THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

convenes the

SIXTH MEETING

PEASE COMMUNITY ASSISTANCE

PANEL (CAP) MEETING

May 10, 2018

The verbatim transcript of the Meeting of the Pease Community Assistance Panel held at the New Hampshire Department of Environmental Services, Pease Tradeport, Portsmouth, New Hampshire, on May 10, 2018.

> STEVEN RAY GREEN AND ASSOCIATES NATIONALLY CERTIFIED COURT REPORTING 404/733-6070

CONTENTS

May 10, 2018

| WELCOME AND INTRODUCTIONS DR. BILL CIBULAS | 5 |
|---|-----|
| ACTION ITEMS FROM JANUARY 2018 CAP MEETING CDR JAMIE MUTTER | 65 |
| PEASE PROTOCOL UPDATE DR. BILL CIBULAS, DR. FRANK BOVE, DR. MARIAN PAVUK | 70 |
| MULTI-SITE STUDY UPDATE DR. BILL CIBULAS, DR. FRANK BOVE, DR. MARIAN PAVUK | 88 |
| PEASE HEALTH CONSULTATIONS UPDATE CAPT TARAH SOMERS | 107 |
| BOARD OF SCIENTIFIC COUNSELORS MEETING IN ATLANTA DR. BILL CIBULAS | 123 |
| CAP CONCERNS PEASE CAP | 125 |
| WRAP-UP/ADJOURN | 129 |
| COURT REPORTER'S CERTIFICATE | 131 |

TRANSCRIPT LEGEND

The following transcript contains quoted material. Such material is reproduced as read or spoken.

In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

-- (ph) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- "^" represents unintelligible or unintelligible speech or speaker failure, usually failure to use a microphone or multiple speakers speaking simultaneously; also telephonic failure.

PARTICIPANTS

(alphabetically)

AMICO, ANDREA, CAP MEMBER BOVE, DR. FRANK, ATSDR CARIGNAN, COURTNEY, CAP TECHNICAL ADVISOR CARMICHAEL, LINDSEY, CAP MEMBER CIBULAS, DR. BILL, ATSDR CLAPP, DR. DICK, CAP TECHNICAL ADVISOR COSTANTINO, COL JOE, AIR FORCE DAVIS, ALAYNA, CAP MEMBER DIPENTIMA, RICHARD, CAP MEMBER DURANT, DR. JOHN, CAP TECHNICAL ADVISOR HARBESON, ROBERT, CAP MEMBER LAZENBY, CLIFF, CAP MEMBER MCNAMARA, KIM, CAP MEMBER MUTTER, CDR JAMIE, ATSDR PAVUK, DR. MARIAN, ATSDR SCHAIDER, DR. LAUREL, CAP TECHNICAL ADVISOR SHEEHAN, JARED, CAP MEMBER SOMERS, CAPT TARAH, ATSDR STONE, TIM, CAP TECHNICAL ADVISOR SULLIVAN, MARK, CAP MEMBER VETTER, SHELLEY, CAP MEMBER

1 PROCEEDINGS 2 (6:00 p.m.) 3 WELCOME AND INTRODUCTIONS DR. CIBULAS: Let's go ahead and get started. 4 My 5 name is Bill Cibulas and I am the acting director of the Division of Toxicology and Human Health Sciences at 6 7 ATSDR and I'm delighted to be able to help facilitate 8 our second meeting this calendar year here in 9 Portsmouth. Dr. Breysse, as some of you know, had a 10 personal obligation this week with his son, sort of 11 caught him by surprise and Pat loves this stuff, Pat 12 loves to work in the communities. He's, you know he 13 wanted me to express his sincerest apologies for not 14 being here. There's good news to talk about, he wanted 15 to be able to share that good news with you guys 16 personally. But again, we all recognize that sometimes 17 we have jobs outside of our work life and sometimes those take precedent. So again, Pat apologizes for not 18 19 being here and wishes us all the best and have a 20 successful meeting. 21 So in the way of opening comments, I do have some of those I want to make but I think we should start 22 23 with introductions and -- well let's start with Jamie 24 and Jamie might have some logistics that we want to... 25 CDR MUTTER: Yeah, just a few reminders. So if we

can remind you to turn off your phone or put it on silent so we don't disturb the meeting.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

Emergency exits are highlighted in red. There's one right back here and there's one over there, so keep those in mind. Bathrooms, out this back door, down the hall, kind of on the right. Let's see, name tents. When you would like to ask a question, please put your name tent up so we can follow those questions. And if you're on the phone, again, if you can put it on mute until you have a question or you do your introduction, we would appreciate it. And that's it. Thank you.

DR. CIBULAS: And don't let me forget with all the members on the phone today to make sure we're constantly asking if there's people on the phone who have something that they want to add.

So let's go ahead and start with introductions and 16 17 I'm going to go to my left. I'm going to save Dr. 18 Pavuk for last, a new member of the team. You've had 19 an opportunity to talk to Marian during our monthly 20 teleconferences. Epidemiologist by training. I'm going to ask him to talk just a little bit about what 21 22 he's been doing, what his experiences are so you get to 23 know him a little bit. But he's a great scientist and 24 you'll enjoy working with Marian right along with Frank 25 as far as the health study goes. He's a new member of

1 the team, really excited to be here. So Tarah. 2 CAPT SOMERS: I'm Tarah Somers. I'm with ATSDR in 3 our Boston regional office. 4 CDR MUTTER: Jamie Mutter, I work at ATSDR as the 5 CAP coordinator. MR. DiPENTIMA: Rich DiPentima, a member of the 6 7 CAP from Portsmouth. MS. AMICO: Andrea Amico, Portsmouth resident and 8 9 co-founder Testing for Pease. 10 MR. SULLIVAN: Mark Sullivan, Pease business 11 owner, CAP member. 12 DR. CLAPP: Dick Clapp, Advisor to the CAP. 13 COL COSTANTINO: Colonel Costantino, Office of 14 the Deputy Assistant Secretary for Environment 15 Safety and Infrastructure. 16 MR. SHEEHAN: Jared Sheehan, Pease Development 17 Authority. Tim Stone, Stone Home 18 MR. STONE: 19 Environmental, an advisor with the CAP. 20 MS. VETTER: Shelley Vetter, owner of Discovery 21 Child Enrichment Center. 22 MS. McNAMARA: Kim McNamara, Portsmouth Health 23 Department. 24 DR. BOVE: Frank Bove, ATSDR. 25 DR. CIBULAS: And Marian, I'm still going to wait

1 on you. Let's go ahead and go to the phone and see 2 who's on the phone. So go ahead and please identify 3 yourself if you're joining us today as a CAP member. 4 MR. HARBESON: Rob Harbeson, CAP member. 5 DR. CIBULAS: Thank you. Others on the phone. б MR. LAZENBY: Yes, this is Cliff Lazenby, 7 Assistant Mayor City of Portsmouth. DR. CIBULAS: Great, we got you Cliff. Next. 8 9 DR. SCHAIDER: Hi, this is Laurel Schaider from 10 Silent Spring Institute. I'm technical advisor to the 11 CAP, and I'll be there in a little bit; I got stuck in 12 lots of traffic. 13 DR. CIBULAS: Great. Thank you, Laurel. Anybody 14 else on the phone? 15 DR. DURANT: Yeah, this is John Durant. I'm a 16 technical advisor to the CAP. 17 DR. CIBULAS: Great, welcome, John. Anybody else? 18 DR. CARIGNAN: I'm Courtney Carignan, Michigan 19 State University, technical advisor to the CAP. 20 DR. CIBULAS: Welcome, Courtney. Anybody else? 21 Alayna. 22 MS. DAVIS: Hi. 23 DR. CIBULAS: Go ahead, introduce yourself. 24 MS. DAVIS: Hi, I'm Alayna Davis, I'm a member of 25 the CAP and a cofounder of Testing for Pease.

