To start off with this inventory, we use the definition that the program had on 9/11 agent, which basically was a chemical, physical, biological, or other hazards that were reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area or at the Pentagon site or in Shanksville, Pennsylvania. However, we found that this definition was too limited in scope. So we changed the definition, modified it, and updated it.

So again it includes chemical, physical, biological, and other hazards. But those other hazards now include experiences that might cause psychological harm that were not considered before. It includes, of course, peer-reviewed exposure assessments of responders, recovery workers, and survivors, as the study did before. But we expanded it to add those hazards that were not identified in those published, peer-reviewed exposure assessments, but that we could reasonably assume to have been present at any of the three sites. These include environmental risk factors such as heat, cold, solar exposure. If I can have the next slide.

To start off with the inventory, there was a list of agents listed on the first periodic review of cancers. And thus, we reviewed them to make sure that they met our definition and include them on our list. Then we hired a contractor who helped us identify 9/11 agents based on what we had at the time, the original definition of 9/11 agents. So what they did is from the catalog of studies that we had from the program that Travis had put together at that time, the contractor identified any exposure assessment study or report that had agents listed there. And also, the contractor developed and conducted a literature search to fund any additional studies that may identify 9/11 agents. Then the program reviewed the methods and results and provided the contractors that were provided to us, and then we harmonized and corrected results based on the new definition.

So we have, and you are going to see that we have, the list of agents—next to my presentation in your book are those agents that have been identified to date. This inventory is not an in-depth document. It will be updated as additional information of hazards is identified and obtained.

So I'm going to cover the different categories of hazards and how we arrived to each one on the list. If I could have the next slide.

Using those agents that were identified in peer-reviewed literature, we used studies that reported air and settled dust. And for those, our methods include all the data or reports of chemical agents detected or in area dirt samples or settled dust or wipe samples. These samples must have been collected at one of the 9/11 disaster areas during the attack, response, or recovery periods. And we only took studies where the concentration or the amount identified on the sample was equal or greater than the lower limit of detection

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of the sampling and analytical method.

In this group, we excluded several studies that were not independently peer-reviewed or that reported chemicals identified in other studies, so a secondary source of report. And then in those cases, we went back to the original report to get the information first-hand. And we also excluded one study that reported concentrations in water runoff. The particular reason we excluded this study was water collection locations were outside of the 9/11 disaster area, so it was very difficult to ascertain whether those chemicals pertained to the impact or not.

Now we, of course, in every issue, we always come up with uncertainties. So one of the issues is metals. When a chemical had a metal component, but is identified as such—for example, calcium sulfate—then we listed the agent as calcium sulfate. But sometimes there are methods that are destructive, and all that is reported is the metal. So there methods such as ICP plasma analyses that destroys the chemical and all you get is, like, cadmium. But you don't know if it started as a compound or it is just the metal that was found there. So we put on the inventory the information that we had on hand. Unless more information was available, we just listed the metal.

Also, if I can have the next slide, other sorts of studies that were looked at were biological monitoring studies. And for those we took studies that most reported on persons exposed during the impact, response, or recovery periods, and that have an appropriate comparison group that were not exposed during the impacts. The biomarker level in the exposed group must have been significantly higher at the 0.05 level than in the non-exposed group. And whenever possible, we considered the half-life of the chemical agent in this biomarker sample. So for example, a specimen that has a very short biological life that was obtained months after the recovery effort finished would not be considered a result of the exposure. We excluded studies that did not have sufficient information that a chemical was present at the site during the attack, response, and recovery.

Then we come to the other categories. What are those chemicals that reasonably assumed to have been present? For that, we used the best available evidence and professional judgment that was provided by the program site. As such, we included chemical hazards that are typically found at implosion and demolition sites; also those related to fires, those that are found in rescue operations, and at disaster medical assistant team stations. For example, common gases and vapors in fires.

If I can have the next slide, Mia. You will see on your document, this is the table that lists all chemical hazards. I hope you can see it. We list the chemical. We also list the chemical abstract service number, or CAS number; the source of the study where the listing or the studies where the

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agent was; or if it was reasonably assumed to be present, then we say so. And then we know if there are other synonyms to the name of the agent, we put them on the table. So we identified 349 chemical agents present or expected to be present during the attack and recovery effort.

Okay, moving on to physical hazards, if I could have the next slide. So for those that were identified within the peer-review literature, we did not find any exposure assessment studies that identified physical hazards that met the criteria for indication. We then have to assume that they have been present. And we knew, based on reports and what we knew and the knowledge of the people that had been there and their professional judgment, that there were physical agents that people were exposed to. And this includes solar radiation, heat stress conditions, and cold stress conditions; also slip, trip, fall, and noise vibration; and also hazards that are typically found at implosion and demolition sites and also related to fire.

So if I can have the next slide, you can see the table that lists 14 different physical hazards, and these, as it said there, are all reasonably assumed to have been present.

Moving on to biological hazards, again, the literature searches did not produce exposure assessment studies that helped us identify biological hazards that met the criteria for inclusion. So based on the best available evidence, and professional judgment of the program, we concluded that those biological hazards include blood-borne pathogens. One the next slide, you see table three, you see blood-borne pathogens and the reason why they were included.

Moving on to the last category, if I can have the last slide, we have other hazards. So for including those other hazards, the methods we used were related to experiences that might cause psychological harm, and include traumatic and stressful exposures. And those experiences must have been significantly associated at the 0.05 level, with increased risk for a health outcome after adjustment for other mental health exposures. And they have to have been compared with an appropriate control group.

There are a number of exclusions on this category: studies that failed to achieve statistical significance; studies that reported crude, unadjusted analyses—next slide please. Metanalyses and reviews that included only exposures reported in other published papers; and also studies that did not differentiate between individuals who were unexposed to the 9/11 attacks and those exposed.

