Verbatim transcript

Meeting of the Scientific/Technical Advisory Committee (STAC)
World Trade Center (WTC) Health Program

February 9, 2023

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WELCOME AND INTRODUCTION, MEETING LOGISTICS

DR. CARREÓN-VALENCIA: Well, good morning. It's 11 a.m. Welcome to the meeting of the World Trade Center Health Program Scientific and Technical Advisory Committee. I'm Tania Carreón-Valencia and I am the Designated Federal Officer for the STAC. I would like to extend a very warm welcome to our committee, the NIOSH staff that are joining us today, as well as members of the public who are following these proceedings via webcast.

As it is a custom in our meetings, I would like to ask for a moment of silence to remember the people that were killed during the terrorist attacks of 9/11. We also remember those responders and survivors that have died since then, as well as others who have died or suffered from terrorist attacks around the world.

[Moment of silence.]

Thank you. So, before I hand the meeting to our Chair, I want to remind you that the World Trade Center Health Program STAC is subject to the rules and regulations of the Federal Advisory Committee Act or FACA. And for that reason, we develop minutes for our meetings. So please be aware that this meeting is being recorded to produce the minutes that will be posted on the Committee's website in a few weeks. I have also asked members of the Committee to refrain from commenting among themselves by text, emails or any other means regarding matters that have to or will be discussed at these meetings. Member communication is part of the public record, and it will be added to the minutes of the meeting. And so, for the record, I was made aware that one member sent our Chair copies of two public comments that were

later posted on the docket, but no further communication ensued.

I also want to remind you about the FACA rule that relates to public comments. Members of the comment—of the public—can submit comments to the STAC to consider as it develops advice for the World Trade Center Health Program Administrator. And one way to submit comments is to mail their comments to the NIOSH docket. We did not receive any comment via mail, snail mail. Also, another way is to provide online comment on the NIOSH docket on the Regulations.gov website and, as of 10:55 a.m. this morning, we have received four comments on the docket. Members of the Committee have been asked to monitor the docket and read the comments. The docket will close today at midnight. Another way to sign up and to provide comments is to sign up to present at the meeting during the designated times for public comment. Today, that will happen at 2:15 Eastern Stan—p.m. 2:15 p.m. Eastern Standard Time. And we have six commenters who will have five minutes each to provide their comment. All comments will be part of the public record.

Also, under FACA rules, we need to do a roll call of committee members at the beginning of the meeting and after each of the breaks to ensure that we have a quorum. As I call the names of the members of the committee, please unmute yourself and indicate your presence for the record, and if there are situations that would change your conflict-of-interest status since you last submitted your OGE-450 form. Also, please, if I mispronounce your name, let me know.

Now, so I'm going to start with our Chair. Liz Ward?

DR. WARD: Present, no changes.

DR. CARREÓN-VALENCIA: Thank you. Sophie Balk?

DR. BALK: Present, no changes.

DR. CARREÓN-VALENCIA: John Comiskey?
DR. COMISKEY: Present, no changes.
DR. CARREÓN-VALENCIA: Chandra Davis won't be able to join today. Joanna Gaitens?
DR. GAITENS: Present, no changes.
DR. CARREÓN-VALENCIA: Mridu Gulati won't be able to join today. Mariama James?
MS. JAMES: Present, no changes.
DR. CARREÓN-VALENCIA: Anita Jose won't be able to join today. Indrina Kanth won't be able to join today. Michael Larrañaga?
DR. LARRAÑAGA: Present, no changes.
DR. CARREÓN-VALENCIA: Steven Markowitz? We'll come back to him. John Meyer?
DR. MEYER: Present, no changes.
DR. CARREÓN-VALENCIA: Debra Milek?
DR. MILEK: Present, no changes.
DR. CARREÓN-VALENCIA: Lawrence Mohr won't be able to join today. Jason Ostrowe?
DR. OSTROWE: Present, no changes.
DR. CARREÓN-VALENCIA: Aarti Surti won't be able to join. Glenn Talaska won't be able to join. So, going back to Steven Markowitz?
DR. MARKOWITZ: Yes, sorry, I was on mute. Yes, I'm here, no changes.
DR. CARREÓN-VALENCIA: Okay, so we have ten members present and that is a quorum. And because our quorum is very narrow, I want to ask you that if you have to leave at any point to please let me know when you leave and when you return. We need to make sure that we keep quorum at all times.
So, we are ready to start, and I want to turn it over to Dr. Ward.

AGENDA AND ANNOUNCEMENTS

DR. WARD: Thank you very much, Tania, and thanks to the NIOSH staff that's done a great job in preparing everything for this meeting. I don't think I have any announcements or—and I don't think I need to review the agenda except to say that Tania has circulated a new

agenda that just had a slight change this morning so hopefully everybody has seen that, and also hopefully everyone has had a chance to look at the public comments that were posted this morning before the meeting.

Tania, do you think it would be appropriate that we go around, everybody gives a brief introduction?

DR. CARREÓN-VALENCIA: Sure. I think that will be great.

DR. WARD: Okay. So, I'm Liz Ward and I was an epidemiologist at NIOSH for 21 years and then worked at the American Cancer Society for 16 years, and I've been chairing the Committee since it started about 10 years ago. And Steve? You're left uppermost on my screen.

DR. MARKOWITZ: Yes, hi, Steven Markowitz. I'm an occupational medicine physician epidemiologist at City University of New York, been involved with World Trade Center issues since the beginning, 2002, ran one of the clinics for ten years in Queens, and I'm a returning member. I was a lapsed member of this committee, but I served between 2011-2020. I'm very happy to be back. Thank you.

DR. WARD: Thank you. Tania, should we limit it to the members of the STAC or do you want to have the—just the STAC? Okay. John? I'm looking across my screen and just doing it in order of my screen. John?

DR. COMISKEY: Yes, good morning. John Comiskey, I'm a Professor of Homeland Security at Monmouth University. I'm a 9/11 first responder. I was an active New York City Police Lieutenant at the time.

DR. WARD: Thank you. Joanna?

DR. GAITENS: Hi, I'm Joanna Gaitens. I'm an Associate Professor at the University of Maryland School of Medicine, and this is my first official STAC meeting, and I'll say most of my work has really been dealing with Veteran populations and doing medical surveillance for those who have various types of metal exposure related to retained fragments.

DR. WARD: Thank you. Michael?

DR. LARRAÑAGA: Yes, hi, I'm Michael Larrañaga. I am a consultant and an industrial hygienist in Dallas, Texas. I am also Editor-in-Chief of the *Journal of Occupational and Environmental Hygiene*, and I help companies keep their workers safe.

DR. WARD: Thank you. Jason?

DR. OSTROWE: Hi, everybody, I'm Jason Ostrowe. I am an Assistant Professor of Criminal Justice at St. Joseph's University. From 1999 until 2015 I was a member of the New York City Police Department, and I was a police officer on 9/11, during 9/11 and thereafter, and one of the first responder representatives.

DR. WARD: John?

DR. MEYER: Hi, I'm John Meyer, I'm the Director of the Division of Occupational Medicine at Mount Sinai and—which encompasses the World Trade Center programs. And in my spare time, I edit the *American Journal of Industrial Medicine*.

DR. WARD: Thank you. Sophie?

DR. BALK: Hi, I'm Sophie Balk. I'm a general pediatrician. I work in a Federally Qualified Health Center in the Bronx that's—and I work for the Children's Hospital at Montefiore. Professor of Pediatrics at Albert Einstein in the Bronx. I work with American Academy of Pediatrics on environmental health issues.

DR. WARD: Thank you. Mariama?

MS. JAMES: Sorry about that. Sorry. I'm Mariama James. I am a survivor. I'm the parent of survivors, the daughter of survivors. Actually, I lost my dad to 9/11-related disease last year. My mother has had a Stage IV terminal cancer diagnosis since around 2017. She worked at Deutsche Bank across the street. And so, my experience with 9/11 and the resulting health impacts is direct in several ways and, over the past two decades I guess, I have been a community advocate and leader on this issue, the voice of survivors. I am a

	member of Community Board 1, the Co-Chair of the Quality of Life Committee as well as the Treasurer, and I'm a member of the Survivors Steering Committee as well. Thank you.
DR. WARD:	Thank you. Debra?
DR. MILEK:	Hi, I'm an occupational medicine physician. I was at Mount Sinai in 2001 and for the first decade after, treating World Trade Center-related patients. I am currently consulting at the University of Washington in Seattle.
DR. WARD:	Thank you. And the next person's name I have on the screen is Amine? Amine? I don't…
DR. CARREÓN-VALENCIA:	I believe that's the person doing the transcript of the meeting.
DR. WARD:	Ah, okay. Could you help me then because—so is that all the committee members?
DR. CARREÓN-VALENCIA:	I think so.
DR. WARD:	Okay, great. The one thing I was hoping we could do before we get started also is Tania, would you review the procedure for raising your hand in Zoom just so everybody is aware? So, when we get into the discussion periods, we do find it really handy if people can raise their hand. It just facilitates an orderly discussion. So, Tania's going to review with us—including me because I always forget—how to raise your hand in Zoom.
DR. CARREÓN-VALENCIA:	So, at the bottom of your screen on Zoom, there is a button that says "Reactions." If you click on the Reactions button, then you will see at the bottom of it, it says "Raise Hand." So please click on that button and we will acknowledge and know—yes, Steven is doing it right now. So, I will let Liz know, in case she can't see everybody, that it's on so we can follow the orderly procedure.
DR. WARD:	Thank you. Okay. So, I think now we turn to Dr. Howard for opening remarks.

OPENING REMARKS

DR. HOWARD: Oh, thank you, Dr. Ward. Good morning and welcome to the Fourteenth Meeting of the Scientific/Technical Advisory Committee for the World Trade Center Health Program. I want to thank each of you for taking time from your busy, busy schedules to participate in the Committee and offer your advice to the Program, and specifically the Administrator, me, about the charge that I'm going to give to the Committee. Your participation is so welcome and so appreciated.

I want to also welcome to the members who are returning to the Committee—Dr. Gulati, Dr. Markowitz, Dr. Talaska. I also want to extend a warm welcome to the new members—Dr. Comiskey, Dr. Gaitens, and Ms. Indrina Kanth.

In December of 2022, Congress passed the 9/11 Responder and Survivor Health Funding Correction Act as a part of the FY '20-'23 Omnibus Appropriations Spending Bill. The Funding Correction Act provides $1 billion in supplemental funds for the World Trade Center. Recently, the Program experienced several transitions in patient care delivery contracts, including a new contract administrator of the Nationwide Provider Network, and a new pharmacy benefit manager. Commander Brittany Rizek will provide an overview of the state of the World Trade Center Health Program including the implementation of these two new contracts. In addition, Dr. Travis Kubale will provide an update on the Program's research portfolio and new initiatives that the Program has put in place to disseminate research findings to program members, to clinicians, and all program stakeholders. Recently, we partnered with the David J. Sencer CDC Museum to launch *Health Effects of 9/11*, which is an online exhibition devoted to raising awareness about the ongoing health effects

linked to 9/11 exposures and telling the stories of those impacted. I invite you to visit the exhibition by following the link that Travis will provide to you during his presentation.

Following this Committee's recommendation to add uterine cancer to the list of World Trade Center-related health conditions eligible for coverage by the World Trade Center Health Program, the final rule adding all types of uterine cancer, including endometrial cancer, to the list was published in the *Federal Register* on January 18th, 2023. Program members with certified uterine cancer can receive treatment covered by the Program at no out-of-pocket cost on and after January 18th, 2023.

Commander Hannah Dupont will provide the Committee an overview of the status of uterine cancer coverage by the Program.

Finally, I seek your recommendations and advice regarding changes to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of World Trade Center-Related Health Conditions*. As you are aware, when adding a health condition to the list, the Administrator may take a range of actions as a result of the Science Team's evaluation of the evidence. In general, such actions depend on the weight of evidence supporting a causal association between the health condition in question and exposures to 9/11 agents. In preparing their evaluation of the evidence for the Administrator, the Science Team categorizes the weight of evidence pertaining to the non-cancer health condition in one of five evidentiary categories: one, substantial likelihood; two, high likelihood; three, limited likelihood; four, inadequate likelihood; and, five, no likelihood. The proposed changes to the non-cancer policy and procedures clarify the weight of evidence categories and thresholds for Administrator action. These changes are substantive and in accordance with the Zadroga Act, I request the STAC's input. Dr. Robert Daniels will present an overview of

the policy and procedures for adding non-cancer health conditions to the list and will describe the proposed changes to you in detail.

So pursuant to the Zadroga Act, I am asking the Committee to review and evaluate the revised policy and procedures for adding non-cancer health conditions to the list of World Trade Center-related health conditions. Specifically, I seek your advice on two questions. One, does the revised language under Section IV B of the revised policy and procedures adequately clarify the five weight of evidence categories used for grading a causal association by the Science Team? Two, are the evaluation criteria established for each weight of evidence category clearly defined, reasonable, and appropriate to appropriate link to an action? I certainly am looking forward to receiving your advisory recommendations from today's meeting.

I want to again thank you, each and every one of you, for your service on the Committee, and I wish you a good meeting today. Thank you, and back to you, Dr. Ward. Dr. Ward, I think you're on mute.

DR. WARD: Thank you. I'll try not to do that each time. And our next speaker will be Commander Brittany Rizek talking about the state of the World Trade Center Health Program.

STATE OF THE WTC HEALTH PROGRAM

CDR RIZEK: Hi, good morning. Mia, are you going to share slides this morning? That's a yes. Tania, I can see your face. Can you give me a head nod if you can hear me fine? Awesome.

All right, well, good morning, everyone. My name is Brittany Rizek. I am the Deputy Director for Management and Business of the World Trade Center Health Program, and today I'm going to

just briefly go over the state of the Program in terms of numbers around enrollment, growth of the NPN, and the categories of certifications, look a little bit at drug usage, and service delivery contracts, and look a little bit at the future. Go ahead, Mia.

So, this is just a quick snapshot of the enrollment growth. And as the end of the last fiscal year, the Program has had about 122,000 enrolled members—85,000 responders, around 37,000 survivors. As a reminder, the legacy members are individuals who were being treated prior to the establishment of our program in 2011. You can see there's noteworthy growth in the general responder category and tremendous growth in our survivor population at almost 700% since 2011. Next, Mia. Can you go back one? There we go.

So, the NPN growth has been very significant as we expand outreach and our members are moving outside of the New York City Metropolitan Area. So, we'll talk a little bit more about the NPN here in a few minutes. Next slide.

And here you can take a look, the monthly enrollment numbers are pretty steady throughout the year. We have anywhere between 200 and 500 members enrolling monthly, and in 2022, we had a pretty significant increase in both our responder and survivor population in March and then also in September. We always have an increase in September with our outreach around the commemoration activities, different outreach events. I'll give you a second to look at that. I apologize; they're a bit small. Next slide, Mia.

So, this is important as we, as a program, are always planning for the future and what our clinical center workloads look like in our NPN. We have a lot of transfers moving between CCEs, as you can see, lots going in, lots going out. But of note, we do have, in the last year, we had over 700 moving into the NPN. So post-COVID

work is now commonly remote. We have snowbirds moving toward the warmer states. So, a lot of growth in our NPN this year. Next slide.

And here's a peek at the members with certifications by category. You can see aerodigestive disorders are our highest certification category but, of note, some of these members have certifications for maybe two or three aerodigestive conditions, so maybe someone has asthma, rhinitis and sinusitis. They're only listed here in each category as once. And you can take a quick look down this slide. You're good. I'm used to driving.

So chronic rhinosinusitis, we certified both rhinitis and sinusitis, and these figures are based on the number of members certified for each Zadroga Act condition. So given that there are sometimes multiple certifications, as I said, this slide counts the member only once. Next slide, Mia.

I'll give you a second to take a peek at the information. So, here's a visual of our cancer certifications separated by members. We have responders on the left and survivors on the right. Around 2,000 cancer certifications are approved annually by the Program, pretty similar numbers between our responders and survivor populations if you look at that bottom total. We're around 2,000 for both each year, annually, for responders and survivors. Of note, you can see there is a difference in the types of cancers by member category. All right, next slide, Mia.

A lot of scientists here who like to look at the data. And this is just, when you think about how the Program processes information and makes decisions to approve cancer certifications, the total decisions processed refers to the number of conditions that have been received and reviewed by NIOSH but are not awaiting a decision. Conditions that are under review are what's already been received by us and are awaiting decision. And then

conditions that have not been reviewed by NIOSH as well. So, you can see the total processed by NIOSH over the last decade has been around 50,000.

Go back—I just want to make note of the denials. We have a very specific requirement for certifications as they come in. So that number is low because the requests that come in have to align with the requirements around our policies. All right, now you can jump to the next one.

It's a little bit tiny, but here's a shot so you can see the certified rare cancers and the numbers and instances for each. Pretty similar between responders and survivors, although you have the neuroendocrine drops and the pancreas. Okay, next slide please. Change of pace here. We know what conditions we cover, so this is a glance at our top 15 drugs by cost up on the top left, and then our 15 drugs by claim volume. And at a glance, these align with the top certified conditions that we showed you earlier with those aerodigestive conditions. Next slide, Mia.

So, as Dr. Howard mentioned, the Program has had a number of changes to our service delivery vendors in the last year. In 2021, MCA, Managed Care Advisors, they were awarded the NPN contract with the go-live date of August 1, 2022. And our pharmacy benefit manager is now Express Scripts. They were awarded in 2021 as well with a start of healthcare delivery of June 1st. Our third-party administrator or our claims adjudication vendor, they were awarded over the summer of 2022 but that was protested and that is currently still under protest, so no movement on that. And then our Clinical Centers of Excellence, they were awarded in October. And if you've been with the Program, you'd have known these—on the left side, those are responder clinics and then on the right side, we have Health + Hospitals. William Street Clinic is a newer clinic that was awarded

this past year, to serve our survivor population. In the past, they were for overflow because, as you saw, we had that tremendous increase in survivor membership. Next slide.

So, the NPN, this was the first time we've had a vendor change. We've had many challenges. They, Managed Care Advisors took over August 1. We did a lot of really great things, some successful warm transfers for our most sick patients, those high-acuity members, case manager to case manager. I think this is number is—we're over 41,000 as of this week, calls taken in through the NPN call center to support members accessing a new healthcare network. There has been a member and provider portal that has been developed and implemented so that NPN providers and members can access information about their healthcare, and for providers receiving payment and submitting claims. Right now, I believe this number is down just this week. It's around 860 members who are in case management—that changes, obviously, as acuity changes for our membership—and then around 300 in intensive case management. To date, these numbers are fairly accurate as of this week. Close to about 600 annual monitoring exams, we call those AME; and about 600 initial health evaluations. And I know folks, a lot of you did some training yesterday, but that initial health evaluation is provided to both the responder and survivor population. It's that first-time monitoring exam. Our responder population then goes into annual monitoring, and then our survivor population has access to the annual monitoring if they become certified for a condition. Since go-live, NPN has been able to certify over 1,000 members and 1,500 conditions. So, we have a number of submissions that come in with multiple requests for certifications on each. LHI/OptumServe is the predecessor contractor, and they are continuing to serve us for processing claims runout. So, any

services that are still being submitted for payment are still going to LHI/OptumServe. Thanks, Mia.

So, as I mentioned, we did have very challenges, very complex transitions. The call center and chat functions, there were very long wait times early on. August, September and October, there were fairly long wait times for members to access the call center and to figure out what they needed to do next. There have been significant improvements since November to ensure that members have access to care, and we really like the direction that is going.

There was also a fairly large gap in the providers. So, the LHI network versus the MCA network were fairly different, and so we have to really dig into that network and identify the network gaps, both geographically and specifically for different specialty providers and clinics. We are currently working with MCA to continue recruitment of providers, but the Program and NPN are authorizing seeing providers who are out-of-care right now to ensure that continuity of care.

All right. The pharmacy benefits manager, so this was implemented June 1st of 2022, switched from MCA/Optum—MCA was actually, I think they were a small business at the time—to Express Scripts. They have done a tremendous job transferring a lot of data, a lot of records and prescriptions over into the new Express systems, transferred 13,000 members from the Optum Rx Home Delivery into the Express Home Delivery, and have filled over 380,000 prescriptions since they went live in June.

A couple—you can go back one. I just want to mention a couple of the new things that were implemented. Just pharmacy networks for both responders and survivors. Different—a little bit of a difference in the prior authorization process of a member, being some of the CCE review to ensure that the member got the

authorization a little bit more quickly if the member was seeing a provider that wasn't embedded within the CCE. And then we also added a member portal.

With any vendor transition, there are challenges. Lots and lots of data had to be transferred to ensure that the information from one vendor to the next vendor made sense in both of the different systems. Lots of training, because we have such a unique program with that limited model. We continue to do ongoing training. The call center as well, when we think about the uniqueness of the Program, bringing call center staff from a previous job into this job just—that training is really, really key, and we did see some bumps early on June, July, August. A little bit different of the coordination of benefits system but that has—we have overcome that and ESI has done a tremendous job to work with our program. Also had a couple of primary payer issues where our survivor population is required to coordinate benefits, but our responder population isn't. So, lots of just things to tweak as we make sure we're able to get our members the care they need.

