge. But I don’t think that we are—I mean we certainly can present new evidence, but we can also interpret the body of evidence that existed before in terms of the previous STAC recommendations, the previous Federal Register Notices regarding addition of cancer-related conditions, the White Paper.

So, it’s not as if we need to say, well, we're disregarding most of the evidence related to things in Methods 1, 2, and 3 because the Program has determined that the cancer doesn't meet the criteria based on those matters. We can still use the data and the evidence that was considered by the Program informing a basis that there is a reasonable scientific rationale for recommending that uterine cancer be added.

DR. DYDEK: Well, I didn’t mean to limit it to new evidence, but is one possible decision by a committee to say, yes, and here's why because we think there are inadequacies in the database that would support the recommendation of no?

DR. WARD: Would anybody else care to address that question? Okay, I’ll take a stab at it. I think some of the arguments that we're presenting in the summary slides could be interpreted to say that we're saying there's an inadequate database. But I think the sense of the Committee is that there is enough scientific data to make a recommendation in the context of recognizing the limitations of especially the studies of World Trade Center populations and the studies related to industrial carcinogens.

So, I think we want to put an emphasis on the logic and the rationale for why we would still support the addition of the condition rather than emphasizing the inadequacy of the database, because that sounds very close to insufficient evidence. And that’s not for us to determine, but I think there is substantial evidence; we just need to interpret it. Nick?

DR. NEWMAN: Just looking at the revised charge, the recommendation where there is a reasonable scientific basis—and reasonable scientific basis is a fairly wide thing to fly down, or drive your boat down, or whatever metaphor you want to use—and encourage us to supply any additional scientific evidence not presented to you by the Program that may also serve as reasonable scientific basis.

So, it’s basically what would a reasonable scientific person think of what we're saying? I believe we couldn’t draw the conclusion that, oh, I brought my umbrella, therefore it’s going to rain. But we could say, oh, okay, well, it’s very cloudy and the barometric pressure is going down and there's this front coming in, and I have my umbrella and it’s probably going to rain. And I think what's been presented so far in terms of the cancer

mechanisms, similarity to other cancers, etc., I think there's a reasonable basis there. I wouldn't say that there's like a Rock of Gibraltar, but for almost—I mean I'm a clinician, I've been doing this for 20 years, very few things are resting on a Rock of Gibraltar. A lot of it is like, okay, well, this is a reasonable thing to do.

So, I guess I don't feel like—maybe I'm echoing John Meyer from before; I think we've already discarded Bradford Hill and all the criteria. We're left with, is there a reasonable scientific basis? And from what I get from the conversation is, yes, we feel there is. And we have to fill in the specifics but, based on what we've been told, there seems like there's enough to connect some of the dots together. Maybe not every dot, but there's smoke and we just have to find the fire. I'll stop with the metaphors.

DR. WARD: Tania?

DR. CARREÓN-VALENCIA: Liz, I just want to clarify something. Mia has just shared with me one of the slides that we also had, during orientation on Monday from Lee Gardner. In a subcommittee, members of the subcommittee are special government employees, so members of the Committee. And it follows some FACA requirements and has to report to the parent committee. In a workgroup, there have to be at least two members of the Committee, but you can also have additional subject-matter experts if you require them. It's not subject to FACA and it also has to report to the Committee or the subcommittee from which it emanates.

DR. WARD: Thank you, that's great clarification.

DR. CARREÓN-VALENCIA: Yes.

DR. WARD: Jason?

DR. OSTROWE: Hi, thank you. I just wanted to echo what Nick was saying and I wholeheartedly agree with it. And I think this idea of reasonable scientific basis can be direct or indirect. And what I'm hearing is that there seems to be a lack of direct empirical evidence, but there's plenty of indirect empirical support. And what I've heard over the last day and a half I think substantiates this idea that there is certainly a reasonable scientific basis indirectly through mechanisms by which this cancer is similar to other cancers in how it proliferates and what causes it. And what I'm hearing is an argument that says there is a substantial amount of empirical evidence, it's just indirect.

So just wanted to echo what Nick was saying as what I've heard over the last few days, and I fully support that idea.