And a side thing: this is a tricky category because there have been a number of studies that report on the traumatic experiences of people that live in California, Oregon, and other areas just because they still went with something on television. So we excluded all those studies from those reports

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from the inventory.

So in terms of uncertainties, you will see what hazards are listed. But there were certain social support factors, such as lack of family support, that we addressed that are not really related directly to the exposure, but can modify an individual's post-9/11 experience. However, they are not considered psychologically harmful 9/11 experience, and for that reason we excluded them from the inventory.

We only use hazards that were identified on the peer-reviewed literature. There were no other hazards reasonably assumed to have been present that the science team identified. So on the next slide, you will see Table 4, that lists some of the 26 different hazards that we identified, and the sources for that information.

If I can have the final slide—I want to acknowledge the contributors, the people that put together the inventory. Paul Middendorf was the leader on this effort, and was assisted by Geoff Calvert and I. And we also had a great group of contractors that we worked with from ATL and ORAU.

So that's the end of my presentation. I will be happy to take questions.

DR. WARD: Thank you, Tania. This time we will start on this side with Micki.

MS. SIEGEL DE HERNÁNDEZ: Thank you. I have a few questions. What were the additional hazards? I saw duration of work, but shift work is not included, and considering all the work that NIOSH has done about extended shifts and shift work, I would recommend that that be added.

Two, reasonably assume, I would also add to the biological hazards, mold hazards, and can speak specifically to the sites such as the Verizon Building, where literally it was like stalactites and stalagmites because of the water from the fire department to put out the fire that was there. And I wanted to know if you also considered, besides the hazards created by the collapse of the towers, you also have the hazards created by the work that was happening at the site. So I am wondering if you looked at any other occupational hazards, for example, with ironworking, for the ironworkers, that may or may not have been in other peer-reviewed studies.

DR. CARREÓN-VALENCIA: We will look into that. Thank you for that suggestion.

DR. WILKENFELD: Thank you for the presentation.

DR. WARD: A reminder to state your name.

DR. WILKENFELD: I'm Marc Wilkenfeld. I'm curious about the biologic hazards. How should we translate that critically in terms of the conditions that are related to the work? If someone comes in with Hepatitis B—in other words, if you have exposure, it's a broad category, and you have exposure to blood-borne pathogens, which can, theoretically, result in transmission of disease. We have never really thought about that from a clinician point of view. So how do we deal with that?

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Maybe I'm asking the members of the Committee also? And if you're going to list it, right, if you list the carcinogen, then it's logical to assume that if you a see a patient with cancer, then there's a relationship. But if you're listing biological hazards, what should we do if we see someone with a disease that comes from biological hazards, which I haven't seen and also we don't look for it?

So this is my question: you're listing a hazard, but there's no monitoring for it, right?

DR. CARREÓN-VALENCIA: Right.

DR. WILKENFELD: And there's no inclusion of it. So why are you listing it? You're listing it but you're not doing anything about it.

DR. CARREÓN-VALENCIA: We're presuming that people were exposed to it through handling of cadavers.

DR. WILKENFELD: Right. So we're not screening for it, which is probably way too late. We didn't screen for it. So what do we tell a guy who contracted Hepatitis B in 2002 with no other risk factors? And he asks the examining physician whether this could be related to the work that he did after 9/11? And he sees the list of hazards, and it includes biological hazards. there's a gap, is what I'm saying.

DR. CARREÓN-VALENCIA: Right. I don't know.

DR. WILKENFELD: I think the residency director is going to answer me, I think.

DR. HOMISH: If the person has no other risk factors, not just from that time period, but since that time, and I would then ask if there was any breakage of the skin doing work at ground zero, anything that plausibly could have led to absorption of Hepatitis B, and in the absence of that, I wouldn't attribute it, because you have no positive scientific evidence that that exposure circumstance actually does lead to hepatitis B.

I'm in agreement that it's listed in this inventory, because you're better off with a broader inventory than an ostensibly narrow one. But it doesn't meant that that particular agent or any agent here necessarily led to disease at Ground Zero.

DR. WILKENFELD: And I agree with you. So if they did have a break in the skin, they were punctured in some way, there's no mechanism to deal with that in terms of getting the condition covered. I guess it's like a black hole almost. You're exposed to a hazard, but—it's like saying they were exposed to a carcinogen that we know causes a certain cancer, and therefore we're including the cancer. I'm not saying to include it as a covered condition. I'm saying to make a decision one way or the other.

DR. HOMISH: Marc, personally, what I would say is, "maybe, maybe not; let's move forward and see how we could help you."

DR. WARD: Okay, I think Steve is the next person.

DR. MARKOWITZ: Steven Markowitz. Were OSHA measurements included at all in the

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chemical inventory? Some of them may have made it into peer review, but if they didn't, OSHA did a number of measurements down there. I didn't see it in the reference list, so I am just wondering how it was addressed.

DR. CARREÓN-VALENCIA: I think we excluded government reports for that reason, because they were not peer-reviewed. I know there were also other reports that I even called or contacted the main author to determine what level of peer review was there on those documents. And since he couldn't confirm, they were not added to the inventory. But I can certainly check with him on that part.

DR. MARKOWITZ: My guess is that most of the agents that OSHA measured are included in their list, because it's very comprehensive. And I understand the problem of—there were private entities that were doing measurements. And we don't have really good access to the quality assessment of those measures. So I get that.

MS. NORDSTROM: Hi, this is Lila Nordstrom. I have two questions. Well, one observation and one question. My observation about the other hazards section is that it doesn't seem to include any exposure that would have resulted from returning after the attacks to the environment. And I think that for a lot of community members, and I mean responders as well, there were stressors related to the cleanup that wouldn't have necessarily have been present on the day.

