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PEASE COMMUNITY ASSISTANCE PANEL (CAP) MEETING

October 26, 2023

The verbatim transcript of the Meeting of the Pease Community Assistance Panel held virtually on October 26, 2023.

C O N T E N T S

October 26, 2023

P A R T I C I P A N T S

(Alphabetically)

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BARRETT, TYRA, ATSDR

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DILLS, KIM, NCEH/ATSDR

DIPENTIMA, RICH, CAP MEMBER

FERRARI, MATTHEW, USAF

MCLLELAN, TONI, CAP MEMBER

MCQUILLEN, BILL, CAP MEMBER

MUGFORD, CHRISTOPHER, ATSDR

PAVUK, MARIAN, ATSDR

REH, CHRISTOPHER, ATSDR

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SHAHEEN, JARED, CAP MEMBER

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SULLIVAN, MARK, CAP MEMBER

WEEMS, MEGHAN, ATSDR

WYTON, PAM, NCEH/ATSDR

P R O C E E D I N G S

(6:00 p.m.)

WELCOME AND INTRODUCTIONS

MS. WYTON: Okay.

MS. BARRETT: Awesome. Thanks, Pam. Hi, everyone. My name is Tyra Barrett, and I'm here from ATSDR. Thank you for all of us who were able to join this evening to meet with the Pease CAP members. I first want to go ahead and do a roll call for Pease CAP members. And so, when I call your name, just let me know if you're present and on the line. First, I'm going to go with Miss Andrea Amico?

MS. AMICO: Hi, I'm here.

MS. BARRETT: All right. Thanks, Andrea. Next, Elizabeth Shaheen? Next, Toni McLellan?

MS. MCLELLAN: I am here and on the line.

MS. BARRETT: Thank you, ma'am. Next, Bill McQuillen?

MR. MCQUILLEN: Hello.

MS. BARRETT: Hi. Good to see you.

MR. MCQUILLEN: Present. Likewise.

MS. BARRETT: Karen Anderson? Courtney Kerrigan? Michelle Dalton? Alana Davis? Rich DiPentima? I'm going to get a right one time. I'm going to get it right one time.

MR. DIPENTIMA: Here, DiPentima.

MS. BARRETT: DiPentima, okay. Got it. Thank you, sir. Lieutenant Colonel Matthew Ferrari?

LT. COL. FERRARI: Yes. I'm here.

MS. BARRETT: Thank you. Martha Fuller Clark? John Durant just emailed me and said that he had a last-minute emergency. So, he won't be able to join us. Laurel Schaider? Joe Ryan? Jared Shaheen, sorry.

MR. SHAHEEN: Here.

MS. BARRETT: Thank you.

DR. REH: Tyra, did you catch that Laurel's on?

MS. BARRETT: I didn't catch her.

DR. REH: Yeah, she's on.

MS. BARRETT: Must have just -- okay, she just joined. Okay. Good to see you.

DR. SCHAIDER: Hi. Good to see you.

MS. BARRETT: Mark Sullivan? I know -- I think I saw him. I think he might have stepped away, and Shelly Vetter also just emailed me and let me know she wouldn't be able to make it. So, I'm going to go ahead -- did I miss anybody from our CAP? And I see Patrick Carroll on from -- I see Patrick Carroll on, if you just want to give a mic check, say hi.

MR. CARROLL: Good evening. Thanks for having me.

MS. BARRETT: Yeah, no problem. Thanks for you to be -- good for you to be here. So, now I'm going to go down our list of ATSDR folks. First on my list, I'm seeing Chris Reh?

DR. REH: Here.

MS. BARRETT: Next, I see Captain Tarah Somers? Hi, Tarah. I see Dr. Marian Pavuk.

DR. PAVUK: Hello.

MS. BARRETT: I see Meghan Weems.

MS. WEEMS: Good evening, everyone.

MS. BARRETT: Evening. And I see Chris Mugford.

LCDR MUGFORD: Present. Good evening.

MS. BARRETT: Good evening. Is there -- and last but not least, I would be very remiss to not give a shout out to Pam Wyton. She is like the magic behind everything. She is our NCEH/ATSDR folks, so thank you, Pam, today for facilitating, helping with our logistics today.

MS. WYTON: Hi, everyone. Happy to help, Tyra. Thank you.

MS. BARRETT: No problem. And is there anyone I may have missed?

MS. DILLS: Hi, Tyra. It's Kim Dills from policy.

MS. BARRETT: Hi, [inaudible] you Kim. Hi, Kim. Good to see you. Good to hear you. Okay. Without further ado, I'm going to go ahead and get started with our Pease study update. [Inaudible] Oh, yes?

MS. AMICO: Sorry, Elizabeth McKenna from Senator Shaheen's office is trying to get in and she's having trouble. So, they can resend her the link?

MS. BARRETT: Yeah. Sure. No problem.

MS. AMICO: Thanks.

MS. WYTON: I'm sorry, what was the name?

MS. AMICO: Elizabeth McKenna from--

MS. WYTON: Okay. Thank you.

MS. BARRETT: Thanks, Andrea. Next, let me go ahead and let Marian give an update.

PEASE STUDY UPDATES

DR. PAVUK: Hello. Good evening, everyone, I hope that she's able to get in quickly. For-- For those of you that haven't been on some of our recent calls, I'll just provide a little bit of a summary and update going further back than we usually do so that everybody's kind of in the picture. As you -- or as most of you know, [inaudible] study has been part of the multisite study project, some 8,000 health outcome was our first site. Also, people called it a pilot site or proof of concept site. But nevertheless, it was the first site where they use the protocol tools and information to use the protocol and other instruments that would later be used in the multisite study. And also, the plan for the Pease site is that the Pease data will be aggregated with the multisite study. So, multisite has seven additional sites. The goal, similarly, like for Pease, will still enroll around 1,000 adults and to aggregate it then together. So, we got through the approvals and other things in 2018-19. And study enrollment started 2019, was interrupted in March 2020 by COVID, and restarted again in October, November, I believe. And then the enrollment ended in December, the end of December 2021. So, we spend quite a bit of time at the beginning of the study preparing the office and contractor and associates' training and being able to perform the tasks on the study related to data collection, primary data collection, and enrollment of participants. And those was -- that was very beneficial. Then later, as we were able to award the contract for the support of [inaudible] study, our operating manuals, procedures, and training were very beneficial so that they

already knew what to do. So, then it take us some time from the end of enrollment at the end of '21. We had worked -- we have worked with [inaudible] on preparing the data and finishing the analysis. Of course, finishing analysis of the samples, reporting the PFAS results and clinical results to participants, I think that it was all completed sometimes about March, April 2022. And that contract then ended in August 2022. And by that time, we were able -- although in retrospect more time wouldn't have been needed probably, but we were able to put the dataset together and prepare a version, a draft of study report. So, here, I'm catching up kind of with the update, as we have talked about it over the last couple calls. There is a Pease study report at that time was prepared and sent for external peer review in November 2022. And we have received comments, I believe, in February '23. And that report -- I think just to get kind of the terminology right, at the beginning, the report was called something like final report. It is not a final report. It's a Pease study report. It was something that we had available at the time, and we thought that this would be available sooner. That we could provide this community with something that could be cleared before our analysis of health outcomes with PFAS is completed. So, the report that I refer to, that includes study demographics as -- describes the cohort, kind of how we collected it. It also provides some data on the order consumptions, as this is -- well, it was the main pathway of exposure to be straightforward. Then it provides tables and figures that describe PFAS concentration. In this cohort, we managed to enroll and get blood in PFAS, analyzing 776 adults and 180 children. So, it includes that and comparisons with [inaudible] 2017 and '18 and a little bit of comparisons also to the New Hampshire biomonitoring program results. And then it also includes just general descriptions of the outcomes that were reported, self-reported by the participants, and also those reported by healthcare providers on the same participants. So, that's what's in this report. The report doesn't include the analysis, statistical analysis of health outcomes that PFAS. So, the report went through the preclearance and then entered the clearance proper ATSDR, went through the whole [inaudible] in ADS, and cleared the OPE Office of, I keep forgetting, Performance Evaluation and -- Policy -- Performance.