And lastly, looking to the future, if we think about the cohort of anybody who was exposed, there—most of our membership's going to be over 65 in the next 10 years. So, we're going to be looking at kind of that intersection between aging and the conditions that we cover. So, we have a lot of primary risk factors with this aging, including hearing loss, osteoarthritis, diabetes. And what does this really mean for us as a program as we want to ensure the quality of life of our members?

So, we do have a challenge making sure that we are getting the resources we need to our membership so they can maintain that quality of life, but also making sure that we're being good fiscal stewards of the federal dollar and providing services for only

those conditions that are 9/11-related.

So, the Program is really looking to find continued innovative ways to recruit behavioral/mental health providers. As of right now, we're—that's tough across the nation—as well as end-of-life and home health providers nationally.

Oh, that scared me. So, we are continuing to look—and I said those innovative ways. We want to make sure that we're able to meet the needs of the population as they age, and we're really going to be focusing on that over the next ten years.

So, thanks so much. It's great to see everybody, and I got to meet a couple of you yesterday. Appreciate your time.

DR. WARD: Thank you, Commander Rizek. I think we have about ten minutes for comments or questions regarding Dr. Rizek's—Commander Rizek's—presentation. So, I'll look for any raised hands. Steve.

DR. MARKOWITZ: What are "administrative closures" in the cancer slide? There were some several thousand administrative closures. Lack of proof of the cancer? What was that?

CDR RIZEK: It could be anything. Usually, an administrative closure isn't usually medically related. It's there wasn't enough information on the piece of paper that's submitted and we just, we closed it out because they resubmitted a WTC-3. But it also could be there wasn't enough information, and it didn't meet the requirements of making the submission or submitting it. So, we just administratively closed it, as opposed to denying it, which opens up an appeal right.

DR. MARKOWITZ: Yes, and I have a second question that on the new national provider, I think the slide showed something like 500 or 700 examination—monitoring exams per month, or per time period. But there are 30,000 people in the national program, so I didn't quite understand that particular piece of data.

CDR RIZEK: Numbers are low. We're working to increase the number of IHEs,

or initial health evaluations, and annual monitoring exams very quickly. One other focus is, we're ensuring is that people who are in active treatment have access to their treatment they need, or people who need treatment are getting in right away. And we're ramping up on the AMEs/IHEs.

DR. MARKOWITZ: Thank you.

DR. WARD: Jason?

DR. OSTROWE: Thank you. So, cancer obviously is one of the biggest problems, if not the biggest problems, in the 9/11 responder population, particularly thyroid cancer or skin cancers, things of that nature. Now, the issue is that when survivors and first responders go to have their annual physical or annual checkup at their centers for care, they do not do any cancer screening whatsoever. Zero. And as a matter of fact, you'll have a doctor there, the provider will tell the first responder or the survivor, "Oh yes, thyroid cancer is a real big problem in the 9/11 community, but I can't touch—I can't check you. You have to do that on your own." So, I'm wondering how we could do a more sufficient job of adequately screening people for cancers, specifically like thyroid cancers and other cancers. How can we do that?

CDR RIZEK: Well, I'm going to turn that over to one of our clinicians. I am a non-clinician. But your point is taken very well. We do—the Program does provide monitoring or screening for various cancers but the point's well-taken in terms of can we do that at the monitoring exam.

DR. OSTROWE: Sure. You know, like I think the issue is is that, you know, coverage is great to have after the fact. That's also after the fact you have thyroid cancer. And the mere fact that we know that, in people that were exposed to the 9/11, whether they are responders or survivors, are coming down with cancers at, you know, statistically significantly higher than the general population and

it's causal. But yet when you go for your annual physical at the center for care, the providers there refuse to do any—they feel they can't. So, I wonder how that could change. I think that that's, you know, really missing something there.

CDR RIZEK: Thank you.

DR. WARD: So, would one of the clinicians care to address that question? Geoff or Dori?

DR. CALVERT: This is Geoff. I could take a crack at it.

DR. WARD: Great.

DR. CALVERT: So, we do cover screening for cancers where the U.S. Preventive Services Task Force assigned you their Grade A or B, meaning the benefits exceed the risks of that screening. So, the types of cancer that USPSTF endorses with those grades is colorectal cancer, lung cancer, breast cancer, and cervical cancer. So, we do cover screening for those four types of cancer. For thyroid cancer, USPSTF does not endorse the screening because they haven't found sufficient evidence that the benefits for such screening would exceed the risks.

And then to your statement about the screening people's necks for thyroid cancer, I guess I'm surprised that they wouldn't do a neck exam, at least to palpate for potential nodules in the thyroid. So, thanks for raising awareness about that. We could go back and check into that. Does that answer your questions, Jason?

DR. OSTROWE: Yes. Yes. No, it does. Thank you, and I appreciate that, and I appreciate the perspective. I just think that, you know, what you're describing just sounds like a lot of bureaucracy getting in the way of people's health. And we do know that there is a causality between—or a causal relationship between thyroid cancer and other types of cancers and exposure to toxins on 9/11. And sort of to say that, you know, we're basing that—we're basing our risk-to-reward ratio off of something else other than,

you know, specific to the 9/11 population I think is, I understand that point of view. I just, I don't know if it's working for the people that need it the most. And, because we know that this is causing its own—you know, I just think this is something that really needs to be addressed.

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

DR. MARKOWITZ: Yes, just a quick question, Britt. On your rare cancers slide, I spot pancreatic cancer, both survivor and the responder population. So why is that considered a rare cancer, pancreatic in particular?

CDR RIZEK: I'm pulling up my slide.

DR. MARKOWITZ: It may have some—something to do with the way the Program defines rare cancer.

CDR RIZEK: Dr. Anderson, do you know how we define that? Or Jessica?

MS. BILICS: Yes, this is Jess. Can you hear me okay?

CDR RIZEK: We can, Jess.

MS. BILICS: Yes, the definition in our regulations for rare cancers is a cancer that is less than 15, an incidence rate of less than 15 per 100,000 per year in the U.S. population.

DR. MARKOWITZ: Okay. You might want to double-check that.

CDR RIZEK: It may have changed. I mean, and I know the initial population was 2009 so it may have changed since we defined it initially. We can double-check that. Thank you.

DR. WARD: I wanted to make one comment about Jason's comment, which is that—and I thought that was the point that Steve might be making is that one of the things we have to contend with in occupational risk cohorts is that where we identify a higher risk in an occupation, the screening recommendations may differ. And it's been a struggle, I think, for example for lung cancer screening, to formulate recommendations—to apply recommendations for screening in the general population to occupational populations at higher risk. So, I just want to reinforce that this is something

that the World—the Program may want to consider in the future about when there are cancers found to be at higher risk, does the risk/benefit calculation change, and should the consideration be different than that, you know, developed for the general population by the U.S. Preventive Services Task Force?
And having the last word, it's 11:44 and I wondered if—so I think we should probably move on. We do try to keep to the agenda at these meetings because we know, especially members of the general public, are coming in and out to listen to parts that they are particularly interested in. So, thank you, Dr.—Commander Rizek for your helpful presentation. A huge amount of data. And all the slides for these meetings are posted on the World Trade Center Program site, so if you want to go back and review all that data in more detail, it will be available online. And I'd like to turn it over to Travis Kubale who will be speaking about the Health Program—the research program update.

WTC HEALTH PROGRAM RESEARCH UPDATE

DR. KUBALE: Thanks, Dr. Ward, and it's nice to be here and brief the Committee. The objective of this briefing is to update the STAC members on a series of ongoing initiatives. And I'm sorry, Mia, we'll go to the next slide.
A series of ongoing initiatives that are designed to develop data visualization platforms that maximize access and use of research information, and to increase research opportunities and scope, to increase the pool of potential World Trade Center Health Program researchers, and to maximize access to and transparency of the World Trade Center Health Program research grant funding information. Next slide please.
The initiatives that I'm going to briefly touch on during my talk are

a result really of input from a variety of sources. And the initiatives include the movement of a significant amount of information to visualization platforms located on a revised and updated research landing page, also targeted research solicitations, and avenues for stakeholder input and guidance. Next slide please.

Let's see. Let's go back one, I'm sorry. Okay, go one more. I'm thinking we're (inaudible @ 00:45:45). Let's see. What does the next slide look like? I'm sorry.

Yes, let me talk about… This is the slide that, as Dr. Howard mentioned, that I wanted to go over, and he mentioned this in his opening remarks. And I want to make the Committee aware of this. This is an award-winning *Health Effects of 9/11* online exhibit site. And it's an especially useful resource for 9/11—or, I'm sorry, for STAC members, stakeholders, and members and researchers. And Rhonda Nembhard and Emily Hurwitz led the team, with stakeholder input, that designed and got the exhibit going. And the exhibit is a recipient of the 2022 Health and Safety Visual and Virtual Exhibit of the Year Award. This online exhibit is one of the best that I've ever seen. It's easy to navigate, with humanely presented details on the victims and the historical—and historical recordings, and primary and secondary documents. And Mia, if we could go back one, I'll start again with that slide.

This is the—as we mentioned previously—the Program is now in the process of moving a massive amount of information to visualization platforms that are located on this reorganized research landing page. Now, this initiative was led by Kristen Iker and involves the coordination of multiple NIOSH divisions—branches including Research, Communications, and Technical Solutions, and multiple NIOSH and CDC divisions including the Office of Extramural Programs and the CDC Office of Grants

Management. Our primary goal here is to work as hard as we can to provide a structural framework that is required to facilitate and support a high level of stakeholder knowledge and involvement with World Trade Center Health Program research. And then, Mia, if we can go to the next slide and then the next slide. Yes.

So, I want to say one thing first as we move into some of these platforms. This is a brief description of some of the characteristics of the research publication platform that I'm going to show you. I want to say just a couple of things. These are all research publications related to the World Trade Center disaster, starting with the first one on World Trade Center cough in October of 2001, and they are included. And to do that, we've learned to employ a strategy that uses frequent—and they're actually daily, 365 days a year—of broadly defined searches to get a complete capture of World Trade Center-related research. And we do, you know, benchmark and make sure that we are capturing everything once a year with our RAND partners. Again we, in the past as you all know, we were updating research publications about every six months, and now they're updated weekly. And they also provide what we think are multiple search options, making it easy for people to move through a massive amount of information. Next slide please.

Again, what we're trying to do here is to create a dashboard that will facilitate the use of research information and evidence in program planning and clinical decision-making. Functional component of the dashboard include topic areas, so if you're interested in publications that relate to cancer or World Trade Center youth or emerging conditions, it's easy to find those. We also, toward the bottom of the screen, you can see we have a search that you can do to look at World Trade Center outcomes that are covered and also non-covered outcomes.

We also, to the right of your screen, have a link directly—this is updated in real-time—to Altmetric, which is a mechanism that we use to track where our research is being mentioned online. And how we use this, for example Dr. Max Lum, as you all know, watches this very closely and noticed recently that we had a significant amount of interest from Spanish-speaking media outlets. He worked with Dr. Alejandro Azofeifa, and they developed our first Spanish-speaking blog describing World Trade Center research. Next slide please.

We have also worked very hard to create, for the first time—and it's rather unique—a grants, World Trade Center grants, research grants dashboard. And this again was the result of a collaborative effort among program staff, again led by Kristen Iker, and staff from the NIOSH Office of Extramural Programs, Dr. James Yiin and Dr. Allen Robison, and also the NIOSH Finance Office, Mr. Larry Rhodes. Also, because of the complexity of the information that is involved here, research stakeholders provided invaluable design and data organization input, and I am especially grateful to Dr. Zoey Laskaris, Dr. Rachel Zeig-Owens and Dr. Grace Nippard. They were so helpful in helping us design this platform. Next slide please.

This gives you just a brief overview. You can see the number of current projects, the number of projects that, over the course of—you know, since the Program started—that had been selected, and the total awarded amount. We also have dropdown topic areas, so if you want to look at just projects related to respiratory disease or mental health or cancer, you can do that. We also have a dropdown for cohorts, so if you're interested in just responders or survivors, or both, you can do that as well. Next slide.

What's of interest, certainly to us, where we're looking where in

our program do we have high production, maybe low flow production where we need to be aware of those kinds of items. We also have the capacity to search by institution and PI. And below, at the bottom, you can also then click on the specific project—and go to the next slide please, Mia—and it takes you to the NIH Reporter where you can actually read the abstract and the Public Health Relevance Statement. Next slide.

I want to switch gears just a little bit, and particularly for new members of the STAC, and say a little bit about how our research solicitation and funding is structured. And there are just a couple of important points that I do want to make here. One is that the management of the World Trade Center Health Program research solicitation and funding, it's managed external to the Program. All aspects of solicitation and review of project proposals are managed by staff of the NIOSH Office of Extramural Programs who are expert in this. This is led, of course, by Dr. Allen Robison. Dr. James Yiin is the program official for World Trade Center, and Laurel Garrison is the scientific review official for the Program. The process is competitive. The projects, again, are independently reviewed. And the makeup of our portfolio is really based on the quality and the quantity of proposed research. Next slide please. This gives you an overview of sort of the highlights of our 2022 solicitation. A couple of points that I want to make. This was the first time that we posted—it was posted in August of 2021 for the 2022 applications cycle—and that's a survivor-only research solicitation. And this was, you know, based on stakeholder recommendations, and that is a—not only a current but a lasting feature of the solicitation platform that we use now for projects. We were able, in this last cycle, to add projects, as you can see, focusing on individuals exposed to the disaster as youth, and on emerging conditions. And those included health-related quality of

life and cognitive decline for survivors. The research applications remain strong. We were able to add projects focusing on CVD, mental health, and emerging conditions focusing on aging, particularly frailty, and intervention strategies related to that. Next slide please.

In this cycle, in 2023, we are for the first time—and it's, so far, we have been able to get and will be reviewing several, we think, very strong applications related to lifestyle medicine. And this current solicitation was really designed and implemented by Program medical staff based on their knowledge and expertise, with input from CCE clinicians. And we're excited about that process and how that occurred. The scope also does, it does include issues related to cognitive impairment and polypharmacy which is, of course, as you all know, defined as the use of five or more regular medications. Next slide please.

I point this out as I want to make a couple of points. The Program, as part of all research announcements, solicits input from researchers and stakeholders for consideration, and we do that by utilizing the *Federal Register* Notice mechanism. Stakeholder recommendations and concerns are considered for inclusion, and what you see here, which is a guidance note, is to researchers. And these notices are published directly in research announcements, and we put them usually with funding and project period updates and so we know that researchers will see them and read them. Next slide please.

A point that I want to make is, here, is that we are aggressively pursuing—this is an initiative led by Dr. Santiago-Colón and Dr. Kristi Anderson—and we are pursuing establishing collaborative relationships with research institutions to identify and attract new researchers, and certainly including early-career investigators, with specific research interests and experience. These are some of

the early institutions; there are others that are already on the list just since this slide was created. But as you can see, the University of Michigan, Harvard, and the University of Kentucky School of Public Health are three of the ones that we are working very hard to establish these collaborations with. I also want to say that the staff is very involved in mentoring early-career researchers, and specifically we have been able to take advantage of the CDC Hispanic Internship Program which we hope, in the future, will increase our research participation. Next and final slide, I think. Again, thank you. It's an honor to be able to come back and speak with the Committee and thank you very much.

DR. WARD: Thank you.

DR. KUBALE: I'll turn it back to you, Liz. Yes.

DR. WARD: Thank you for that very informative presentation, and I'm opening the floor for comments or questions. Sophie.

DR. BALK: Hi, thank you so much for the presentation. So, I'm a general pediatrician so I have a pediatric-focused question. So, I see that you've looked at funding projects for World Trade Center youth and you're going to be looking at cancer in people exposed as youth. So, I had a question about the online exhibition page. There's, I didn't see any—it looked like an amazing exhibition, but I didn't see anything about people exposed as youth, pregnant people, and the effects that, thinking about the effects that they will have over a lifetime, which is quite long. I just wanted you to comment on that.

DR. KUBALE: Thank you very much. I know that there are, you know, ongoing modifications that'll be made, you know, to the site. What I would ask that you do is to please put in writing your suggestions and comments, and send them through to Tania, and I'll make sure that the team gets those, and we can look at that certainly. Thank you.

DR. BALK: Thank you.

DR. KUBALE: And I appreciate it. I'm glad you went to the site. Thank you very much.

DR. BALK: Thank you very much.

DR. KUBALE: And if you have any other comments or suggestions, please, please reach out to us through Tania.

DR. BALK: Thank you.

DR. KUBALE: Thank you.

DR. WARD: Steve.

DR. MARKOWITZ: Yes, hi, Travis. Thank you for the great summary. A question. Later on, we're going to be talking about causal criteria and helping NIOSH with those things. I wonder, in thinking about new conditions that are subject to petitions or NIOSH's own analysis, when new conditions arise and there's questions about whether they're causally related to World Trade Center, does that get translated to the research agenda?

DR. KUBALE: Well, it can. I mean, there are a couple of things that I would say and thank you for the question. First of all, there—it can be tricky to sort of understand that relationship between research and petitions, and so Dr. Daniels, there were others, wrote a commentary that we do have on the website that sort of explain that process. So, I would refer members to that. And yes, we work closely, so Dr. Daniels understands and knows what the emerging conditions are, and we understand, and they use the database that we have when they're making that determination. So, I would say that yes, we do communicate and talk about those issues.

DR. MARKOWITZ: Thank you.

DR. KUBALE: In that respect.

DR. WARD: Debra?

DR. MILEK: I'm wondering, with all the research and data, do all the clinical centers use the same history and physical? And if so, or not, when

was that last updated?

DR. KUBALE: Well, that's a good question and that's really one for either Dr. Kristi Anderson or Dr. Geoff Calvert. I'll defer, Debra, to them if I may.

DR. CALVERT: Hi, this is Dr. Geoff Calvert. So yes, thank you for that question. The exams and the questionnaire instruments that are used at the CCEs and NPN are all very similar, but they, across the cohorts, they vary slightly. For the most part, they were created back when the Program started in 2011, but we are actually—it's nice that you asked the question about revising it—we are actually undertaking an effort currently with the data centers to examine the questionnaire instruments as well as the components of the examinations, to determine what could be updated, what could be changed, what could be added or removed. So, thank you for your question.

DR. MILEK: Thank you.

DR. WARD: Jason.

DR. OSTROWE: Thank you. I'm wondering if there has been any research conducted on the first responders, survivors who have discontinued their treatment or discontinued going to the World Trade Center Health Program, and I would wonder why they would do that. And one of the things that I'm thinking about is, you know, people who are suffering from these ailments don't necessarily want to be treated as a, you know, like a study subject. Rather, they want to be treated by—as a person who's in need of treatment and prevention. So, I'm just, I wonder if there has been any study in that area.

DR. KUBALE: Well, thank you for the question. Part of this may go to either Britt or someone else, but here's what I would say about that. There is a very robust Retention Committee that gathers, you know, Jason, that kind of information on our membership and

about those issues. Research has not been directly involved in a project other than monitoring that information and that data. But it is collected, and retention and methods to ensure that are certainly ongoing. Britt, I don't know if you want to add anything more to that about the Retention Committee and their work.

CDR RIZEK: Yes, you're spot on. Some of the things we're also looking at are the differences in CCE cohorts and versus responders versus survivors in the retention piece there because of the differences in allowable services. If our survivor population—if a member who is a survivor is not certified, like I said earlier in my presentation, they aren't eligible for that initial health evaluation. So that retention piece is a little bit tricker when we don't really have something to give back to. So, we're looking at how we measure that retention piece but yes, you're spot on with the—the retention workgroup is an ongoing workgroup that's always looking at different ways to keep our folks coming back.

DR. WARD: Great. Tania and then Jason.

DR. CARREÓN-VALENCIA: Well, I'll let Jason, in case this is a follow-up question.

DR. WARD: Okay.

DR. OSTROWE: Thank you, Tania. Thank you, Tania. Yes, it is and it seems to me that this is something that goes beyond just like, you know, a quantitative analysis and a retention group. You could do a qualitative analysis of people who have discontinued and try and find out what are the reasons that they discontinued their, you know, whether it's treatment or their monitoring, and what it has to do, if anything, with the Program itself and the way that I think many responders would probably say they're treat—they feel as if they're treated more as a scientific subject rather than, you know, an individual that's in need of medical care.

DR. KUBALE: Well, Jason, thank you. I appreciate that. And please, again, write that in a comment to Tania and we will certainly consider it, and

we'll look at ways that we can do that. That type of program research is certainly within the scope, and we appreciate your idea, and we will look at that and consider. Thank you.

DR. WARD: Thank you. Now Tania.