And then, I also wanted to know in the list of chemicals, does that include chemical compounds that would have, if two chemicals were present but combined to create a more dangerous chemical, like all of the combinations of chemical compounds included in that list?

DR. CARREÓN-VALENCIA: Well, you mean interactions between agents?

MS. NORDSTROM: Yes.

DR. CARREÓN-VALENCIA: First of all, no. The inventory only lists the agents individually. But I understand your point—the interaction between exposures may cause a higher response. We are just listing the agents right now, and not going beyond that.

MS. NORDSTROM: Okay, thanks.

DR. GULATI: Hi, thank you. This is actually very helpful. This is Mridu Gulati.

I have a couple of questions, probably related to much of the prior conversation. So it's helpful to have a list, although it's also helpful to have context of the list too. I suspect it's more granular than this somewhere else.

So one question I have is—are all the hazards listed here, we should presume that they were all there, or at least one person, that they were exposed at enough of a level to potentially cause disease, or were they just present?

And then my second question is do we have some sense of, or is it needed, that some of these exposures were more prevalent at a specific place and

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time and occupation? Would there need to be any sort of validation? If somebody says, "I'm a survivor, and this is because I'm a first responder." That was my second question.

And then, thirdly, just a comment. I assume for some of the other disease processes, autoimmune diseases, and neurologic diseases, there is obviously a lot of literature on these individual hazards separately. So as we're going through and studying to see if there are associations to the explosion at the World Trade Center, I presume that some of these studies are, some studies external to World Trade Center exposures are also being used and weighted into evidence of figuring out if there are associations with neurologic and autoimmune diseases, if that makes sense.

DR. CARREÓN-VALENCIA: Yes. So let me go back to—actually, can you repeat question one?

DR. GULATI: My first question is are we to presume that each one of these chemical hazards were in a sufficient dosage at some point for somebody to have disease? Or were they just in presence? And if they were, were they present for everybody or only specific populations? And how are you going to determine this?

DR. CARREÓN-VALENCIA: We don't know. But we are assuming that not everybody was exposed to everything. We just know that they were present. So we don't know how much that each person was exposed to individually. We don't know, with certainty, that—well, we know that certain populations must have been exposed more than others to certain agents as opposed to others, but we cannot actually use individual exposures to that one. But we assume that all these agents were present there at some point or another. So that is probably towards your second question.

Yes. They were there in different points in time, probably. They might all have been present, but we don't know. I based them on what is reported in the scientific literature, and we assume that must have been present based on our professional judgment.

DR. WARD: I am wondering as you are trying to explore new disease exposure relationships, if you can't necessarily find it in the cohort itself. If somebody looks at a chemical hazard, one that is listed, and they know that there's an association with dementia or something down the line, how does that become a work-related, exposure-related condition? Because people can just look up a lot, and be like, "Well, I was exposed to this and I looked this up, and now I know I have this disease," even if it's not necessarily a World Trade Center-accepted condition.

DR. CARREÓN-VALENCIA: Well, one of the uses of these inventories, and Jessica is going to talk more about this on the next presentation, but once we do scientific evaluation of the evidence to determining theories on the condition that it could be added to the list of covered conditions. Dr. Howard may determine that there might

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be a high but not substantial evidence. And for that, direct us, the science team to look at what has been published about all these specific agents and health outcomes.

So I believe now we have a list that we can start with, that we can use to look at that information. So that's one of the uses of these inventories.

DR. WARD: David?

MR. NEWMAN: This is David Newman. Thank you for that presentation. This is an area that I have a great and longstanding interest in, professionally and personally. I have a number of comments to make.

I think the most minor one, first; in Table 4, Other Hazards, there is a lack of precision in the terminology. It should not be listed as hazards, or other hazards, at all. It should be listed as Risk Factors for Exposure Scenarios in which you might be exposed to hazards. These are not the hazards themselves. But that's pretty minor, and it's great to see the beginnings of a list like that defined as factors.

The reliance on peer-reviewed and other studies is, of course, absolutely essential for obtaining this information, but it is also, particularly in the context of 9/11 and its aftermath, extremely limited. So I would suggest that you might want to consider to becoming more open to an examination of the data as distinguished from the studies. Not to the exclusion of one or the other, but the addition of data; there are, at a minimum, hundreds of thousands, and that's the low end of the estimate, of sampling results of 9/11 and its aftermath, the vast majority of which are reassuring or non-detect, and a small minority of which are identifying both contaminants of concern, or concentrations of concern.

This latter, smaller body of evidence is the body of evidence that is most consistent with the health outcomes that we are dealing with today. And the larger body of data, which was reassuring at the time, is obviously less relevant in many cases. So I would suggest that a renewed effort to obtain and examine these data would be likely to be at least somewhat helpful in these efforts.

To that end, the organization from which I am retired, the New York Community for Occupational Safety and Health, collected thousands, and maybe tens of thousands of pages of data for either an independent sample of results which the organization hopefully still has, and I'm sure would be glad to make available for examination. The EPA panel for which I served, as did Micki and Catherine, EPA World Trade Center expert technical review panel, had a subgroup which I chaired, called the Subgroup on Other Sources of World Trade Center Data. And our efforts might be of interest to your efforts.

Let me just quote from what we attempted to do, but did not accomplish. The

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objectives were issue number one: the many thousands of results of Lower Manhattan environmental sampling efforts that were conducted by and for private organizations and individuals comprised—this is, by the way, to put it in perspective, May 2004. The many thousands of results of Lower Manhattan environmental sampling efforts that were conducted by and for private organizations and individuals comprised a potentially important part of post-9/11 environmental data, yet have not been collected for public access or scientific evaluation.