1 DR. CIBULAS: Great. And so let's -- we've got a 2 few members in the audience and I don't want to put you 3 on the spot, but if you would like to introduce 4 yourself, let's start Joe, if you would introduce your 5 colleague who's here with you today? COL COSTANTINO: I've got Lt Freeman Holifield, б also in the same office as me. You might be seeing him 7 8 in the future. 9 DR. CIBULAS: Dr. Chan, you want to introduce 10 yourself? DR. CHAN: Ben Chan, I'm a state epidemiologist 11 with the Division of Public Health Services. 12 13 DR. CIBULAS: Suzanne, would you like to introduce 14 yourself? 15 Sure. I'm Suzanne Condon, I'm DR. CONDON: retired Associate Commissioner of Public Health in 16 17 Massachusetts and consultant to ATSDR and CDC. 18 DR. CIBULAS: Great. So that's who I know, but 19 please, if you would like to introduce yourself, sir. 20 Sure. Dennis Malloy, State MR. MALLOY: 21 Representative from Greenland and Newington. 22 DR. CIBULAS: Wonderful. Ma'am. 23 MS. HOLMES: Sarah Holmes from Senator Shaheen's 24 office. 25 DR. CIBULAS: Wonderful. Ma'am?

1 MS. HOLMES: Kerry Holmes from Senator Hausman's 2 office. 3 DR. CIBULAS: Sir. MR. SANDIN: Peter Sandin, New Hampshire DES and 4 5 member of the Pease clean-up team with the air force. DR. CIBULAS: Wonderful. 6 Sir. 7 MR. MANGAFICO: Joe Mangafico, parent. Thanks for coming. And ma'am. 8 DR. CIBULAS: MS. NICHOLS: Sharon Nichols from Congresswoman 9 10 Carol Shea-Porter's office. 11 DR. CIBULAS: Thanks. Sir. 12 MR. THOMAS: John Thomas, resident. 13 DR. CIBULAS: Good. 14 MR. HEWETT: Jim Hewett, Portsmouth resident. DR. CIBULAS: Wonderful, thanks. Okay. 15 So last 16 but not least, Dr. Pavuk. 17 DR. PAVUK: Thank you, Bill. Thank you Bill for 18 the kind introduction. I'm basically by training I'm a 19 chronic disease epidemiologist in the Division of 20 Toxicology and Human Health Sciences at the ATSDR. I'm 21 honored to be here to be part of this effort, this important effort at ATSDR. Has been involved for some 22 23 time and that I had privilege to join and work with 24 Frank a little bit more on advancing and moving forward 25 to the goal of conducting the health study in Pease and

multi-site study on health effect of PFAS. I -- my educational background, as I mentioned, I have studied at the University of Iowa where I joined a program in preventive medicine environmental health. It was the Master of Sciences program. I was the National Institute of Health Fogarty International Fellow there. Then later at College of Public Health at the College of Medicine, College of Public Health I joined the division of epidemiology; it was department of epi and I got my Ph.D. in epidemiology. Before that I have an M.D. at the Comenius University from Bratislava, Slovakia.

1

2

3

4

5

6

7

8

9

10

11

12

13 My research interest from early on focused on environmental exposure to industrial toxicants and 14 15 chronic diseases. In the beginning it was mostly on 16 cancer, later on it was on the other chronic diseases, 17 more focused on endocrine disrupting chemicals so a lot of studies that we did was focused on diabetes, 18 19 cardiovascular disease, metabolic syndrome, thyroid and 20 related diseases.

After graduation I have joined College School of Public Health at the University of Texas, spent several years there working mostly on exposure assessment and human biomonitoring with analytical labs that focused on exposure, as I mentioned, industrial chemicals,

persistent organ halogen pollutants. We did a lot of work on dioxins and polychlorinated biphenyls. We had labs in Germany, Canada, United States and mostly human health samples, but also food from soil and some other environmental things.

1

2

3

4

5

22

23

24

25

While being in Texas I also work on projects on б 7 ranch hand study or air force health study and I later 8 joined SpecPro which was contractor to Air Force Health 9 and Research Lab as epidemiologist on this large effort 10 funded by Department of Defense with a 20 years 11 perspective study of Air Force veterans that sprayed 12 Agent Orange and other herbicides during the Vietnam 13 War between 1963 and 1971. And the 20 year follow up 14 study followed about 3,000 veterans who sprayed Agent 15 Orange for morbidity outcomes and 20,000 group for mortality outcomes. So my role there is epidemiologist 16 17 and later it's scientific director to directly work on all research and scientific efforts and provide 18 19 presentations and reports to advisory committee set up 20 for the study under FDA and also to joint sessions of 21 Congress and Senate for Veterans Affairs Committee.

> A number of studies came out of this study, more than 60 publications and a lot of the highlights of the study was also that it majorly contributed to veterans being compensated for service related diseases related

to Vietnam War by Veterans Administration. From San Antonio Brooks Air Force base then I joined ATSDR in 2006, early 2007. I came in as part of the team that was working on consortium of universities that worked on a project in Anniston, Alabama. Anniston, Alabama was the location of Monsanto chemical plant that produced polychlorinated biphenyls. It was a group of chlorinated chemicals that has wide ranges that had wide ranges of industrial uses and were banned in late 1970s. So the study focus really on was a community based study and focused on the residents of Anniston that lived in close proximity to the former production site. The area was contaminated, the soil, landfills and the study followed a long period of litigation in Anniston at Monsanto Chemical Company.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

25

So the first Anniston study we call Anniston 16 17 Community Health Survey, the data collection happened in 2005, '07 and I was coordinator and investigator a 18 19 number of different studies. We published about more than 15 publications on this effort in collaborations 20 with our partners at universities, University of 21 22 Buffalo, University at Albany, Upstate Medical Center 23 at SUNY Syracuse, Emory University and others. 24 Several years after that I attended dioxin

meetings and international symposium on polychlorinated

1 biphenyls. I had the opportunity to meet the Director 2 of National Institute of Environmental Health Sciences 3 and we came up with the proposal to fund a follow up on the Anniston Community Health Survey which we were able 4 5 to fund and conduct in 2014 and I served as principal investigator on that study. We have built on the 6 7 first study program, we have built a bigger data base 8 and stored samples, serum samples and worked with a 9 number of laboratories and have joined our program and 10 built on the first study. So in the second study we 11 have expanded the degree getting collaborators at the 12 University of Kentucky, University of Louisville, more 13 groups at NIEHS and also at following our collaboration at University of Buffalo. Really I think there's a 14 15 high relevance in a sense to this program where we do 16 plan, you know, collect number of data and samples that 17 span, you know, sometime and that we are developed and 18 worked on different capabilities, not only the ten 19 ATSDR but in larger group of academic collaborators 20 that we do plan to involve and integrate in this current effort. 21 Thank you.