DR. REH: Policy, it's our policy.

DR. PAVUK: Policy, yeah, yeah, policy the first time. Thank you, Chris.

DR. REH: [Inaudible] got you.

DR. PAVUK: And so, we're getting closer, so it still needs to clear Office of Science. One, first [inaudible] is Office of Science too, and then that will be the end of the clearance. The report, the plan to release the report, the report to be released to be on our website has to go through File A compliance and some communication clearance before it can be put on. So, this is happening in the horizon, and this is, you know, getting closer, I would say. And so, we were also asked to prepare presentation slides to accompany the report so that we can have a call and kind of go over, you know, what is in the report, to show you some slides when the report is released. So, they'll be, you know, in contact over that as this developed and then, you know, this is clear, then we'll be able to, you know, try scheduling those things. Did you want to on this, Chris?

DR. REH: Other than we're getting -- you know, we're excited, we're getting close to the end to where we can share the data and share the information. And you know, we need to start thinking about when to schedule that CAP meeting where we go through the results and the findings and give you guys time to react and ask questions. But we're super excited to be getting closer every day to the end.

DR. PAVUK: So, I do understand that. Miss Andrea and other members of CAP, you know, that is something -- you know, it's not necessarily new to you. You already know where the kind of your exposure is, and you are really anxious to see us moving on the analysis of health outcomes, and that is ongoing. All right? So, I'm going to kind of describe a little bit the steps that we are taking and where we are on that part. As I mentioned, we did receive the dataset last year in September from [inaudible]. We tried to work with them, you know, to create the variables that will be used in the analysis. But as happens with a complex study design like this, you know, we're still in data management phase. You really discover what shape the variables are in when you start the analysis. So, we studied -- we started the analysis, and using the variables and a lot of times you have to go back and correct and fix some of the coding that has been done or any errors that came up or simply change the variables, because they're not -- what was prepared is not something that is useful or usable for us. So, we're spending quite a bit of time on that. We have discovered some of the LabCorp variables that were complicated [inaudible] provided from LabCorp, and kind of you don't get one results [inaudible]. They kind of make

like two or three rounds for different things. Like, you know, the [inaudible] hormones are related, all of those, basically. They do not do one run, but they do three. So, there has to be some calculations performed, and after which, we discovered we were incorrect. So, we're working on that, fixing it. And of course, part of that [inaudible] I've been using this dataset is did they [inaudible] on multisite? Right? So, the same coding was used in multisite. So, figuring out what the issue was and how to resolve the problem will also help us to resolve the same issue on the multisite faster. So, nevertheless, there are still parts of the data that we are -- still have to work on. So, this will take some time. We did manage to fix part of that so that we can all go on, but there's more variables that we would like to get. But there's also steps to be taken on medications, steps to be taken on occupational history, but don't necessarily use those [inaudible]. We did some medications that we were doing for like lipids and [inaudible], but the whole area is a very, very large section, very complicated part. So, the steps that were done there were correct. There just needs to be two more steps to make it useful for us. So, that's one part. And then the other part, we, of course, have a plan of -- we had broad analytical plan, fairly detailed in protocol. So, we have revisited, and as you may have heard on my previous updates, that I have approached the management with providing additional resources and support. And I'm happy to report it and did have -- we did receive generously time and effort for our senior statistician, you know, at the division and another experienced person that can help us with the slides and with some other communication things. So, we have started working more closely a few weeks back as we got back from the OPI call, and I'll describe a little bit later during the multisite update. And so, Michael was not involved in Pease, so he had to be kind of reintroduced to the dataset and what would have been done and what we were developing, you know, more detailed plan of what we want to tackle. So, the first part really is the, you know, self-reported health outcomes and provider reported outcomes, self-reported via [inaudible]. And kind of evaluating the models that we preconceived earlier and seeing like how the data really lines up. So, we look at a number of things, linear logistic regression and [inaudible] quadratic forms, [inaudible] that Frank put in, and then progressive restrictive cubic splines, which at the end turn out to be something that really describes the data in form of PFAS, that kind of exposure response association that we are most likely going to use. We're also -- so as I said, we went through the first set of those models using basic, you know, adjustments that seem to be -- that seem to be working okay. There's age, sex, and family history, but we

did manage to fix that part. And of course, you know, there's a lot of confounders for each. Child outcomes, you need to have a separate set. So, our next steps are -- for me, we are reviewing the -- we have a lot of reviewing those results. And we some signals, and we'll be grouping those and then kind of expanding on and going in more detail when we do see the results at Pease. So, this is the first phase, then the other phases are the clinical tests and biomarkers that can complement the self-report. Right? So, if we talk about hypertension, we want to also use blood pressure measurements. Right? When we talk about heart disease, we want to use the lipid profiles, right, that we have to support as lipids are a risk factor for heart disease. For diabetes, we have number of glycemic parameters, glucose, insulin, glycated hemoglobin, that can build a case that, you know, the people report, but if you give the measurements for everyone. Right? So, a species is not a very large sample, obviously, to things like heart disease, diabetes, or the [inaudible] numbers. Right?? But for -- like what I actually mentioned last time, for less prevalent diseases, the numbers are smaller for kidney or liver, you know. Or even thyroid disease I think is sufficient for this one. But like kidney and the liver, I mean, in 800 adults, you wouldn't expect to have large numbers. And as most of you remember, those that are smaller, hence the aggregation of data from Pease and also in other sites to be able to have larger sufficient numbers in the multi-site study analysis. So, really, our focus will be on those that we can do here, right, and then addressing the others and just to illustrate the scope. Right? There are 50 self-reported diseases for kids and adults. There's 100 clinical test biomarkers and then for continuous, but then they -- you have to have them for clinical cut points. So, that goes to, you know, 170. So, we're like looking at over 200, you know, outcomes that we want to go through and then kind of [inaudible] it out for some meaningful, you know, presentations that we can do. And then it gets me to the point, why are you doing this? Right? The ATSDR policy on PFAS or practice [inaudible] policy practice has been to release the data to community first before, you know, writing manuscripts or presenting the scientific meanings. So, that is the goal of our health care -- our health outcome analysis at this point, is to prepare the results for that community meeting and to present the results to the community first. So, I think that's what I had in my notes here for the piece. So, I'm happy to open it up for questions.

MS. AMICO: [Inaudible] Yes. Thank you very much for this update. I appreciate you, you know, going through all of this. It just seems like not much has changed, though, since we met in June. And we had a CAP call in June, and it was my understanding that

the first part of this report was going to be available, you know, in the fall for our community. And you were planning, you know, to release this information and it seems like the issue is, it's still in clearance. Am I understanding that?

DR. PAVUK: Correct. I mean, since we met there, I mean, we have received, you know, four sets of comments with, you know, 36 comments with about 70 questions in them that we have addressed in the preclearance process. Then we have received additional 47 comments for an Associate Director of Science, with additional 30 questions inside embedded. So, we have done, you know, very extensive responses to the process. And this is the process that we have. The report has the same results and conclusion as it had in June. But I am on seven sets of -- this is the seventh set of responses that we've been -- we've been answering or responding to.

MS. AMICO: And who are asking -- who are these comments coming from? Is it within ATSDR?

DR. PAVUK: Correct. Right. So, [inaudible]--

MS. AMICO: Your own agency [inaudible]--

DR. PAVUK: So, first set -- let me explain. So, first set, since this was externally peer reviewed, right, so we have received, you know, 30 pages -- 20 pages of external peer reviewers comments. Right?

MS. AMICO: And was that--

DR. PAVUK: Pardon me?

MS. AMICO: When was that?