DR. CARREÓN-VALENCIA: Yes. I want to go back to Sophie's question regarding the evidence that is evaluated for petitions. Dr. Daniels is going to talk about that but every *Federal Register* Notice that we publish with the evaluations of the evidence, when there is insufficient evidence to add a condition, Liz, all the information that—all the evidence that was reviewed, and each study is reviewed with, individually and its strengths or limitations are described, as well as the whole body of evidence. So that information is certainly available for researchers when they are planning their submissions for funding for the Program.

DR. WARD: Thank you. John?

DR. COMISKEY: Yes, I have a question, really going to build on what Jason said. So, I'm a participant. I go for an annual screening. And I wonder, in the sense of it's not a traditional physical. You're going in for World Trade Center screening and there may be other things in that person's—just like an annual physical, you go to your regular doctor—that may actually overlap. So, I'm trying to get a sense of how we could do both really, is facilitate the research needs of the STAC as well as really trying to give… I'm not looking for comprehensive care but to understand that the client or the patient may not really understand the difference or the purpose of the actual physical. I know that was more of a comment than a question.

DR. WARD: Would someone from NIOSH want to comment?

DR. KUBALE: I would leave this to, you know, Geoff. But John, thank you for the, you know, the comment and the guidance that, you know, on this. We appreciate that. I don't know if Geoff or Kristi or Dori

have anything that they'd like to add?

DR. CALVERT: Yes, I could—thanks, Travis. I could—again, this is Dr. Geoff Calvert. So, John, thank you for your comment. And as I mentioned previously in response to another comment, we are looking at the monitoring exam and the components of it. So, it's going to be a long-term process, that whole process of looking, doing that examination and looking for ways to improve the exam. But your feedback and your thoughts are very helpful. I'll share that with the folks who are contemplating and reviewing the exam, to keep in mind that, to both address the research needs as well as the service needs, providing the services for the members. So, thank you.

DR. WARD: Thanks. Sophie?

DR. BALK: This is a different subject. I had a thought about a different research question. It also comes from my perspective as a pediatrician. It's about climate change. So, the climate is changing and we know that kids are a vulnerable population for a number of reasons. I'm just thinking, is the World Trade Center cohort at increased risk of climate change effects by virtue of being exposed? I haven't thought about it but it's—I'm trying to think about climate change in most things that I do now, and how they—how climate change affects health conditions, for example asthma. So, I don't know if anyone has comments on that or thought about it.

DR. WARD: John?

DR. MEYER: Yes, hi. Just in short answer as Sophie's—and obviously the question is much longer—we have a group here who have, who are working on kind of bunging together, parlaying within the World Trade Center cohort along with subsequent environmental monitoring data, heat, particulates, etc., etc. and looking at the possibility of increased vulnerability in the World Trade Center

cohort. That's kind of just getting off of the ground, and you can sort of put that under pilot work in progress. But it is on some people's radar screen, particularly in our environmental epi people.

DR. WARD: Thank you.

DR. BALK: Because I think it has to be on—I don't think it's on, like, in my cohort of general pediatric clinicians, it's not so much on people's minds but it really needs to be, in everything that we do.

DR. MEYER: Yes. Yes. There are some ideas of looking at it which are kind of coming down at us right now from this group.

DR. WARD: Tania?

DR. CARREÓN-VALENCIA: Yes. In response to Sophie's earlier question regarding youth research and what is posted on the online exhibition, I received that comment from Anthony Gardner from our communications program that he said that yes, we have some content in the online exhibition regarding youth impacted by the World Trade Center-related exposures. So, he says that there is an editorial cartoon created by Ali Shapiro, who was a Stuyvesant High School student at the time, and it can be found in a specific section that I will send you an email later about. He also said that there is another drawing by a young girl who created an image of her doing a breathing test.

DR. WARD: Thank you, Tania. So, we are at the end of our time for this discussion. Debra, did you want to make a brief comment?

DR. MILEK: I have a brief question, back to the clinical evaluations, in relation to Jason's comment. Does the same clinician see the patient or does the patient get whoever is on that day, i.e., is there a relationship between the patient and the clinician evaluating them which might address the issue?

DR. WARD: Kristi, you can address that question or Britt?

CDR RIZEK: I'm happy to address that. At the clinical centers, the monitoring

and initial health evaluations are done by a fairly small subset of people. So, if you've been assigned to Mount Sinai or NYU for five to ten years, you're likely seeing the same provider each year, which does develop a very nice rapport. In the national program or the Nationwide Provider Network, it could be a little different if—with changes in vendor, you might be required to change providers. But the goal is to have you seeing the same provider each year.

DR. WARD: Thank you. And I do think we need to break for lunch. But you know, as has been said several times, if after these discussions, you have further comments about the matters, please go ahead and forward them to Tania and the Program will certainly consider them even though we didn't have time, or they didn't come up during the meeting.
So, we will adjourn until one o'clock. So, it's really important that all members try to come back, yes, just in time because we are so close to a quorum.

DR. CARREÓN-VALENCIA: Yes, and also—

DR. WARD: And we'll do a roll call when we come back.

DR. CARREÓN-VALENCIA: I'm sorry to have interrupted you.

DR. WARD: That's all right.

DR. CARREÓN-VALENCIA: I'm having some issues. But I also want to ask all the members to please just don't leave the Zoom room, just turn your microphone and your camera off and come back after lunch.

DR. WARD: Great, thank you, Tania. We'll see you all at one o'clock.

[Lunch.]

DR. CARREÓN-VALENCIA: [Welcome] to the meeting of the World Trade Center Health Program Scientific/Technical Advisory Committee. I'd like to welcome, once again, our members and also the members of the

	public who are joining via webcast. And so, to ensure that we have a quorum, I'm going to do another roll call. So, I'm starting with our Chair. Liz Ward?
DR. WARD:	I'm present.
DR. CARREÓN-VALENCIA:	Sophie Balk?
DR. BALK:	Present.
DR. CARREÓN-VALENCIA:	John Comiskey?
DR. COMISKEY:	Present.
DR. CARREÓN-VALENCIA:	Chandra Davis is not here. Joanna Gaitens?
DR. GAITENS:	Present.
DR. CARREÓN-VALENCIA:	Mridu is not here. Mariama James?
MS. JAMES:	Present.
DR. CARREÓN-VALENCIA:	Great. Anita is not here. Indrina is not here. Michael Larrañaga?
DR. LARRAÑAGA:	Present.
DR. CARREÓN-VALENCIA:	Steven Markowitz?
DR. MARKOWITZ:	Present.
DR. CARREÓN-VALENCIA:	John Meyer?
DR. MEYER:	Present.
DR. CARREÓN-VALENCIA:	Debra Milek?
DR. MILEK:	Present.
DR. CARREÓN-VALENCIA:	Larry is not here. Jason Ostrowe?
DR. OSTROWE:	Present.
DR. CARREÓN-VALENCIA:	Aarti is not here. Glenn is not here. So, we still have ten members present and a quorum. So, I give it back to you, Liz.
DR. WARD:	Thank you. So, our first presentation for the afternoon is on the status of uterine cancer coverage and it will be given by Commander Hannah Dupont.

STATUS OF UTERINE CANCER COVERAGE

CDR DUPONT:	Thank you very much. Would you like me to share or—I can, I

wasn't sure if it was going to be driven by someone else.

DR. CARREÓN-VALENCIA: Yes, Mia is going to. She's pulling your slides right now.

CDR DUPONT: Okay, great. Okay, thank you so much. So, my name is Hannah Dupont. I am the Chief of the Medical Benefits Unit at the World Trade Center Health Program, and I'm really glad to be here. Thank you all for inviting me. Today we'll be talking about uterine cancer coverage, how we prepared for it, how we implemented it, and what we're being covered—what we are covering now after it was added to the list of conditions. And go to the next slide.

Prior to January 18th, certain types of uterine cancers were covered based on that definition of meeting rare cancers. Jess read off that—Jess Bilics read off that definition earlier. And these were uterine sarcomas and invasive cervical cancer. Endometrial cancer, however, is not considered a rare cancer, and it was therefore not covered.

As of January 18th, 2023, it is covered. Endometrial cancer is covered. And so, we look at uterine cancer as an umbrella term over uterine sarcomas and endometrial cancer. So, in order to operationalize this new coverage, we had to add endometrial cancer and endometrial intraepithelial neoplasia to our benefit system in order to allow for coverage. Next slide.

So, for the remainder of this presentation, I'm going to refer to uterine cancer as endometrial cancer since that is what we had to add to our systems.

In preparing for this implementation, we prepared for months just as everyone waited for months for this to happen. Our pharmacy identified all the drugs needed to treat uterine cancer and updated the formulary. Within my medical team, we updated our benefits systems with the appropriate endometrial cancer condition codes so that members can be certified with those specific codes. We updated our systems with the procedure codes

for the types of treatment we covered; and we updated and wrote a document describing the eligibility criteria and how we cover endometrial cancer. Our training and education team developed training for CCE and NPN providers on coverage and eligibility criteria. And through our Contracts Unit, we provided technical guidance to the CCEs and NPN regarding claims submission and adjudication so that they would know specifically how everything was going to work. Next slide.

Our Communications Unit did a fabulous job. They developed a comprehensive communications plan to raise awareness of the addition of uterine cancer/endometrial cancer. They developed a press release to send to media outlets which resulted in extensive coverage. They developed social media messaging; updated our Program website, news page and handbook; developed messaging for use by the CDC and for the CDC to actually use with press and the Congressional offices. They sent a letter to every member notifying them of the addition of the condition to the list, communicated with many of our other partners, VCF, WTC Health Registry, our outreach and education partners, and the CCEs/NPN to ensure that everyone was using consistent messaging. They updated FAQs for our website and informed call centers of messaging, developed an article for the newsletter that releases later this month, and translated all of the communication to Spanish, Chinese, and Polish. Next slide.

So, for this, this gives a little bit of the statistics on the kind of communication we put out. So, we mailed out 113,482 letters, and you can see that there was quite a bit of engagement on social media, on Twitter and Facebook. And we had over 400 hits on our web news article on the website. And then these are all links that will take you directly to different news outlets to read the articles that were disseminated. Next slide.

So, to go into our certification and eligibility requirements, when the CCE and NPN clinical directors put together the certification requests, they have to ensure that the expo—that the member meets the exposure requirements for certification, and that the diagnosis happened after four years since the date of their first 9/11 exposure. So, the latency period is four years, which is the same as all of the other solid cancers. And then there must be a definitive pathology report attached to the WTC-3 request. Next slide.

And then treatment coverage. So, in general, we are covering diagnostic endometrial sampling to confirm diagnosis of endometrial cancer. We are following the NCCN clinical practice guidelines and covering surgical management, radiation therapy and chemotherapy. We will also provide medically necessary treatment for endometrial cancer and endometrial intraepithelial neoplasia. And then we do cover, if there's any early or premature menopause that results from the surgical management, we will cover treatment for that as well as fertility-sparing treatment if it's necessary.

And that is all that I have but I'm sure that there are comments or questions so I'm happy to take any and all of them.

DR. WARD: Great, thank you. So, the floor is open for comments and questions. I'm not seeing any hands yet. I will say that that presentation was really informative because, you know, as a STAC member I hadn't ever thought about all of the complexities of implementing coverage of new cancer sites, but the Program has done it in the past, I know, and has—certainly has a good model for it and it seemed very comprehensive and well-thought through.

CDR DUPONT: Thank you, I appreciate that. Okay. Steve.

DR. MARKOWITZ: And so, I—that was a great, very succinct presentation—I have a

question about the premature menopause. It's really a more general question about secondary conditions or consequential conditions. I'm not sure what term exactly is used.

CDR DUPONT: Yes.

DR. MARKOWITZ: This is when there's some outcome, some secondary health effect, that occurs not because of the primary health condition but as a result of where—as a result of the treatment of, right? So later on, we're going to be looking at various policies and procedures for adding non-cancer conditions. Do these, do the policies apply? How do you look at consequential or these secondary conditions? Do the same—are the same criteria used at all, or is there a separate sort of set of policies and procedures around these consequential conditions?

CDR DUPONT: So, in this specific example, the early or premature menopause would be considered, like you're saying, it's called a medically associated condition or a MAC. And those MACs, MACs are certifiable, and they should be certified in order to be treated. And the way we look at MACs is it has to be the result of treatment of the certified condition or as a result of progression of the certified condition, like the progression of the disease.

DR. MARKOWITZ: And is—

CDR DUPONT: So, it's, yes, it's related to treatment or progression of disease.

DR. MARKOWITZ: And how is that decided? I mean, in this case it's obvious, right, but in other situations a little less obvious. Is there a—how's that, how is decision-making in general made regarding secondary conditions?

CDR DUPONT: I'm going to call on also Dr. Calvert and Dr. Anderson if they'd like to chime in. We do have a clinical consultation team that often makes these kinds of determinations following that definition that I just described. It can be complex. Dr. Calvert, did you want to offer any feedback?

DR. CALVERT: Sure. So, we would cover those medically associated conditions if there's solid evidence in the literature to support either that the disease does progress in that way or that the treatment can cause those types of side effects.

DR. MARKOWITZ: Okay, so later when we look at, when we discuss the changes in the policies and procedures, they don't apply to these medically associated conditions, right?

DR. CALVERT: Correct.

DR. MARKOWITZ: Thank you. Thanks.

CDR DUPONT: Thank you. Any other questions or comments?

DR. WARD: Tania?

DR. CARREÓN-VALENCIA: Yes, I just want to add to what Hannah said. Those of you that participated in the deliberations for adding uterine cancer might remember the white paper that the Science Team put together. So as a result of the comments from three peer reviewers, for which I am extremely grateful, that covered lots of detail on endocrine disruption, we updated the white paper to add a more thorough definition of endocrine disruption that was provided by the Endocrine Society which I know you, the STAC, used that definition but we didn't have it on the white paper. We also, in the absence of a comprehensive list of endocrine-disrupting chemicals, we matched the Inventory of 9/11 Agents against all available lists of known or potential endocrine disruptors both in the U.S., the European Union, so we added that table to the white paper as well as we worked with Rachel Weiss, who was putting together the final rule, to add the comments and addressing the comments from the peer reviewers. So, you can find the final white paper on the STAC Meetings website under the September 28-29 meeting. Just for your information.

DR. WARD: Thank you, Tania. It's good to know that material is there. I was wondering what the peer review comments had been, and so I

guess they're there too. Great. Well, I look forward, as someone who was part of the workgroup, and I know there are others here who were part of the workgroup. I really look forward to looking at that, and I'm glad that the Program was able to make that change. So, any other comments or questions on this?
Okay, so Tania, we have the—the agenda has us beginning the discussion of policy and procedures for adding non-cancer conditions at 1:30. Do you want to start early or do you want to defer?

DR. CARREÓN-VALENCIA: Yes, I think we can start early with Dr. Daniels's presentation and continue discussion. Public commenters are scheduled to join the Zoom call at 2:00 but we can do it—that's scheduled at 2:15 so you can start the presentation, asking questions, and even maybe some of your deliberations before 2:15.

DR. WARD: Great, thank you. So, we'll go right ahead with your presentation.

MS. WALLACE: Can you—can we get one second? There's an issue with the public seeing the link right now so we just want to refresh it.

DR. WARD: Sure. Sure. Well, let us know when to start.

MS. WALLACE: Okay.

[Pause.]

DR. CARREÓN-VALENCIA: So, I have asked Doug if he could share his screen with his presentation.

POLICY AND PROCEDURES FOR ADDING NON-CANCER CONDITIONS

DR. DANIELS: Hi, everyone. I guess we're having technical difficulties so I'm going to find my presentation and share my screen, and hopefully that will work. I turned my camera off because I can't do all of it at once, I'm afraid, but I'll turn my camera on for questions. How will

that be?

DR. WARD: That's great. It is always nice to see a face associated with a voice.

DR. DANIELS: Okay. Hopefully you can see my screen.

DR. WARD: Yes.

DR. DANIELS: Wonderful. Well, shall I get started then, Tania?

DR. CARREÓN-VALENCIA: Yes, please.

DR. DANIELS: Let me put it in slide show. There, is that better?

DR. CARREÓN-VALENCIA: Yes, it looks great.

DR. DANIELS: Marvelous, okay. So, I'm Doug Daniels. I'm the Associate Director for Science for the World Trade Center Health Program, and I believe this might be the first time I've ever addressed a committee so the pleasure's all mine. It's good to—it's been a wonderful conversation thus far and I'm looking forward to comments and questions as I move forward through this procedure. So, I'm going to talk about revision to the policy and procedures for adding non-cancer health conditions to the list of World Trade Center health—World Trade Center-related health conditions.

So, the last time this procedure was revised was back in 2019. And if you look at the revision history, we usually go two to three years between revisions. It's been a living document and as the Program has evolved, we've made changes as necessary. The aims of this revision, there were really two substantive aims here.

One was to align this policy with the policy and procedures for adding cancer to the list of World Trade Center conditions and, specifically, the rationale and nature for how we handle STAC recommendations. The Committee may remember, we revised the cancer policy and procedures back in 2021, and the driver there was when we were working on the uterine cancer recommendations, and we made some revisions to that procedure to clarify that, you know, the Administrator can act on

recommendations from the STAC provided a reasonable basis is included with that, with those recommendations. So, that language we wanted to also include in the non-cancer policy and procedure. That's number one.

Number two is to clarify the criteria that we used in the Science Team to assess the likelihood of a causal association. So as Dr. Howard mentioned briefly, the Science Team identifies the evidence and evaluates the evidence, and they place it in one of the bands that describe the strength of that evidence or weight of that evidence of a causal association. These bands have always existed since the very first promulgation of the procedure but we felt, moving forward, that we needed more clarity in what each one meant. And so those were the aims of the revision, this, for this draft that we're sharing with you today.

Okay, so this slide is just showing the table of contents for the draft procedure. It's a long procedure; I apologize for that. It's 17 pages. And this table of contents is found in the first two pages. And essentially, I don't really want to go through line by line the procedure but essentially, you know, there are seven sections. Section I identifies the statutory authority. Section II talks about how the process is initiated. We know that we can go through this process either at the discretion of the Administrator or through the petition process. Section III is how the Science Team identifies the evidence for its evaluation. You'll see that all three of those sections, they are not bolded. That's because essentially there's no substantive changes to those three sections.

The first substantive changes show up in the blue bolded sections, specifically section IV, which is how the Science Team conducts its evaluation, starting on page 5, and in particular IV.B, which is how the Science Team evaluates the evidence and provides its advice to the Administrator. So those are the first substantive changes in

the procedure.

The very next section is Administrator actions. And as you would expect, because we did clarify the roles that the Scientific/Technical Advisory Committee plays in this process, those were substantive changes as well. So that's V.A and then of course, the Administrator can act independent of the Science Team evaluation. He can act on STAC recommendations. And you may recall that, you know, that's exactly what happened with the cancer decision with Method 4. We clarified Method 4 in the cancer P&P to basically make it clear that the Administrator can use the recommendations from the STAC provided that they also include a reasonable basis that is completely independent of the Science Team evaluation to move forward with a notice to propose a rule to add the condition.

So, the rest of this section, section VI and section VII, are really just administrative sections that talk about the inner workings of the STAC as well as peer review and rulemaking. Again, these two sections really haven't changed since the prior procedure.

So, I will draw your attention—again, I put page numbers here on this slide, but it gives you kind of an idea of where we are in the procedure, where we're really interested in input from the Committee.

Now, I talked about the Science Team evaluation and the likelihood bands. Again, I stress, these bands have always been there. But what we found was lacking was a better description of what they truly meant. And this became important because we've had such a growth of the literature from the World Trade Center Health Program Research Program that has made evaluation much more complex. And so, we've got considerable amounts of information that we needed to understand better what the bands really mean. And again, I'll just go through the bands.

The trigger for moving forward for a rule proposed change is substantially likely. So, the evidence supports that a causal association between the 9/11 exposures and the affected 9/11 population is substantially likely. And then it's graded, right. There's a continuum of probability here. So, it goes down a notch each time. So, the next level is high likelihood. The level before that is limited evidence of a causal association, and then we get into the realm where there's inadequate evidence of a causal association. We simply just don't have any information, right. That happens sometimes, especially for rare outcomes. And then finally, the last level is there's evidence against a causal association. So that sort of goes against the rule of thumb of science. We typically don't prove the negative. However, in this case, that would be the other end of the spectrum of the probability continuum. Okay.

So, moving on, all right. So, the Science Team evaluation itself, it provides support for the Administrator actions, and we're just advising the Administrator here. So, the very first action is: "The Administrator may request (…) second-level review by the Science Team when there is a finding of a high, but not substantial, likelihood of causal association." So again, this particular request and this second-level review has always been in place. And essentially it, you know, our—currently, the evidence that we are originally restricted to is evidence from, you know, descriptive or analytic epidemiological studies of 9/11-exposed populations, right. So that's kind—that in the procedure.