DR. CIBULAS: So you can see that Dr. Pavuk brings a lot of experience at the community bases. We're excited to have him as a member of the team. The team is really expanding. I would guess, Frank help me out,

22

23

24

25

there are 30 or 40 people already engaged in the PFAS activities across NCEH ATSDR. I mean, the team is continuing to expand. Dr. Breysse is personally engaged in all of it and it is really a priority at NCEH ATSDR, the work that we will do in Pease as well as the work that we'll do across other communities in this country with similar situations. So I'm excited. We talked about transparency and so when we bring new key people onto the team we want to make sure that you have an opportunity to meet them personally and we'll share, you know, their experiences with you and I'm happy to bring Marian here today. I'm sorry? DR. PAVUK: Answer questions. DR. CIBULAS: Oh, Marian wants to know if anybody has a question for him and his experiences before we move on.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

25

17 But he'll be a big part of the team working 18 with Frank on health study. We have other people 19 that are going to be engaged in the health study but 20 these are your two primary scientists right now that are engaged in the work here at Pease and will be 21 engaged in the work of a multi-site study when we 22 23 receive funding to move forward on that. 24 So let's go ahead and start with what I think

is really good news in the way of opening comments.

1 Last January we weren't able to bring as much good 2 We had the National Defense Authorization Act news. 3 authorized at that time but no appropriation so there was a lot of things we couldn't say at that 4 5 time and made things a little uncomfortable at the meeting, as we all recall. But finally in April we 6 7 had the omnibus appropriations bill pass. Federal agencies are now funded, the Department of Defense 8 9 is funded. And along with that, the National 10 Defense Authorization Act was appropriated and we 11 have \$10,000,000, as all of you know, coming to 12 ATSDR by way of the Department of Defense in 13 coordination with the National Institute 14 Environmental Health Sciences. Pat and Linda have 15 been talking about things and now we're moving 16 forward. And so the really great news, I see 17 somebody put the paper up here today, is it the Portsmouth Herald, the article in the paper. 18 I know 19 that Senator Shaheen has been working on a press 20 release, whether it's actually out or not I wasn't able to find it today myself but clearly it's coming 21 out if it's not out. But really great news and the 22 23 people in this room should be congratulated for all of their hard work. Senator Shaheen and her staff 24 25 should be congratulated as are others who worked so

hard to make this happen, to make sure that there are monies moving forward to do critical work on perfluorinated substances which not only affect the water system here and you personally and other people, but tens and hundreds of thousands of other people across the United States who have similarly found out that they or their family members have been drinking water with these substances and wonder what that means for them, what does it mean for their children. And so we're excited as can be that the appropriation has come forward and we are as excited as we could possibly be that we will be conducting what we are calling a proof of concept study in Pease to test drive the research protocol for the multi-site study.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 So what does that mean? So that means that 17 with these funds that we have this year we have 18 committed to move forward on a couple of things and 19 one of them is getting the health study started. 20 And what has been decided then is that we will take 21 the research protocol that has been developed by 22 Frank and Marian and we're going to talk about that 23 a little bit tonight. We're going to talk about 24 what the status of that is, but we intend to start 25 with Pease as a proof of concept, if you will. The

1 first community that we will be working with and 2 what we will be doing with sort of test driving the 3 protocol which means that we're going to test and validate the approach, the collection, the methods, 4 5 the questionnaires, tools and procedures, everything 6 that we will be doing with any other site that 7 eventually joins us as part of the multi-site study 8 is going to be done here at Pease. It's going to be 9 done first and we, you know, we may find out some 10 things as we test drive through the Pease community 11 that we want to tweak here and there so to make 12 things even better for, as we move forward. But 13 also the other good thing is that the data that 14 comes out of our studies here to the effect that we 15 can answer some questions specifically for you; as 16 you know, you recall the feasibility assessment and 17 we do have a big enough population here in Pease to possibly look at some end points. So that's a real 18 great thing and we'll be able to do that and share 19 20 directly with you. But just as importantly, as you 21 understand and have come to learn working with us that there are a lot of end points and possible 22 23 health concerns that we don't have a big enough 24 population here in Pease. And I know you all 25 understand that and that's the beauty of the multisite study. So bringing in a larger population with similar exposures will allow us to look for other end points that we just don't have a big enough group here for and it's, like I said, it's a success for the community here at Pease where we will be starting and it's also a big success for the other communities across the country. So I mean, really you know, congratulations to everyone in this room that's worked so hard on this and thank you, you know, Senator Shaheen and her staff and others. I know there are others who -- that have worked to get this appropriation to come through and we're just, you know, completely excited about the opportunity to start moving with it.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

So I have a couple other, I guess, sort of 15 16 talking points that I just want to make sure that I 17 hit and make sure we get through all of these and we 18 can ask a couple of questions, but again, we'll be 19 getting into some more of this as we move forward. 20 As I said, and I want to just repeat this again, ultimately the data collected at Pease will be 21 22 rolled into the larger multi-site study and as you 23 know, sites there have yet to be determined. This 24 year with the funding that we will be receiving, we 25 will be starting with Pease, but to move into other

studies later on we're going to need additional funds in subsequent years so we will all be waiting to see what the congressional language looks like and what the funding looks like for years to come. But we will be starting with this first \$10,000,000 our work here in Pease.

1

2

3

4

5

6

7 Part of the reason, as everyone knows, of why 8 we're starting with Pease, it starts that we -- it 9 starts with the fact that we have a great 10 relationship already with the community. That's a 11 very important part to the success of any community 12 health study that you have a community that wants to 13 work with you and so that's a big part of the reason 14 why Pease is selected. Another reason, of course, 15 is that there's been a lot of work done here at 16 Pease already, right? We know a lot about the 17 exposure assessment, but we know the water 18 distribution system. You've had biomonitoring done 19 here. And so all of these things, you know, 20 contribute to the fact that this is the right place to start and to, again I use the term which we're 21 22 going to be used, to sort of test drive the research 23 protocol and make sure that, you know, we've got 24 everything exactly right as we continue to move 25 forward with other sites in the future.