DR. WARD: I'm just scanning the screen for hands. So, when Emily was clarifying the process, she said—and it makes perfect sense to me—that we would not take a formal vote today because we're voting not just on the

	recommendation, but also on the scientific rationale for the recommendation. And that has to be written so that it can be fully evaluated by the Committee. But she also suggested that we might consider taking a formal vote that would give direction to a working group or a subcommittee as to what the substance of their report should be and what the direction the group wants to go in. So, Tania, would you think, do we need a motion, and do we need to have some exact language for the informal vote?
DR. CARREÓN-VALENCIA:	Emily? I want to clarify; you are talking about forming a workgroup, right?
DR. WARD:	I think that's the way we were leaning, although as usual, I get a little confused which is which. But I do think a workgroup, yes. Right now, I think that that makes the most sense.
MS. HOWELL:	I would recommend developing a written description on the screen for everybody so everybody can be clear on what you're voting on. And then take the individualized vote and, you know, you can appoint, once you have—if you motion and vote to create a workgroup, then you can appoint people to it, etc.
DR. WARD:	Okay. So, Ann, are you ready to come in and start typing on the screen so that we can all see the language that we're agreeing to?
MS. RIDDLE:	Yes, I will go ahead and share my screen.
DR. WARD:	Thank you. So, would any member like to propose the language and Ann will type it on the screen? I'm struggling with it myself.
DR. MEYER:	So, do you want me to give it a try? I was writing something down.
DR. WARD:	That would be great.
DR. MEYER:	So, a motion to create a workgroup to write a report describing a reasonable scientific basis for adding uterine cancer as a covered condition in the World Trade Center Health Program.
MS. RIDDLE:	Try a little bit slower.
DR. MEYER:	Oh, I'm sorry. To write a report describing the reasonable scientific basis to add uterine cancer as a covered condition for the World Trade Center Health Program.
DR. WARD:	Does anyone have any concerns about that language, either in terms of—
MS. HOWELL:	I think, Liz, it's proper to receive a second on the motion and then debate the wording.
DR. WARD:	Okay. Is there a second for that motion? I'm looking for hands.
DR. OSTROWE:	I'll second.
DR. WARD:	Mariama? Okay, I see Mariama's hand.
MS. JAMES:	Well, no, I had already put mine up to comment on, but if we shouldn't comment on it, I'll take it down.

DR. WARD: Okay, so who seconded the motion?

DR. JOSE: This is Anita, I'll second.

DR. WARD: Okay. So now we have the motion open for discussion.

MS. JAMES: Okay, now put it back up.

DR. WARD: Okay, Mariama, go ahead.

MS. JAMES: So, I don't disagree with the language, but I felt that the Administrator's clarification on what we had originally been sent made it more broad where we didn't have to necessarily put ourselves in a box and use language like "scientific basis." Although that may be what the intent is at the root, I don't think you necessarily have to say that. Or you could maybe say "scientific and/or logical" basis. I mean it sounded like the was giving room for common sense the way that I read it or interpreted it, which may or may not be correct.

DR. WARD: Thank you. Robin?

DR. SASSMAN: Should we add in somewhere to the effect of "A report describing the Committee's conclusion and evidence supporting that conclusion," or something of that nature?

MS. RIDDLE: One more time, "Committee conclusion or"?

DR. SASSMAN: Yes, "Write a report describing the Committee's conclusion and supporting evidence and scientific basis to add uterine cancer as a covered condition."

DR. WARD: Thank you. Jason?

DR. OSTROWE: Hi, thank you. Perhaps I missed it and maybe this is a question possible for Jess. It's really a process question. The creation of this committee and the process by which it has to go through may take some time. Would you be able to give us an estimate of the difference between us doing this process today and taking a vote today, and doing this subcommittee process?

MS. BILICS: You mean just in terms of the additional time it would take to do the subcommittee kind of a thing?

DR. OSTROWE: Yes, in sum and substance, I just really want to have a sense of the difference in the amount of time it would take assuming the outcome of this report that the subcommittee would send forward would be the same as the conclusions that we would draw on our own. What would be the time difference there?

The reason I bring this up is because during this period of time, women are still coming down with uterine cancer and not being covered. So, I think there's like an immediacy aspect of it that I'm really curious about.

MS. BILICS: Yes, I think we're probably talking about two to three months' difference. I don't know, Emily, correct me if you think differently.

MS. HOWELL: So ultimately the Committee has to get a recommendation to the Administrator within 90 days from yesterday, which I believe we'd counted it at one point. I think it winds up being December 27th. So ultimately, regardless of whether there's a subcommittee empaneled or not, the full committee would have to come back and have that recommendation to the Administrator. The whole Committee also has to provide rationale for their recommendation, so it's a matter of whether in the time left today there's enough time to put together rationale to provide with that recommendation if we wanted to take that full vote.