DR. PAVUK: So, that was in February. So, we received those in February, and we have revised the report following those comments and provided, you know, detailed responses. We are required to respond to every single comment or insinuation that they make. So, you know, there's 35-page document with just responses to external peer reviewers, and we have revised the report. For example, they wanted to see the exposed and small unexposed group that we enrolled separately instead of being together. That was their kind of one overarching comment that we change the tables there and, you know, presented different figures for enhanced comparisons. Right? So, then the preclearance process started. And you know, we have our set chain of people through the division director that provide comments and check like whether our responses to external peer

reviews are appropriate. Right? So, once we responded, that's when it advanced to preclearance in May.

MS. AMICO: Okay.

DR. PAVUK: And they get us back on those, as I said, the four sets of comments through the office division director. Right? So, that was four people there that provided additional comments on top of the comments from the external peer review. Right? So, then, you know, that went to actual proper -- clearance proper. Right? And there were additional comments from division director and additional comments from Associate Director of Science, as I said in September and October.

MS. AMICO: Okay. But do I understand you correctly, that it's gone through seven rounds internally?

DR. PAVUK: Correct.

MS. AMICO: So, ATSDR internally needs to -- is that normal for a document to go through seven rounds after it's gone through external peer review and then--

DR. PAVUK: Yeah.

MS. AMICO: Like that -- I don't know. That seems like a lot.

DR. PAVUK: Yeah. That's the process that they came up with, and you know, we are -- I mean, me personally, have been critical, you know, and not happy about the system. But that's what we are stuck here. I mean, this is very simple exposure report, basically. Right? So, that's why we were hoping that this would be released rather quickly. Right? So--

MS. AMICO: I think the community was hoping that too, and I think we -- I mean, I -- and I worry if it takes this long for a simple exposure report, how long [inaudible] a data -- now like the other report that you're talking that has all the--

DR. PAVUK: Will be really complicated, yeah.

MS. AMICO: Much more complicated. So, I mean, realistically, what can our community expect in terms of getting actual results from ATSDR? I mean, we're almost two years after data collection stopped in our community, and we still don't have the simple report, even though we were told multiple times, like it's coming. It's getting through clearance. It's coming. It's coming. We--

DR. PAVUK: Again, as I said, we only got the data and working on the data. You don't get the data when the enrollment ends.

Right? I mean, so you have to understand that that part, you know, is not the line in the sand. Like, oh, you ended at enrollment. Right? I mean, it did take another nine months just to get the first complete dataset prepared. Right? So, I would suggest that you start at that point, right, when we actually received all the PFAS result, clinical results, [inaudible] results, and the dataset, and that was in September 2022. It was not at December '21. Right?

MS. AMICO: Okay.

DR. PAVUK: So, we couldn't start work on this in December. It's not like we didn't work on it. I mean, that's how long it takes to prepare the dataset and get -- I mean, the dataset has 4,500 variables. So, it's not like we were just idling here. You know?

MS. AMICO: Sure. I guess what I -- what we've been asking this whole time and -- is can you give us some timelines? And I feel like every time we get a timeline, it keeps moving on us, and I respect that these things take time. I understand that. But you know, for the simple report that you're talking about, I don't quite understand why.

DR. PAVUK: I understand. I agree with you. I agree with you.

DR. REH: So, you know, we don't make up the process. The process is put on us by the Office of Science and CDC and our Office of Science and our CIO. And there's different parts to the clearance process, and the whole process is designed to ensure scientific integrity and that what the data show and what the analyses show are aligned, and this takes time. At times, it does take multiple rounds of review. We do our -- you know, it doesn't sit around. We do our best to keep it moving and to keep working on it. So, and we'll still continue to do that. We track it at different levels of the process. What would be helpful here, Andrea? Would you like to see a timeline of how the review process works? What would be helpful?

MS. AMICO: Yeah. I don't -- I think it might be helpful if -- you know, I don't know, I think, yeah, definitely understanding your timeline better and understanding the process better. You know, a while ago, you guys did away with our monthly CAP calls because you said, you know, we're busy. We're doing data analysis. There's not a lot to report out to you. Maybe we need to go back to having monthly calls so you can keep us informed as to where we're at in this process when we have these large gaps of time in between meeting with you. You know, here I was thinking all summer, like you guys are working on this report, and we're going to have a community meeting. You guys said you

would come up in person and give us a community meeting this fall. And then it took a lot of prodding to even get this meeting scheduled. And then we get it scheduled, and I can respect that there's things internally on your end, Marian. Seven rounds of comments, like you've been working on that. From my perspective, though, it's just like, here we are meeting again. And it's just like, oh, it's still in clearance. It's still in clearance. So, yeah, I think definitely having better transparency, from all of you about where this is at and all the hoops that you're having to jump through, because it is frustrating on the community side of things. You know? We're not researchers. We're not scientists, but we are people who dedicated our time and gave our blood, and we're exposed to chemicals, you know, unbeknownst to us and want help and want answers and have been leaning on your agency to help provide us those answers. And you know, frankly, we don't have any yet. And we just keep being told -- like you keep kicking the can down the road. And you know, I have people coming to me in my community saying, gee, my kids have high cholesterol. Gee, my kids have testosterone levels that are really high. Like what does this mean? Are other people seeing this? Like what are we supposed to do with this information? And you guys have just been radio silent for a really long time. You know? Like there's just been not a lot of engagement with our community to update us, to give us any information. And that's why we started working with you all in the first place. So, I absolutely think we need to get back to more frequent communication with you. We need more transparency on your timelines. And frankly, I just -- this clearance process just seems -- you know, it just seemed really excessive and long. And I just don't know if there's anything -- you know, Chris, you're like, this is just the process. Well, how do we change this process? How do we speed this up? Because--

DR. REH: It's -- if I -- it's an administrative process that's part of where we work. It's not something that was just put in place for this study. It's for everything that we do, and I -- there -- and I'm going to draw a line on opening up our administrative processes to the CAP. We'll tell you about them. We'll explain them. I hear your comments. But I -- you know, these are processes that we don't just make up, and they've been in place for years. So--

MS. AMICO: But you know--

DR.REH: I -- [Inaudible] we're not -- we haven't been just sitting on the report and waiting for things to happen. We are working hard to get it moving, but we also have other things

that we do too. So, it's -- I hear your points, and I get them, but the process is the process.

MS. AMICO: Sure. Chris, do you think it's acceptable that our community has not received any report from ATSDR in almost two years since data collection stopped? Do you think that it's been an acceptable -- you know, are we being [inaudible]--

DR. REH: Well, it -- I'm not going to answer that, but it's -- I -- we try to get it out as quick as possible. But as soon -- as Marian rightly pointed out, as soon as data collection stops it -- there -- it -- you know, it doesn't mean we have the data and it's in a form that we can start writing a report. The samples have to be analyzed. We have to get the report. We have to clean the data. There's a lot of steps in there.

DR. PAVUK: So, Andrea, I mean, you remember there was like a report on private [inaudible]? Right? You know, when we still had the in-person, you know, meetings and before we started -- or once we started, you know, the Pease Health Study. Right? I mean -- and I think that report took like, probably like two years. Right? You know? So, I think that you are aware on like how this was set up. Right? I mean, that we do have this issue with how this clearance is implemented. Right? And I've been [Inaudible] -- I've been bringing this up to -- this is my fifth director. Right? And I mean, with each director, you know, we're trying to bring it up and try to change or at least modify the process. Right? I've been on the receiving end of this. Right? Like each of my papers took about average clearance was 11 to 13 months. Right? So, that is bad for me and my partners and coauthors, right, to go through. Right? And the last time, when Dr. Breysse came and got Dr. John Decker in charge of the process, and the process was kind of revised, right, and the implementations of parts of it has changed. Right? But then then came the COVID and PFAS, and you know, there's litigations and other things, you know, that made the CDC kind of really trying to check everything and not being able to release the stuff. Right? So, I mean, you've seen it with COVID research. Right? Everybody else got their numbers out before we got the numbers out. Right? So, they have put, again, a new review process. I mean, they are working on it, the CDC, moving forward things, and there's a lot of that on the CDC website. But guess who's in charge of that process?