So the study will be carried out on the ground by a contractor selected by CDC. So things are sort of tricky, to be honest with you. There's a lot of legal stuff going on, Pat and his deputy, Donna Knutson spent two Mondays ago in the Pentagon with legal teams trying to sort out exactly how these monies are being transferred from the Department of Defense to ATSDR. This year it's going to be by way of the Economy Act, which basically means that the monies are coming to us in a way that we actually have to go out with a contract this year, which is fine. You know, I can -- once we have our contractor selected our team will be working intimately with that contractor to make sure that 14 15 everything is done, you know, to our goals and 16 satisfaction, but that's how it will be carried out this year. There will be a contractor selected who will be working closely with Pat and Frank and 19 Marian and all of the steps that are going to take 20 place to get moving here in Pease and to get things going. So there's a lot of things associated with getting a contract out at the end of a fiscal year. And so, you know, usually the way it's supposed to work is the federal agency will know its budget and can be anticipating contracts and cooperative

1

2

3

4

5

6

7

8

9

10

11

12

13

17

18

21

22

23

24

25

agreements and things early into the fiscal year and by early summer everything's in place. Well, we didn't know for sure, right, until mid-April that these funds were going to come forward. So there's a big team right now working on developing the statement of work for the contract to make sure we get it in place, to make sure we get it funded by the end of the fiscal year, which for us is by September 30th. So that's going to be -- that's taking up a lot of our time but it's the government and that's the way things work and so a big part of what we're doing right now is getting that statement of work together and then it's going to go out and we're going to get this contractor and it's got to be in place by the end of September. We don't see any issues there, but there's a lot of work associated with it.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18 So today we're going to be talking about the 19 draft research protocol. I know I've looked back in 20 the notes and I said in January that after it was gone through external peer review that we would get 21 22 it to you and I had said that I thought we would do 23 that in March. Well, it's May now and so we're a 24 little late on that, but we will be going through 25 that tonight. I apologize, we weren't able to get

it to you more than a few days prior to this meeting, but we're going to go through it today, we're going to go through some of the peer review comments and give you an opportunity to comment, ask questions. Jamie has set a goal of May, what is it for --

CDR MUTTER: 14th.

1

2

3

4

5

б

7

DR. CIBULAS: -- May 14th to get any comments 8 9 back at this stage. But that's okay if you can't do 10 it because there's going to be a wonderful 11 opportunity coming up that ties in with getting it 12 approved by the Office of Management and Budget which means it will eventually go out for a 60 day 13 14 public comment period where everybody will get an 15 opportunity to see it and provide comments. So to 16 the extent that you have any comments over the next 17 week or so, would love to have them. If you have 18 comments today, you know, we'll tweak the protocol, 19 but our goal and I have a timeline here, our goal is by the end of this month, May 28^{th} , to have the 20 21 package completed and ready to start its approval process. And so that's why we've given this May 14th 22 23 deadline to try to give us any immediate comments 24 that you might have. But again, I want to assure 25 you that we'll be working closely with you on the

timeline, sharing every step along the way with you, and when it goes out for the 60 day public comment period associated with the OMB procedures, you will again have an opportunity to continue to provide comments on that.

Let's see, please keep the draft protocol 6 7 confidential. It's been shared with you, it's been shared with Colonel Costantino at the same time. 8 9 I've shared it with Dr. Chan, but it is a draft at 10 It -- we ask that you keep a close hold this time. 11 on it. It has not formally been cleared yet by CDC, 12 HHS and ultimately the Office of Management and 13 Budget. Until that's done it's still considered draft, but you know again, we ask you if you could 14 over this, you know, until the end of May until we 15 16 release it for the public comment period that you 17 keep it close hold and keep it confidential.

1

2

3

4

5

18 I think I'm getting towards the end. I can 19 tell you that once we get to the period where it 20 goes out for 60 days there will be a link where we will actually record all public comments that come 21 22 in, including any comments that you have. And I 23 believe all of those public comments are -- will be 24 available for anyone to see and if not we will -- I 25 think that's the way the process works, make sure

that you all have an opportunity to see what comes in also.

1

2

3 My last note here is that ATSDR's commitment to this community is unwavering. I hope you understand 4 5 that. You know, we value your input, we value what 6 you have done to, you know, bring this issue to 7 where it is right now and we have a commitment to 8 this CAP and we will keep you apprised of every step 9 as it's moving along. I know you'd like that things 10 move -- see things move faster than what the 11 government sometimes works at. So you're going to 12 hear me tell you that even though we hope to have 13 the package done and moving forward by the end of 14 this month, our projected timeline which includes 15 the Office of Management and Budget's review, CDC 16 and HHS clearance as well as the IRB process, puts 17 us at late summer before we're actually on the 18 ground here doing the work associated with what's in 19 the protocol. That doesn't mean we won't be working 20 really hard up and through that time along with getting everything cleared and approved during this 21 22 time through the Office of Management and Budget. 23 Once we have the contractor on place by the end of 24 September there are things that can start moving 25 also with that contractor. A lot of logistics that

1 that contractor can be working out with the Pease 2 community, you know, developing relationships with 3 Dr. Chan's office and the local health department. Things associated with, you know, blood collection 4 5 and other things that they'll have to work out to make sure that once we've got the final approval 6 7 we're ready to go with everything. So there's a lot 8 of things, logistical things that are going to take 9 place during that period also. And through our 10 teleconferences and through our meetings here, we 11 will keep you apprised of those steps and keep you 12 engaged. And if there are things that you might be 13 able to assist us with throughout this process, 14 we'll all look for those together and see where they 15 might, you know, what that could be. But we'll keep you apprised and, you know, we'll continue to work 16 17 as a team moving forward. But bottom line, again, I think really exciting news moving forward with 18 19 We're looking forward to further funding Pease. 20 where, you know, we'll be bringing on sites on the multi-site study so that we have that information 21 along with your information so that we'll really be 22 23 able to make a difference and get a really good 24 understanding of what the health effects that might 25 be associated with perfluorinated compounds in

1 drinking water are. Rich. 2 MR. DiPENTIMA: Thank you. I think you may 3 have answered my question --DR. CIBULAS: Okay. 4 5 MR. DiPENTIMA: -- but I just want to get it The \$10,000,000 you have for this fiscal б clear. 7 year, I assume you'll have a contract -- a 8 contractor and a contract signed by the end of this 9 fiscal year, before the end of the fiscal year. 10 Will that, in effect, encumber that \$10,000,000 so 11 if it's not spent per se by the contractor at the 12 end of September that that money will still be 13 available for the contractor to continue beyond the 14 fiscal year? 15 DR. CIBULAS: Oh, it's one year money, I 16 believe. But the idea is with this \$10,000,000 17 right now a statement of what -- there's a four part 18 statement of work being developed. Okay. You'll 19 recall that if you've looked at the National Defense 20 Authorization Act there is a second component which 21 is an exposure assessment that's to take place in no 22 less than eight military or former military bases, 23 right? So part of that \$10,000,000 is going to go 24 into the exposure assessment. We have -- the Act 25 stipulates that it has to be started within six

1 months and so we've got a whole 'nother team at 2 ATSDR that's working on that right now. But that's 3 part one of the \$10,000,000 under the statement of work. The second part is going to be a data 4 5 management contract where we've got to get somebody together, a contractor who's going to manage all the 6 7 data that's coming in, clean it, make it -- make 8 sure it's collected appropriately and it can be in a 9 -- it's coming in the same way that the data is 10 going to come in from the other sites, et cetera. 11 So that's part two of the statement of work, and 12 part three is in community engagement. So that's a 13 very big part of the future success of everything we 14 do so there is going to be possibly another 15 contractor that's going to work with us to make sure 16 that the community engagement part of this is done 17 to the best that it can be. And then the fourth 18 part is our work at Pease. So we do anticipate that 19 the \$10,000,000 will be used up completely on those 20 four pieces. So I think that's the answer to your question. And I'm going to ask anybody on my team 21 to feel -- help, you know, feel free to jump in and 22 23 help me out here if I say anything egregiously 24 incorrect or anything like that. But that's the way 25 it should work and yes, we need to have that

contractor on board; or contractors, it could be up to four different contractors, you know, for this first \$10,000,000. Andrea.