Issue number two: the additional thousands of results of environmental sampling efforts conducted in their own quarters by government agencies also comprise a potentially important part of post-9/11 environmental data that had not been collected for public access or scientific evaluation. So our efforts should be made to capture, centralize, and evaluate this data, to make it accessible. And there were reasons for that, which I don't have to go into now.

We propose that EPA, which is the operative organization in this effort, should solicit voluntary submission of the environmental sampling data from building owners, building managers, apartment owners, tenants, tenant organizations, private employers, private sector workers, unions, government agencies, and public sector works and unions.

We also propose that EPA seek the assistance of the following organizations in encouraging their members, clients, or constituencies to voluntarily submit environmental sampling data: insurance companies, AIHA, metro AIHA, ACGIH, laboratories, environmental consultants and cleanup companies, community boards and community organizations, physicians and other healthcare professionals.

And we noted that certain organizations are required by law to share environmental sampling results. These include government agencies subject to the Freedom of Information requests, public and private sector employers upon request by their employees or unions. We propose that such—I won't go into the proposals.

We identify the limitations, the likely limitations of such efforts which, again, were not undertaken. But the limitations, and you note some of them in your presentation. We noted that in most cases, submission of data would be voluntary. If there would be difficulties of outreach; that there may be insurance and liability issues; that in some cases, confidentiality would have be surrendered if data were to be of use; if the quality of data could not be assured in all cases; that the sampling methods varied and results could not always be compared, and there would be project, cost, and staffing issues. Nevertheless, we believe that these data would be relevant and I suggest we recommend and consider some of these efforts.

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Also, I will share this you if you don't have it. But it lists the participants in the panel that I would suggest that you might want to talk to and add on your subgroup. This included folks from the EPA and OSHA in this document. Thank you.

DR. WARD: Thank you. Micki, did you want to speak?

MS. SIEGEL DE HERNÁNDEZ: Micki Siegel de Hernández. So I second what Dave said. There is also publicly available data on both buildings that for whom that data had to be made public, like the Deutsche Bank extensively sampled. And again, many of the contaminants may already be on the lists that you have, but I think it just adds to the body of knowledge.

I also wanted to respond to Mridu's question. One of the things that we do know from looking at lots of sampling data is that it was not homogenous. So not only wasn't every person exposed to every one of those contaminants, but it varied. It varied by location; it varied by the work that people were doing. It varied by people who were outside, inside, there were so many differences. So it is very hard, now, to make any kind of determination. That's why we're in this position.

The one part—two questions that I had: have you looked at any differences between the sites? I know we talk about the World Trade Center site; Pentagon; Shanksville, and there I don't know if there's been any…it wouldn't have been identical… if there's been any separation of data. And the second question is have you also started to talk about your potential uses of this list besides attribution in addition to contaminant attribution for a particular disease?

DR. CARREÓN-VALENCIA: To answer your second question, no. We haven't looked at it other than for petition but, as I was explaining before, in case there was relatively strong but not sufficiently, so that we might review available information, and also to assist in the evaluation of submissions. But in that respect, no, we haven't looked at other potential uses. Now, the inventory is available on our website for anybody to see and use. So we are hoping it can also serve as a resource for researchers.

And your first question?

MS. SIEGEL DE HERNÁNDEZ: I'm sorry, you want me to remember it? Oh, I asked if you had looked at data, separated it out for different sites?

DR. CARREÓN-VALENCIA: For the different sites. No, we didn't. But that is something I can look into.

MS. MCVAY HUGHES: Hi, Catherine McVay Hughes. I'm just following up on Micki and Dave. In terms of the buildings, as Micki says, it's different depending on the location. It was also different depending on what floor you were on, and how far away you were from the site. And it also depended on the size that could get through the window, whether it was closed or open. So I just wanted to emphasize the complexity of it. Thank you.

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DR. DYDEK: Thomas Dydek. When there is such variability, what is sometimes done is to construct a worst-case scenario, and then to compare to worst-case exposure to known levels that would cause various disease states. And it goes back to the question I had addressed this morning about trying to separate out the physical manifestations from the mental. This is a little off the topic of your presentation, but I am wondering if anybody has looked at other very traumatic events? The Las Vegas shooting comes to mind; those people would have suffered the psychological problems without the chemical exposures. And do you know if anybody has looked at that to see what their ongoing health concerns are from Las Vegas versus what we have here?

DR. CARREÓN-VALENCIA: No, I haven't looked at it. But that is certainly something I could look into.

MS. SIEGEL DE HERNÁNDEZ: Can I just make a brief follow-up comment on that just to help out? In part, the 9/11 agent, we dealt with the psychological components of that. The traumas of exposure were not necessarily dust, chemical and others, even though they can have psychological effects themselves. A number of the psychological parameters had to do with traumatic loss; traumatic injury; witnessing horror; traumatic changes in one's business, or home, or community; things like that that went into being a 9/11 agent, as we think of agents, here.

Trying to characterize psychological agents in the way we are used to characterizing chemicals and physical and fibers and things like that, the lexicon doesn't quite work but we try to marry it in this document.

MR. FLAMMIA: Anthony Flammia. I have to support Dave Newman on this for the third one. Of the sources of the World Trade Center data, similar to a data share and fusion center type of network, or an information sharing type network, to share the conditions and everything within one type of data base or a data management system—it's just like 9/11: failure to connect the dots, and that's what was in the 9/11 report. Failure to connect the dots; you read it often in the report. If we don't connect the dots, we're going to have a more of a health crisis and more deaths.

Is there an information share mechanism within the organization?

DR. CARREÓN-VALENCIA: In terms of…

MR. FLAMMIA: Just within the program itself, the World Trade Center monitoring program. Is there an information sharing type network with the World Trade Center Program that shares information similar to what Dave is saying?