DR. REH: You know, we're -- Marian, we're going down a rabbit hole here talking about COVID and all of that. So--

MS. AMICO: I guess, I appreciate this is a process. I appreciate these things take time. I think my frustration is it's not been

very clear. I mean, I thought when we met in June, that we were going to have this information this fall. Okay? And we don't, and I recall from a -- from earlier in the year, we were initially going to maybe have this information in July. So, it seems like the goalposts keep moving. So, I'm--

DR. PAVUK: No, we've said it will be in clearance in July, as we are providing updates to DOD and others. And it is -- I mean, it is with Office of Science, one and two, which should be the last step of this review. You know?

DR. REH: It's nearing the end. Yeah.

DR. PAVUK: So, I don't know like how extensive or excessive their comments are going to be, but it is the last steps. So, hopefully, you know, we are -- I mean, we may -- I'm hopeful that we may be getting this done in November. You know?

MS. AMICO: Okay. So, can I back up for a second? Did you say that DOD is reviewing this?

DR. PAVUK: No. We are saying [inaudible] to DOD, so I remember, you know--

DR. REH: DOD is the quarterly [inaudible].

DR. PAVUK: So, that's what--

DR. REH: None of our -- we never have the polluter review our reports.

MS. AMICO: Okay. I guess I misunderstood what Marian said. That's why I was clarifying.

DR. PAVUK: No, it just updates because they -- this is the -- this is the interagency [inaudible].

DR. REH: There's nothing in -- you know, we have, in cases -- in many cases, you know, we get our funding to do the work just like in Pease and the multisite, through DOD, through the NDAA. But we have to have processes in place to keep them at arm's length, because even though they're giving us the funding, that doesn't mean they have a right to review things or to see free copies before you see them or any of that, so.

MS. AMICO: Okay. So, you don't let them review this information, but you give them updates on where you are in the process?

DR. PAVUK: We have to provide updates quarterly because they provide the funding.

DR. REH: It's part of the way the NDAA is written. Quarterly, we provide updates, but they are basically where we are with the work. We don't give them data or health effects information or minutes from this meeting. If they want to get minutes for this meeting, that's why a DOD person is invited.

MS. AMICO: Okay. So, could--

DR. REH: They haven't seen the report, or we don't send them any materials.

MS. AMICO: Okay. Great. So, would you commit to providing us a timeline on when we can get this information, more transparency into the process, and where it's at? And then can you commit to giving us more frequent updates than you have been doing?

DR. REH: So, I'd be happy to do more frequent updates. You know, we worked with you guys on changing the schedule. We had -- you know, we dealt with this similar to CAP [inaudible] June in that, once we got past all the initial work and the data was collecting and we were in the analysis phase, we reduced the number of meetings. But if you want to go back to more frequent, we can definitely do that. Do you want to have them in person? I've been pushing for in person for a while. That's fine too. If you want a timeline on our review process, I can see how we can get that.

MS. AMICO: Okay. Yep. And just more—

DR. REH: So, I'm hoping I agreed to everything you just said.

MS. AMICO: Well, and more transparency into the process too. Like it sounds like there's multiple steps it has to clear, right, to get to the final. So, if you could tell us, like where is it at? You know, what other agencies are reviewing it or things like that?

DR. REH: No, other agencies are reviewing it at this stage other than, you know, who normally would review these documents like this within CDC.

MS. AMICO: Okay. But we don't work for CDC, so we wouldn't know that, Chris. Like we're asking for more transparency at [inaudible]. This moves a lot. Okay? Because [inaudible] there, we don't know. We're just -- we're out here waiting for information from you. You know? Like ATSDR's role is to help communities. Right? You guys talk about all these processes internally, and I understand that, but it's like we are leaning on you to help us. You know? So, we need you to help us understand your process and the time things take. And if you set

expectations that you meet those expectations, and if you don't, you're going to let us know why.

DR. REH: Yep. Fair enough.

MS. BARRETT: I see Rich [inaudible] having--

DR. REH: Loud and clear.

MS. BARRETT: His hand up for a minute.

MR. DIPENTIMA: Yes. I'll lower my hand in a minute. I have couple of questions. I've got just a follow up. Could you please give us that -- at least the best guess of a timeline, if you can, based on where the review is and where you're expect it to finish? Number two, the elephant in the room that I'm concerned about is, how will--[Inaudible] I'm saying this gently, but a proposed government shutdown affect your processes in this coming time?

DR. REH: Yeah. So, let me take the shutdown one first. So, if there is a shutdown, we'll all be out of work. And so -- and when the federal government is shut down, we are not allowed, per federal government rules and regulations, to take work home with us and work on it. We're not even allowed to access our emails during a shutdown. And so, if a shutdown does occur, that's -- we -- the process will stop as will everything else that happens during a government shutdown. Now, Rich, what was your first question?

MR. DIPENTIMA: Just to -- we -- you mentioned earlier about the possibility of just giving us a more updated or realistic timeline I guess the best you can with now considering the shutdown.

DR. REH: Yeah. Yeah. Let me go back and check it. Since the report is with the Office of Science, this is the last step for our review process. And let me go back and check and see where it is and then I can provide the timeline.

MS. BARRETT: Okay, Laurel, I see your hand up.

DR. SCHAIDER: Hi, everyone. Yeah. To Andrea's point about like, you know, the community wanting to have updates as soon as possible, I totally appreciate that or understand that there's many layers to the approval process. I was curious within the constraints that you have, is it possible to do a community update before the report is finally cleared or at least to be preparing the slides so that they can be reviewed and ready to go the second that report is ready, I mean, that's not [inaudible]? We're paid in stats here to summarize the PFAS

levels and the demographics. Like is it -- was it a requirement for you to have that report cleared before you could share summary PFAS statistics with the community? And if that was the case, can you work on--

DR. PAVUK: [Inaudible] short answer is yes.

DR. REH: Yeah. We cannot release uncleared material. I mean, that's just -- we cannot. But what we can do, which we are committed to doing, is share it with the community before it goes public. And we definitely will do that.

DR. PAVUK: And we are working on the slides so that we have the slides that we can present at the time that the report is released.

DR. REH: Laurel, I don't know if I answered your question.

DR. SCHAIDER: Yeah. I mean, I guess I -- like in terms of, I guess, the results that you're -- that ATSDR [inaudible] present in the presentation have to be coming from a cleared report. I'm just wondering if it's possible to have submitted that as a separate document for clearance, like those slides? And could you provide an update on when you plan to submit those slides for clearance?

DR. REH: Well, the slides will be based on the cleared report. So, they will go pretty quick. And I'm not necessarily convinced we need slides. I think what everybody wants to see is the report. You know, the slides will be just summaries of what's in the report for presentation purposes, but we can talk about what's best for the community. You know, if you prefer a slide presentation of the data along with the report, we can do that. But that slide deck -- slide decks like that, especially once the report is cleared, go pretty quick.

DR. SCHAIDER: Given where you're at with the review process, do you expect any changes to the results themselves? Like is the review process leaving changes in the calculations and [inaudible]? Or is it just the interpretation?

DR. REH: Yeah, fair question. So, as I see it, from what I've seen of the report, and I haven't seen it in the past few weeks, but the clearance process has not changed the findings or the data.

DR. SCHAIDER: Okay. I mean, I guess I was envisioning for a community presentation that you would have slides and kind of--

DR. REH: Yeah. We can do that. Yeah. Yeah. Yeah.

DR. REH: Then I guess I'd encourage you to -- you know, since the results are probably not going to change, you know, to work on those and have those ready to go as soon as the report is ready. And I don't know if it's possible to have that in review in parallel, or if it has to be one and then the other, but--

DR. SCHAIDER: Yeah. Okay.

DR. REH: Okay. Thank you.

MS. BARRETT: Okay. Are there any additional questions?

MS. AMICO: I just have two. So, I know we're talking about the simple paper, right, which seems like it would be easier to get put forth. And the other paper is going to be much more complicated. So, can you give us an estimate as to how long that information will take to be able to report that out to our community?