MS. AMICO: First of all I just want to say thank you very much. This is really exciting news and the Pease community is extremely appreciative of this opportunity, so thank you very much. Thank you to Senator Shaheen's office as well.

So yeah, I have a few questions. You talk about the exposure assessment but that would not be applicable here, correct? The exposure assessment is what you're going to do at other sites?

DR. CIBULAS: That's correct. Anything, as we understand it, Frank help me out if I say something wrong, but anything that's going to be done for those communities that participate in the exposure assessment will have or will be done here for the community at Pease.

MS. AMICO: Okay.

1

2

3

4

5

6

7

8

9

10

11

12

19

20 DR. CIBULAS: So that's correct, we do not 21 anticipate Pease being part of the exposure 22 assessment.

23 MS. AMICO: Okay. And how many communities do 24 you think will be participating in this exposure 25 assessment?

1 DR. CIBULAS: The legislation says eight. 2 DR. PAVUK: At least eight. 3 MS. AMICO: Okay. DR. CIBULAS: At least eight is what it says 4 5 and I think that's the goal. I think that is the 6 goal to have eight where our staff will be doing 7 some re-con, if you will, to try to identify some of those bases that we know would fit in well with 8 9 characterizing the exposures. And so we would 10 anticipate that our staff at ATSDR will probably 11 provide a number of good candidate sites for this 12 exposure assessment. The exposure assessment, if you read the language, is to inform the multi-site 13 14 studies so, you know, we want to get some good 15 information out of there and so eight is the target 16 right now. 17 MS. AMICO: So just to be clear, if you 18 selected a site for the exposure assessment that 19 doesn't necessarily mean that site will be in the 20 actual multi-site study. 21 That's absolutely correct. DR. CIBULAS: 22 MS. AMICO: Okay. 23 DR. CIBULAS: Yeah. 24 MS. AMICO: And do you have a criteria in terms 25 of who could be part of the exposure assessment?

1 Have you released any of that publicly? We hear 2 from a lot of community leaders across the country 3 so this obviously comes up a lot, so folks want to know across the nation how can they be part of this. 4 5 You know, they're anxious to be part of this. 6 DR. CIBULAS: Yeah. Frank, can you help me out 7 on that? DR. BOVE: Yeah, just hold on for one second. 8 9 DR. CIBULAS: Okay. 10 DR. BOVE: See if I can get in here. I don't 11 know if this is actually out in public yet. 12 DR. PAVUK: No. They have --13 DR. CIBULAS: A little bit closer to the mike, 14 Frank. Go ahead Marian, if you can help, go ahead. 15 DR. BOVE: Can you hold on for just one second while I find this? 16 17 DR. PAVUK: I mean, the criteria has not been 18 released publicly so the process for exposure assessment or exposure investigation as it's called 19 20 also has to undergo the process of OMB review but 21 different one than ours. Ours is considered for the 22 purposes of OMB review as research by doing exposure 23 assessment and biomonitoring. It's not research 24 because they do not collect data on health outcomes. 25 MS. AMICO: Okay.

1 DR. PAVUK: So slightly different procedure. 2 DR. BOVE: They have some criteria or issues 3 that they'll look at and those include obvious ones, magnitude of the exposure, so how high the 4 5 contamination is in the drinking water, the length of time the water was contaminated, and the ability 6 7 to characterize the drinking water system, how 8 complex is it. Is it simple like Pease, for example 9 or is it more complex like say Warminster where 10 water is coming different ways and different parts 11 of the town are served by different wells. And if 12 there's been some past biomonitoring that might help 13 rise a site to consideration and what kind of 14 mitigation has been done. So these are, you know, 15 pretty common sense. And again, this may change, 16 this is still a draft pre-decisional whatever they 17 want to call it, so it may change. 18 MS. AMICO: Okay. How do you anticipate 19 communities would know once you guys iron these --20 this criteria out? Would that information go 21 through their state health department or how would a 22 community become aware that you're looking for 23 communities interested in participating in this

exposure assessment?

24

25

DR. BOVE: Well, I think and originally we were

hoping to do some kind of competitive process and because of the way the money is going to be given to us from the Department of Defense, at least the way we understand it now it can't be a competitive process. We have to select a site. So we're going to probably use these criteria and like sites that way.

8

9

10

11

12

13

14

18

1

2

3

4

5

6

7

MS. AMICO: Okay.

DR. CIBULAS: Whereas, on the other side once we get to the multi-site study our intent at that time is that there would be a competitive process and we would put criteria out that's out. So the two different halves are moving in two different directions at this time.

DR. BOVE: Yeah. And it's because of the way the money is coming and because we have to do eight sites this year because of the --

MS. AMICO: Right. Okay.

19 DR. PAVUK: I mean, the understanding of the 20 government contracting process, the money needs to 21 be allocated. It doesn't need to be spent by 22 September, you need to set up the contract, 23 contractor then can carry over the money and to do 24 the tasks that are in the contracts. 25 MS. AMICO: Thanks. Dr. Cibulas, you had

1 mentioned the work to start in late summer, but you 2 didn't specify what year. 3 DR. CIBULAS: Oh. MS. AMICO: Do you mean this year or next year, 4 5 just to be on the record? 6 DR. CIBULAS: It's next year, I'm sorry. 7 MS. AMICO: Yeah. DR. CIBULAS: It's 2019, yeah. You know, we 8 9 did send you the one pager on the OMB process, 10 right? We did send that and it does say, you know, 11 nine to 12 months is the normal time frame for a new 12 information collection going through OMB. We've 13 generally had a little bit better success than nine 14 to 12 months. I know there's a backlog there. 15 Sometimes things can take a little more of a 16 priority than other things and we have an 17 opportunity to tell them what our priorities are and 18 we're going to do our best to push this through. 19 But that is the -- that's the big issue. But again, 20 as I said, there are things that we will be working 21 with with the contractor during that time that this 22 is going through OMB review. 23 MS. AMICO: Okay. 24 DR. CIBULAS: Yeah. 25 MS. AMICO: Are there any other processes or

1 delays that you can anticipate that would bring us 2 beyond starting in the summer of 2019? 3 DR. CIBULAS: I can't. You two have more experience with epi studies than I have, but go 4 5 ahead. DR. PAVUK: Well, if I may backtrack just a 6 7 little bit. So what we're going to do, we have put 8 together study protocol for Pease PFAS health study 9 proof of concept, so there are two major components 10 that need to happen before the start of the actual 11 health study and one of those -- one of those two 12 components are the approvals that's the process for Office of Management Budget and Institutional Review 13 14 Board. So those are the institutions that basically 15 are approving for us our primary data collection 16 because we are going to collect data with 17 identifiable information, medical information, 18 medical history, occupational history, residential 19 history. So anyone who does research on human 20 subjects using government money through government 21 needs to go through this process. The first major 22 part of that process is basically having the 23 instrument having the protocol of what are we going 24 to do, what health outcomes are we looking at, who 25 are we going to recruit, how are we going to sample.