However, if we have evidence that suggests a high likelihood of a causal association and we're just missing some pieces, then the Administrator can, at his discretion, direct the Science Team to expand the lit. search to authoritative information that is published in the U.S. And the examples that are given are, you

know, the National Toxicology Program, from NTP; the toxicological profiles from ATSDR; and EPA risk assessment. So those are just three examples of an expansion that we could use to further our evaluation.

Section V, it specifically requests—the Administrator can request the recommendation of the STAC at any time, independent of whatever the Science Team evaluation finds. So that's always available. And that is supported also by a finding of high likelihood of a causal association. So, we want to be judicious on when we involve the STAC, and so the feeling is if we're close to substantially likely but not quite there yet, we may—the Administrator may choose to bring the STAC in for recommendations. That's the way the procedure is drafted now. He can, his other actions of course, he can publish a Notice of Proposed Rulemaking which is supported by a finding of substantially likely. He can publish a Notice of Not to Propose a Rule which is supported by a finding of no likelihood, and then he can publish a Notice of Insufficient Evidence which is supported by, again, the finding of either limited or inadequate evidence.

Okay, so I only have six slides. I thought I'd leave as much time as possible for comments and questions. So really, this is just reiterating the charge that Dr. Howard put forth in the very beginning of this meeting, but we're asking the STAC to evaluate the procedure and determine if it, if the revised language adequately clarifies the five evidentiary categories used for grading a causal association by the Science Team, and are the evaluation criteria of each evidentiary category clearly defined, reasonable, and appropriately linked to an action? And honestly, that's all I have so I think I'll turn on my camera—

DR. WARD: Great.

DR. DANIELS: Going to stop sharing.

DR. WARD: So, this is Liz. I'm going to jump in for a second, and maybe you could put the charge back up for just a minute.

DR. DANIELS: Oh, okay.

DR. WARD: Because I wanted to talk about it. So, you know, when I read this charge, you know, part of me initially thought, well, they're really asking for a yes or no answer. And I thought it would be really useful to clarify the role of STAC deliberations in this. So, you know, the STAC is here to advise the Administrator and basically, our role is to provide comments on this proposed rule, not to say yes or no to the questions asked in the charge. We have no authority to approve or disapprove these kinds of decisions or these kinds of policies made by the Administrator. But on the other hand, there's been a very long history, I think, with the STAC that, you know, when the STAC has provided comments to the Administrator on every ques—any question—I think they have been taken very seriously.

So, I think what the Program is asking us to do is to provide advice. We can raise substantive concerns even if we have no immediate solution to address them. We can make specific suggestions to the wording or the policy to the Administrator. And those would be made in the form of a letter. So, what we would do is we would have people—what I suggest we do, okay, if we can discuss, and we'll first of all open the floor for questions because it's really important that we clarify anything that's not clear. And then I think it would be really helpful to just have some open discussions and try to identify whether there are themes that are emerging among the members that we could sense are really consensus recommendations, and we can have motions to actually include them in our recommendation to the Administrator. I think where there's no consensus, I think what we've heard earlier in this meeting is there is an opportunity for

individual STAC members to make comments through Tania to the Administrator. So, if there are issues that are discussed that the STAC doesn't really reach consensus on, I mean we'll have a vote on the motions, then there's still the freedom for the STAC members and others to express those concerns.

So, I just wanted to get that on the—those, that framework on the table because, you know, when I first read this, I said, "Are we going to be asked to say yes or no to these questions?" and obviously that's not what is intended from the charge. And so, so anyway, my thought would be we open the floor to questions. We have a really open discussion, have everybody make their comments, and then we try to see if there are emerging themes that seems to be close—you know, that the STAC Committee can really achieve, likely to achieve consensus on through motion and voting.

And Tania and other members of the STAC, have I misspoken on any of these points?

DR. CARREÓN-VALENCIA: No, you haven't misspoken.

DR. WARD: Thank you. Okay. So, let's start off with—I guess we can go back to the camera now and start off with any questions that people have about the presentation or the written document. Okay, not seeing any hands so I guess we'll open the floor for discussion.

DR. MARKOWITZ: I'm sorry, I was a little slow, Liz. Can I ask a question?

DR. WARD: Of course.

DR. MARKOWITZ: Yes, sure. So, in the document that we were given, it talks about four outcomes under section IV.A, and it then describes under IV.B the four outcomes. And in one of those outcomes, it combines limited and inadequate, but the charge to us relates five outcomes, and I was just wondering, in the writeup, why you didn't—why you didn't divide it into five different outcomes just to make it clearer.

DR. DANIELS: Yes, that's a great question. It is somewhat confusing, and I apologize for that. So, there are five levels that we look at. However, the actions that are taken with respect to limited and inadequate, if we determine either one or those, are identical. So, in some ways, it's really four out—you know, four different actions that can be taken. So, although there are five described, limited and inadequate, there is no difference in what happens if we find either, either/or.

DR. MARKOWITZ: Okay. I have another question. When I was reading this, the two categories, sufficiently—excuse me—substantially likely versus high likelihood, I had to go back and forth to remember which one was more likely. And then I finally caught on that substantially likely meant there was better proof than high likelihood. I wonder whether you considered plainer language like "sufficient", sufficient evidence of causation, instead of substantially likely. It just, well, I'm not going to speak to the pros and cons, but I'm just wondering whether there was some thought given to that kind of language.

DR. DANIELS: Yes, that's a very good question. You know, what we set out to do is try to be consistent with the language since that's been the language used since the beginning of the policy and procedure. And it's really restricted, those levels of likelihood bands if you will, those really reside only with the Science Team. The language that is used by the Administrator is "sufficient." So, he does make a decision based on the input that he gets from us, the Science Team and others, as well as the STAC if you're called on. He makes a judgment whether the evidence is sufficient to propose a rule. So, we reserve that word for the Administrator actions but not for the Science Team.

DR. MARKOWITZ: Thank you.

DR. WARD: This is Liz just interjecting before I go to Debra. So, I guess one of

the big distinctions between the first two categories is that the first one, the substantial likelihood, is really based—it's based primarily on epidemiological studies of World Trade Center populations. So maybe it would help to clarify the distinction, to say that there is substantial evidence from studies conducted in World Trade Center-exposed populations, whereas highly likely is there, you know, there some evidence from exposed populations but additional—I don't know. That seemed to be one distinction that was being made very clearly, so maybe that, something along those lines, could help. Debra.

DR. MILEK: I have to agree with Steve. I had the same issue of distinguishing between the top two categories and even looked up the word "substantial" to see how it fit. Is it possible to also put the definition of what each category means so that the STAC can go back and forth and see if it meets that definitional criteria?

DR. DANIELS: Yes, I don't really know if I fully understand the question. I will say that, you know, the terminology is certainly up for discussion. And you know, if—and we'll take any comments that you have with respect to the terminology and maybe perhaps better words to be used. And as long as it's consistent with, you know, the statutory language—if there's statutory language involved in the specific terminology—then we would certainly entertain changes, especially if it's going to help make the procedure more clear. So, I think those are wonderful comments and we'll certainly take that back with us.

DR. MILEK: Most certainly in literature reviews there are different categories of strength of support for workers' compensation which gives a percentage probability. So, there are possible examples that we could contemplate to make it more transparent.

DR. DANIELS: Certainly. Thank you very much.

DR. WARD: So, are there any other comments along that theme because I

think that certainly was something that occurred to me when I read through it, so—and especially, does anyone have any suggestions for the Program for how that could be worded differently? I mean, when I look at the text of the document, I feel like the distinction is somewhat clear, but the actual descriptors of substantial and highly likely doesn't come across as clearly as the actual text. So why don't we try to stick on this topic and see if anyone has any other comments regarding it?

So, does everyone agree with the concept that I just put forward that, on—when you actually read the document and look at the description of what the substantial and very likely evidence… Is the description in the text, is that clear? Is it just the words, those two descriptors, unclear or is the actual difference unclear when you read the text as to how those two categories are defined? So…

DR. CARREÓN-VALENCIA: Joanna has a comment.

DR. WARD: Thank you. Joanna.

DR. GAITENS: Hi. So, I do think that the description of the text was clear but agree that the actual titles of each category I found a little bit confusing. And I know just one thing that I found myself doing is constantly flipping back and forth and trying to align them all to figure out what the differences were. And I wondered if presenting it even in just a table format may help make things a little bit clearer too so that you could do a quick crosswalk to see exactly where the differences were.

DR. DANIELS: So, this is Doug. Yes, I think the thought of putting it in a table maybe as an appendix of the procedure, again, I'm just—I think that's a wonderful idea, and I think we'll certainly talk amongst ourselves and maybe pursue some sort of revision like that. It wouldn't be very difficult to do, and it would help people walk through the procedure. So, I think that would be a helpful tool.

DR. WARD: Mariama. Mariama?

MS. JAMES: So, yes, thank you. So, I'll remind you that I'm a layperson, not a doctor, but my question is, after going through the document, is the Administrator's ability to engage the STAC like the absolute, only way to do it, or is there any kind of way for the STAC to meet without that being requested?

DR. DANIELS: Yes, that's a great question. What I'm going to do here for a policy response, I'd like to have Jessica respond to that one, if she could.

MS. BILICS: So yes, this is Jess. The STAC does not, is not—does not have the authority to meet without being charged by the Administrator.

MS. JAMES: Okay.

MS. BILICS: So, and the Administrator sets the agenda.

MS. JAMES: Okay. So, I don't know if I read this properly. There was another section that talked about the Administrator versus a scientific panel. The Administrator calling the STAC in versus having a scientific panel to make a review, and you know, both of those may be fine but again, being a layperson, one of my first thoughts was, you know, right now we have Dr. Howard, and he's been a wonderful Administrator, and we've, you know, managed to get (inaudible @ 00:44:06), which is fabulous. What if, for example, we had a different Administrator that was more like, you know, the Postmaster. When he got in, he made a mess. And would we be stuck? Like what is the mechanism, if any, for meeting and addressing issues if, I guess maybe the question is if there's like a rogue Administrator?

MS. BILICS: So, this is Jess again. If there is any changes to the policies and procedures going forward, the law does require us to go through the STAC. So, the law requires us—and this was a change that was made in the reauthorization in 2015—amendments were made to require that the two policies and procedures that were used for, that are used to add conditions, so we had one for cancer and

then this one that we're discussing for non-cancers, any substantive changes to those must go through the STAC for review and evaluation. So, if there is a different Administrator that changes, you know, that makes changes later, there is still going to be the legal requirement to go through the STAC.

MS. JAMES: Okay. I mean, I don't want to take over but, in that consideration, then what—under what circumstances would a scientific team be called in as opposed to the STAC? Under what conditions? Because there was something about a scientific team or the STAC in the document.

MS. BILICS: Oh, I think—okay, I think I get what you're talking about. Are you talking about—so the Administrator can do, there has two options to add conditions to the list. One is either through his or her own discretion; still requires rulemaking. And then there is the option to do through the petition process. In either case, the Administrator can go to the STAC and…

MS. JAMES: Okay.

MS. BILICS: And so, but it's up to the Administrator if he wants to go to the STAC. He does not have to go to the STAC when adding a condition. He does have to go to the STAC if making changes to the policies and procedures about how the Program makes decisions related to how it makes a determination to add a condition. But he does not have to go to the STAC for a recommendation like was done for cancer back in 2012 or uterine cancer most recently. He does not have to go to the STAC for recommendations about adding specific conditions.

MS. JAMES: Okay.

MS. BILICS: He can do that if he chooses to. Is that your question, Mariama?

MS. JAMES: Yes, I believe so. But so, it would also be at his discretion when to engage the Science Team, or is there something that triggers, "Oh, this is a case where I need to engage the Science Team as

opposed to the STAC?"

MS. BILICS: So, the Science Team is always engaged at the Administrator's discretion for, to do the scientific literature review. And if there is a valid petition, the Science Team is also always engaged in doing that scientific literature review. And the outcomes of that scientific literature review are the five options, or four larger categories, that Doug was just presenting.

MS. JAMES: Okay.

MS. BILICS: So, the Science Team is always engaged before making a decision whether or not to add a condition, and that happens at both the Administrator's discretion as well as when there is a valid petition.

MS. JAMES: Okay. Does the scope of the literature go beyond the World Trade Center Program or is it only research performed by the Program?

MS. BILICS: So, in the initial literature review, it is only in the 9/11 population. And one of the differences that is in between that substantial and the high likelihood is that if the outcome of that literature review, the evaluation of all the literature that is a result of that review, ends up in that high likelihood category, the Administrator has the choice to go beyond the 9/11 population, looking at other government bodies, and it lists those, and I'm sure I will get them wrong as I try to rely on doing that without referring to the document itself. But it has, you know, it looks at other government sources, and I mean, Doug, feel free to join me as I flip through pages (inaudible @ 00:48:42) they are but the three that—

DR. DANIELS: Yes, I listed them earlier—

MS. BILICS: Okay.

DR. DANIELS: But it's the National Toxicology Program, it's the ATSDR's toxicological profiles, and the EPA's risk assessments. So those are the three listed. Now, it says "such as" so it could be expanded beyond that, I believe, but those are the three paramount sources

of authoritative science bodies that we would expand our evaluation to.

MS. JAMES: Okay, because limiting the evaluation to the scope of World Trade Center research could potentially pose a concern for the survivor population because we are made up of, let's say, more women than the—you know, and children or people who were children at the time—who are not, you know, neither of those of a demographic which the research, the majority of the research by the World Trade Center Program has been done. It's been done on responders, who are primarily male, and, at this point, you know, middle-aged and older as opposed to millennials and/or females.

DR. DANIELS: Yes, that's a very good point and, in fact, that was one of the limitations that we saw in the evidence for uterine cancer…

MS. JAMES: Right.

DR. DANIELS: …was that clearly, we had limited research on that topic. So, the way the procedure is written is it understands that. It understands that there could be limitations in just that population, and that's why we have the option—we have two options, actually. One option is to expand the lit. search based on, you know, at the discretion of the Administrator, to look at other populations beyond those 9/11-exposed, and also to engage the STAC. And so we have, and the STAC—and the Administrator, if he engages the STAC and asks for recommendations, can act on those recommendations irrespective of the Science Team evaluation and the 9/11 available research. So, we have options built in that enable us to sort of counter these limitations that we have, especially when you talk about vulnerable populations like women and people who were exposed as youth.

MS. JAMES: That's fairly comforting. It would still potentially pose a concern, again, whereas there was a different Administrator, somebody

other than Dr. Howard, empathy, morality, whatever we want to give to it, because we do—I mean, we have knowledge that we have a history in this country of men making decisions as to what is best for women and our health without doing research on us. So, if there was an Administrator that decided they didn't need to review anything else, "I have enough information based on what I'm looking at," then they wouldn't go any further. And that's concerning. I apologize for taking up so much time. I'm sorry.

DR. WARD: That's okay. So, I did have a thought on maybe some wording that would help with the substantial versus very likely. At least for substantial, maybe you could say, "A causal association is strongly supported by epidemiologic studies in World Trade Center and other human populations." I mean, that seems to capture it. I think that's clearer than substantially likely but I'm happy to hear any comments on that from the other members of the STAC, or any other suggestions. I'm not going to make it a motion yet because I want to hear some discussion.

DR. MARKOWITZ: I'd like to follow up on your point but also what Ms. James raised.

DR. WARD: Okay.

DR. MARKOWITZ: Specifically, about the substantially likely, the highest level of proof, which it appears from the criteria that epidemiologic studies in both the survivor and the responder population have to demonstrate that there's risk, if I'm reading that correctly. Is that true? Because I have a comment to make on that. That, in other words, there have to be in place epidemiologic studies from both populations, survivor and responder, that demonstrate the health effect with, you know, sufficient magnitude and precision.

DR. DANIELS: Yeah, that's the way that the current—

DR. MARKOWITZ: Right. Page 7, yes.

DR. DANIELS: Yes.

DR. MARKOWITZ: Yes.

DR. DANIELS: That's the way the current category of substantially likely is described. It would—

DR. MARKOWITZ: Right.

DR. DANIELS: Multiple studies, multiple populations, and consistent, you know, risk estimate. So—

DR. MARKOWITZ: Yes.

DR. DANIELS: So, in our view, I mean, it was important that substantially likely was defining a fairly high level—high bar. But we understood that there are limitations in the research and so that's why we have the second, a little less than substantially likely, high likelihood, because it gives us the wiggle room, if you will, to look at outside of just the 9/11 population and look at other sources of information to make that determination based on the science if it reaches the threshold of substantially likely after you add the additional evidence. So that's kind of—and that's really been the thought process since day one of this procedure. What was missing, and you, practically, you can realize what has occurred is in the early years of the Program, we didn't have very much research. And so nearly everything, when it comes to doing an assessment, an evaluation, would fall in the limited or inadequate category. We simply didn't have the information. Well, that's no longer become—the research, the amount of research that has occurred since the Program is large. And so, we now need to be looking at, you know, the evidence may be on, teetering on that substantial and high area, which will require us to have a more complex evaluation and to consider other sources of information. So, we're entering that era, if you will, and those types of evaluations.

DR. MARKOWITZ: But if you had strong studies from one population or the other, that should be able to reach this highest level of proof even if the other population doesn't demonstrate that. For instance—

because the populations are significantly different by virtue of age, gender among the survivors versus the responders. So, if you had studies in one group that were, clearly demonstrated an effect that didn't occur in the other group, there's no reason that should be downgraded or not reach the substantially likely because you couldn't really adequately address that question in the other group, if I'm making myself clear.

DR. DANIELS: Yes, I think conceptually I agree that if we had a single study of responders, as an example, that showed a large effect size, that clearly indicated a causal association, that we'd be hard-pressed not to say that that's a causal association. And then we would look at, you know, the science behind generalizing those findings to the other population. Now that's conceptually. In practice though, that's not what we see in the research. We see far less compelling evidence across studies of a causal association. So, I would agree that in the instance that if we were to come across the study like you were describing, we would certainly—we would certainly inform the Administrator of that, and he would probably make decisions regarding on how to proceed in a positive fashion based on that.

DR. MARKOWITZ: Just one final brief response. So, you may need to relook at some of the language on page 7, the bulleted items, second to third bulleted items, because they very strongly suggest that you need to seek, consistent across populations, an effect before you call it substantially likely. So, I'll leave it at that. Thank you.

DR. WARD: And that might be something that the Committee can consider as a motion. You know, as the discussion progressed. Because I think that is, you know, it's clearly—I mean, to me it's clearly an issue if the health effect may not have been studied in survivors, or there may have been no studies that could adequately… I mean, I think more often you'll see the effects in responders rather than

survivors, but it could go either way. But in both cases, you know, we have many more female survivors and clearly if we have an effect that's demonstrated in a female survivor population, well, it probably wasn't studied in a responder population because that population includes so few women. So, it does seem to me, you know, aside from the language of the categories, that this is a—this might be a specific recommendation that the Committee would want to make a motion about and include in their recommendations.

So, Steve, you had a comment about my suggestion for the definition or?

DR. MARKOWITZ: I don't think so.

DR. WARD: Okay. Okay. Sophie.

DR. BALK: Just, you mentioned there's a lot more research now, that much more research goes into the first two categories as opposed to the limited and inadequate. Can you just explain how much research there is on the offspring of pregnant people or people who were children at the time of the disaster?

DR. DANIELS: Right. Well, I can give you some information. There certainly has been studies on both populations that you're referring to. We are in the midst of a scoping review for persons who were exposed as minors, and we have identified 195 publications that are, that deal with the 9/11 population who were exposed as minors. So, we hope to have those findings available soon, but there is considerable—more than I actually, to be honest with you, I expected not 195. So, we do have some growing literature on the topic.

DR. BALK: Just, it also leads me—that's great to hear—leads me to ask not about the first two categories but about what if there's limited or inadequate evidence but because of the vulnerability of the population, we're really worried. And does the Administrator

have a role in precautionary action? Like we, because we're so worried about it. That's a different question from what we were discussing about the first two categories but it's on my mind.

DR. WARD: Mariama?

MS. JAMES: Is it incorrect that the funding the entire program, World Trade Center Health Program, needed wasn't passed until recently, that is to include the creation of the cohort in the first place, the younger population and more women?

DR. WARD: What I'd like to do—I mean, you know, as we said previously, the function of the STAC is to provide comments to the Administrator on questions that he puts before the Committee. And I think it really is the primary focus of our meeting today, to take a very serious look at the proposed language for evaluating associations with non-cancer conditions. Because I think the Program is looking to finalize these recommendations and apply them to some conditions that have come to the Administrator's attention, either through petitions or in other ways. So I really would like to focus on that and then if there's a separate—I know there's a lot of interest and a lot of concerns about the scope of research especially related to *in utero* exposures and exposures to younger populations, but I think that really is a separate question and I don't want it to detract from the Committee's ability to really focus strongly on this proposal, because this is our opportunity to make suggestions that could improve it or point out flaws that could be addressed.

MS. JAMES: Yes. No, understood. I just thought that it kind of went to that question in determining, like, who are we even talking about in terms of what we're evaluating if the cohort hasn't been created yet? But I could be incorrect about that. That's where the question came from. It's my understanding that the funding to create the cohort didn't pass until this past November or

December, so it doesn't exist yet.