Once the Administrator has the recommendation of the Committee, he then will have 90 days to evaluate that recommendation, submit it to the paneled peer reviewers, for their review, and publish a notice in the Federal Register. So, it's really, as Jess has been saying, with the two 90-day windows you wind up around six to seven months from the date of charging—which would be yesterday—to when something could take effect for members of the Program.

And obviously if the process of the Committee developing a recommendation goes more quickly than 90 days, then that will shave some time off. But regardless, there would be another three-month period—a maximum additional three months—plus another month before implementation of anything would take effect.

DR. OSTROWE: Thank you.

DR. WARD: Debra?

DR. MILEK: To sort of not predetermine our conclusion before reading the report, what if we say instead of just "the addition of uterine cancer," "evaluating the addition of uterine cancer as a covered condition"?

DR. WARD: And, Robin, your hand is up? No, thank you. Okay.

So, I need the procedure people to tell me how we should proceed now that we have a few variations of the potential changes to the language of the motion that was originally proposed. Emily?

MS. HOWELL: So, people have been debating the wording of the motion. Only that first, Number 1, that Ann is working on is technically on the floor for voting. So, if somebody would like to change—after this discussion thinks that it's appropriate to change it to reflect A, B, or C, they would need to make that motion to formally amend the first motion, if that makes sense, and then call a vote on that question.

DR. WARD: Okay, so everybody has an opportunity to look at the different versions that have been proposed. Does anyone want to make a motion to amend the original motion to change it to one of these or to change it in a different way?

Debra, your hand is up but I don't—

DR. MILEK: No, sorry, I didn't remove it.

DR. WARD: So just from a process point of view, if nobody makes a motion to amend the first motion that was drafted, we will go ahead and take an informal vote on that. This is not—

DR. CARREÓN-VALENCIA: Michael has his hand raised.

DR. WARD: Oh, thank you. It's another background problem. His hand is the same color as his wall. Michael?

DR. LARRAÑAGA: I'm sorry about that. It's funny how that happened.

DR. WARD: It's weird, yes.

DR. LARRAÑAGA: I tend to support B the best because it discusses the Committee's conclusion that we would conclude during this meeting. And I tend to like that one better. So, are we free to discuss for it without a motion?

DR. WARD: Emily?

MS. HOWELL: Again, the only motion that's actually available for voting on is the first one, unless you form a motion to amend it.

DR. LARRAÑAGA: But can we discuss it without a motion, without discussing a vote?

MS. HOWELL: Yes, you can discuss amending it before you actually motion to amend it.

DR. LARRAÑAGA: So for me, I think B is better. And that's essentially all I have on that.

DR. WARD: I guess as a member of the Committee as well as the Chair, I can speak. I think I'm comfortable with—I like B and I think A, I'm comfortable with that as well. I do think that there will probably have to be a second motion regarding whether the Committee has reached a consensus on whether the starting point for the working group should be to support the scientific rationale or not. Because I don't think we're empowering this working group to make the recommendation. I think we're empowering this working group to develop the rationale for the recommendation that we believe the STAC will likely make. We're not setting that in stone, but I do think the working group will need to have a charge as to which direction the Committee is leaning.

Mariama, your hand is up too?

MS. JAMES: Yes, I too am partial to B but, again, would also recommend that "scientific basis" be changed to "rationale" or "logical basis" rather than, again, boxing anything in to being over-specific.

DR. WARD: Thank you. John?

DR. MEYER: Sorry, I always have to unmute. I always put my editor hat on in these so I can't avoid like red-penciling there. I favor B. Can I make some suggestions if somebody is ready to type it here? And I also like Mariama's—what did you just say, "rationale"? So, I would just change B to say "Motion to create a workgroup to write a report describing the