DR. REH: We can -- so let me look at where that is and work with Marian and Megan on that. And yes, we can give a timeline on that.

MS. AMICO: Okay. But you don't have any estimate tonight?

DR. REH: I do not. Marian, do you have anything?

DR. PAVUK: I mean, you know, we are -- again, you know, we may have like -- you know, we had the report document, you know, months back. So, I don't know like how long the clearance is going to take on what we come up with. All right? I would say, you know, they'll be trying, you know, to work on, you know, visualizing the data and putting the figures and tables from our preliminary results that we look at, as I said, from the -- from self-reported health outcomes, right, to start, so that we have, you know, some starting point, and then build on that starting point using clinical tests and biomarkers. And you know, again, we are working on many things. As I said, we have to go back the last couple of weeks data management for Pease and the multisite. It affects both. So, sometimes we are -- I was planning to do something else, and then we had to do this. All right? Because it has to be fixed before we can proceed. Right? But sometime early next year, you know, I mean, I'm thinking, my own kind of timeline on this would be that we have some sort of, you know, result -- the results with tables and figures, you know, in February. Right? That or we may be already on some review version of that. Right? So, we'll have the results. All right? And as I said, since the -- what we are planning to do is the -- to release those at the community meeting. We're not going to put it in a manuscript. I mean, it would be great if we

could work, you know, on preparing a manuscript instead of putting in slides, but we need to do that first. And so, we'll be working on that and are hoping to have, you know, some of the results slides in the spring.

MS. AMICO: Okay. For the second paper?

DR. PAVUK: For the health outcomes.

MS. AMICO: Okay. Okay. I guess just my last thing to say is more of a comment. You know, it's -- this is frustrating for sure. The clearance process, it's frustrating. It's definitely holding up our community getting valuable information. And I also know that this is happening with the Camp Lejeune studies as well. I've been in touch with their CAP members. And so, I think just more a comment for ATSDR leadership, that you, you know, need to be aware of this. That this is concerning to the communities. That, you know, communities are waiting for this information, and we need your leadership and your, you know, help in getting this information out to the communities. Your -- you know, ATSDR is here to help communities. And you know, we want to see that you're taking that seriously and that you are working hard to get this information out to us as soon as possible. It's not just a Pease issue. It's happening at Camp Lejeune too. And it's unacceptable, and we need the leadership to step in and do more. That's why I was hoping Dr. Bernstein would be on this call. I don't -- I haven't seen him yet. I'm not sure if he joined. But I think he needs to be hearing loud and clear from the communities that, you know, we need leadership here, and we need help getting this moved along. Because, you know, our community has been waiting a long time. Thank you.

QUESTIONS FROM THE AUDIENCE

MS. BARRETT: Okay. Thank you. I do want to turn it over to questions from the audience. Pam, if you just to give instructions for the audience if they want to speak?

MS. WYTON: Yeah. So, if any of the attendees would like to ask a question, if you would raise your hand, and I will allow you to unmute yourself.

MS. BARRETT: Pam, are there any hand raises from the line?

MS. WYTON: No, I don't see any.

MS. BARRETT: Okay. Then I'm going to move along to the multisite study update. Marian and-or Megan, if there are any updates?

MULTI-SITE STUDY UPDATE

DR. PAVUK: So, the big update was we finally were able to have a in-person OPI meeting that occurred at the end of September, in Denver Medical Center there. So, all OPIs and investigators from all seven sites in ATSDR attended at the end of September, and it was a two-day meeting, where we discussed the next steps in the study. The enrollments on the multisite study ended September 30th. So, we have been very busy trying to ship, you know, all the outstanding samples that we had to -- for PFAS analysis to division of Life Sciences National Center of Environmental Health lab first. And then also send them to [inaudible] repository for [inaudible] urines and to study for immune analysis stuff. So, we'll be rescheduling. The last samples arrive to DLS yesterday, I believe. So, we have complete set in the lab. Lab has analyzed over 3,000 out of about over 5,000 samples. So, they're making progress. We would like them, of course, move as fast as they can, but we were able to get those in. And as the shutdown may be happening, at this point, it looks like we'll be able to get all the samples to the storage facility, to [inaudible] repository, and to [inaudible] and to the labs by November 17th. So, that was lot of samples that we've been moving over the last was a couple of months. So, the next steps, there's a lot of discussion, but the three major topics really were the data management cleanup and then analysis of and preparation discussions about manuscripts and health outcomes on multisites and creating work groups kind of grouped by the groups of health outcomes. So, the investigators kind of made preliminary plans on what the interests and the needs may be for the adults and smaller children study. The second part, [inaudible] really the clearance and releasing results and communicating results in the community meetings and conferences and others and having the discussion on those processes with the ATSDR management that participated at the meeting as well. Then we also got the updates on the historical reconstruction, the BK workgroups that we have documents that also need to be cleared there per protocol requirements. And then the investigators also told us where they are on the investigator initiated parts of multisite and [inaudible] Denver funded, you know, separate from the core protocol. So, it was a very interesting and, I would say, productive meeting. And it put into focus a number of steps and efforts that need to be put in place and that need to happen during this year or next. Our support contract did -- will end next September and next August and cannot be renewed under current funding mechanism. So, we are on a clock here to try to accomplish and create an aggregated dataset from all of the sites and Pease. That's why our work on Pease is important, and it feeds into our data management work with [inaudible]. I think

we would need some additional support in that area from the point of view that, you know, 30% of the stuff are derived variables. We have even more variables than in Pease. Right? So, we're talking thousands, and we would need some experienced person that have done this before to guide and provide oversight and kind of interface between us, the side investigators, and APT in working while the contract in, but especially after to keep the tabs on this very complex data formation that is underway. I think that's -- there's a summary that has been prepared and reviewed, revised a couple of times. I think it's up for a final -- or kind of finalization. With the management, it should be -- we're hoping -- or they're hoping to have that, you know, shared with them -- with the sites' PIs so that we can discuss the summaries and the steps as they're covered. I think it's like seven- or eight-page document that covers the meeting. Any questions?

MS. AMICO: Yeah, I have some questions. Thank you, Marian. I just want to know timelines again on this one and how our data will be grouped together. And so, I would assume that -- so I'll start with in terms of how you're getting this information out to the community. So, it sounds like each site will have their own community meeting with their results, similar to what we will have a Pease. Correct?

DR. PAVUK: Correct. And yes, and they are -- you know, they're kind of, you know, similar like your position, they would like to have it sooner rather than later. All right? So, a lot of discussions were about, you know, what can they show and present, you know, before, you know, everything else is cleared. You know? Office of Science determined that they will have to clear everything, like [inaudible] clearing for having to release the results to the communities.

MS. AMICO: So, all these seven sites, even though they are not ATSDR, like these are like subcontractors of ATSDR, all of the information released to the community will have to be cleared by ATSDR?

DR. PAVUK: Correct. Yeah. The cooperative partners, so.

MS. AMICO: Okay. So, we can anticipate that these other sites will also experience these lengthy clearance processes like we have experienced here? Because that's the process. Right?

DR. PAVUK: That's the process. That's for Chris.

DR. REH: I -- well, I mean, it will have to go through our clearance processes.

MS. AMICO: Which is very lengthy and takes a lot of time. So, I'm just saying in terms of prepping these communities for how long it's going to take them to get their information, it's going to take a while.

DR. REH: Yes.

MS. AMICO: And do you have any timelines on, you know, when individual sites will be able to release the information? And then when will we as a whole, like all the sites together, will there -- will that aggregated data that will come -- that will produce a report, when will we get to know, as a whole, like how we all look in that study?

DR. REH: I can't say at this stage, just because I need to go back and look where everything is. But we could look at that and provide --possibly provide a timeline.

MS. AMICO: Sure. I mean, Chris, I have to imagine you would have thought these questions would come up. Right? Like this -- the updates you're giving us are just like, yep, we're -- you know, I feel like this is very obvious questions that we would have asked. I'm kind of disappointed that you don't have -- you're not prepared to give us any information on timelines. Like that's really all you can give us right now. So, I'm kind of frustrated that there's no more information that you can share on this call.