DR. WARD: Yes, there is, if I'm understanding you correctly. When it comes to the medical monitoring and claims from healthcare, claims from pharmacy, that information goes into a data center that is managed by cohort, meaning firefighter, general responder, or survivor. So that information is part of what is made available to researchers who then request information in order to refine hypotheses or proposing their funding.

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What this started at, which was the 9/11 agent thing, and do we have a fusion or a centralization of that data? Our program does not, that wasn't really our centralizing function for what we were authorized to do. It doesn't mean we can't think about it, but it just wasn't there.

MR. FLAMMIA: Thank you.

DR. MARKOWITZ: Steven Markowitz. So I'm not going to argue against collecting more exposure data. But I do think some considerable thought should be given to the purpose of collecting additional data, because what we have here is literally hundreds of chemicals that, collectively, if you sort them by class, it could explain most diseases that we know to be related to environmental exposures, whether it is asthma, chronic obstructive pulmonary disease, cancer, neurotoxicity and the like. You can find in this list agents that would cause any of those, and frankly, without knowing the exposure levels, you would be very hard pressed, epidemiologically, to relate these to given outcomes.

So I'm not against collecting more data. But it is going to take considerable effort. And the question is: what's the gain, besides a more comprehensive list? In terms of predicting what might happen to people at or near Ground Zero, that visional thinking should be done before considerable effort is taken to look at private databases and all that.

DR. WARD: Yes, Nicholas.

DR. NEWMAN: I was looking at other hazards. And when you talked about social support factors, like lack of family support, I'm guessing that that is relating to the responders to the 9/11 attacks, and not necessarily the survivors. Because certainly there could be survivors who lost some family support because of the attack, and I don't know how that would be thought about, really. But I just wanted to just clarify if that's really who that was meant for?

DR. CARREÓN-VALENCIA: I don't know but I certainly can look into that. Probably, it meant both. That is possible.

DR. NEWMAN: Okay, that's fine, thanks.

DR. WARD: I just had one comment. There may be a middle ground with respect to how much effort to put into the collecting or centralizing the exposure data. I think it would certainly be good to look at the OSHA data, look at data from a couple of organizations where you have some documentation and the methods that were used. That would seem to be a minimal thing, if you're coming up with a list like this, to expand it a little bit beyond the published literature.

I agree with David to an extent. Maybe not everything that is done may not be super valuable, especially where that data might give some, there might be some quantitative data that might be useful in evaluating particular exposure, like silica for example, where I'm pretty sure OSHA had some quantitative

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data that would be valuable.

DR. CARREÓN-VALENCIA: I get your point.

DR. WARD: Thank you, Tania. So we're ready to move on to our next topic, and we'll be having a presentation from Jessica Bilics, from the World Trade Center Program, on an update on policy and procedures for adding non-cancer conditions.

UPDATE ON POLICY AND PROCEDURES FOR ADDING NON-CANCER CONDITIONS

MS. BILICS: Good afternoon. As we've stated, I'm Jessica Bilics. I'm the policy coordinator and the governmental affairs person for the World Trade Center Health Program.

Let me look at the first slide. So the purpose of me presenting today is to talk through the non-substantive changes that we have made through the policy and procedures for adding non-cancers to the list of World Trade Center-related health conditions.

As I'm sure all of you know this, but just to go over it quickly: here are our definitions of what is a World Trade Center-related health condition. And these were given to us by Congress and then the Zadroga Act. So in essence, it's essentially health conditions, including mental health conditions, for which an individual's 9/11 exposures were substantially likely to be a significant factor in aggravating, contributing, or causing the condition.

This next slide talks about the categories that are covered under the Zadroga Act. So the Zadroga Act gave us a list of conditions to cover, and also gave the administrative authority to add conditions. So the three at the time of passing the Zadroga Act, the three top categories on your slide here, were the ones that Congress included. So the aerodigestive disorders, mental health conditions, and musculoskeletal disorders; however, the third, the musculoskeletal disorders, was only for World Trade Center responders in New York. It was not for survivors and it was not for Pentagon and Shanksville. And that was a Congressional note, that's not a program decision that was in the law.

And I won't read through all these, but this is essentially the list that we have. As we mentioned on the last slide, the administrator was given the authority to add conditions to the list, and has done so by adding cancers and acute traumatic injuries.

So there are two pathways that the administrator can add a health condition to the list of World Trade Center-related health conditions. First, he can do it at his own discretion; and second, through the petition process. And there's been a lot of discussion about that already today.

Of the lists that I showed you on the last slide, there have been two conditions that have been added via the administrator's discretion: the new-onset COPD, and acute traumatic injury. And the cancer was added through

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the petition process back in 2012. Now regardless of which pathway is taken, the process of actually adding a condition has to be done through a rulemaking process.

Just going into the petition process a little bit more; we did create a petition form. It's not required, but it is out there if anybody wants to complete the form, to talk about what condition they want added, and then submit it to the program. I won't focus too much on how we decide on what is a valid petition, but I will go through a couple slides here.

This is a screenshot of our policy that talks through how the program decides what is a valid petition. There are certain things, and we've gone through rulemaking, to communicate what is required in a valid petition. There has to be a clear intent, that the intent is to petition the addition of the condition to the list. There has to the signature by the petitioner, and also they have to state the medical basis for the addition. So basically, connecting the 9/11 exposure to the requested health condition.

We see here on the slide, it gives some examples of how somebody can present that medical basis, and what we would consider valid. We look at peer-reviewed, published, epidemiological studies amongst 9/11 responders and survivors, and we also look at clinical case reports as well. We do receive a lot of submissions that state, "I didn't have this condition before 9/11, I have it now; therefore I think this condition should be added." Such firsthand accounts, anecdotally, though, we do not accept as a valid petition. We would communicate the decision of what is a valid petition to the submitter.