DR. WARD: Right. It's not as if the World Trade Center Health Program has not thought about the issue before, but I think where this is coming from—and possibly someone from the Program can give some examples—and there are epidemiologic studies that have been done. And there have been concerns about chronic conditions where there is some evidence from the survivor and responder population—mostly, of course, adults—and NIOSH is really seeking to finalize these guidelines so that they can rigorously apply them to the conditions that have been emerging among the population that was adult at the time of the exposure, which is the population that has primarily been studied, which I think we all recognize. So, Tania, would you like to comment on that, or anyone else?

DR. CARREÓN-VALENCIA: No, I don't have any additional comments on that.

DR. WARD: Anyone else from the Program? Okay. But I think that should be the focus of our discussion and then if we have time at the end, if the Committee wants to make some comments to Dr. Howard about the other issue, I think we can do that separately from our formal recommendations regarding these procedures and policies.

DR. CARREÓN-VALENCIA: Definitely. So, regarding what you said and what Mariama just said, yes, we just received the funding. So, the Program is giving it very thorough consideration, is looking into it, and certainly we'll involve all our pertinent stakeholders from the conception of the development of the cohort.

DR. WARD: Great. So far, I think we have two substantive issues that have come to the forefront: one being the language being a little bit confusing between substantially likely and highly likely, and the requirement under the substantial likelihood that the studies have been done in both responders and survivors. And I guess

that the results are positive in both. That's kind of implied. So, I think what we could do is propose something slightly different or—and this is just one of many recommendations—we could say that a strong association has been observed either in the responders or survivor population and available epidemiologic studies relevant to the exposures have also observed this association, which I think is—okay, so it's all 9/11 populations. So, I think what Steve was getting at was does it have to be in both? Does the Committee agree, or should we say either strong evidence for one or the other, recognizing that, you know, if it doesn't have strong evidence in both, that's not knocking it out of the park. It's just saying that it will go into the high likelihood category, which will require a more in-depth evaluation. I mean when I read the substantial likelihood standard, it struck me as a very high bar. And my suspicion is relatively few things will fall into that category and the majority of things that would be seriously considered would fall into the high likelihood category where you would have to look at supporting evidence of different kinds.

So, I guess the question is does the Committee see it as a serious problem that very few things will likely meet the definition of substantial likelihood, which I think we want to maybe change the name of? Or do you think it's reasonable to have that bar be set very high and that with the next category down, really involving—that's a more substantial evaluation, I'm not saying that it's not causally associated.

DR. DANIELS: Yes, this is Doug again. I just want to say that that's exactly what the intent of the language was. You captured it precisely.

DR. WARD: Steve, what do you think?

DR. MARKOWITZ: Well, on a practical basis it sounds like it really doesn't matter because if you find it on the responder side or on the survivor side

and not on the other side, it's still going to be taken seriously and you still need multiple epidemiologic studies to demonstrate the effect. So, the outcome for the World Trade Center Health Program participants is essentially the same. In that sense, I guess it seems like a very high bar to require it in both populations. I've got to wonder do we even have any instances except for maybe the obvious aerodigestive ones in which it really has been shown in both populations. But I don't want to get into a substantive discussion of that. So, I guess in that sense it really doesn't matter.

DR. WARD: Michael?

DR. LARRAÑAGA: Yes, thank you Liz. And thank you, Steve, you clarified something for me in my mind. I do think it's a very high bar and I agree that very few conditions would meet that bar. But if there's practically no impact on actually the people that are affected, then I'm not sure exactly why we need to have a different category, if that makes sense.

DR. WARD: So, Doug, did you want to respond to that?

DR. DANIELS: Yes, I think that an argument could be made that we don't need that precise of a definition. We don't need five bins; we need four bins. You can make that argument. However, I will remind everyone that we've always had these five likelihood bins and today, substantially likely for causal association has always been there and we've never reached that threshold. Now, we have added conditions to the list, and we have done so, most recently uterine cancer, not because we have evidence that said it was substantially likely to be causal, but because we had a reasonable basis for doing so as presented by the STAC.

So, there are other options. It is not inconceivable that we may have definitive literature of a causal association down the road. I can't say for sure that won't happen in the future, although I will say it is a high bar. As well, any time you're making causal

inference, it's always a high bar. And so, again, if there wasn't another avenue—like if we didn't have the caveat of highly likely and involvement of an expanded lit search, as well as evaluation criteria, and the opportunity to involve the STAC and their evaluation—then I would say it's a problem. But given that we have those things, I think we still have opportunity here to be judicial but yet appropriate in determining conditions to add to the list. Now, you're right, those things that are already on the list, I would argue that there is literature on some of those things in both populations.

And I think another thing that people are forgetting is, you're right, there are difficulties with survivor membership and doing research the way that they're actually certified as a member. But the vast majority of survivor research comes out of the Registry. And the Registry does a lot of research. And so, there are opportunities for looking at various outcomes, either by the Registry or other researchers extramurally using the population that is enumerated in the Registry. So, there are research capabilities of looking at survivors.

DR. WARD: Yes, so this is Liz. I think one rationale for keeping it the way it is is that in the event that there is a situation where new, strong evidence emerges in survivors, let's say there's already evidence in some studies in responders and then new evidence comes about in survivors or vice versa, that this would fast-track that condition for possible certification. So, it is a high bar, but it also would lead to a fast-tracking of a condition where new evidence emerges that makes it incredibly clear because it's a less complex—the second category is going to be a little bit more time consuming because it's a more complex process. Mariama?

MS. JAMES: I don't want to belabor the point if you're wanting to go on to something else, but the Registry does not include a majority of

the young people. Many of them were left out of the Registry. I don't know if you're aware of that or didn't have an opportunity to apply. And there's a limited number of young people that are being looked at in that population. And there's also been a lot of difficulty in tracking these young people down since they've grown up and moved freely about the cabin in their adult age. So, I don't know how reliable or how sufficient that research is at this point.

DR. WARD: I think we all agree that there is not a large body of evidence on that, but again, this policy isn't intended to focus on the major research gaps. There are other developments in process that are going to do that. But I think we do need to focus on the conditions that have been researched. And, Michael, your hand is up. Did you want to respond or make another comment?

DR. LARRAÑAGA: Yes, I did. Thank you, Liz. Back to my original comment, I'm not a physician or an epidemiologist but, to me, it seems that if you had evidence for causation in one group that that would also be evidence of causation in another group with regards to substantial likelihood. That's to me. I'm just making a suggestion that, to me, that looks...

DR. WARD: I think that's almost to the point of being a clear enough issue that we could formulate a motion and vote on it. It would be interesting to me to see like a sense of the different Committee members whether they basically support leaving the language as it is, recognizing that it's a high bar but, if it is met, it could expedite moving forward quickly or suggesting that if there's strong evidence in one population, either responders or survivors—does the group have a specific recommendation that we're able to agree on this, or not? Are people in favor of keeping it as it is, or making a specific recommendation to change it?

DR. MARKOWITZ: I haven't heard any strong rationale to change it, personally.

DR. WARD: Anyone else? Okay, so procedurally I guess, Michael, if you feel strongly about it and want to make it a motion, we can vote on it. But I haven't heard a lot of consensus on the point. I think we all recognize the concern but because there is a second track that those cases would fall into, it's not like they're being dismissed, it's just that they're not going to meet this very specific high bar.

DR. LARRAÑAGA: Yes, I have to defer to those who have more knowledge than me in that area, and that would be physicians and epidemiologists. But it does seem a little unusual to me. But I'm going to defer to the people who know more about it than I do.

DR. WARD: Great, thank you. So, are there any other issues that the Committee would like to discuss regarding the draft policy and procedures?

DR. MARKOWITZ: Well, I have another issue, but I want to wait for other people because I've been doing a lot of talking.

DR. WARD: Okay.

DR. CARREÓN-VALENCIA: So, Liz, this is about the time where we are starting the public comment period. Now, I understand that there have been some technical issues and it looked like we only have five of the six people commenting. But if it's okay with you, we could listen to their comments and then address the one person that hasn't been able to join after the break and then you can continue your deliberations taking also into account their comments.

DR. WARD: Thank you, Tania. I had lost track of the time, so I appreciate you reminding me.

PUBLIC COMMENTS

DR. CARREÓN-VALENCIA: So, we are going to start, then, the public comment period and, as mentioned earlier, we have six people that have requested to provide public comment. Sorry, let me put my camera on. So,

when I announce your name, please unmute yourself and turn your camera on.

MS. WALLACE: Tania, give me one second to put the time up please.

DR. CARREÓN-VALENCIA: Oh, yes. So, Mia is going to put a timer on and just please stick to the five minutes that you are allowed. You have all received that copy of the redaction policy for public comments and this policy states that we will post transcripts of these meetings and your name will be included in the transcript. Also, if in making a statement you reveal personal information such as medical information, that information will not usually be redacted. So, when you tell me you are ready, Mia, we will call our first commenter.

MS. WALLACE: We are ready.

DR. CARREÓN-VALENCIA: Okay, so our first commenter is Piera Greathouse-Cox.

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

DR. CARREÓN-VALENCIA: We can hear. I can't see you, but we can certainly hear you well.

MS. WALLACE: Wait one second, please, one second because it's freezing, I don't know why. Okay, you can get started, I'm sorry.

MS. GREATHOUSE-COX: Okay. Hi, everyone. Thank you so much for providing me with the opportunity to share my thoughts today. My name is Piera Greathouse-Cox. I'm a member of the World Trade Center Health Program and I sit on the Survivors Steering Committee. Just a little bit of personal history and background: I was 16 at the time of the September 11th attacks and living in an apartment building two blocks from Ground Zero where I remained throughout the first year of the cleanup effort.

In 2019, I was diagnosed with adrenal cancer. When I was approved for enrollment in the World Trade Center Health Program, I felt extremely relieved and grateful to have access to the care offered by the Nationwide Provider Network. But my diagnosis raises larger questions for 9/11-affected young adults

who need and deserve answers in the form of research.

I'm here today to advocate for more studies on the health impacts of exposure to 9/11-related toxins on the tens of thousands of children who lived or attended school in the New York City disaster area. The good news is that in December of 2022, the Senate passed Amendment 6607 which authorizes the creation of a new cohort comprising exactly that population, a population currently understudied by the World Trade Center Health Program, which is focused almost exclusively on mental health impacts. We need more information about cancers emerging in this population. We need more information about non-cancer conditions emerging in this population. And we can meet these needs through more equitable inclusion in studies that satisfy the World Trade Center Health Program's evidentiary requirements for demonstrating causal association between health conditions and 9/11 exposure.

Tracking this cohort over time would almost certainly produce actionable data on subjects who have long gone under-researched. It would also empower survivors to advocate for access to care using studies that meet the World Trade Center Health Program's rigorous standards for admissibility. The bodies the science has been attending to—primarily male, primarily middle-age—are only some of the bodies that were present on 9/11 and during the many months of cleanup. In attending to the physiological impacts on people who are under 18, half of whom are female, would create a significant opportunity for improved outcomes among long-neglected survivor groups like women. In maximizing our ability to identify long-term trends among diverse populations, we can ensure that research keeps pace with the emergence of 9/11-related non-cancers.

But good longitudinal data doesn't just benefit people like me. As

the World Trade Center Health Program adds new conditions and develops more robust medical screening, it will better provide potentially life-saving interventions for all responders and survivors whose health was harmed by the World Trade Center disaster.

As a starting point, the Survivors Steering Committee is calling for the Administrator to request that the STAC hold a meeting to discuss the Program's ideas and plans for the creation of the new WTC cohort before any plans are implemented. As someone with a rare cancer, I'm fortunate to have my medical expenses covered. There are people who need and deserve access to the same excellent World Trade Center Health Program resources that I have, people who may be facing insurmountable medical debt because their conditions cannot be certified, that this is the case for people with autoimmune disorders and other conditions that are increasing in frequency among responders and survivors may be a reflection of inadequate research, research which we now have the authorization to pursue.

My thanks to the STAC for all your work and to everyone present for allowing me to share my thoughts today. I will end here, thank you so much.

DR. CARREÓN-VALENCIA: Thank you very much. So, our next presenter is Ben Chevat. Are you here, Ben? I know you had technical issues. So, we can come back to Ben. I see two people that have joined by phone.

MR. CHEVAT: Hello, can you hear me?

DR. CARREÓN-VALENCIA: Oh, yes, we could hear you.

MR. CHEVAT: A miracle.

DR. CARREÓN-VALENCIA: Yes. So, you have five minutes then.

MR. CHEVAT: Okay, thank you. My name is Benjamin Chevat. I'm the Executive Director of 9/11 Health Watch, a 501(c)(3) not-for-profit created by the New York State AFL-CIO and its affiliated unions. Our

organization is dedicated to making sure the goal of providing quality medical care and compensation for injured and ill 9/11 responders and survivors embodied in the James Zadroga 9/11 Health and Compensation Act of 2010 and its reauthorization in 2015 and 2019 is met. Thank you for this opportunity to give public comment on the World Trade Center Health Program's proposed revised policy and procedures for adding non-cancer health conditions to the list of World Trade Center-related health conditions.

9/11 Health Watch agrees with the Director that given the increased research and more information that is available, there is a need to bring the non-cancer policies in line with the cancer policies. And it appears that these proposed changes would go a long way to achieve that goal, obviously pending the discussion and the issues raised today by the members of the STAC.

On the issue of the Program's research activities, with Congress's recent action as part of last year's Omnibus Spending Bill that authorized the creation of a new, badly needed research cohort to better understand the impact of the toxins in the attacks on impacted populations, especially those that were children at the time, we would take this opportunity to urge the Administrator to have the Scientific/Technical Advisory Committee at some point review and discuss the Program's plans before they are implemented. This new research cohort that Senators Gillibrand and Schumer managed to get Congress to authorize, along with badly needed additional funding for the World Trade Center Health Program will really help fill a huge gap in the Program's research capabilities and will get us a better knowledge and insight into the impact of World Trade Center toxins that we currently don't have. This new cohort will allow for the expansion of what is available from current cohorts to provide appropriate

power and sampling for future studies that may require large cohorts, as well as potential for replication studies. These areas of investigation would include those of non-cancer issues such as reproductive health and cognitive behavioral issues, as well as cancers. We look forward to the Program developing the new study too as soon as possible, but we need to make sure that this new cohort is designed to allow that this vital research can be done.

Thank you. And, Mia, I can email you the text of what I said so the transcribers have an easier task.

MS. WALLACE: Thank you.

DR. CARREÓN-VALENCIA: Thank you. Our next commenter is Lila Nordstrom.

MS. NORDSTROM: Hi, let me know when I can start...

DR. CARREÓN-VALENCIA: You can start now.

MS. NORDSTROM: Great. So, I'm Lila Nordstrom. I'm a survivor and a World Trade Center Health Program member. I'm a former member of this Committee, I'm a member of the Survivors Steering Committee, and I am the Founder of StuyHealth which assists and advocates for young adults in the survivor community. And I've been present for a large number of conversations about the conditions that are missing from the World Trade Center Health Program list, and I've noted that a frequent reason petitions get denied is insufficient data. So, as we discuss the best way to add non-cancer conditions, I think we need to remain mindful of what we came up against in the uterine cancer conversation where previous medical biases meant there was not much preexisting, high-quality data on the condition, that health programs research cohorts didn't include enough women to get good data on the condition either.

And so, while via common sense we could all see that it was unlikely that uterine cancer would be the only cancer not affected by World Trade Center exposures, women with uterine cancer

had to wait a full decade longer for access to care than other World Trade Center cancer victims. And this is, at the end of the day, a program that's meant to provide care for people who are sick in the present. So, as we consider the process by which we're going to add new conditions, we should remember that requiring high-quality data cannot be an excuse for ignoring institutional biases either in the Program's data or just in the medical community more broadly. And I think it's really critical that we think about a clear process for adding conditions that have not been researched and are prevalent in populations like my cohort. We have, for example, lots of reports from StuyHealth members, complaints of non-cancer reproductive health problems.

And you're not going to find these complaints in the Program's data because a lot of these complaints are from people who don't actually qualify for the Program because, remember, there's no proactive monitoring for survivors that don't have a qualifying condition. And of course, young people aren't well represented in the Registry either so these are complaints from people that are fairly absent from all of the major research cohorts that even those that include survivors. And we find the same with autoimmune disorders; they're very common among my former classmates and among other young people who are in school in Lower Manhattan. They're much more common in women. So we can assume that there are going to be other conditions like these that are more common or only present in younger subsets of the population or women.

And as I frequently remind the members of this Committee, or did when I was on it, though your mission here is to discuss the scientific rationale for adding new conditions to the Health Program's list, real people are sick with 9/11-related conditions right now so there has to be a timely and appropriate way to

support their needs that isn't solely reliant on a 20-year research plan that never actually gets underway. But we also need to do our part to address the research gaps in the 9/11 community. And we know that the Program's research has to date been primarily focused on first responders. It's really critical that we establish a new research cohort of people exposed as children. And this time is different because that creation of that cohort was authorized by Congress in 2022.

So StuyHealth supports the SSC's call for the Administrator to request that STAC hold a meeting to discuss the Program's plans for the creation of this new World Trade Center cohort. There has to be ample for stakeholders, including survivors like myself who were exposed as children, to play a meaningful role in shaping any plans for building this cohort prior to its implementation. We've been waiting for decades as we continue to get sick for this youth cohort to be a reality and STAC is really the right forum for this kind of dialog between experts and stakeholders in the Program, so we should do everything we can to ensure that we have the space and expertise to establish this new cohort in a way that's effective and inclusive. And I'm also hoping that the survivor representatives missing from this meeting—because there are quite a few—get an opportunity to relay their thoughts once the CDC HR paperwork issue that was identified last night gets resolved, because there are some missing perspectives just on the Committee right now and that includes the perspectives of the younger survivors that are members of this Committee. Thank you so much.

DR. CARREÓN-VALENCIA: Thank you. Our next commenter is Kimberly Flynn.

MS. FLYNN: Hi, I'm Kimberly Flynn and I speak on behalf on the World Trade Center Health Program Survivors Steering Committee, which I chair. I will focus on some lessons learned from the uterine cancer

deliberation as a way of reflecting on the policy document before us. Adding a new condition depends on the weight of the research evidence that supports a link between exposures to 9/11 agents and that condition. Under the policy, however, adding a new condition depends on the weight of the research evidence "available to the Science Team and that team's interpretation of that evidence." And I think that was the thing that sort of jumped out at some of us when we were actually going through this document. Science Team plays a more critical role than any of us had realized before.

Moving along, because we are unlikely to see overwhelming evidence in epidemiological studies of the 9/11 population any time soon, I will move past the substantial likelihood category to the high likelihood category, the only other category under which there is potential for a condition to be added. It is the Science Team that reports back to the Administrator on the weight of the available research evidence for adding that condition. And that would appear to be the evidence the Administrator weighs in deciding whether to add the condition outright or to engage the STAC or find no action, is that an option.

What we saw in the case of uterine cancer white paper was three limitations or biases regarding the available evidence. Number one, overreliance on epidemiological studies of 9/11-exposed population. So, you know, epidemiological evidence is going to come too late for many survivors and responders who will struggle on their own to get and afford their medical care from doctors outside the Program. Also, the addition of uterine cancer was based on mechanistic studies of endocrine-disrupting chemicals, not epi studies. The scientific rationale provided by the medical directors of the Centers of Excellence was decisive based on the role of endocrine-disrupting chemicals in causing uterine

cancer without this extraordinary effort. My question is: would a uterine cancer petition have succeeded?

Number two, the overreliance on government studies and databases, some of which are outdated, and I'll quote one of the peer reviewers—no, this is from the final rule, it's characterizing the reviewer's comments. The reviewer found the assertion in the 2021 white paper that none of the 9/11 agents identified as EDCs have been found by National Toxicology Program, IARC or the EPA to be known to cause or reasonably anticipated to cause uterine cancer to be misleading because, one, the exposure studied by these organizations may not be comparable to the extents of exposures experienced by responders and survivors—that's the synergy point this Committee is very familiar with—and, two, the reviews conducted by NPP, IARC and EPA are often outdated. Going forward, the Science Team should not rely solely on government studies but should conduct and expand its search of the National Library of Medicine for relevant studies. Maybe appropriate subject matter experts can work with Science Team to ensure a more complete evaluation of the evidence. The 9/11 community deserves a consideration of state-of-the-art research both within and beyond the WTCHP portfolio.

Number three, overreliance on occupational cohorts, including 9/11 responder cohorts, that are overwhelmingly male. Back to the uterine cancer final rule, Reviewer C indicated that, "Women's health and women's health-related cancers have been underexamined and grossly understudied." Mariama James has made this point many times on the Committee. 9/11-affected women and people exposed as children remain grossly understudied. Physical health impacts to children, the most vulnerable to harm from environmental toxins constitute the largest WTC knowledge gap and the most persistent one. The SSC

has long pushed for the WTCHP to create a representative cohort, people exposed as children. Because this cohort would be 50 percent female and followed longitudinally, it would track the emergence of 9/11-related women's health problems, as well as conditions that are not unique to women.