	Committee's conclusion, scientific rationale, and supporting evidence for adding uterine cancer," etc.
MS. RIDDLE:	Did I mostly get that except for adding things in?
DR. MEYER:	"Workgroup to write a report describing the"—oh, "Committee's" with an apostrophe S—"conclusion, scientific rationale"—with an E at the end—"and supporting evidence for adding uterine cancer"—yes, and then the rest could just be cut and paste from there.
DR. WARD:	And if I'm interpreting that correctly, that version of the motion actually incorporates the sense that the Committee's conclusion is likely to be adding uterine cancer, which may get around the requirement to make a second motion, to informally vote on a second motion?
DR. MEYER:	I supposed you could—and I don't know the parliamentary procedure, but you could vote on a second motion and then—you could table this until you had the motion about the conclusion. And so, I think it runs by a parliamentarian too, and I was just trying to wordsmith the motion—
DR. WARD:	Right, right.
DR. MEYER:	Again, favoring B, incorporating what Mariama had to say about it. I would probably not include "logic" because whose logic? But I did like "rationale." So that's my blue-pencil edit or hat rather than my doctor hat.
DR. CARREÓN-VALENCIA:	Liz, I just want to clarify that when you say "adding uterine cancer as a covered condition," that means having uterine cancer as a World Trade Center Health Program-covered condition?
DR. WARD:	Thank you. And, Ann, could you incorporate that language?
MS. RIDDLE:	At this point is it okay to change all of them as World Trade Center Health Program-covered condition, or as another version?
DR. CARREÓN-VALENCIA:	Oh, just the World Trade Center-related health condition, or WTC-related health condition.
DR. WARD:	So, in that first one it would no longer read "To add uterine cancer as a covered condition." It would be "To add uterine cancer as a World Trade Center Health Program-related condition."
DR. CARREÓN-VALENCIA:	Without "Health Program," World Trade Center-related health condition.
DR. WARD:	And that would apply to all of the potential wordings?
DR. CARREÓN-VALENCIA:	Yes.
DR. WARD:	So, did we have a motion to vote on any of the versions of the—oh, so do we have a proposal to amend the Motion 1, the initial motion, which is listed under Number 1, by any of the suggested alternatives? Catherine?
DR. MEYER:	In my experience—I'm sorry, Catherine—in sitting in some of these committees and Robert's Rules of Order, etc., I can accept the—as being the person who proposed it, I can accept an amendment, accept a

	change in the wording if that's simpler, if that's the rules that we're going to follow.
DR. WARD:	Thank you. We'll defer to Emily on that question but Catherine?
DR. MEYER:	That's why I left it.
DR. CARREÓN-VALENCIA:	Yes, I think—
MS. HOWELL:	The person making the motion can accept the amendment.
DR. WARD:	Excellent, okay, thank you. Okay, Catherine.
MS. MCVAY HUGHES:	So, it does appear that 1D is a friendly amendment of the original one.
DR. MEYER:	I accept D as an amendment to my original motion.
DR. WARD:	Great, so are we ready, Tania, to take a vote on that motion, a roll-call vote?
DR. CARREÓN-VALENCIA:	Did we have a second? I didn't hear.
DR. WARD:	Okay, we need a second for the amendment?
DR. CARREÓN-VALENCIA:	I believe so.
DR. LARRAÑAGA:	This is Mike, I'll second.
DR. WARD:	Thank you.
DR. CARREÓN-VALENCIA:	Yes, so you are ready to vote for the amended motion. Liz?
DR. WARD:	Yes.
DR. CARREÓN-VALENCIA:	Sophie?
DR. BALK:	Yes.
DR. CARREÓN-VALENCIA:	Chandra is not here. Thomas?
DR. DYDEK:	Yes.
DR. CARREÓN-VALENCIA:	Mariama?
MS. JAMES:	Yes.
DR. CARREÓN-VALENCIA:	Anita?
DR. JOSE:	Yes.
DR. CARREÓN-VALENCIA:	Michael?
DR. LARRAÑAGA:	Yes.
DR. CARREÓN-VALENCIA:	Catherine?
MS. MCVAY HUGHES:	Yes.
DR. CARREÓN-VALENCIA:	John?
DR. MEYER:	Yes.
DR. CARREÓN-VALENCIA:	Debra?
DR. MILEK:	Yes.
DR. CARREÓN-VALENCIA:	Larry is not here. Nick?
MR. NEWMAN:	Yes.
DR. CARREÓN-VALENCIA:	Jason?
DR. OSTROWE:	Yes.
DR. CARREÓN-VALENCIA:	Robin?
DR. SASSMAN:	Yes.