That's what you have in the protocol that needs to be reviewed by external advisory -- external reviewers and that process we were able to complete and you see our responses in that process.

1

2

3

4

5 So I don't want to talk too long about how the OMB process works, but I will give you some major 6 7 highlights of a couple of steps that need to happen 8 there. So that was the component of approval. The 9 second component of the study is the study execution 10 and the study execution in our current state 11 involves setting up the contract of which the part 12 of the contract is the statement of work that needs 13 to happen that needs to go to different components 14 at CDC, whether it's PGO or Office of Financial 15 Resources and others. Those two processes in a 16 sense work in parallel. We can start contracting 17 processes before we have approvals from OMB and IRB. So we are not just sitting and wasting our time 18 19 waiting till summer to start the contracting 20 process. So that's why putting together the protocol is very important part because it allows 21 22 you to prepare statement of works that include the 23 tasks that relate to setting up study office, 24 engaging state health department, looking for people 25 who participate in biomonitoring and other tasks

that relate to recruitment enrollment and actual data and sample collection. So the -- all the preparatory activities can happen in the process before the OMB approval, but you cannot directly contact or enroll people until the final OMB approval happens. So that's the timeline. You can start the next day, but until that happens you can't really contact the people.

DR. CIBULAS: So Andrea's question was do we anticipate that there could be any other delays --

DR. PAVUK: Okay, so --

1

2

3

4

5

б

7

8

9

10

11

12

13

DR. CIBULAS: -- that would keep us out of the field by late September.

14 DR. PAVUK: So let me just in broad strokes 15 highlight the process. It starts with really 16 putting together an OMB package. OMB package 17 includes the protocol which will be slightly changed in sense of requiring a little bit more detail in 18 19 some components that OMB works on. It also needs to 20 have all the attachments that include the contacting 21 participants, calling them, setting up appointments, 22 inform consent that they have to sign before getting 23 a part of the study and all the other forms. Ιt 24 also includes supporting statements A and B which 25 are special documents on what and how we're doing

explaining to OMB. Before the package goes to OMB it has to be cleared and reviewed by Health and Human Services and which takes about 30 days or so and also by ICRO office at CDC that actually handles the topic.

1

2

3

4

5

There is the 60 day public comment wait time 6 7 for in the first part of OMB process as Bill 8 mentioned. So you're talking about one month 9 getting the package to the OMB then about two months 10 of getting the 60 day Federal Registry notice 11 published and the public comments, then response to 12 those public comments, revising the protocol and 13 publishing 30 day Federal Registry notice. Thirty 14 day Federal Registry notice is basically the final protocol in all the attachments and all the 15 16 materials that go to OMB. So in that window there's 17 a little bit more back and forth OMB reviews the 18 responses to public comments and other comments and 19 after that is published the actual OMB review 20 starts. So you really go through period of about three, four, five months before OMB starts reviewing 21 22 your whole package. So then OMB by law has minimum 23 of 60 days to start reviewing but our experience 24 over the years have been mixed. Sometimes it may 25 take them three months, sometimes it takes six

months, it may take up to nine months to even get to review of the package. Then they schedule a call with you, require changes, major adjustments, minor adjustments. So really the estimates are not so much on our end are those of getting the package to OMB and working through those windows of 30 day and 60 day notice. Then it actually is with the OMB, it really depends on OMB like how quickly they move on the current situation with OMB.

1

2

3

4

5

6

7

8

9

10

11

12

13

DR. CIBULAS: So that's a maybe.

DR. BOVE: So, I mean, we said this before that OMB is going to be the place where it could get delayed.

DR. PAVUK: But also, so it may get delayed at 14 the same time, as I was saying, during the time 15 16 that, you know, packages is getting ready or getting 17 to OMB we need to also obtain CDC IRB approval. So 18 that's the period of time when the similar package 19 goes to one of the CDC review boards, it needs to be scheduled, reviewed, provide usually voluminous 20 comments that we need to address. So that process 21 22 also takes a couple of months that we are doing in 23 parallel while the package goes through OMB. And as 24 I said, during all those months, the other part of 25 the team that is focused on the contractual

activities can address some other things that we will be talking later about or we can at least highlight what can be done on the ground before that happens.

5 DR. CIBULAS: So I would say our commitment to б you is to provide a timeline. Pat is holding us as 7 best as he can to timelines now. We'll share these 8 steps that Marian has gone through, we'll give you estimated timelines and we'll keep you posted if 9 10 there's any snags or anything going on that could 11 push a deadline or a timeline back. But that's what we'll do. We will make sure that you understand the 12 13 steps. Pat's putting deadlines as best as he can on 14 all of these and he's holding us to them and like I 15 said, some things with OMB we can't control but 16 we'll give you an estimated timeline when certain 17 steps will fall in place and we'll keep everybody 18 apprised. 19 MS. AMICO: Okay. Thank you. 20 DR. CIBULAS: Frank, did you -- were you going

to add something?

1

2

3

4

21

22

DR. BOVE: No.

MS. AMICO: Thank you very much. That
explanation was very helpful actually. Thank you.
Can you talk to me a little bit about how you guys

vet contractors, you know, like if you're going to be using contractors to carry out this work. How do you -- how do you go about doing that, how do you go about finding the contractors?

1

2

3

4

5

6

7

DR. CIBULAS: Well, you're in the process right now, Frank, with Camp Lejeune, if you want to talk about it.

DR. BOVE: Yeah. I mean, we put out a request 8 9 for proposals so that -- which is based on the 10 statement of work. So contractors then provide us 11 with their bids and how they're -- their technical 12 proposal and how they're going to meet the statement 13 of work and also the costs. And we set up a small 14 panel to review it of staff at ATSDR to review it 15 and grade the contractors. And we don't give the --16 necessarily give the contract to the lowest bidder 17 and we look at the technical proposal and if the 18 technical proposal one, is very good and but more 19 money we may go with that. And so it's -- we do 20 look at costs. If the costs are astronomical from one contractor they may take them out of the 21 contention. But again, we look at the technical 22 23 proposal in particular and grade and that's what we 24 grade them on that. And if they have a high grade 25 on that that's likely they will get the contract.

MS. AMICO: And who are these contractors, are they scientists, are they academics, who --DR. BOVE: No. They're companies like say

1

2

3

4

5

6

7

8

Research Triangle, RTI, Battelle, Westat, and NORC which does a lot of opinion research. I'm trying to think of the usual gang of contractors.