DR. REH: Okay.

MS. AMICO: Do you have--

DR. REH: I'm sorry. I'm sorry it's that way.

MS. AMICO: Me too. Me too. I'm missing basketball events and sports with my kids, because I want substantial updates to share with my community. So, yeah, I'm sorry too. Do you have a timeline as to when you can give us this information after this call? A week? Could you report back to us on when we can expect this information to be available to communities who really want and need this information?

DR. REH: So, I'm going to have to, tomorrow, assign this to someone to track it up while I'm away for the next two weeks.

MS. AMICO: Okay.

DR. REH: But I will commit to doing that.

MS. AMICO: Okay. Thank you. My other question is, you know, regarding the contracts and the renewed funding. So, are you

needing additional funding for this work? Or are the contracts going to be renewed under the existing funding for these sites?

DR. REH: This was the last year, but-- Yeah. This is the last year of the cooperative agreement.

MS. AMICO: Okay.

DR. REH: And so, I don't know enough about contracting and things like that to be able to answer that, but our policy people are on, and I will leave that with them.

MS. AMICO: Your policy people, are they on the call tonight?

DR. REH: Yeah. Kim Dills is on and others. Yeah. Yeah.

MS. AMICO: Is Kim able to answer that question?

MS. DILLS: Hi, Andrea. Unfortunately, I'm not. I don't handle the contracts and such, but we can definitely get an answer for you soon.

MS. AMICO: Okay.

DR. PAVUK: So, the idea for the MRDs, at least, is -- if I may, is that they'll have a no-cost extension to be able to work on the stuff. They may have -- be allowed to even keep probably some of the money if they have some leftovers, to put that to the funding maybe next year. But the way that the NDA was set up and the contract is basically saying that the support contract will end and the NDA money is unlikely to be available after that point.

MS. AMICO: So, these sites will be continuing to work on the multisite study for a good while, because we know that they have to get the data and analyze it and get everything they say to be cleared. Right? That's going to take years. We're seeing that [inaudible] here.

DR. PAVUK: And this was -- this is -- [Inaudible] so this usually how this works, that basically people are not paid for that after that kind of data is collected. I mean, this project actually was kind of designed that they would have couple of years to work on it with funding. Right? The delay of the COVID pushed it out, so you know, when they were not able or allowed to be collecting. So, basically, our buffer was lost due to year and a half of COVID. But it is not unusual that cooperative agreements do not provide money for actual -- you know, when things are -- need to be written up. That's unfortunate that that's how it's set up, but that's not unusual.

MS. AMICO: Okay. So -- but, okay, but the expectation is there's going to be a couple more years at least work -- of work at these sites.

DR. PAVUK: Oh, absolutely. I mean, you know, it took a decade on [inaudible]. You know?

MS. AMICO: So -- okay, so once the funding is up though, it's just done? There won't be additional funds for these sites to continue to work out or to finish the work?

DR. PAVUK: You mean the -- not from our side probably, but that's not for me to decide.

MS. AMICO: Okay.

DR. PAVUK: As I said, we've worked on, you know, other projects where, you know, investigators have to find their own funding to continue to have the staff. I mean, it's preferable when you have all the staff. Right? But -- and that's what makes it difficult. Right? When you're funding ends and you have to let the stuff go, you cannot do things as fast as if you had money for more staff. Right?

MS. AMICO: Yeah. I guess that's my worry. We have seven sites out there who their funding is running up soon, but they still have years of work ahead of them. And every site is different. Some are universities. Some are different. So, if they don't have the resources to continue to work, what's going to happen if they can't get part of the study in and get this analyzed and get this into meaningful information for communities?

DR. PAVUK: Well, I mean, they -- you know, they have to show the commitment, you know, in their sites. And again, I don't want to speak for them. I'm just saying that that's the situation on NIH grants, the same as if there's uncooperative agreements. You know? The funding basically covers certain period of time. And then you come [inaudible] with the papers and reports usually is not covered by the NIH funding. I mean, you only get a limited time to do that.

MS. AMICO: Okay.

DR. REH: And that's the way the funding came to us. It was seven years of funding, and we're getting close to the end of that.

MS. AMICO: Okay. Thank you.

MS. BARRETT: I see Laurel has her hand up.

DR. SCHAIDER: Hi, everyone. Yeah, I have a lot of thoughts and questions, but for tonight, I'll just ask one thing. So, for the sites, there's a no-cost extension, and we can extend our funds for an extra year beyond next September. And you said that the ABT contract runs out next August with no chance to be renewed. And then you'd also said that there is -- after that ends, that there's some statistical support that ATSDR can provide. And there's going to be a lot of data management beyond--

DR. PAVUK: We don't have that yet. So, I'm bringing that to, you know, management attention that that need will arise once that ABT contract ends. So, I'm just trying to, you know, give everybody heads up inside of the agency that that need is there and needs to be addressed. That it will not go away. That like similarly to Pease, right, just because they finished and sent some dataset, you know, doesn't mean it ends the data management work. So, that's what I'm saying. How, you know, that will be addressed specifically, you know, I don't know yet.

DR. SCHAIDER: Okay. And so, for the individual sites, whatever money we have leftover, we can carry on into a sixth year. ABT contract's going to run out next August. Is there going to be any ATSDR paid support beyond the end of next September to help with data management, to help with cross team coordination? Do you all have a no-cost extension? Or is your time going to run out at the end of year five, and the sites are just going to be on their own without any ATSDR staff being -- having funding to continue to support the studies?

DR. REH: Well, it -- we don't get special funding for this. We pay for it out of our normal budget. I guess I'm trying to understand the question.

DR. SCHAIDER: So, you're -- so ATSDR staff time to work on the multisite study is not covered by multisite funding?

DR. PAVUK: Correct.

DR. REH: That's correct.

DR. SCHAIDER: Okay. So, ATSDR staff will be able to continue--

DR. REH: They're already paid with our normal budget. Other -- because if we did it that way, we would end up at the end of a project like this with people who are unfunded.

DR. SCHAIDER: Okay.

DR. REH: FTEs who are unfunded.

DR. PAVUK: So, there's--

DR. SCHAIDER: And so, that like support staff can continue into the no-cost extension year and beyond, potentially? I guess I feel like there's going to be a lot of data management [inaudible]--

DR. REH: I think this is something -- Laurel, I think this is something that you guys need to discuss in your multisite meetings.

DR. SCHAIDER: Yeah. Yeah. That's fine. I was just--

DR. REH: Yeah.

DR. SCHAIDER: Yeah.

DR. REH: Because that's -- they'll have the right--

DR. SCHAIDER: Just trying to figure out the timelines.

DR. REH: Yeah. They'll have the right contracting people on, and so.

MS. AMICO: May I ask a follow-up question? So, Senator Shaheen was successful in getting an additional $20 million in the NDAA last year for the multisite study. So, that $20 million just less than a year ago, where is that funding going to go? Is that getting pushed out to the site so they can continue to do this work beyond? You know, where is that money going?

DR. REH: Yeah. So, the sites got their normal funding for the multisite study, and then we gave each site additional funding to do investigator initiated work.

MS. AMICO: But that was -- the investigator initiated work, wasn't that part of the initial funding?

DR. REH: That was part of this past year's funding.