DR. CARREÓN-VALENCIA: Aarti?
DR. SURTI: Yes.
DR. CARREÓN-VALENCIA: Leigh?
DR. WILSON: Yes.
DR. CARREÓN-VALENCIA: So, you have 14 yes votes, the motion is carried.
DR. WARD: Thank you. And would it be appropriate at this time to discuss forming the subcommittee?
DR. NEWMAN: Workgroup. Workgroup.
DR. WARD: I mean I would propose that we ask for volunteers, if that's agreeable to the Program.
DR. CARREÓN-VALENCIA: I don't see why not. Emily, is that okay?
MS. HOWELL: Yes, yes. I would just say that the number of members of the workgroup should be less than quorum of the full committee to avoid any confusion.
DR. WARD: Okay. So, Ann, I guess the minutes will record, but if you would like to in addition record the members who volunteer. I will certainly volunteer. And would anyone else who would like to volunteer just raise your hand and we'll read through the names of the people whose hands are raised? Robin.
DR. BALK: Hi, this is Sophie. Can I ask a question about timeline and who would be doing the first draft?
DR. WARD: I am happy to do the first draft. I mean I already started—I thought about the draft when I was pulling together the PowerPoint slides today to summarize the sense of the Committee's opinions. And then I also have a lot of background in knowing what's gone before in terms of the STAC recommendations. So, I'm more than happy to prepare the draft that the subcommittee works on.

I think one clarification we'll just need from a procedural point of view is that, for example, Robin volunteered to write a section on a topic and so we'll need to clarify what the procedures are, if it's possible, for Committee members to volunteer to write sections that I would then incorporate in the overall draft. But we'll probably have to discuss that internally and then at the first meeting of the subcommittee, we'll discuss all of those procedures and make sure we're doing everything in a way that is consistent with the rules.
DR. BALK: Given other obligations, just what is your sense of practicality when things would really get going, like tomorrow or a month from now?
DR. WARD: I would say realistically it would probably take me about a week to pull a first draft together based on what I have up until now. So, then we would plan on circulating that draft and then meeting a few days after that to work together and maybe come up with what we believe is a draft that's

ready to—I don't think we have any major disagreements. I think there's just a sense from the Committee that it's extremely important that this report really as effectively as possible describes our scientific rationale for the Administrator.

So hopefully it may just be one round if we have a draft and then we meet together as a workgroup—or at most, maybe two meetings—and I think we will be close to the point where we could—and, again, this is all based on my sense from discussions we're having thus far—I think we would be at a point where we could ask NIOSH to schedule the full meeting and go ahead and have that finalize the document. So that whole process could probably take about a month or five weeks would be my best guess.

DR. BALK: I also see you have four people listed. Do you want another volunteer or is that enough?

DR. WARD: I would say if someone is interested, we'd be happy to have another person.

MS. RIDDLE: There we go.

DR. WARD: Great. And the members who are—you know, and obviously there will be, I don't know how much time we'll allocate for the next STAC meeting, but we obviously will have input from every member of the Committee before we finalize this report. So those who are not participating in the workgroup will have ample opportunity to provide their input—as well as the public, I guess, because we will also probably take comments from the public with regard to the draft document.

Okay. So, Tania, where are we in terms of our agenda and time?

DR. CARREÓN-VALENCIA: We still have time for more discussion or if you think we have finished with this, we can move on to the next topic which is the peer review discussion.

DR. WARD: Sophie, did you have your hand up?

DR. CARREÓN-VALENCIA: If you think we have exhausted this, we are ready to move on, we can certainly move on.

DR. WARD: Emily has her hand up. Emily?

MS. HOWELL: I just was going to ask have you actually—if you're forming the workgroup, then you do have to actually vote on it.

DR. WARD: I'm sorry; I'm not clear what we need to vote on.

MS. HOWELL: If it's a motion as opposed to the Chair just appointing the workgroup, then you would need a voice vote of concurrence that this is how the workgroup will proceed.

DR. WARD: Okay. So should we go ahead and do our roll call vote of concurrence, Tania?

DR. CARREÓN-VALENCIA: Should we, Emily, have another vote? Do we need another motion?