DR. CIBULAS: Frank, so how do they get their expertise that they need to --

9 DR. BOVE: Okay. So they oftentimes have in-10 house expertise and then they subcontract with other 11 contractors who have a specialized expertise. For 12 example, a contractor working on the cancer 13 incidence study at Camp Lejeune they might 14 subcontract out with a group that's worked with 15 cancer registries, for example. They may not have, 16 but they may subcontract with people who do it all 17 the time, for example. So and do you have --

18 DR. PAVUK: I think -- I think the question was 19 more about, you know, where the pool kind of comes 20 I mean, a lot of those contractors work with from. 21 ATSDR or with CDC for years so people know their 22 performance and their strengths in different fields. 23 Many of the contractors specialize for different 24 things, whether it's data collection or data 25 management or other activities. So these are on one

hand established relationship that they have with CDC but also as the RFBs are open, you know, other contractors may send their proposals to CDC. So it's not necessary that the -- for some contracts that -- some contracts are kind of closed to those that already have contracts with CDC and those are major corporations like Battelle, SAIC or Westat. But those would be open competition contracts and such.

1

2

3

4

5

6

7

8

9

10 MS. AMICO: Okay. And so I'm a parent of two 11 small children that I hope will participate in this 12 health study. Who can I expect to be interfacing 13 with when the study starts, these data collection 14 contractors or, you know, like who will I be dealing 15 with when my children participate in the study, 16 directly?

17 DR. PAVUK: Well, that would be a combination 18 really of factors. I mean, they would be -- the way 19 this is usually set up since we are involved and we 20 are the originator of the contracts we are overseeing the contract. So on some of the aspects 21 providing you information, an invitation letter, we 22 23 would be working with the state health department or 24 some local organization and the letter would be from 25 The actual posting and management of them.

addresses and finding the contact information, other things, that would be work of the contractor. So you would be getting, for example for getting or setting up appointments you would be getting a call from the contractors.

MS. AMICO: Okay.

DR. PAVUK: But if you have questions about 7 8 what we're doing and why we're doing, the CDC would 9 have to have set up a phone line and email address 10 where you can send the questions and request about 11 the study and general conduct of what the 12 information is, what do we do with consent forms. 13 So both contractor and us are involved in different 14 capacity on that.

15

1

2

3

4

5

6

MS. AMICO: Okay.

DR. BOVE: Right. But the contractor will have trained staff that will collect your information, for example, administer a questionnaire, get your blood sample and so on.

20DR. PAVUK: Correct. So the actual collection21and staffing will be on the ground here will be22contractor.

23

MS. AMICO: Okay.

24DR. PAVUK: So we'll be here to super -- to25come here to check on what is the setup, is the

1 place -- we would have to approve, you know, 2 selecting checking study office, do they have 3 everything that they need to have, is there a lab, where are the centrifuges, is there a backup. 4 So 5 all this goes into the contract that they have to 6 provide that somebody needs to go and check so we 7 need to be part of that process, you know, see how 8 the interviewers are. They have to have 9 certificates of training, HIPAA training, other 10 training required for NIH. So all those things, you 11 know, we need to be involved in. 12 MS. AMICO: Okay, thank you. Do you have a 13 Pease contractor lined up or you're inactively 14 pursuing one or... 15 DR. CIBULAS: Like we said, it's part of the 16 four part statement of work and so at this time, no. 17 We will have the contractors in place for each of 18 the four components which includes the work here at 19 Pease by the end of September or sooner if we can, 20 so not yet. 21 MS. AMICO: Okay. Thank you. 22 DR. CIBULAS: Yeah. So Jamie reminded me to 23 remind everyone we are recording and so please 24 remember to identify your name so that our 25 transcriptionist has it correctly when we have the

notes. So Alayna.

1

2

3

4

5

6

7

8

9

10

MS. DAVIS: Hi. So one of my first questions was at the, I don't know if it was at the last meeting, but it was mentioned that for the study, the multi-site study, not necessarily the exposure assessment, that there is the possibility of nonmilitary sites being used. So how does that work if the exposure assessments are just military sites, how do you assess those sites to find out if they're a good fit for the study itself?

11 DR. CIBULAS: So whether or not we can have 12 non-military sites as part of the multi-site study 13 will depend on the language that we get next year. It will depend on, as Pat put it to me, he would 14 like to have the flexibility if there was a perfect 15 16 site, for example, that would complement the other 17 sites that would give us that missing piece that 18 we're looking for to really be able to address the 19 question. He'd like to have that flexibility just 20 in case there is a non-military site. But we don't know the answer yet on whether or not there will be 21 22 any non-military sites part of the multi-site study. 23 So it will depend on the language and it will depend 24 on, again, whether -- if the language gives us the 25 flexibility then it would depend on whether or not a

proposal came in. You know, these will go out as hopefully as a research cooperative agreement with an opportunity to be competitive that they would, you know, provide information that would allow us to, as I said, make the decision that this is a good site that will really compliment the other sites that are going to be part of this study.

1

2

3

4

5

6

7

DR. BOVE: Yeah, I mean, there are some issues. 8 9 I mean, if most of the sites are sites that have 10 AFFF contamination, then you put a site in there 11 that's -- that has a totally different source like 12 an industry -- or then it'll stand out, it won't 13 mesh with the other sites very well. So that's one consideration, but that doesn't rule out other sites 14 that are non-DoD sites. But there are other options 15 too. I mean, these studies are using effect 16 17 biomarkers, getting blood samples from people. There are other studies that can be done on sites 18 19 besides these kinds of studies and so we're pursuing 20 and we're thinking about pursuing studies such as what I was involved with back in New Jersey years 21 22 ago where we looked at drinking water contamination 23 and looked at small for gestational age, pre-term 24 birth, birth defects, cancer incidence and so on and 25 compared towns that were totally served by

1 contaminated water and towns that weren't and 2 compared them that way. And got a lot of useful 3 information out of that and we can do that in particular with some sites where the entire town is 4 5 receiving contaminated drinking water and there's a 6 comparison -- comparison towns that can be looked 7 at. So we don't have to do -- we can do other kinds of studies as well at these non-DoD sites. 8 But 9 we're trying to be flexible here and again we'll see 10 what the legislation is. 11 MS. DAVIS: Okay. So the first year is focused 12 on military sites? 13 DR. CIBULAS: The exposure assessment is, yes. 14 That's correct. 15 MS. DAVIS: Well, essentially the first year of 16 funding. 17 DR. CIBULAS: Yeah, that's correct. That's correct, yes. 18 19 DR. BOVE: Yeah, the first year of funding is 20 on the eight exposure assessments. And the exposure 21 assessments are a sample of the population, a small 22 sample where blood is obtained and urine is obtained 23 and analyzed for PFAS only, okay, not for any health 24 end points. It's purely an expo -- and hopefully 25 we'll also be getting in that process some

1 information on the drinking water system so that if 2 these sites -- so that we'll be able to evaluate 3 whether any of these sites should be part of the multi-site study or not. 4 5 MS. DAVIS: Okay. And then in regards to the timeline for us, at what point do we as community б 7 members start engaging in the community to that 8 interest in being participants? 9 DR. CIBULAS: I would say -- guys you help me 10 out, I would say once we have the contractor on 11 board things are going to start moving, logistics 12 are going to start coming in place and --DR. BOVE: You mean for the eight -- the eight 13 14 sites --15 DR. CIBULAS: She's talking about --16 MS. DAVIS: No, no, no, for the Pease 17 community, like at what point do we, I mean, when 18 should, I mean, who's going to guide us on engaging 19 the community to figure out who can participate, who 20 would want to participate --21 DR. BOVE: Oh, okay. Okay. 22 MS. DAVIS: -- so that we're ready to go when 23 you guys have gone through your own BIRB process. 24 DR. PAVUK: As I mentioned earlier, once the 25 contract is awarded to the engagement activities can