I won't read through all these, but here is a list of all the conditions of the petitions that we have determined are valid, to date. And we have published on all except that last one, which should be out in about a month or so. So this is 23 of, I think, 130 submissions that we have received, have been determined to be valid petitions. There's a lot of overlap in some of those others that were not determined to be valid. We have seen a lot that have reported the same medical basis for autoimmune conditions, for neurology, etc., as well as, like I said, some of the people were just stating, "I didn't have this condition pre-9/11, I have it now; and therefore…" We do not consider that a valid petition.

The next slide here is just a screenshot of our actual policy on how we go through a valid petition to make a decision on whether to add a non-cancer condition. And I believe the last time there was a presentation here, and this is impossible to see—it's even hard to see on my printout, but impossible to see on the screen here—but there is a flowchart in your books, I believe, that talks through this whole process about what can happen once we get it; what happens in the scientific review process; and then all the different functions

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for how the program makes decisions: whether or not to add, whether or not to go to the STAC, etc. That is a good flowchart to refer back to as you go through slides.

So here—this talks about once we've made a decision that there is a valid petition, or the discretion of the administrator wants to go to the science team, we look for a scientific literature review from the science team. And after the scientific literature review in 9/11 populations, so it's looking at scientific studies done on survivors and responders, and then the science team does an evaluation of the science. So they are looking at the science quality evaluation—and this is one of the first changes that was made since the last time you reviewed—is that this used to be called, "Limitations" and we've reclassified it a bit to think of it more broadly as an evaluation instead of a limitation. So in essence, did the study report address the confounding issues and the exposure assessment issues, blinding, etc. And it gives a little list of those there.

The evaluation also looks at the application of the Bradford Hill criteria. And while the Bradford Hill criteria was in the policy that you saw previously, we added the citations and a little bit more explanation of what those criteria were that we look at. So the strength of the association, the precision of the risk estimate, consistency of association, biological gradient, and plausibility and coherence.

And then lastly, the evaluation considers whether or not—like, if a study was just in an FDNY population, does the evidence of that study apply to other responder populations and the survivor populations? So can it be expanded to the population as a whole, the 9/11 population?

So after the science team goes through the review and makes the recommendation to the administrator, there are basically four options. And I will go into more detail about each one.

The first option is the evidence that the science team in their lit review supports a causal association between 9/11 exposures and the requested condition. So in that case, the administrator would propose, through rulemaking, a decision to add the condition to the list. I'll go into that a little bit more here.

So here, the first thing we would do, we'd go through the rulemaking process, is to publish a notice of proposed rulemaking, an NPRM. And that's in the Federal Register, which is the government's newspaper. And once it's published, there is a comment period. And we would have a comment period of at least 45 days. And part of that is because we have, as you can see here, the independent peer-review. That was actually added after the GAO reviewed our addition of cancer, they decided there should be an independent peer review of the process. And so when Congress reauthorized

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the program in late 2015, they required that there was an independent peer review added to the process of adding a health condition. So I will talk about that in a little bit more detail, and I don't know if, Tania, you are going into that more in your next conversation or not.

So the independent peer review process. We have determined that we will look and seek, solicit, recommendations for peer reviewers. While we don't necessarily know the conditions that we may consider in the future, we have an idea of some, so we would seek information from the recommendations from the STAC, from you all, as well as a solicitation in the Federal Register from the public and any other interested parties to give feedback on recommendations for specific peer reviewers.

When a condition is actually going through the rulemaking process, the administrator would have to pick three individuals to be the peer reviewer for the condition and balancing out the expertise, given the specific health condition, whether or not the person has provided peer review service, and any conflict of interest, etc. There is one more slide on this. And so in balancing, if there are any extremes in scientific views between the three reviewers, the administrator would consider that and ensure that any bias in minimized, etc.

Once the three independent peer reviewers are selected, they are given a charge and 30 days to fill the charge. They have to write a report to the administrator, with three questions addressed: is the reviewer aware of any other studies about the condition that should be considered; have the requirements of the program's policy procedures been fulfilled; and has the program's interpretation of the available evidence—is it appropriate, and does it support the conclusion to add the condition?

Those reports would have to go back to the administrator within 30 days, and the program would public those in the docket with the rulemaking docket. And they identified the reviewer, but we don't actually assign the reviewer's name with the specific comments.

So at the same time as the peer review, so the peer review is the first 30 days of the public comment. But the public comment would be at least 45 days. So there's at least 15 days after the peer review process for the public to see what the peer reviewers comments were, consider those if they want to address those in their own comments themselves. So they could address them before the public peer review comment period, or the 15 days after that. And then the program itself, once the comment period has closed, considers all the comments from the peer reviewers, as well as from the public, and considers those in whether or not to add the conditions. So based on the comments themselves, the program would decide whether or not to public a final rule adding the condition, or make a decision that there was insufficient

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evidence at that time.

The second outcome of the scientific evaluation would be what Tania referred to in the last presentation as a "high likelihood." So there's not substantial evidence that the condition is causally associated with 9/11 exposures, but there's a high likelihood. So in this case, the administrator has three options in our policy:

First, they could ask the science team to go into another scientific review of non-9/11 populations. I will go into a little bit on that soon. They could also request a recommendation of the STAC. Or they could publish a Notice of Insufficient Evidence in the Federal Register. If the administrator decides to go to the science team and ask for review of the non-9/11 health studies, you can see here that we have—they look at the studies that are of 9/11 agents, which Tania just spoke about, and compared those to the health conditions. And I won't go through the definition of agents again, but that is the third revision that we made to the policy, was basically tying that definition of 9/11 agents to the newly created inventory of agents.