MS. HOWELL:	I think the Chair can take an all-in-favor voice vote without doing individualized in something like this.
DR. WARD:	Okay. So, can we do a voice vote on whether everyone is in favor of forming this workgroup and appointing the members that are listed on the document?
COMMITTEE MEMBERS:	Aye.
DR. WARD:	Okay, any nays? Okay, thank you. John, you had your hand up?
DR. MEYER:	No, I'm sorry; I was just going to suggest everyone raise their hand, mostly because (inaudible @ 00:58:19) out, but that's, maybe that's just me.
DR. WARD:	Yes. Okay, good.
DR. CARREÓN-VALENCIA:	Mariama has her hand raised.
DR. WARD:	Mariama?
MS. JAMES:	I have a procedural question. Is there going to be such a time that arises where we will discuss the testimony that we heard, or do we just mull that over on our own, or how does that work? The public comments, I mean.
DR. WARD:	Yes, so I think we should certainly allude to the public comments related to uterine cancer in our report, which I started doing in the draft slides. So, we can certainly discuss the—what I'm not clear about is whether—I don't think—some of the public comments did not pertain to the addition of uterine cancer and then some of them I think are certainly worthy of the Program's consideration, but I wouldn't think that belongs in the STAC recommendation on this particular matter. Tania, do you agree?
DR. CARREÓN-VALENCIA:	Yes. Of course, you have a specific charge and so you should follow that charge. However, all the comments are part of the public record and will be on the docket and the minutes of the Committee and will be taken into consideration.
MS. JAMES:	Yes, that was really my question in terms of how compelling or not the Committee felt those comments were, how do we make that known or is that not necessary, how that part of the process works?
DR. CARREÓN-VALENCIA:	Certainly, like Liz said, they can be considered in the recommendation that the Committee will make to the Administrator. And Liz already alluded to that in her slides as well.
DR. WARD:	Okay. We have two ways to proceed. I think we're all growing a little weary, so one thing we could do now is go back through the slide set and try to add points that we think we'd like to be included. If we decide not to do that, I will go through my notes of the discussion that we had and incorporate those comments as I see appropriate in the draft that we would prepare for Committee review. I see that Catherine and Nick both have their hands up, so we'll go ahead and let them speak.

MS. MCVAY HUGHES: Yes, hi, just following up on Mariama's comment. One thing that Kimberly Flynn had mentioned that I thought was really important which is that it's a research-to-care model and that is something that should just be acknowledged, I think, in the report.

DR. WARD: Okay, great, thank you. Nick?

DR. NEWMAN: The only thing I would bring up, and this ties in to what Mariama was saying, part of the charge says I welcome the Committee's views about the Program's research direction. And so, it's certainly not unreasonable to have some statement about what we think the research direction should be. So, I do know from a previous meeting that I attended, out of that came a specific statement that there should be something to address young-adult and child health research. And the Program has responded both with that and other things. So, it's not unreasonable for us to make other statements or recommendations that are related to the research program.

DR. WARD: I agree with that. So, one question I had, Tania, it just occurred to me that the transcript that's prepared for this meeting may be really helpful in incorporating some of this into the final report. I mean I don't think it's critical, but do you know what the timeframe will be for me to get the transcript to review?

DR. CARREÓN-VALENCIA: No. I think it usually takes two weeks for the transcript. Maybe a little bit more. Mia might be able to clarify that. And then of course you and I need to review it and certify it before it's shared.

DR. WARD: Right, right.

DR. CARREÓN-VALENCIA: In the past we would just post the transcript on the website, but now as the vehicle, I mean as the transcript is not enough, I need to produce full minutes of the meeting.

DR. WARD: Okay, good.

DR. CARREÓN-VALENCIA: The transcript will provide the background, but it won't include also other information like the chats, and other—and comments that are on the docket.

DR. WARD: Okay, so I won't wait on that to write the draft report.

DR. CARREÓN-VALENCIA: Probably not.

DR. WARD: Because I know there is a sense of urgency about moving this forward and not delaying it. Well, is there anyone who would like to discuss this matter further at this point, or should we move on to the next agenda item, which is recommendation of peer reviewers? Does anyone object to moving on? Okay, I don't see anyone.

And I do have one question before we discuss the peer reviewers, Tania. So, if people feel like they'd like to do a little bit more research and

recommend peer reviewers and they're not prepared to do it today, is there any mechanism by which members of the STAC can submit those names to you after the meeting?

DR. CARREÓN-VALENCIA: No, actually, that's what I was going to say. No, you don't need to come prepared today with recommendations. You can certainly send them to me and we will share those recommendations with the Administrator, of which he will choose three peer reviewers to conduct the peer review of the Notice of Proposed Rulemaking, and make sure that all the scientific (inaudible @ 01:05:40) that the Program takes into account follow the rules. So those peer reviewers will conduct their peer review and prepare a short report that we will also post in the docket.