Now that this new cohort has been authorized by Congress, the SSC is asking the Administrator to convene the STAC for a public meeting to discuss the Program's ideas and plans for creation of the new WTC cohort. Subject matter experts should be engaged as presenters and those include Dr. Joan Reibman, Survivor Program Medical Director. In addition, survivor stakeholders, including survivors exposed to the disaster as children, must play a major and meaningful role in shaping cohort-related plans prior to any implementation.

In order to succeed, this effort will need robust, ongoing survivor engagement. The 9/11 community has always really benefitted from the public dialog between experts and stakeholders that happens at STAC meetings, and we are confident that we will do so again. Thank you.

DR. CARREÓN-VALENCIA: Thank you. The next comment is from Rhonda Villamia. And I know she was having technical difficulty joining. Are you in, Rhonda?

MS. WALLACE: She's on the phone so she may need to unmute herself.

DR. CARREÓN-VALENCIA: Okay, just ask her to unmute. I don’t know. Well, let's go to the next person and then we can go back to Rhonda. Let's see, so we have Nancy Keegan, right? I don’t see her. She was here.

MS. WALLACE: She was here.

DR. CARREÓN-VALENCIA: Oh, here she is. Nancy, can you start your comment? Nancy? Or Rhonda. I don’t see Rhonda anymore. Oh, here, somebody is in the waiting room. Rhonda, did you join?

MS. VILLAMIA: Hello, can you hear me?

DR. CARREÓN-VALENCIA: Yes. Are you Rhonda?

MS. VILLAMIA: Yes.

DR. CARREÓN-VALENCIA: Yes. Okay, please go ahead. You have five minutes, okay?

MS. VILLAMIA: Thank you so much. I'm Rhonda Villamia. I was a disease relief volunteer. Thank you, STAC members, for lending us your listening ear. Today I voice the main points from my written statement. I understand that extending the timeframe from 90 to 180 days for determining whether a condition is certifiable would give NIOSH more time to research peer-reviewed studies among the 9/11-exposed population. My concern is that few studies will be found. In my written statement, I elaborate in great detail the battle I waged early on when our coverage was via other grant-based programs before the World Trade Center Health Program was implemented. During our regular treatment visits and annual monitoring, we were not given opportunity to share new symptoms or diagnoses given us since our previous visits. When I would bring these to their attention I was flatly told, "This is not WTC-related," and they would not be included in my office visit or monitoring notes. We were instructed to discuss these with our PCP.

In 2009, after attending numerous 9/11 health-related activities and traveling to Washington D.C. with busloads of responders and survivors in support of Congress passing the Zadroga Act, I was hearing the exact same complaints from the majority of the participants. I realized at that point that mine was not an isolated case. Although since 2003, I've been voicing my concerns about this to my clinic social worker, I was unaware of how widespread it was. But in 2009, I began to understand it was happening in other World Trade Center clinics. So, I advocated for better tracking to determine whether significant clusters of emerging symptoms and conditions could possibly be linked to the World

Trade Center. Especially disconcerting was that women's health issues weren't even on the radar, yet while on these EC trips and subsequently when posting online requests for our ladies to contact me if they were experiencing any female reproductive issues, I received an overwhelming response.

Though not included in my written comment, I would today ask that research be done on our disaster relief cohort who are predominantly women that came from throughout the U.S. and Canada in two- to three-week rotations, many of whom may not be enrolled in the World Trade Center Health Program. This would also include familial pairs such as siblings and parents and children who volunteered together.

So, my point in all this is significant raw data has been lost due to earlier World Trade Center programs neglecting to include references to our every symptom and/or diagnosed conditions in our medical records. Aside from women's issues, I've heard repeated mention of skin rashes, autoimmune disorders, and connective tissue abnormalities, among others. I myself had had urticaria eruption since 2009 and initially eight occurrences between 2009 and 2016, then 45 occurrences between 2019 and 2020; each of these manifested while under periods of extreme stress. Though my dermatologist linked it to my World Trade Center-certified PTSD, I tried in 2016 and 2021 to get this certified as a secondary condition, but NIOSH did not certify it.

I would ask NIOSH to consider certifying this skin condition as related to stress and depression, mental health conditions that are previous in our 9/11 community. I would also request consideration to be given to autoimmune disorders such as fibromyalgia, rheumatoid arthritis, chronic fatigue symptom, Hashimoto's thyroiditis, vitiligo, etc. Additionally, cardiovascular disorders have increased within our community and research

should be done on this. Many of us have had very beneficial results from holistic protocols and I would request NIOSH consider expanding these to be in parity with the VA's Whole Health Program. This would promote wellness while being cost effective in preventing secondary conditions developing from pharmaceutical side effects, which would require the World Trade Center Health Program to cover that secondary condition. Lastly, I'll end my comment by stating that our current coverage hasn't been satisfactory and possibly outright negligent. Among other things that I mentioned in my written comment, treatment has been interrupted due to former LHI providers not being in-network with (current @ 01:45:33) health services and in some cases, this has literally been life-threatening. Something has to change. I appreciate your consideration of all that I've said. Thank you.

DR. CARREÓN-VALENCIA: Thank you, Rhonda. And I see Nancy, are you able to speak? It looks choppy. Nancy? Yes, please go ahead with your comment.

MS. KEEGAN: My name's Nancy and I live on Washington Street just south of where the World Trade Center once stood. When I was (eight @ 01:46:42) years old, my Catholic grade school took us on a fieldtrip to New York City to see the World Trade Center just jut up out of the earth like Oz and I would literally be in their shadow. Do you need me to stop?

DR. CARREÓN-VALENCIA: Nancy, you are breaking up. Maybe it would help if you turned your camera off. Liz, it looks like Nancy's having some technical difficulties, so I was wondering if maybe we could break for recess and try to address Nancy's issues and come back with her comments and then the STAC continue their deliberations.

DR. WARD: That sounds like a great plan because we're actually past time to break anyway, so good.

DR. CARREÓN-VALENCIA: Okay, so we'll see everybody back at 3. And, Nancy, please stay on

the line, we will try to resolve your issues.

[Break.]

DR. CARREÓN-VALENCIA: And also, welcome back again to those that are following the webcast. I'm going to make another—last one—roll call of the members to make sure that we have a quorum, starting with our Chair, Liz Ward?
DR. WARD: I'm here.
DR. CARREÓN-VALENCIA: Okay. Sophie Balk?
DR. BALK: I'm here.
DR. CARREÓN-VALENCIA: John Comiskey?
DR. COMISKEY: I'm here.
DR. CARREÓN-VALENCIA: Chandra is not here. Joanna Gaitens?
DR. GAITENS: I'm here.
DR. CARREÓN-VALENCIA: Mridu is not here. Mariama?
MS. JAMES: Present.
DR. CARREÓN-VALENCIA: Anita Jose is not here. Indrina is not here. Michael Larrañaga?
DR. LARRAÑAGA: I'm here.
DR. CARREÓN-VALENCIA: Steven Markowitz? I can see you. John Meyer?
DR. MEYER: Here.
DR. CARREÓN-VALENCIA: Debra Milek?
DR. MILEK: Here.
DR. CARREÓN-VALENCIA: Larry is not here. Jason Ostrowe?
DR. OSTROWE: Here.
DR. CARREÓN-VALENCIA: Okay, Aarti is not here and Glenn is not here. So we still have ten people and we have a quorum. And I see that Nancy joined by phone—or somebody joined by phone—is that you, Nancy, Nancy Keegan?
MS. WALLACE: It looks like you're muted, Nancy.
DR. CARREÓN-VALENCIA: It looks like Nancy is still having some technical difficulties. We

have provided access information via email, text, and also other people that are commenting that invited her to join so that hopefully anybody can assist her. So, in the interest of time, Liz, do you want to continue your deliberations and then we can hear Nancy when she's available to speak?

DR. WARD: I think that makes sense.

DR. CARREÓN-VALENCIA: Okay.

STAC DELIBERATIONS AND RECOMMENDATION

DR. WARD: So, I appreciate the public comments and I wanted to just briefly review if any issues were brought up by the commenters pertinent to the document that we had discussed. And one of them that I picked up on, which I don't think Doug talked about in his presentation, is the rationale for the change from 90 to 180 days, if that's correct. I don't even recall reading it in the document, but I probably missed it.

MS. BILICS: This is Jess with the Program. There is no change in timeframes in the P&P. I think that person was confused with something else.

DR. WARD: Okay.

MS. BILICS: There is (inaudible @ 00:03:29) timeframes in the proposed P&P.

DR. WARD: Okay. Okay, great. So are there any—so, you know, I think we've kind of—I mean, this is really our opportunity to give Dr. Howard and the Program substantive feedback on the documents that we're discussing. So, are there any issues that people have that we haven't already discussed?

DR. MARKOWITZ: This is Steve Markowitz. Can I chime in, Liz?

DR. WARD: Of course, yes, that's what I'm hoping for.

DR. MARKOWITZ: I want to pick up on something that Ms. Flynn said in the public comments and also, it was actually something I wanted to raise before this public comment section, which is when you look at the

high likelihood group and what kind of information the Science Team looks at, we learn that they look at the 9/11 studies and they can look beyond the 9/11 literature. And the way it's written right now, it looks like they review—I'm actually reading here—"additional peer-reviewed scientific information," but which is obtained from authoritative scientific sources published by the U.S. Government. So, the way it's written now—and I don't know if this is the intention—is that they're restricted to looking at U.S. Government sources. And they mention ATSDR and EPA and National Toxicology Program, which, fine. I would hope that they look beyond that, the peer-reviewed literature beyond just the authoritative U.S. sources. It's unclear from the document. And so, I don't know whether we need to make a recommendation about this, but they should look at the peer-reviewed literature that is relevant initial the non-9/11 populations certainly beyond just the U.S. authoritative sources.

But there's a second point I think which true more generally, which is I think they need to look at the broader scientific literature to try to figure it out. Again, this is for the high likelihood—and I would extend it to the limited likelihood—of groups. They need to look at non-epidemiologic studies and a broad range of studies to try to figure out whether there's likely to be causality.

And I mention that for a couple of reasons. One is, if you actually look at—Travis Kubale this morning briefly presented the research portfolio and increasingly in the World Trade Center portfolio what they support is non-epidemiologic studies. They're looking at imaging for cognitive decline. They're looking at various genotypes, biomarkers. And this is World Trade Center research that is supported by the World Trade Center program. To the extent that it's relevant for the issues of causation, it should be

brought into the discussion. That's in part why that research is supported. And that's increasingly true.

The second point is that—and one of the presenters made it this morning—the World Trade Center Program is entering, in my view, a more complicated phase because of the aging of the population and the overlap with chronic conditions that the population is otherwise at risk of. And I'm not trying to ignore the young people; it's just a different question. And so, the issues of causation for non-cancer are going to get increasingly complicated and I think that what the Science Team looks at should be a broader literature about these chronic conditions that could be brought to bear the decision-making regarding 9/11.

So, for those two reasons—both the World Trade Center supported research, the nature of the conditions that are likely to be brought in the future—I think the Committee should support a motion that would encourage a broader look at scientific literature which would include clinical, mechanistic, biomedical, and mental health literature that's relevant to the issue of 9/11-associated exposures. Thank you.

DR. WARD: That sounded very close to a motion, so I was wondering if Geoff could type it for us. We haven't had discussion on the point, but I think it's worth preserving those words because I will say that, in the past, the STAC has made this recommendation and we've discussed these policies and procedures. And so there may very well be substantial support for it in the Committee. So, Steve, would you like to make a motion?

DR. MARKOWITZ: Sure. I would move that in these policy and procedures, in consideration of cases in which there is either a high likelihood or a limited likelihood of causation by 9/11 exposures, that the Science Team and the evaluation process in general considers studies beyond epidemiologic studies to include a range of peer-

reviewed literature involving clinical, mechanistic, biomedical, and other mental health studies that are relevant to the issue of 9/11-associated exposures. Something like that.

DR. WARD: Great. So, I would like to hear some discussion around that point because I do think, as I said, it's an important point and a comment that we have made before in discussing this document. Does anyone want to speak in favor or opposed?

DR. LARRAÑAGA: I'm in agreement. This is Mike.

DR. GAITENS: I would agree as well.

DR. COMISKEY: This is John. I'm strongly in agreement.

DR. CARREÓN-VALENCIA: If I can provide a point of clarification.

DR. WARD: Of course.

DR. CARREÓN-VALENCIA: I want to remind the Committee that we have 90 days from receiving the valid petition to the publication of the Register Notice and the review of the evidence and conducting the literature reviews or summarizing of evidence on 9/11 populations. And so, adding all of this additional literature, it might prove difficult for the Science Team within the time constraints that we have. Not that you can't recommend those to—or get the Administrator to do that.

DR. WARD: Yes. And I know there are different members now, but we have discussed that before and the only way I think we could recognize that point is to say "to the extent feasible" in our recommendation so that it opens the door to doing that. It's less restrictive, but it's not saying you have to or exactly how you would do it, but it opens the door—and again, a lot of this is an iterative process. And as you read the literature, you get a sense of what's there and what's not there. So that would be one potential friendly amendment, just to add "to the extent feasible."

DR. MARKOWITZ: Yes, I agree with that friendly amendment.

DR. WARD: So, Geoff, I think you were going to type these and show them on

	the screen?
DR. CALVERT:	Yes, I've typed it out so let me see if I can share my screen.
DR. MARKOWITZ:	And while you're doing that, let me just ask, does the STAC need to write some sort of rationale for our recommendations?
DR. CARREÓN-VALENCIA:	Emily, do we need the rationale? I think we do, right?
MS. HOWELL:	I'm not sure if you can hear me well. You need a second for Dr. Markowitz's motion so that it can be debated. And then for the rationale, you do not have to provide one generally. Often, when we're looking at petitions, we ask you to do that, but certainly a rationale is very helpful to the Administrator in considering your recommendations at any point.
DR. CARREÓN-VALENCIA:	Thank you, Emily.
DR. WARD:	So, we need a second. Would someone please second? I guess I can second as Chair, right? Okay, so I second. And then there was the friendly amendment "to the extent feasible," which would go after I guess right before the end of the first sentence. And I guess in terms of the rationale there are several reasons. One is that the universe of government documents regarding toxic exposures is somewhat—I guess you could say it is substantial, but it's not comprehensive; that not all types of exposures have been addressed by these government agencies and some of the documents are outdated. And the goal of the review is to get to include the best scientific evidence there is and that often cannot be fully accomplished by just including the government documents, although that is definitely a time-saving way to go about it. So, what else can we say in the rationale?
DR. CARREÓN-VALENCIA:	I also want to remind the Committee that when we put together the whitepaper and we look at the evidence—for example, from IARC and NTP—we look beyond their evaluation and anything that was published after the evaluations were completed. So, we try to update the existing evaluation.

DR. WARD: So, in fact that's something you could do, or you already do, but it doesn't seem clear from the way the policy and procedures for the non-cancer conditions is written.

DR. CARREÓN-VALENCIA: We did it for uterine cancer.

DR. MARKOWITZ: Let me ask you a point of clarification. In terms of writing up the rationale, I'm not sure who does that. Will that be done from the transcript of this meeting or is this something that we need to take notes on now?

DR. WARD: I would think if we can come up with a succinct statement about the rationale—so basically the way our recommendations get transmitted is I write a letter to Dr. Howard, and I state and summarize the recommendations that were agree upon at the meeting. And obviously Dr. Howard always looks for the rationale behind our recommendations. I think that's important to him. So, we could vote on the language of the recommendation. Also, if we could come up with a succinct version of the rationale we could vote on the whole statement, I think. Tania, would you agree with that?

DR. CARREÓN-VALENCIA: Yes.

DR. GAITENS: I have a question. Because I know, Liz, you were saying for part of the rationale—and, Steve, I think you even mentioned this—was that it sounded like they were limiting additional reviews or looking at data from ATSDR, NTP, and EPA. But I guess I didn't get that when I read this, because they talk about that second-level review of scientific evidence and so isn't that part where they would look at some of the other at least epi studies that would be available, or am I completely misinterpreting that part?

DR. WARD: Tania, would you like to answer?

DR. CARREÓN-VALENCIA: Yes, we would look at available epidemiologic evidence to support the initial. But certainly, those authoritative reviews, especially like the tox profiles from ATSDR, have also mechanistic

information, annual studies that we can look at and consider in the evaluation.

DR. WARD: But I think what you're saying is that you would restrict your searches on the scope of that information to these published government documents, not a PubMed search.

DR. CARREÓN-VALENCIA: Yes, initially yes. And then we could expand the PubMed search, or at least that's what we did for uterine cancer expanding the—do not only a PubMed but many other searches. I mean we search other search engines for information published after the evaluation, in this case by IARC, was already published. So, it wasn't a thorough PubMed review, it was just based on the years after the IARC evaluation was published, which limits also the scope of the search. But I'll let Doug comment also on that.

DR. DANIELS: To avoid confusing the cancer P&P, which is somewhat still different from the non-cancer P&P, here are the current rules. And I think you should work to these rules with your motion with respect to making changes. But the way it works now is the Science Team evaluation is limited initially to epidemiologic studies. Now, that doesn't mean just longitudinal cohort studies, but epidemiologic studies of 9/11-exposed populations that have been peer-reviewed and public. So that's where we start. Now, that could be clinical studies. That could be biomarker studies. They're forms of epidemiologic designs that would be suitable. If we are in the high category then, at the discretion of the Administrator, we can open up the search and include evidence from authoritative scientific information published by the U.S. Government. And we give three examples. But it is limited to only that, so we don't go outside of that. And it's always been that way since this publication was first published in 2014. And as alluded to by Tania, the reason for this was we're under some pretty step time constraints to provide information and respond accordingly.

So, we don't do a full PubMed search for these evaluations. And we never have. So, if you're making a recommendation to do other then that's fine, but just that's what we currently do now.

DR. WARD: Right. And that was my understanding as well. So, I think the intent of Steve's initial recommendation was to say that you should go beyond that because there are substantial limitations to the availability of data in that universe of publications, but in order to reflect that the STAC recognizes that that could be extremely broad and it may not always be feasible, we added the words "to the extent feasible." And I do recall very specifically we had that discussion in the context of the 90 days before. So, we've made this recommendation before and the Program has not changed the policy and procedures in relation to it, but we can make the recommendation again.

DR. MARKOWITZ: But I think there are a couple of additional parts of the rationale that are new: one is that the research that the Program itself supports is not necessarily increasingly but clearly includes non-epidemiologic studies and, secondly, the nature of conditions gets more complicated. No, it's not aerodigestive, it's autoimmune. It's things that are difficult and are going to be increasingly difficult because of the aging population. So that's I think another piece of the rationale whereby they should go, to the extent possible, beyond the epidemiologic literature.

DR. WARD: Yes. And I think where we're having a little bit of a difference of opinion, Steve, is—and I think Doug said this—that for me, all of those other types of studies, including the clinical and the—I mean most of those studies in my mind would often fall in the same category as epidemiologic studies because if you have a defined population and a defined outcome, you can call it an epidemiologic study. But I think we want to get language that reflects our consensus so we could even say consider studies—we

could take out the word "epidemiologic" and just say—because it does seem like the primary thing is that they're reviewing the database from 9/11 population studies—we could make the specific recommendation that it includes all of these different types of studies. But I think if we took "epidemiologic" out that might solve that problem in the definition of what an epidemiologic study is. How do you feel about that, Steve?

DR. MARKOWITZ: That's fine. I'm just reading the language here: "…that go beyond the studies of peer-reviewed and published 9/11 populations." And we don't want to get into a discussion of where epidemiology starts and stops, but there are population studies that would fall into this category. It's hard to write this by a Committee.

DR. WARD: Yes, and it is true that the document itself does refer to published epidemiologic studies, so I guess that's the language we're stuck with and it's just how that's defined.

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

DR. WARD: Oh, thank you, Michael, go ahead.

DR. LARRAÑAGA: Yes, thank you, Liz. Thank you, Tania. A quick question. Is the intent of this for the Science Team to do this every time they look at a condition? Or in the absence of studies that show a correlation or something like that, then they have the flexibility to go to other authoritative sources? Because the way I read it currently it's telling the Science Team every time consider studies that go beyond. So just a little clarification.

DR. WARD: Steve, did you want to clarify?

DR. MARKOWITZ: I think to the extent they can—and the 90 days is a severe constraint—that when their initial review suggests high or limited, that they should look beyond the 9/11 epidemiologic studies and beyond the U.S. authoritative sources. Yes, I think they should do that. And I think in fact the example that Ms. Flynn raised for the uterine cancer and the role that endocrine-disrupting chemicals

played in some of that decision-making, I wasn't part of the STAC then, but most EDCs are considered EDCs not necessarily based on human evidence at all. So clearly it came in there. So, yes, I think they should do it. When their initial consideration is high or limited to the extent possible, they should look at relevant literature.