MS. AMICO: Okay. So, the--

DR. REH: Your -- it -- we can give you an accounting, if you so desire, if you want that, of where the multisite money is. I--

MS. AMICO: Also, I guess it just -- you know, again, from the community side, I don't work internally, I don't understand all the layers and things that go on, you know, our senator has been incredibly supportive here and [inaudible] and getting funding so we can get answers and questions, you know, through the agency that's supposed to be helping us. And so, if she was able to get an additional $20 million less than a year ago and we're hearing that the sites are going to run out of money soon and that their work -- you know, they have to do this work unfunded

and there's years and years of work ahead of them, yes, it would be very helpful to better understand on the community side, you're getting $20 million, where's that going? And is it going to the site so they can continue to do this work? Because, I mean, ultimately the goal is to get answers to the communities. Right? The health studies are to help answer community questions and concerns. So, we want to see them completed, completed well. We want the data to be well organized. You know? And so, we want to know that each site is getting the support and the funding they need to carry out this work thoroughly and well done so we get the answers that we need. You know, I don't want to be at the end of this process and still feel like we have lots of questions or things weren't managed well. You know? And so, are you feeling confident that all of these -- the Pease study and the multisite study are on the right track and everything's going well, Chris? Are you confident with everything in the way that it's going?

DR. REH: I -- well, yes, I am. I know our people are working on it, and we're doing the best we can. So, yes, I am.

MS. AMICO: Okay. Okay. Great. So, yeah, if you wouldn't mind looking at, you know, helping us understand that extra $20 million and where that went when you get back to us on timelines for all these projects too, that would be great. If you wouldn't mind adding that to your list.

DR. REH: Yeah. I'm going to have to see how we can get that to you. I just don't know the process for doing stuff like this, but it's all part of the public record. So, I'll just have to see how that can be done.

MS. AMICO: Okay. Appreciate it.

NASEM PFAS REPORT UPDATE

MS. BARRETT: Thank you. Are there any other questions? Okay. Not hearing any. I'm going to kick it over to Chris to give some NASEM updates.

DR. REH: So, the NASEM clinician brief is in the final stages of review. It's cleared our internal review processes. I think right now it's at the CDC Office of Science, which is the last step. So, we're expecting very soon that we'll be able to share it. By very soon, I mean in a couple of months that we'll be able to share that. So, we're excited to get that out and get it done. It's been a long journey. But it's -- that's about all I can say about it at this stage. Are there any questions?

MS. AMICO: Yep. So, when we met with you in June, you had said that this would be out like late summer, early fall. So, we're now end of October, and now you're saying it's going to be a few more months?

MS. AMICO: Yes. Okay. And what--

DR. REH: The clearance process took longer. It's a difficult -- it's a complex document, and we continue to push it forward.

MS. AMICO: So, I just want to make sure I understand, ATSDR paid NASEM to convene this panel and write this report in these recommendations. They did that.

DR. REH: ATSDR and NIEHS, that's correct. We funded it.

MS. AMICO: Yep. Great. You funded this work, and then this report was issued July of last year.

DR. REH: Right.

MS. AMICO: And for over a year, we've been hearing you say you're revising your recommendations, and then since June, we've heard that they're in clearance. And now, it's still in clearance. So, I don't know, are you not seeing the problem with the clearance and how long these things take? And--

DR. REH: I see it, but these are processes that are put on us. These are business processes within the agencies that we work. We -- you know, we do the best we can with the processes that we have. And they're designed to make sure the integrity of the science is there. The NASEM report is a little different in that it's on that edge of -- because of medical guidelines versus not medical guidelines. And there's other parts of that that make the clearance more complex and make the report complex. And so, we've been pushing it forward as best we can.

MS. AMICO: Okay. Well, I want you to know what the NASEM report means to communities, because in there, it recommends that exposed people get blood tested. It spells out medical screening guidance. It tells physicians what to test for when people have been exposed. This is critically important information that real people need today. Right? So, yeah, you know, I appreciate your process. I appreciate it's going to take time, but you know, I just am not feeling any sense of urgency internally on ATSDR's part to understand that this guidance will help real people who have been affected by this exposure right now. There's many communities that aren't part of health studies, and health studies are different than medical monitoring. This is real information people could use today. This is real information

that physicians, when they see something come out of your agency, are going to look at and respect and implement. And the longer you wait, the less chance that communities have to get access to this information to get that recommendation to blood test them, to check certain labs, and run certain tests on them because they've been exposed. And these are people's lives. These are people's health. So, you know, this should be a top priority in getting this out. You've had this information since last July. And you told us in June, it would be out the late summer, and it's end of October. And now it's being kicked down the road a few more months. Like I'm just -- I'm super frustrated. I know you can sense that, but it's just like This is real people's lives. Like we have been exposed. Thousands of people, millions of people have been exposed. We need help. We need answers. We're leaning on you. You're getting lots of funding to help us. And we're just getting delay after delay after delay after delay. You know, I just -- I need you to hear that loud and clear. I understand this is your job, and you have these processes. This is our lives. These are our family. Like these are real people who have been exposed, who are experiencing health effects, who need help now. So, I need you to hear that loud and clear. I need you to be a leader. I need you to take charge and work to get this faster into the hands of the right people so it can help the people who are relying on you to help -- you know, we're relying on you to help us. We need you to step up and move this along please.

DR. REH: Thank you for that. We -- I appreciate the feedback. We'll definitely see how we can communicate better on timelines, and we're doing everything we can to move this forward.

MS. AMICO: Okay. Last question on this. What is your plan to put your -- put the -- once you revise your guidance that gets cleared and is made public, what is your plan to educate providers, state health agencies? What are you going to do to get this information in front of physicians and healthcare providers so they can start medically monitoring their patients, testing their blood for PFAS, looking for health effects? What are you going to do to get this information out once you can finally release it?

DR. REH: Yeah. So, we have an environmental medicine group within ATSDR. And they are -- have been through the summer and are making plans to have physician education, because you're right. This is going to land on the plate or the desk of people who -- even physicians who may have never had a class in environmental health or thought about it. And we're going to have to really do a lot of work in educating these folks, not

only from a standpoint for adults, but also for children and pediatricians. Because it'd be, you have something like a recommendation or a guideline, any medical guideline and the physicians who are there to administer it are not -- don't know anything about it. That's problematic, because then what you'll get is -- and we've seen this, I know you have Andrea, where people go to their physician and say what about PFAS? And the physician's never heard of it or never dealt with it. And so, it's going to be a priority.

MS. AMICO: Okay. So--

DR. REH: It is a priority.

MS. AMICO: Is there any -- like other than just saying, yes, we understand. We have to educate physicians. Do you have a plan? Do you have a plan to roll this information out? And could you share any information--

DR. REH: Anything like this comes out with a rollout plan and next steps and that. And for the physician guidance, the rollout plan has been developed. And it's in -- it has to go through clearance too. It doesn't take as long as complex scientific documents, but yes, we do have a rollout plan that is in place and we're working on.

MS. AMICO: So, once the document is cleared, there will still be a further delay in the rollout plan, because that'll have to be cleared? Or can they be cleared at the same time?

DR. REH: It's being cleared right now.

MS. AMICO: The rollout plan too?

DR. REH: Yes, ma'am.

MS. AMICO: Okay.

CAP QUESTIONS AND COMMENTS

MS. BARRETT: Are there any additional questions? Okay. Not hearing any. I want to open up to any general CAP questions or comments.

MS. MCLELLAN: Tyra, I have a comment. This is Toni. Or a question rather. There was a Pease study participant at one point in time that posed the question about what's the availability of blood testing? This is aside from anything in the report, but where can -- people that participated in the study that had their blood drawn, where can they go to get

follow-up PFAS testing? Was that information ever circulated with participants?

DR. REH: I'm sorry, Toni, can you ask the question differently? So, are you looking for names of labs that can do the testing?

MS. MCLELLAN: Yeah. A community participant in the study asked where they can go to get their blood level of PFAS tested as a follow up aside from the study.

DR. REH: Right. I think Tara can help with that. Tara, is that something you can help that community member with?