I also want to let you know that individual comments won't be included by this Committee. The names of the peer reviewers will be published or noted, but individual comments won't be attributed to them individually.

DR. WARD: Great. Go ahead, Tania.

DR. CARREÓN-VALENCIA: No, I was going to about the discussion, but if you have other questions or comments, please go ahead.

DR. WARD: I've actually managed in my small office to misplace my copy of the agenda, so I was just going to check if this is the final agenda item or if we have other items to discuss.

RECOMMENDATIONS OF PEER REVIEWERS AND DISCUSSION

DR. CARREÓN-VALENCIA: This is the final item on the agenda and then, of course, closing comments and then adjourn. So, we can certainly move to that if there is no further discussion on recommendations.

MS. BILICS: This is Jess. It looks like Michael and Mariama's hands are both up.

DR. WARD: Thank you. Okay, Michael?

DR. LARRAÑAGA: Thank you. A quick question: are there any limitations to who a peer reviewer could be? For example, can a peer reviewer be somebody from another federal agency or outside—

DR. CARREÓN-VALENCIA: No. The only limitation that the rule has is that a peer reviewer should not be from NIOSH.

DR. LARRAÑAGA: Thank you.

DR. WARD: Okay, Mariama?

MS. JAMES: I was going to ask that as well; and also, if there is a pool of any sort of potential reviewers from which to pick?

DR. CARREÓN-VALENCIA: Right now—oh, I mean yes, right. We issued, and the rules established that we have a pool, but we haven't been very successful in forming a pool. I think we have maybe one or two but in his charge, and maybe

Emily or Jessica can clarify further, but Dr. Howard is asking for experts on the specific topic on this recommendation that you can suggest to him and not the members of the peer review pool that currently the Program has, which I think it's one or two.

MS. JAMES: Is there anybody that's sort of like nominated themselves as a potential specialist or expert in this area, or no?

DR. CARREÓN-VALENCIA: No, not in this area, no. We haven't received—the person or persons that we received—this happened I think at least a couple of years ago.

MS. JAMES: I see. Great, thank you.

DR. CARREÓN-VALENCIA: Sophie, you have your hand up?

DR. BALK: Right. Just with regard to what qualifies expertise, I would ask that there be consideration of someone who is expert in early-life exposures: prenatal exposures, preconception exposures, and exposures to children who were either living or going to school in the area. So that's not necessarily an expert in uterine cancer; that could be a pediatrician. I have at least one person in mind who knows a great deal about endocrine disruptors in early-life stages and a couple of other pediatricians who have expertise in critical-life-stage exposures. So, I don't know if you want their names now or you want me to email them, but it's a request for that kind of expertise.

DR. WARD: So, Sophie, I have a question about this and maybe it's a good time to ask it. When you're talking about the importance of that in relation to the uterine cancer determination, I struggle a little bit because uterine cancer is probably really pretty rare in people under 35 or 40. And so even the youngest member of our cohort has not yet reached the age of 20 or may have just reached it. So, I guess are you thinking long term that these individuals may in the future be affected by uterine cancer? Because that concern is not so much relevant to the group of adult women who are experiencing the uterine cancer diagnoses now.

DR. BALK: Right. I am thinking that certain things aren't known yet because, who knows, we might see unusual cancers at an early stage like we did with DES. Like clear cell adenocarcinoma of the vagina is very unusual, yet it occurred in greater numbers unexpected in those female children exposed prenatally. So, we really don't know. That's my concern.

DR. WARD: Yes. I mean some of those would probably be covered under the childhood cancer designation and under the rare cancer designation. But I guess it's possible that if a case of uterine cancer occurred at a very early age, it would need to be noted as a World Trade Center-related condition in order to be covered.

DR. BALK: Plus, doesn't this go out to 2090 or something?

DR. WARD: It does, it does. I just was wondering to what extent we should focus on that area as part of the scientific rationale. I think it's important to acknowledge it, but the extent to which we need to elaborate on it in our rationale was what I was questioning.

DR. CARREÓN-VALENCIA: I'm starting to think that maybe the Committee will be more or better equipped to provide recommendations for experts once you develop your scientific rationale and your scientific basis so that you know what your recommendation will cover and then identify experts based on that.