The body of literature the science team looks at when looking at evidence that is high likelihood but not substantial is other government sources, such as the toxicological profiles from ATSDR, the monographs from the National Toxicology Program, and the human health risk assessments from the EPA. So it is limited to those governmental sources, and I believe it will be open to other governmental sources, but those are the three we have identified at this time.

Basically, this review is searching for whether or not this information fills a gap that was in the review in the 9/11 population research, whether or not it supports or strengthens the information that was found in the 9/11 population, or counters any of the limitations that were identified in the 9/11 population. It also compares the exposures that are talked about in those 9/11 studies to the 9/11 exposures; so the route of the exposure; the intensity, duration, physical form, etc.; and then looks to see if there were any limitations such as is that information inconclusive or outdated.

As I mentioned, if there was a high likelihood, the administrator had three options. One of those other options is going to the STAC. And if the administrator decides that the expertise of the STAC would be helpful in making a decision, he could ask that the STAC consider making a recommendation on whether or not to add the list. The other options are to add the condition, or to publish a Notice of Insufficient Evidence.

I'll just go into the STAC option a little bit more here. If the administrator decides to go to the STAC, he has to make the decision within 90 days of getting a petition. And once the administrator writes, and it would be a letter to the chair, there is 90 days. And he can extend the 90 days that the STAC

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has to make a recommendation up to 180 days. And the STAC has to write a written report to the administrator making a recommendation.

After receiving the recommendation from the STAC, the administrator would then have another 90 days—this is a cumulative, long process—to make a decision on the STAC's recommendation. And one thing to point out, which I don't think is thought of a lot by most people, is that the Zadroga Act, unfortunately prevents us that if we go to the STAC, it no longer gives us the option to publish a notice that there is insufficient evidence. It only gives us two options once you go to the STAC: to add the condition, or to publish an FRN that says there is no causal relationship. It does not give us the authority to publish an insufficient evidence at that time.

So the third option, after the scientific evaluation of the 9/11 population research is that there is insufficient or inadequate evidence at the time of a causal association. So at this time, the administrator would publish a federal register notice citing the reasons why we feel there is insufficient evidence, and that we would consider future research if it becomes available.

And then fourth option is that the evidence is non-causal association. Not that there is some support, but there is so support to add. We have yet to do that. Most of our FRNs have been about the insufficient evidence, if not the adding of the cancer.

So those are the four options, and with each one, there's a lot of little options. And anywhere that there is a point where you could reach the Notice to Propose a Rule linking to add a condition, it reestablishes that rulemaking process. And you can see in the flowchart, we did the stoplight theory where there is red, yellow, and green. And the reds are basically where there is no causal relationship; the yellow is where there is insufficient evidence; and the green is where there is the rulemaking process.

And that's it for today. I am happy to take questions and discussion.

DR. WARD: I just have one clarification question. If something comes to the STAC, you said there is only two options: The Federal Register Notice proposing, and the determination not to add a condition. But if that second condition is made, that would not preclude it from being nominated at a future date, or would it?

MS. BILICS: Our understanding is that that does. There would have to be new evidence, but we couldn't reopen the existing evidence.

DR. WARD: So if there's new evidence, it could be reopened. Whereas, if it were considered insufficient evidence, you could reopen it at any—without new evidence, you would look at it.

MS. BILICS: You could, yes.

DR. WARD: But you probably wouldn't. I would, eventually.

But I guess what I'm saying is it doesn't—bringing to the STAC and coming up ultimately with the conclusion that it is not going to be a covered condition

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at that time does not preclude reconsideration if there is additional evidence.

MS. BILICS: Yes. It's just a higher bar to come over the next time with the evidence.

DR. WILKENFELD: It would have to be pretty substantial, because you're making a public spectacle of what is normally a scientific discussion within the program. So you would be making everything public. So it would have to be a pretty substantial study that would suddenly appear, that we would know nothing about, ahead of time.

It's certainly possible, but it's not probable. And the issue is you're making a big public record that you're going to have to reverse yourself on.

DR. WARD: And I just wanted to clarify that because I think that's the first time I have heard that particular nuance in the process.

DR. WILKENFELD: As you know, in your tour of tours in cancer, we had you as the chair to help us through that process. So in some of these other conditions, which are different than cancer, it's a little different situation.

DR. WARD: Catherine?

MS. MCVAY HUGHES: Looking at the very large flowchart here on page 133, in the best case scenario, what is the shortest amount of time for the process to go through?

MS. BILICS: So the shortest amount of time is if we get a petition that has clear medical basis, and it quickly goes to the science team. That could happen in the matter of a week or two. And then I would say, 90 days from when we got the petition, to publishing an NPRM, would be the fastest it could happen. And then the comment period, 45 days, and then the time it takes to write the final rule or the decision not to publish a final rule. So I guess that's probably about six months would be the shortest period of time.

DR. WARD: Steve?

DR. MARKOWITZ: Steven Markowitz. So getting back to this issue; it's a huge disincentive to refer an issue to the STAC because the outcomes are quite limited, right? Is that the intent by the law, or is that –

MS. BILICS: That is the Zadroga Act. So that is not a public program decision.

DR. MARKOWITZ: I just have a question about when you decide to look at non-9/11 scientific evidence, and you are restricted to the scientific evidence published by the US government. Does that mean that research that is conducted by university scientists that is published in peer-reviewed literature, that is not the government, that you don't look at that literature?

MS. BILICS: I will defer to Tania, because she is more the expert on that.

DR. CARREÓN-VALENCIA: Well, yes we do go through those documents. As you know, we only have 90 days from the receiving of the petition to coming to that. So we really have to look at all these 200-something agents and at outcomes. So these sources, authoritative sources, summarize available evidence. So it comes from universities, and public research.