DR. LARRAÑAGA: Thank you.

DR. WARD: Okay, so I withdraw my—given that the language of epidemiologic studies comes directly from the document, I withdraw my recommended change. So, Steve, as the person who proposed it and the members of the Committee, is the way this is stated something we want to vote on? Or are there any additional proposed amendments to the language? And of course, does everyone—then we'll have the vote to see if you agree with it, but do we all feel comfortable with this as stated or are there any more friendly amendments, or unfriendly amendments?

DR. MARKOWITZ: Just while people are trying to just clarify the language a little bit, line 2, "…with respect to the consideration of health conditions for which a high or a limited likelihood" of causal association—

DR. WARD: Very good.

DR. MARKOWITZ: —is being assessed, and then you can take out the next two words, "categories" and "that." At least it looks like English now.

DR. WARD: It's always good to look like English. So, is the sense that we should vote on this? And, Tania, maybe you can give us some guidance; do you think we should vote on this and then move on to a rationale statement?

DR. CARREÓN-VALENCIA: Yes. So, you have a motion and then you had a second so yes, I can do a roll call about the votes.

DR. MARKOWITZ: I think you should open it up to further discussion in case there is input.

DR. CARREÓN-VALENCIA: If you want further input.

DR. WARD: Of course, yes. So, any further discussion or recommended changes to this language? Michael, your hand is up.

DR. LARRAÑAGA: Yes, thank you. So, I think we could shorten it a little bit by saying on the peer-review line, U.S. Government published 9/11-exposed—well, I don't know if that works. I'm trying to get rid of that—that or "published by the U.S. Government." In retrospect, I'm not sure it'll work so I withdraw my motion.

DR. WARD: Anybody else? Steve?

DR. MARKOWITZ: Yes but… No, I think, Michael, you're right, that peer-reviewed should go before epidemiologic. It needs to be moved up.

DR. WARD: Yes, that's a good idea.

DR. MARKOWITZ: Yes, one line about that where it says "peer-reviewed," cut that and move it up to the next line right before "epidemiologic." "Go beyond peer-reviewed epidemiologic studies," just one line, yes, right there. And then you can take out "and published."

DR. WARD: One minor suggestion. In my mind, mechanistic includes toxicologic studies, but do you think it's worth mentioning toxicologic studies separately? Because mechanistic could be interpreted to mean only in human populations and I do think there may be some relevance sometimes of other kinds of studies. Or do you think that broadens it too much?

DR. MARKOWITZ: No, that's a good idea.

DR. WARD: Okay. So, are there any other recommended changes to this motion before we vote on it? Okay, then I guess we're ready for a vote.

DR. CARREÓN-VALENCIA: Okay, so I will take roll call of the vote. So, Liz?

DR. WARD: Yes.

DR. CARREÓN-VALENCIA: Yes. Sophie?

DR. BALK: Yes.

DR. CARREÓN-VALENCIA: John?

DR. COMISKEY: Yes.

DR. CARREÓN-VALENCIA: Joanna?
DR. GAITENS: Yes.
DR. CARREÓN-VALENCIA: Mariama?
MS. JAMES: Yes.
DR. CARREÓN-VALENCIA: Michael?
DR. LARRAÑAGA: Yes.
DR. CARREÓN-VALENCIA: Steven?
DR. MARKOWITZ: Yes.
DR. CARREÓN-VALENCIA: John?
DR. MEYER: Yes.
DR. CARREÓN-VALENCIA: Debra?
DR. MILEK: Yes.
DR. CARREÓN-VALENCIA: Jason?
DR. OSTROWE: Yes.
DR. CARREÓN-VALENCIA: Okay, the yea had it; the motion is carried.
DR. WARD: Great. And I was going to suggest—so I have one other thing that I think at least that we want to make a motion about and whether there is any resolution to the problem that everyone had about telling the difference between substantially likely and highly likely. So, I think I came up with a suggestion, we can talk about it and then I can make it a motion, if I can find it. So, I would say for the substantially likely that we say something like a causal association is strongly supported by studies in 9/11 populations. And I don't know whether we need to change the highly likely category, but I would almost say possible rather than highly likely. Because I think the 9/11 studies, I think highly likely is also a pretty high bar to set to trigger that second-level review—or strongly suggested or some wording. But I think for the first one, just capturing the evidence strongly supports the association really gets much more to the heart of the matter than saying substantially likely versus highly likely.

	So, I would make a motion at least to change that first descriptor to causal association is strongly supported by evidence from studies in 9/11 populations. Mostly just to clarify what I meant, not to change the meaning of what is said. So, is there a second to that motion or discussion before we get a second, or disagreement?
DR. MARKOWITZ:	I would second that.
DR. WARD:	Okay, so Geoff, do you want to type that as a motion so that the Committee can see it? Okay, good.
DR. COMISKEY:	Can you just make that a little bit bigger, or a lot bigger?
DR. CARREÓN-VALENCIA:	If you can go to View and then do Page Width as well on the top ribbon where it says View.
DR. WARD:	Yes, I got it.
DR. CALVERT:	You want it bigger?
DR. CARREÓN-VALENCIA:	Yes, just Page Width, I think there's an option.
DR. CALVERT:	Page Width, okay.
DR. CARREÓN-VALENCIA:	There.
DR. WARD:	So, I think what we want to say is change "substantially likely" to "causal association is strongly supported." So, I guess it's change "causal association is substantially likely" to "causal association is strongly supported," so it just needs a little rearrangement. Yes, so basically, we're saying—I would just add the words in that first parenthesis, I would say add the words "causal association" in there.
DR. CALVERT:	So, you want me to, I'm sorry, move—
DR. WARD:	I guess it is repetitive, but I think the language that we're changing is "causal association is substantially likely" to "causal association is strongly supported."
DR. CALVERT:	Oh, okay.
DR. WARD:	So, it's just adding those words "causal association" to that first—no, you don't want to change the whole thing. You just want to

	add "causal association" in the first line.
DR. CALVERT:	Yes. So, this should be substantially?
DR. WARD:	No, no, no. Take the existing language, which is "causal association is substantially likely"—okay, so type that first—okay, end quote, and then say "to" and then take out everything—yes, yes, yes, and then just add parenthesis at the end. No, no, no, no. Now just go back. Go back. The phrase that I'm proposing to change to is "causal association is strongly supported by evidence in 9/11-exposed populations." So that's my proposal.
DR. CARREÓN-VALENCIA:	You need to—exactly—end the quote.
DR. WARD:	Yes. And it's really only—it doesn't change the meaning, but it just, I think it's going to make it clearer for people to differentiate the language that way. I don't know if it works within the legal framework or other frameworks that NIOSH had when they drafted this language, but it's clearer to me. Michael?
DR. LARRAÑAGA:	Liz, are you referring to the last sentence of the "Substantial Likelihood Standard" paragraph?
DR. WARD:	No, I guess I'm talking about the—basically I'm talking about—okay, so on page 7 it starts out with "Substantial Likelihood Standard."
DR. LARRAÑAGA:	Yes.
DR. WARD:	And I guess I'm saying that for many of us that's really—and I guess you could leave that in, but you could say—I would say to clarify it by that the "causal association is strongly supported by evidence in 9/11 populations." Because that I think is what it means.
DR. LARRAÑAGA:	Okay, I see. So, you're recommending changing essentially the "Substantial Likelihood Standard" to "causal association is strongly supported by the evidence in 9/11-exposed populations"?
DR. WARD:	Right, right.
DR. LARRAÑAGA:	Okay, I just wanted to be clear.

DR. WARD: Yes, so I guess that's really where the specific change would be. I guess you could keep the "substantial likelihood" because it means that "causal association is strongly supported by evidence in 9/11-exposed populations" because I think that captures more clearly the intent.

DR. LARRAÑAGA: Yes, I agree with you. Essentially, it's a summary of what's said below, just more descriptive?

DR. WARD: Right, right. Then you could go on to say, "Strong association means that"—or we interpret strong association to mean is an association that cannot be—or we could just say "This association cannot be explained by chance, bias, etc." So, you could keep the rest of the paragraph, but just change that first sentence. So, is everybody clear on what we're proposing? Is if you have the document in front of you, it's on page 7 under the subheading of "a."

DR. CALVERT: Liz, do you want me to change the motion?

DR. WARD: What do you mean?

DR. CALVERT: Like do you want me to refer to page 7?

DR. WARD: Maybe, yes, good idea. Yes, so basically we can go—

DR. CALVERT: Oh, okay.

DR. LARRAÑAGA: So, Liz, if I may, the words "causal association is substantially likely," they are found in the last sentence of that first paragraph. So that's kind of the way the motion reads to me is you would only be changing those words in the last sentence.

DR. WARD: Well, no, it says—and I guess I was confusing a little bit, but part of me was saying we get rid of the whole phrase "substantial likelihood" because it is so confusing with high likelihood. But as it's evolving, I'm thinking at the very least we should say that what we mean by "Substantial likelihood of causal association" is that the "causal association is strongly supported by evidence in 9/11-

exposed populations." And then we go on to say, "There is high confidence that," blah blah blah.

DR. LARRAÑAGA: I understand, but the way that the motion reads, the only place that the first half of the motion reads is in that last sentence. So, the motion reads we would just change that last sentence.

DR. WARD: No. Oh yes, no. So, Geoff, can you go into the document and pull up the first paragraph under "Substantial Likelihood Standard" and then we can just make the change to that paragraph?

DR. CALVERT: Yes, let me find it. Hold on, I'm going to stop sharing.

DR. GAITENS: While he's looking for that one, can I just ask, since we're talking about changing that language for one of the five categories, for the category that's "inadequate likelihood of causal association," I find that wording a little odd. Could we consider changing that one? I mean essentially aren't we saying inadequate evidence of causal association?

DR. WARD: I think maybe what we're saying is inadequate evidence to assess causal association.

DR. GAITENS: Yes, I like that.

DR. WARD: Yes, so we could vote on these individually or if there are others like this, we could vote on them as the group. Okay, so now we're on the right-hand screen. I've got to move my participants so I can see. Okay, so under "a." so we would say "Substantial likelihood of causal association means that the association is strongly supported by evidence in 9/11-exposed populations by study or by studies in 9/11-exposed population. There is high confidence that these associations cannot be explained by"—and go down to the rest of the paragraph.

DR. DANIELS: So, this is Doug, I don't know if it's wise that—here's my caution, because substantial likelihood standard as it's written now applies to this within the evidence from 9/11 population and it also

applies if we expand the review to the U.S. Government authoritative bodies.

DR. WARD: But that's only for the high likely category.

DR. DANIELS: But the point is that what happens is if you do the second-level review is you fill the gaps, so you would go from high to substantial. I agree with the message, what you're telling me is you would like to describe substantial likelihood to indicate a strong association; the evidence indicates a strong association causal association, or strongly indicates a causal association. I'm fine, I understand that, but if we're going to do wordsmithing on this paragraph now, I think they're so interwoven with other parts of the procedure that we might get bogged down. That's all I'm saying.

DR. WARD: Yes, that's a good point. Again, what I was trying to address is so that it's clear in everyone's mind how the distinction is made between substantial likelihood and high likelihood. And when I read through the text, the key thing appeared to me that there was strong support from epidemiologic evidence broadly defined in 9/11 populations. But we don't have to suggest that change. It's really just—and if anyone has any better suggestions—I think at least five people said that they could not get straight in their mind the difference between substantial likelihood and high likelihood. There was a suggestion earlier which I think we could incorporate of making a table to make it easier for the reader, everyone to understand that. But, yes, my effort was only to clarify the definition of what is going to fall in that category as part of the initial review, not to say that that would apply to the final determination. So, somebody was making the distinction—I think it was Doug—between the categories that are established by the Science Team in their initial review and the final decision by Dr.

Howard that an association is causal. Doug, could you clarify that again?

DR. DANIELS: Yes, so yes, that's exactly right. So, we, the Science Team, which is only providing advice, we live in the world of these likelihood bins and so that's how we would report our findings to the Administrator. But the Administrator, he weighs that evidence and may weigh recommendations from the STAC, whatever other evidence that comes to him, and makes a determination whether or not it's sufficient to support a proposed rule change. So that's how it works. So, the word is sufficient in his action, but our word is we're just providing advice with respect to the likelihood of the association. And, again, I know that's a subtle difference, but it is a difference, nonetheless.

DR. WARD: Yes, so I guess we can—there is one minor editorial suggestion just to make it less repetitive. In the third line just change "means a causal association," delete "a causal" and just say "the," "means that the association," and then take out "the" because we don't need to repeat that.

DR. LARRAÑAGA: So, what you're suggesting is replacing the first sentence there with this?

DR. WARD: Yes, yes.

DR. LARRAÑAGA: I think this reads better now.

DR. WARD: Yes, and I think it just clearer as to what they're actually saying.

DR. LARRAÑAGA: And then you would leave the last sentence there, "The scientific evidence demonstrating that a causal association is substantially likely and includes the following"?

DR. WARD: Right, right.

DR. MARKOWITZ: That's good.

DR. WARD: So, are we ready for a roll call vote or were there any further comments? Did we have second? We had a second, yes, okay.

DR. LARRAÑAGA: Doug, as it is now, is this going to create or change the way you

respond to the (inaudible @ 00:51:27) as you were describing earlier?

DR. DANIELS: I don't think so. I think we're defining it and we're considering substantial likelihood by saying it means as strongly supported by the evidence. I will say that we will most likely, since our categories are not—I will probably take out the 9/11-exposed populations because, again, the threshold is dependent on what evidence is reviewed. So currently, you're right, the initial review would only include 9/11-exposed populations as it's written now. But, again, we apply the same standard when we open it up to additional literature. I mean that's maybe a minor point, but I think it's sufficient just to say "supported by the evidence" and leave it at that.

DR. MARKOWITZ: So, if you were to say "by peer-reviewed evidence," and then take out "in 9/11-exposed populations," would that do it, Liz?

DR. WARD: Say it again, Steve.

DR. MARKOWITZ: Just to add on to what he said, "by peer-reviewed evidence."

DR. WARD: I guess what I'm trying to get at is how do we draw the distinction between the first and the second category? And it looks to me like—and, again, we're talking about the initial determination by the Science Team versus any final determination. So, when I read these categories I am thinking that this is the guidance that the Science Team is going to use to evaluate the condition and report their findings to Dr. Howard. So, as I read this as it's defined that if the Science Team reviews the evidence and finds strong evidence of an association in 9/11-exposed populations, they will put it in Category 1 and they will make that recommendation to Dr. Howard. If the Science Team finds evidence in 9/11-exposed populations that does not meet that high standard, then that triggers all the other processes. So, I guess what we're confused

about is I was trying to delineate more clearly what the basis of the Science Team's initial review of the evidence would comprise.

DR. DANIELS: Yes, so just to be clear, the way it's written now under highly likely, if we do a second-level review we can find, based on the additional evidence by the second-level review that now it is substantially likely. So, we have that—that's what the procedure says so use it—it's not dependent on 9/11 research, it's dependent on the evidence that's reviewed, if that makes sense.

DR. WARD: Right, but I guess that's the thing. And maybe it's fine the way it is. I was just trying to clarify in my mind the difference in what—I mean I guess it's the question of it's the difference in what happens. Because it looks to be like the Science Team, if there are multiple studies in 9/11 populations that show a dosed-response association, it never goes to the second-level review, it just gets fast-tracked. And so, I guess what I'm saying is the definition that leads to the fast-tracking of this is comprised of studies in 9/11 populations. But if other folks don't agree that that's a clarification and it actually might harm the document, then I can withdraw the motion.

DR. MARKOWITZ: I'm a little confused here because would you ever land on substantial likelihood unless there was proof in 9/11 populations? That's a question for NIOSH.

DR. DANIELS: Okay, yes. So, there are two ways to get there. We can get there looking just solely at 9/11 research and we can get there if we initially find it is high and we expand the search and we find that the additional evidence supports substantially likely.

DR. LARRAÑAGA: So, all three of those bullets aren't required to come to a substantially likely finding? You could use one of those bullets, for example, you could use bullet 3 or bullet 1 and 3, but not—I mean, are all three required?

DR. WARD: That's how I read it.

DR. LARRAÑAGA: Yes, that's how I read it also.

DR. DANIELS: Yes, that was a completely different issue though than what I just addressed.

DR. LARRAÑAGA: Okay, I misunderstood, sorry.

DR. DANIELS: Okay.

DR. WARD: No, but I think actually maybe—I can happily withdraw this motion, but I think the underlying issue that we're addressing that maybe it's not something we can resolve in this meeting but maybe we can make a recommendation that it be resolved is that there's a difference between reading through the categories that will be used for the initial Science Team determination and the categories that will be used in the final determination. And maybe there could be a table that's created that—it's almost like the IARC table, and I can share with somebody. They have different categories of carcinogenicity and one is there's substantial evidence in humans for the carcinogenicity. And so that goes to Group 1, known to be carcinogenic in humans, where Group 2B would include things like there's some evidence in humans and there's some mechanistic evidence. You know what I'm saying? So, it's almost like you have to go through—there's two separate categorizations. One is the initial determination by the Science Team, which I think we all recognize is really, really important because it really determines whether the question goes on to any more detailed review or not.

But the second is the categories that the—it's the categories that the evidence will be divided into. Really it only happens for those that fall into Category B. So, unless you fall into Category B, nobody's going to look—nothing further happens. So anyway, I think that's their confusion and I'm happy to withdraw the motion if it's just taking up time. But I think it would be nice for the—I

don’t know if anyone from the Program is getting the point or thinks it's unclear.

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

DR. WARD: Okay, Michael.

DR. LARRAÑAGA: Thank you, Liz, and thank you, Tania. I wasn’t going to make a suggestion to withdraw, but I was trying to help clarify. If all three of those bullets are required, then I think we should leave in 9/11-exposed populations in this description. If not all three of those are required and you can, as I understood it, use other evidence besides both groups of 9/11-exposed populations, then I think the strikeout is appropriate. So, I mean that’s kind of where I was going. I wasn’t making a suggestion to withdraw the motion.

DR. WARD: John?

DR. COMISKEY: Yes, just a quick clarification. If it requires all three, the wording should be "is substantially likely to include all of the following." It doesn't say that. So, in that case, any one of those could qualify. So that’s the wording that—that’s how I read that. You would need to say, "all of the following."

DR. LARRAÑAGA: That’s why I asked for the clarification because to me it does read that "all of the following are required."

DR. WARD: And a way to amend that would be to say "Peer-reviewed evidence in 9/11-exposed populations," we could put, "All of the following are required to support this determination by the Science Team."

DR. LARRAÑAGA: Could NIOSH advise on—respond to whether all those three are required and how they do that? Because I'm unfamiliar with that and that would help me with just understanding this motion.

DR. MARKOWITZ: It sounds like we're questioning for only 9/11 studies to be used in the determination of substantial likelihood, when I think Doug that the window was open for non-9/11 studies to be used in this category. Is that correct, Doug?

DR. DANIELS: I'm sorry, I was typing another thing. Could you repeat the question?

DR. MARKOWITZ: Sure. What we're saying seems to be that only 9/11 studies are included in the consideration of substantial likelihood. But I thought you were saying you were opening the door or the door was open to non-9/11 studies contributing to meeting this standard. Is that true that non-9/11 studies are or could be used in determination of this level?

DR. DANIELS: Well, I will say that this needs further discussion I guess with our policy folks as well. And so perhaps this isn't a good time for me to respond to that question. There is some discussion on that, and I think we're a little confused.

DR. WARD: Yes, because I do think, Steve, that the confusion stems from if you read this as just outlining the results of the initial review by the Science Team, I'm reading is that the Science Team will only put things in this first bucket of substantial likelihood based on studies in 9/11 populations and the evidence must meet the three criteria. That does not mean that eventually, if things are bumped to the second category of highly likely and a fuller review is done taking into account studies in other populations that the conclusion will be that there's—what's the difference in the wording? There's substantially likelihood and what's Dr. Howard's final determination? What is the language he would use?

DR. DANIELS: It's sufficient. If you go to section V—

DR. WARD: It's sufficient, okay.

DR. CARREÓN-VALENCIA: Can you, Geoff, go down to number 2?

DR. CALVERT: Here? Keep going?

DR. DANIELS: To Section 5.

DR. CARREÓN-VALENCIA: Yes, go down a little more. So that's where Dr. Howard directs the Science Team if there is evidence to go beyond 9/11 populations. In my mind, number one, it's only limited to 9/11 populations and

the Administrator can direct the Science Team in number 2 to go beyond those studies.

DR. WARD: Yes, that's what I'm trying to clarify.

DR. LARRAÑAGA: Me too. And if that's the case, then in this motion I would leave the strikeout and not include the word "all" in the last sentence.

DR. WARD: Right, because it really is—well, it's—I mean we wouldn't be—I mean that sentence would still be there from the original text, I guess.

DR. LARRAÑAGA: Yes, leave it as-is.