DR. WARD: That's true. I mean I think if anybody has someone already in mind that they think would be great because they're familiar with the field, I think it's fine to share them with Tania. But I think we may come to have more recommendations as we prepare the report and even look at the published literature. There may be some papers that we see where the authors would be a very strong candidate for a peer reviewer.

DR. CARREÓN-VALENCIA: Right. And certainly, we can include that as an agenda item in the next Committee meeting.

DR. WARD: Great. Well, I don't know if we need a motion to close the meeting, but I think we're ready. I know it's been a hard two days and I thank everyone for your continued attention and your participation and your valuable comments. I think we really have—although there have been times when I felt like we were getting bogged down because we were not sure of the way to—the procedural issues I really feel like we did accomplish a great deal during the meeting, and I know that we'll be able to move forward expeditiously in pulling our recommendations and documentation together so that we can make a timely recommendation to Dr. Howard. Does anyone else have any remarks that they'd like to conclude with before we end?

MS. JAMES: I have one last procedural question, if I may.

DR. WARD: Sure.

MS. JAMES: As a representative of survivors, so like a community, is it appropriate for me to ask the survivors what they think or the Survivor Steering Committee what they think or who they might recommend?

DR. CARREÓN-VALENCIA: Emily? I can't see that as a problem, but Emily?

MS. HOWELL: Yes, I mean the Committee members can bring back to the full committee their recommendations for the full committee to vote on. So that can be informed by the individual committee members' personal research or professional knowledge, etc. So, I think it just has to be clear that this committee is the committee that actually makes the final recommendation to the Program and the Administrator.

MS. JAMES: Yes, of course. Thank you.

DR. WARD: I'm going to turn it over to Tania for the last comments, but did anyone else have anything they'd like to say before we turn it over to Tania? Okay, not seeing any hands. Tania?

ADMINISTRATIVE ISSUES AND CLOSING REMARKS

DR. CARREÓN-VALENCIA: Well, I can't thank all of you enough for a very productive meeting and for providing your insight and expertise to the World Trade Center Health Program and the Administrator. I also of course want to than Liz for her leadership and for running these meetings so effectively. And also, I want to thank Mia Wallace, all our presenters, many of my colleagues at NIOSH who have contributed a lot behind the scenes to make sure that everything runs smoothly, that we have documents ready for you, and that the information was shared with the public in a timely manner.
So that's all I have. Liz, you need to adjourn the meeting, and thank you all.

DR. WARD: Yes, thank you. And before I adjourn, I wanted to second Tania's comment. As a Committee member, I am very grateful to all the work that the NIOSH staff and others have done to prepare for this meeting. And I think it's one of the best organized and certainly the best preparation in terms of the staff providing the background for the scientific issues discussed that we've ever had. And I really applaud them for doing that. It's made our whole meeting much more effective. Well, thank you all. I've really enjoyed getting to know all of you who I didn't know before, and hopefully one day we will see each other again in person. But I think we did pretty well for a remote meeting, and I appreciate everyone's participation. The meeting is adjourned.

[Adjourn.]

GLOSSARY

ALS	Amyotrophic lateral sclerosis
CDC	Centers for Disease Control and Prevention
DES	Diethylstilbestrol
EDC	Endocrine-disrupting chemical
EDT	Eastern Daylight Savings Time
EPA	Environmental Protection Agency
ESU	Emergency Service Unit
FACA	Federal Advisory Committee Act
FDNY	Fire Department of the City of New York
FRN	Federal Register Notice
GERD	Gastroesophageal Reflux Disease
GU	Genitourinary
IAMQ	Interviewer-Administered Medical Questionnaire
IARC	International Agency for Research on Cancer
IRB	Institutional Review Board
MAC	Medically associated health condition
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NPRM	Notice of Proposed Rulemaking
NTP	National Toxicology Program
OEP	Office of Extramural Programs
PBA	Patrolmen's Benevolent Association
PCB	Polychlorinated biphenyl
PFAS	Per- and polyfluoroalkyl substances
PTSD	Post-Traumatic Stress Disorder
RCT	Randomized control trial
RFA	Request for applications
RNA	Ribonucleic acid
SMR	Standardized Mortality Ratio
SSC	Survivors Steering Committee
STAC	Scientific/Technical Advisory Committee
TCDD	Tetrachlorodibenzo-p-dioxin
USPSTF	United States Preventive Services Taskforce
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