DR. WARD: I will say, when this particular issue has been discussed at STAC meetings in

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the past, we have raised some concerns about it only because many of these government documents may be outdated, or the government may not have chosen to review a particular substance. And frequently, if we're looking at a particular condition, you could narrow it down to maybe five or ten suspect substances and do the more traditional thing, which would be to do a PubMed search and look for the most highly relevant literature.
And you know, we've debated this at length. I just wanted, especially for new STAC members, to say this issue has been discussed before and there are some different—NIOSH has made the decision of how it will proceed, but there were some concerns. And I think some of those concerns, we could probably raise them again because from a scientific point of view, they are concerning. But we understand that the program has certain limitations.

MS. BILICS: Thank you.

DR. WARD: Anthony?

MR. FLAMMIA: Yes, hi. Anthony Flammia. Could you tell me what the gist of who puts in these petitions?

MS. BILICS: Most of the submissions that we see from are coming from members themselves; people who were exposed either as a responder or a survivor and have the condition themselves and are asking for it to be covered. We have seen—the cancer one came from the New York delegation. That was from nine members of the New York Congressmen and the two Senators from New York. The prostate cancer came from one of the NYPD union groups, and the Patrolmen's Benevolent Association. We have seen attorneys. But it is mostly from members themselves that have it.

MR. FLAMMIA: Thank you very much.

DR. WARD: Lila.

MS. NORDSTROM: Lila Nordstrom. I have two quick questions. One is—is there any way for a petition to be under serious consideration without there having been any research on a 9/11 closed population? Let's say something that's a known effect of a certain kind of exposure that we know people have experienced at the World Trade Center, but it has not been researched on World Trade Center-exposed populations? Because it looks like in order for the petition to get started, there has to be research done on the 9/11 exposed populations.

MS. BILICS: So it could be called a valid petition if the research isn't in the 9/11 population. So if one of the 9/11 agents that's in the inventory is provided as medical basis to the health condition itself, and we have seen that with manganese and Parkinson's, it was not in the 9/11 population. So it could be determined a valid petition, but the first step once it is determined a valid petition is looking in the 9/11 population. So if there isn't any evidence in the 9/11 population there would not be sufficient evidence to add it.

MS. NORDSTROM: Even if it is in a population that has not really had any research done on it

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within the 9/11 population.

MS. BILICS: That is the correct policy, yes.

MS. NORDSTROM: That seems problematic. Okay, one more question. Have you received any—you said you get a lot of submission from people that are in the program that want their condition to be considered. Is there a way, if you get a lot of "illegitimate" petitions for one particular condition, does that trigger any response if there is a trend among the "illegitimate" petitions just because it's people reporting some sort of illness?

MS. BILICS: It doesn't unless there is some sort of scientific medical basis to make it a valid petition.

DR. WARD: Any other questions or comments for Jessica? Should we take an early break? Okay, so we will go ahead and take our break 15 minutes early. It's now about 2:30, so we'll come back at 2:45.

[Break.]

PEER REVIEW UPDATE AND DISCUSSION

DR. WARD: So our next presenter is Tania, who will be updating us on peer review.

DR. CARREÓN-VALENCIA: Thank you. So, and we have been discussing what Jessica presented before issuing a final rule, if there is evidence that support a causal association for adding a condition to the list of current conditions. Then the Program issues a Notice of Proposed Rule Making, and then we have independent peer review. So the peer review needs (inaudible @ 00:22:30) to review the evidence that is put forward by the science people.

And so one of the projects for the STAC is to develop a pool of potential peer reviewers. And so one way our program does that one, by requesting recommendations from the STAC, and also publishing a solicitation in the Federal Register.

So we published our last solicitation for peer reviewers in 2017. So I think it's probably time to publish a new solicitation for peer reviewers. This solicitation was promoted on our program's website, on NIOSH eNews, it was taken to the steering committees, both responder and survivors, and we also discussed this with you at the last meeting. So you, the STAC, didn't give us names of potential peer reviewers, but you suggested us to contact journal editors and to share the notification or the solicitation letter and ask them if they could share it with their peer reviewers, and so we did, but it has been a challenge.

I have—granted, I did this not that long ago—but I haven't received too many responses from journal editors, although a few of them have recommended peer reviewers. I talked to you before on that email in preparation for this meeting.

We, the Program, would appreciate receiving comments and suggestions for peer reviewers, so if you have any, please bring them to me or send them in

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G L O S S A R Y

ATSDR	Agency for Toxic Substances and Disease Registry
CCE	Clinical Center of Excellence
CDC	United States Centers for Disease Control and Prevention
CDC-INFO	Centers for Disease Control and Prevention National Contact Center (1-800-CDC-INFO)
CME	Continuing Medical Education
CUNY	City University of New York
DOE	Department of Energy
DOL	Department of Labor
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
EPA	Environmental Protection Agency
ERHMS	Emergency Responder Health Management System
FDNY	Fire Department, City of New York
FEMA	Federal Emergency Management Agency
GERD	Gastroesophageal Reflux Disease
HHC	New York City Health and Hospitals Corporation
IRB	Institutional Review Board
LHI	Logistics Health Incorporated
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIMS	National Incident Management Systems
NIOSH	National Institute for Occupational Safety and Health
NPN	Nationwide Provider Network
NYPD	New York Police Department
ODAR	Office of Disability Adjudication and Review
PTSD	Post-Traumatic Stress Disorder
SSC	Survivor Steering Committee
STAC	Scientific/Technical Advisory Committee
SUNY	State University of New York
VCF	Victim Compensation Fund
WTC	World Trade Center
WTCHP	World Trade Center Health Program

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