CAPT. SOMERS: Yeah. Hi, Toni. I think I know the event you're talking about, when this came up on the -- this was a while ago. Right? [Inaudible] I'm reaching back into my memory. Right? I know on the PFAS Reach site there's some information that -- so ATSDR can't endorse labs outside of, you know, like non-government, you know, like our CDC lab. I believe though in other communities, we've referred to the PFAS Reach has some information that's out there. I think the challenge for that individual, I know it was because of the New Hampshire, right, the rule in New Hampshire that insurance companies now are supposed to be able to cover a PFAS test. And he got stuck in kind of a loop, right, where there was like not -- like the insurance and the provider didn't have a place to refer him to. I think that's what I'm remembering back. So, let me go back and see. We did get -- I think information was provided to that individual, but I can double check. Unless you think there's a -- this is a bigger -- this is a bigger question that's coming up again, or was it just—

MS. MCLELLAN: No. It was a question some time ago, and I was on a leave of absence. So, I didn't see the information circulated. I'm sure if that person had that question about where can I go to have my levels tested, there are probably other participants out there wondering the same thing. How can I follow up on this?

CAPT. SOMERS: Right. I believe for that individual, we tried to get an answer. But I think our New Hampshire state partners have some information on their website about this issue, because it did become a bigger challenge. But I think that New Hampshire rule that I'm remembering, it is -- I think it's for some insurance has to cover it. Right? It's not like all private insurance covers now. I thought it was like government insurance. Right? Like if you're -- I'm trying to remember all the intricacies of it, but it's -- so it is there, but it can be challenging to access. You're right. So, I will -- for my takeaway, I'll circle back with our New Hampshire folks and see

if they have a succinct sort of answer for that to give to community members that can help guide them through that process. And if they have more information on like specific types of insurance that, you know, who they -- which labs they can use. So, let me see if we can track that down.

MS. MCLELLAN: Okay. Great, thanks [inaudible].

DR. SCHAIDER: Sure. I'll just add that the PFAS Exchange website created by the PFAS Reach study does have two resources. I just put the links in the chat. One is a general fact sheet with types of questions to ask, which might have been types of tests, like what a test can tell you and can't tell you. And then we have another online resource that we try to keep updated with information about blood testing labs. Most of them rely on a phlebotomist getting a typical blood draw. There is a home finger prick blood test available as well. We also don't endorse specific tests but try to put the information out there in a consistent format, because every test has a different cost and a different list of specific PFAS chemicals that it can test for. So, I put those two links in the chat. I don't know for the ATSDT folks, if that's something that you can share with participants as well. But please feel free to. We -- you know, we want this information to be helpful.

CAPT. SOMERS: Yeah. Hi, Laurel. I have actually referred some community members to that because, again, at ATSDR we're in a -- you know, we can't say use this lab or that lab, because that's like an endorsement of a lab then. So, I've referred them to your materials which you talked about last.

DR. SCHAIDER: Yeah. [Inaudible] we're also not endorsing, but we just -- we compiled all the information so it's in one place. We're not recommending one over another.

CAPT. SOMERS: I know, but we have a challenge even doing that. So, thank you for being able to do that.

DR. SCHAIDER: Yeah.

MS. BARRETT: I see Rich has his hand up.

MR. DIPENTIMA: Yeah. I just had follow up a little bit on the roll out of the recommendations in terms of physicians. I think that it might be worthwhile once we do have that to work with the communities individually and maybe set up programs here within each state. So, we can work with the different medical organizations, you know, the Pediatric Society, the Nursing Association, and others so that we can get the information out to the providers here locally. So, we know the people here. We

know the medical community. We know the -- you know, the public health community. I think we can help in each individual state work out a little subplan, if you will, to get the information out to providers and open up a good dialogue so we can make sure that they understand it and answer their questions appropriately. So, we can get this done quickly and efficiently.

DR. REH: Yeah. Very much agree, Rich. And you know, we're looking at our regional offices to play a role in doing that, because they have -- you know, folks like Tara, who's in your region, has contacts with all those state people that can help facilitate that.

MS. BARRETT: Okay. Andrea, I see your hand up.

MS. AMICO: Yep. So, I have a question that I've asked in other meetings too, in terms of a longitudinal component to our study. And you know, we keep -- we hear that it's being considered. And so, I was just wondering if there's any update on the plans for a longitudinal aspect to a study, to the Pease study, to the multisite study? And you know, when you say you're considering it, what does that mean? You're looking at a protocol? Like you're just thinking about it? What -- you know, where does--

DR. REH: Yeah. [Inaudible] Good question. So, what do we mean? We've always said that we'd like to see the data from the multisite. and the Pease study before we do that. That was verbiage that Pat gave you guys when he was here. And that's still what we want to do. It's going to require resources to do it, and we know that. We have a registries group at ATSDR. I've had them earlier this summer to start thinking about what it'll take to do such a registry. So, that if we get the resources and we can make it happen, that they've already thought about it, since they're not -- instead of starting to think about it five months from now or whatever the money, if it does come through, comes through the resources. So, it's still something we're very interested in, not only from the standpoint of Pease, but also for the multisite and even possibly for non-multisite exposure assessment sites, which makes it bigger, so.

MS. AMICO: Okay. So, you are starting to work on a plan, even though you don't have the funding, is that what I'm hearing you say?

DR. REH: Yeah. There's some things that they can do -- our registries group can do to get prepared. It's similar to what we're doing with some of the environmental health incidents that have been occurring in Hawaii. You know, we're looking at some registries possibly there, and we don't have the resources yet

to do it, nor the authorization. But if we do get that, which we're expecting, we're already down the road of planning what's needed to do it and how would we -- what type of registry this would be.

MS. AMICO: Okay. And then one other question, you said, you know, yes, we need to see the data from the multisite study. Do you mean that you need the data? Or do you mean that all the reports have to be cleared and published?

DR. REH: Just see the data. Just see the data.

MS. AMICO: Okay. So, it's possible that you could make a decision on the longitudinal aspect of extending this work before the community even knows what the results are? Because you're going to see the data that we're not going to see yet, because it's going to take a while to clear the report. Is that--

DR. REH: I'd have to talk to my policy and comms people on how that would flow. But I -- if I had to ballpark it right now off the top of my head, I'd say that could be a possibility.

MS. AMICO: Okay. Okay. And then my last question was just around staffing. I know Marian had mentioned in his update that a senior statistician and some other experienced person has assigned to help. Are you feeling that for both the Pease study and the multisite study, you have enough staff to be able to work on these projects? Is staffing an issue at all in terms of any types of delays?

DR. REH: You know, staffing is an organizational thing that is part of -- that's determined by the budget we get from Congress and the president. And you know, we have other things that we have to staff up too. For instance, we have about 100 community health assessments going on right now. We have the tox profiles we do. We have other communities that we engage for other substances. We have our emergency response. So, you know, anytime I can free up a staff member to help out on a big study, I do, but I also have to -- there's pluses and minuses in doing that if you -- for the organization where I have to make -- where you have to make decisions as to where to deploy people to meet all aspects of our mandate.

MS. AMICO: So, let me ask my question a different way. Do you have enough staff to carry out the Pease and the multisite study?

DR. REH: I believe we have the right staff, yes.

MS. AMICO: Do you have enough?

DR. REH: You know, you're -- I feel a little uncomfortable answering the enough part, because it seems like it's bordering on sensitivities related to how we talk about resources in the [inaudible] for someone in my position. I'll have to go back and ask someone first before I can answer that one.

MS. AMICO: Okay. It really is not supposed to be a trick question. I'm just curious--

DR. REH: I understand that, but there are also federal regulations that prohibit me from talking about things like money and budget and lobbying for budget and resources.

MS. AMICO: I'm not asking anything about that, but okay.

DR. REH: Well, you are in my mind, so it makes me nervous, so. But I'll ask and see what I can say.

MS. AMICO: Thanks.

WRAP-UP/ADJOURN

MS. BARRETT: All right. Are there any additional questions before -- okay, not hearing any. I just want to give a last chance to the community to ask questions. Pam, if you can just reiterate the instructions for how committee members can raise their hand to give any questions.

MS. WYTON: Sure. If any of the attendees would like to ask a question, please raise your hand at this time, and I can unmute you. I don't see any, Tyra.

MS. BARRETT: Okay. I'm not hearing any. Again, I want to thank you all for meeting with us tonight to discuss these updates. And I'm going to let you guys go and have back your evening. Thank you and have a good one.