DR. WARD: Yes, yes, so we can take it out in the amended text.

DR. LARRAÑAGA: For me, this—

DR. WARD: Yes?

DR. LARRAÑAGA: This describes what I think you're trying to accomplish.

DR. WARD: Yes, and I will say even it's a little out of order in terms of our process, but the time is getting late. It may be that we could—after we vote on this mechanism that we suggest that the Program review the language and the text to make clear that the difference between these categories as described as the initial determination by the Science Team versus the conclusion of sufficient evidence, that either Dr. Howard can conclude that there's sufficient evidence either based on the recommendation of the Science Team or initial determination or the further investigation done for things that fall into the second category. So somehow make it clear that it's not like you're going to promote things from Category 2 to Category 1 after the fact, after the investigation. It's a completely different process where the Administrator considers the recommendations of the Science Team in determining what conditions there is sufficient evidence for. Am I making myself clear? As these meetings go on, I feel like I become less and less clear.

DR. LARRAÑAGA: Yes, that was clear and thank you for indulging me on my

	questions. And, Steve, thank you for asking a better question that was clearer than what I was trying to ask.
DR. MARKOWITZ:	Is it time for a vote?
DR. WARD:	Yes, I think all we need to do—I think the consensus is to remove the strikeout in "9/11-exposed populations." And the rationale for this one I think could be very brief. And we don't need to wordsmith it now, but basically, it's just to make it more clear to the reader what the distinction is between substantially likely and high likely. So, it's really just a clarification.
DR. LARRAÑAGA:	I think what I heard was to keep the strikeout in 9/11. If they don't require all three bullets, then we would keep the strikeout.
DR. WARD:	But I heard that they do require it. Tania's nodding her head. Tania, clarify.
DR. CARREÓN-VALENCIA:	Yes, in the first, the substantial likelihood, is exclusively on 9/11 populations. It's in the second level, number 2, that the Administrator can direct the Science Team to look beyond 9/11 population.
DR. LARRAÑAGA:	Okay, thank you for the clarification.
DR. WARD:	Okay. So, Tania, I think we're ready for a vote.
DR. CARREÓN-VALENCIA:	Okay, so those voting for the motion. Liz, is that a yes, no?
DR. WARD:	I think we were frozen for a minute. I think we're having connectivity problems.
DR. CARREÓN-VALENCIA:	Oh, okay, yes, I can't—can you hear me better now?
DR. WARD:	Yes.
DR. CARREÓN-VALENCIA:	Okay. So, I'm going to read the names and you tell me if you vote for or against the motion or abstain.
DR. CARREÓN-VALENCIA:	Okay, so I will take roll call of the vote. So, Liz?
DR. WARD:	Yes.
DR. CARREÓN-VALENCIA:	Sophie?
DR. BALK:	Yes.
DR. CARREÓN-VALENCIA:	John?

DR. COMISKEY: Yes.
DR. CARREÓN-VALENCIA: Joanna?
DR. GAITENS: Yes.
DR. CARREÓN-VALENCIA: Mariama?
MS. JAMES: Yes.
DR. CARREÓN-VALENCIA: Michael?
DR. LARRAÑAGA: Yes.
DR. CARREÓN-VALENCIA: Steven?
DR. MARKOWITZ: Yes.
DR. CARREÓN-VALENCIA: John?
DR. MEYER: Yes.
DR. CARREÓN-VALENCIA: Debra?
DR. MILEK: Abstain.
DR. CARREÓN-VALENCIA: Okay. And Jason?
DR. OSTROWE: Yes.
DR. CARREÓN-VALENCIA: Okay, so the yeas have it and the motion is carried. Liz, I would like to ask if before moving if we could listen to Nancy Keegan and her comment.
DR. WARD: Sure.

PUBLIC COMMENT (CONT.)

DR. CARREÓN-VALENCIA: Nancy, are you able to provide your comment now?
MS. KEEGAN: Yes, sure. Can you hear me okay?
DR. CARREÓN-VALENCIA: Yes, you have five minutes, okay?
MS. KEEGAN: Okay, great, thank you. Just tell me when to start.
MS. WALLACE: Let me bring this up now.
DR. CARREÓN-VALENCIA: Mia is going to set the clock but, if not, I can count. Yes, she's about to start the clock. She will tell you when.
MS. KEEGAN: Okay.
DR. CARREÓN-VALENCIA: She is ready.

MS. WALLACE: You can start.

MS. KEEGAN: Hi, my name is Nancy Keegan and I live on Washington Street just south of where the World Trade Center once stood. When I was 12 years old my Catholic grade school took us on a field trip to New York City to see the World Trade Center. The Towers seemed to just jut up from the earth like Oz and I had never seen anything so magnificent. Little did I know that 20 years later I would literally be living and working in their shadows, much less running for my life, choking on the ash as they collapsed. I often shopped there, worked in a neighboring restaurant, and walked my dog around the Deutsche Bank. All of us in this small neighborhood were closely connected to the Towers. To say that my tiny studio apartment in a tenement building is two blocks away from the South Tower is true yet misleading being about 600 feet away. I was home on 9/11 along with some of my neighbors. We evacuated on our own, guessing at what we should do and where we should go. Once out the door, we scrambled away, barely able to breathe in the heavy dust clouds, not even realizing the South Tower had done the impossible and collapsed. While inside we had already been engulfed by it and the sheer force of the collapse penetrated even closed windows and doors with smoke, ash, papers, and the detritus of modern office towers: plastics, heavy metals, silica, asbestos, and all that comes with freely burning petroleum.

Later our blanketed building was only cleaned by our super. The EPA cleanup came a year and a half later and, to put it mildly, did not inspire our confidence. My neighbors and I were already exposed to this all-encompassing toxic brew and some of us are sick as a result. Pre-9/11 I used to walk miles around Manhattan, running up and down a dozen subway staircases every day. I tended a 25-foot packed bar by myself for ten hours straight and

manned a small restaurant five or six days a week where I would deliver food to tables, clear dishes, run the stockrooms for supplies, cases of wine, racks of glasses, etc. I can't do any of these things anymore and feel certain I never will.

Within five years of the attack, I started getting sporadic, unexplainable skin rashes. In 2014, I began experiencing more serious and mysterious symptoms: crippling fatigue, muscle pain, and weakness. I developed such chronic joint and muscle pain and such debilitating fatigue that I became unable to work or sustain the activity level I once had. I continued to live and work in the neighborhood and have met many survivors who struggle with the same types of symptoms.

Getting our uncovered conditions diagnosed has been an obstacle course and, for many, an unaffordable one. When we residents go to our non-World Trade Center doctors telling of our 9/11 exposures, asking if our symptoms like those of rheumatoid arthritis or neuropathy could be related, the doctors brush it off. We can be completely dismissed. The doctors would then cite the EPA that the air had been safe so all of our symptoms, even the respiratory ones, were deemed unrelated.

For the many of us who suffer with a variety of problems that are not currently 9/11-certified such as fibromyalgia and undifferentiated connective tissue disease, credibility is paramount. For example, UCTD is one of the severely debilitating connective tissue disorders. Suspected of being autoimmune in nature if it is linked to 9/11, which is certainly consistent with my experience, there could be protocols for getting the appropriate diagnostic tests and therapies without having to convince disbelieving doctors to order them. It would be so helpful to be assigned one doctor who knows and understands our cases and provides the continuity of care we need. In my case, different

doctors gave me different diagnoses. After multitudes of tests, I was diagnosed with fibromyalgia by one and two other doctors said it was UCTD. Then another believed I had lupus and started me on hydroxychloroquine. Then after waking up covered in hives, I tried to reach the doctor but couldn't according to the clinic rules. I ended up in the ER and then hospitalized due to a severe allergic reaction to the medication. I had simply been left to my own devices.

The inclusion of a variable of autoimmune conditions and of others would end this runaround and the dismissiveness without some people ultimately falling through the cracks. It would get us the care we need. In the last decade new medications have been developed offering much help but affording them is a real issue. So many people do not have Cadillac—or should I say Tesla—health insurance. And how can any new condition be added for coverage when the World Trade Center Health Program doesn't have any means to keep track of any new diagnoses? I have long thought that new questions on the monitoring exams and a simple, program-wide database would reveal these disease patterns so the Program would be alerted and then focus research on those emerging illnesses. It's inconceivable that it's been 10 years since the Program has added a non-cancer. Responders and survivors were engulfed in an unimaginable environmental disaster. It's not at all surprising so many would be now suffering with a host of chronic diseases. What is surprising, and actually shocking, is that the Program hasn't added a non-cancer in these ten years. Whatever process is set out in this policy document must lead the way out of this stalemate.

Finally, I want to say that I am incredibly grateful for the other World Trade Center healthcare that I have received. I really shudder to think where I would be without it. I thank you all for

your consideration and hope that in the future many more of us will be able to receive the care that we truly need.

STAC DELIBERATIONS AND RECOMMENDATION (CONT.)

DR. WARD: Thank you. So, we have left less than 15 minutes and I wanted to say that when the STAC has a substantive discussion on an issue, if they can't resolve at the meeting where it's brought up, there is an option to form a workgroup to address the issue and come back to another full meeting of the STAC with a recommendation. I don't have a sense that we need to do that here. I don't think there are any major issues that were raised or any really outstanding points of discussion that we have. I think we're a little short on time to wordsmith the rationale. I do want to make sure though that there are no other issues that the—so I would propose that for the rationale that if the Committee is comfortable that I try to draft some—it's not something the Committee has voted on, but it would draft some language to explain to the Administrator why we have made that recommendation. I think that for the second recommendation the rationale is straightforward and more clearly explains what the difference is between substantially likely and highly likely. But are there any other significant issues or motions that we have not considered that someone would like to bring to the table?

DR. MARKOWITZ: I do have a question. Maybe it was answered before. The charge to us sites five bins. The document has four bins and one of those bins is Dr. Gaitens's point about they provide inadequate and limited. Personally, I think there should be a separate section for limited and a separate one for inadequate because they're different. But I don't know exactly what the Program's plan is. Maybe that is the plan already.

DR. WARD: Well, I think Doug explained they were combined in terms of the results and action. But, again, I think that's where a table might be really useful is you would have a table and you'd see that there were these two categories, but then that the results and action was put into a combined category. So, I don't know if we can wordsmith it proper—I mean we can certainly try to wordsmith that point because I think it's fairly simple, but I think wordsmithing the issue of making the distinction between the initial categories and final action in the document, that to me is really where that question falls.

DR. MARKOWITZ: Yes, and I wasn't suggesting anything substantive. It was just it would indicate it more clearly to the public if they were separated, that's all.

DR. WARD: Right, right.

DR. MARKOWITZ: They could do that if they wanted to without a recommendation from the STAC.

DR. WARD: Right, right. Certainly, I know the Program has heard all of this discussion today and while the recommendations that we send to Dr. Howard in the letter will be posted on the website, and (inaudible @ 01:19:55) Committee is heard by the Program staff and that they will certainly consider all the points that were made in our discussion. I think we're having some connectivity issues. My internet seems to be going in and out. So, I don't think we need to vote on the Committee empowering me to draft the rationale or not. I just know that we've run out of time to do it as Committee, unless somebody has some quick words that Geoff wants to type.

DR. CARREÓN-VALENCIA: But certainly, you all agree on a table?

DR. WARD: I think so, yes.

DR. CARREÓN-VALENCIA: It's a recommendation. Yes.

DR. WARD: Yes. Should we make that a formal—I mean do we have time to make that a formal motion then?

DR. CARREÓN-VALENCIA: You could make a motion, yes.

DR. WARD: Okay, so let me give a crack at it. The Committee recommends that the Program develop a table that clearly delineates the categories that will be used at different stages of the deliberation process. Does that capture it? Geoff, can you put it up?

DR. CALVERT: Yes, I'm a slow typer, though.

DR. CARREÓN-VALENCIA: No, you are great.

DR. CALVERT: Let's see, I did have some language.

DR. WARD: Okay, Geoff, I can repeat again. So, the Committee recommends that the Program develop a table that clearly delineates the categories that will be used at various stages of the deliberations.

DR. CALVERT: Actually, I was going to share my screen, hold on. All right, so I'm sorry, start over again, Liz.

DR. WARD: The Committee recommends that the Program develop a table that clearly delineates the categories that will be used at various stages of the deliberations at various stages of the review process. And that gets on the issue of Dr. Howard's final decision versus the initial decision and it kind of gets on the issue of the ultimate combining of limited and inadequate respect to actions taken. So, I think that would really help clarify some of these issues that we've all struggled with collectively. Does anyone want to second that motion?

DR. GAITENS: I second.

DR. WARD: Any discussion or modifications? Okay, Tania, I guess we're ready for a roll call vote.

DR. CARREÓN-VALENCIA: Okay, Liz?

DR. WARD: Yes. Oh, Jessica is raising her hand.

DR. CARREÓN-VALENCIA: Okay, Jessica?

MS. BILICS: You could probably still go through the motion, but I was going to

	ask though if the Committee does agree with Dr. Markowitz's recommendation about separating out the limited versus inadequate, it would be really helpful for us to have that as an actual recommendation versus just us—
DR. WARD:	Okay.
MS. BILICS:	But if the Committee does agree with that, we would appreciate having a recommendation.
DR. WARD:	Okay, so let's, let's you know—should we do a quick vote on this and then move on to Steve's recommendation and do a quick vote on that?
DR. CARREÓN-VALENCIA:	Yes.
DR. WARD:	Okay. Tania, you want to do the roll call vote on this? Or were we in the middle of it?
DR. CARREÓN-VALENCIA:	I can read the names again. Okay, so Liz?
DR. WARD:	So, this is for Motion 3 and then we're going to have Motion 4?
DR. CARREÓN-VALENCIA:	Motion 3.
DR. WARD:	Yes.
DR. CARREÓN-VALENCIA:	Sophie?
DR. BALK:	Yes.
DR. CARREÓN-VALENCIA:	John?
DR. COMISKEY:	Yes.
DR. CARREÓN-VALENCIA:	Joanna?
DR. GAITENS:	Yes.
DR. CARREÓN-VALENCIA:	Mariama?
MS. JAMES:	Yes.
DR. CARREÓN-VALENCIA:	Michael? Steven?
DR. LARRAÑAGA:	Michael is yes.
DR. CARREÓN-VALENCIA:	Okay, Michael yes. Steven?
DR. MARKOWITZ:	Yes.
DR. CARREÓN-VALENCIA:	John?
DR. MEYER:	Yes.

DR. CARREÓN-VALENCIA: Debra?
DR. MILEK: Yes.
DR. CARREÓN-VALENCIA: Jason?
DR. OSTROWE: Yes.
DR. CARREÓN-VALENCIA: Okay, the motion is carried.
DR. WARD: Great. So, Steve, would you make Motion 4?
DR. MARKOWITZ: Sure, whenever Geoff is ready.
DR. WARD: Geoff, do you have Motion 4 typed already?
DR. CALVERT: No, but go ahead.
DR. MARKOWITZ: Okay, so the Committee endorses the use of five what are called weight-of-evidence categories—that's straight from our charge—and recommends that these five categories be described in separate sections of the policy and procedures document.
DR. WARD: Or do you mean in all sections or be described consistently, be maintained?
DR. MARKOWITZ: Well, the problem right now is that they combined two of the categories into one section. It's on page 10, number 3. And I don't think we were weighing in, so to speak, on the content of the categories, just that they should be presented as separate categories.
DR. WARD: Sorry, we're really having some internet problems. Tania, can you repeat what you said?
DR. CARREÓN-VALENCIA: I was saying mutually exclusive categories.
DR. MARKOWITZ: Yes, that's fine, that's fine.
DR. CARREÓN-VALENCIA: I'm not trying to guide you anywhere.
DR. MARKOWITZ: No, no, no, if it's clear. Any other suggestions?
DR. WARD: Rather than separate, maybe all? Because I guess the separate sections is a little confusing?
DR. MARKOWITZ: I see.
DR. WARD: Or be maintained in all sections of the document?
DR. CALVERT: As appropriate?

DR. MARKOWITZ: Sure. Hopefully you understand what we mean.

DR. WARD: Right, exactly. Okay, so I'll second Steve's motion.

DR. CARREÓN-VALENCIA: Mariama has a question.

DR. WARD: Oh, sorry, Mariama, go ahead.

MS. JAMES: Yes, I don't know if we can or need to or if so, if yes to either of those, if it's appropriate to do so here. But in consideration of the testimony that we heard today and then residents, personal residents for me, going through some of those autoimmune issues and having a millennial child that's also experiencing some of them and a Gen Z child that may be dealing with some of the reproductive issues, I just wonder if there is a place where it's appropriate and we're allowed to delineate some sort of protections. Because it's 2023, and this is something that goes through 2090, and I just found myself thinking about the quote learned some time in school a million years ago, "What did you create here? We created a republic if you're willing to keep it." And I just have concerns about a time where there will be people who are not willing to keep it, or at least properly, and if there's a way to sort of protect against that, against what's being done here today and what's been done here in the past.

DR. WARD: Yes, I don't think there's a way to address it in the context of this meeting. I think one thing that has been heard I think by the Administrator and the Program staff is numerous recommendations that the STAC be called together again to discuss the new legislation regarding a cohort of people who were exposed as children and young adults. But I don't think we can address it here. I think in the time left, which we're already one minute over time, all we can do is—I mean I think we all feel that we've had a thorough discussion of the P&P and we're in general agreement. I think what we need to do is have a roll call vote on the last motion and then we probably need to move to adjourn

	the meeting or at least—unless there are any further announcements that Tania needs to make. So, Tania, would you like to do the roll call vote?
DR. CARREÓN-VALENCIA:	Yes. So, for this Motion Number 4, please say yea, nay, or abstain. Liz?
DR. WARD:	Yea.
DR. CARREÓN-VALENCIA:	Sophie?
DR. BALK:	Yes.
DR. CARREÓN-VALENCIA:	John?
DR. COMISKEY:	Yea.
DR. CARREÓN-VALENCIA:	Joanna?
DR. GAITENS:	Yea.
DR. CARREÓN-VALENCIA:	Mariama?
MS. JAMES:	Yea.
DR. CARREÓN-VALENCIA:	Michael?
DR. LARRAÑAGA:	Yea.
DR. CARREÓN-VALENCIA:	Steven?
DR. MARKOWITZ:	Yes.
DR. CARREÓN-VALENCIA:	John?
DR. MEYER:	Yes.
DR. CARREÓN-VALENCIA:	Debra?
DR. MILEK:	Yea.
DR. CARREÓN-VALENCIA:	Jason?
DR. OSTROWE:	Yes.
DR. CARREÓN-VALENCIA:	Okay, all ten voting for the motion and it is carried. Thank you.
DR. WARD:	Thank you. So, when I write these up, I will just say that these were the substantive matters that were discussed by the STAC, and we reached consensus on these recommendations—or the four motions carried. And I will transmit those to Dr. Howard by letter. Tania, is there anything else we should discuss in the way of announcements or administrative issues, closing comments?

ADMINISTRATIVE ISSUES AND CLOSING REMARKS

DR. CARREÓN-VALENCIA: I just want to thank you all again for a very productive meeting and for providing your recommendations to the Administrator. I also want to thank of course our Chair for running a very productive and efficient meeting. Thank you so much to Mia Wallace, Doug Daniels, and the members of the Science and the Policy Teams. And there are many other people at NIOSH that work behind the scenes to make this meeting happen, so thank you to all of you.

DR. WARD: Yes, I'd like to add my thanks to everyone on the Committee for their incredibly useful and productive comments. And we're struggling with some tough issues, and I think it's great that we were able to come up with some recommendations that we have very strong generally consensus on. So, I appreciate everyone's input.

DR. LARRAÑAGA: Thank you, Liz. Thank you, Tania.

DR. CARREÓN-VALENCIA: Thank you. So, you're adjourning, Liz?

DR. WARD: I think we can adjourn. Unless anybody has some final words that they'd like to say, I think we can adjourn.

DR. MARKOWITZ: Thank you.

DR. WARD: Okay, thank you. Goodbye.

[Adjourn.]

GLOSSARY

ATSDR	Agency for Toxic Substances and Disease Registry
CCE	Clinical Center of Excellence
CDC	Centers for Disease Control and Prevention
EHC	World Trade Center Environmental Health Center
EIS	Express Scripts, Inc.
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act
IARC	International Agency for Research on Cancer
LHI	Logistics Health, Inc.
MAC	Medically Associated Condition
NIOSH	National Institute for Occupational Safety and Health
NPN	Nationwide Provider Network
NTP	National Toxicology Program
P&P	Policies and Procedures
STAC	Scientific/Technical Advisory Committee
WTC	World Trade Center
WTCHP	World Trade Center Health Program

CERTIFICATION STATEMENT

I hereby certify that, to the best of my knowledge and ability, the foregoing transcript of the February 9, 2023, meeting of the World Trade Center Health Program Scientific/Technical Advisory Committee (STAC) is accurate and complete.

Elizabeth Ward, PhD
Chair, STAC