1 start so then the process is initiated. 2 MS. DAVIS: But where --3 DR. CIBULAS: We have our monthly calls and we're going to keep --4 5 MS. DAVIS: Yeah. 6 DR. CIBULAS: -- you apprised of everything 7 that's going on. I'm sorry. 8 MS. DAVIS: Yeah, because I mean we need to 9 inform the community that this is something that 10 they need to consider and so we have to kind of have 11 a heads up to make sure. 12 DR. PAVUK: This is like fall, that would be 13 like October, November of this year, you know, to 14 start getting you informed of what activity, how you 15 can participate and help us with those activities. 16 So I would presume that that would be in that window 17 of October, November this year that this will be 18 discussed in more detail. 19 MS. DAVIS: Okay. And then my last question 20 right now would be when you're talking about the 21 contractors that you're going to --22 DR. CIBULAS: Hire. 23 MS. DAVIS: -- yeah, hire and take proposals 24 from, how much information do you share with them so 25 that they can decide what to write the proposal on?

DR. CIBULAS: The statement of work, the depth of the statement of work.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

DR. BOVE: Yeah. All the contractors get a -and see a request for proposal which is based on the statement of work, so that's what they see --

MS. DAVIS: So that includes the --

DR. CIBULAS: -- which is very much built on the protocol itself that we've been talking about.

DR. BOVE: Yeah, it's built on the protocol. So the protocol is broken up into tasks, okay, and so and then they address each task in terms of how they're going to do it and how much it's going to cost and how much staff the contractor will need for each task. So it's broken down by hours and all that. So that's what we get from the contractor. Okay. So they all have the same information and they respond to it.

MS. DAVIS: Okay. And then how long is thatprocess to pick the contracts usually?

20 DR. PAVUK: Well, that depends, you know, how 21 many people respond to those but I think is the 22 minimum two or it must be three.

23DR. BOVE: Well, for Camp Lejeune it was24strange because we had to wait until we got the25money. And in fact, we haven't been able to award

1 the contract yet until all that gets ironed out. So 2 it's actually a process that the RFP went out in 3 November, we got the proposals back in December, we weighted them by January then there was back and 4 5 forth with the contractors and we had some 6 questions, for example, so sometimes that process 7 happens, we're not clear about what they're 8 proposing to do. While we may have some issues with 9 it, they're not putting enough staff time or 10 something like that and we want them to elaborate. 11 So the process can -- it may take only two or three, 12 three or four months maximum, but --13 DR. PAVUK: We don't even have that much time 14 right now, so --15 DR. CIBULAS: Yeah, so it's got to be let by 16 the end of September as we said earlier, it's got to 17 be done by then. DR. BOVE: This will be quicker. 18 19 Okay. And then is there an IRB or MS. DAVIS: 20 OMB process in regards to picking the contractors, 21 like do they have to approve them or are these 22 contractors already approved by OMB and IRB, like 23 does that delay anything? 24 DR. CIBULAS: That's our responsibility. 25 That's the government's responsibility.

1 DR. PAVUK: We have to provide them with those 2 approvals so that they can start the work. 3 DR. CIBULAS: Yeah. DR. PAVUK: They cannot start the work, they 4 5 using, we are getting those approvals, not the 6 contractor. 7 MS. DAVIS: Okay. So my question, I guess, is 8 does that choosing the contractors have to go 9 through a process with IRB or OMB? 10 DR. BOVE: No. No. 11 DR. CIBULAS: So let me mention that Laura --12 Laurel, is that right, Schaider has joined us and 13 she has a question, so go ahead Laurel. 14 DR. SCHAIDER: Hi, thanks. I wanted to follow 15 up on Andrea's question about the exposure 16 assessment and there will certainly be many 17 communities that would like to be a part of that, so 18 I was wondering if you could talk a little bit more 19 about where you'll get the information to help make 20 that decision and whether there's anything that 21 community members in these affected communities can 22 do to provide you any additional information or help 23 you evaluate whether they'd be good candidates. 24 DR. BOVE: Yeah, we're not the ones who are 25 actually doing that work, that's another division.

1 But what they've been doing is, of course, using the 2 UCMR 3 data, for example, and then following that up 3 with any information they can get about those particular wells that were tested and about anything 4 5 they can find about the water system without having to do detailed effort of getting data from these 6 7 water systems, water companies. So I think that 8 that's basically what they're doing. I would guess 9 that if communities, people in the communities can 10 do some of that work on their own, for example, find 11 out more about the water situation in their 12 community, the history of the contamination, 13 anything they can find out, that's useful 14 information and I think that they should provide us 15 with that information if they can -- if they have 16 it, they can get it. 17 DR. SCHAIDER: And who would they send that to? DR. CIBULAS: Why don't we do this, Jamie, at 18 19 our next teleconference why don't we bring the group 20 in that's responsible for this and let's let them talk a little bit more since we don't have 21 22 satisfactory answers to those questions and I think 23 it would be better if we bring Rachel in and just 24 have her to teleconference. Is that fair, we'll 25 bring the right people in to answer those questions?

DR. BOVE: But if I -- if you were advising community people that's what I would advise them to do is see what information they know about their system and their situation, how long the exposures have occurred, anything that might be useful in characterizing exposures or at least getting a sense of what the situation was. That's always useful information and if they have it, you know, that would be helpful. So we'll give you, we'll find the person that you should send it to, I think that's the key thing.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

DR. CIBULAS: Yeah. So we'll make that an action item to make sure that that occurs at the next meeting. Andrea.

MS. AMICO: I just wanted to follow up on one thing on the exposure assessment, you talked about testing urine, but we didn't do that here at Pease, so can you tell us what you would be looking for in the urine of these other sites and you know, what might we be missing here if we didn't have our urine tested?

DR. BOVE: Do you want me to handle it or do you want to handle it? Well, either one of us can handle it. Well, urine, we'll be looking for the small chain PFAS and although my understanding so

1 far it's hard to detect anything in these situations 2 like here. And the kinds of endpoints we would look 3 at urine we're actually going to look in serum anyway so I don't see a whole lot advantage of 4 looking at urine. However, we're developing new 5 techniques over time and so it's not a bad idea to 6 collect urine if you can and to store it and see and 7 have it available for a later time when the 8 technology may catch up with it and be able to 9 10 detect these smaller chains better than they do now. 11 But right now, if you collected urine and tested it 12 you probably wouldn't see anything and that's 13 because the technology is just not there. So we 14 have it in the protocol. We didn't talk about it in 15 the feasibility assessment because I didn't think it was useful. Since then there's been more 16 17 discussion, it's still not clear it's useful, but I 18 think Dr. Breysse wants to have that option to look 19 at urine at a later date when the technology may 20 catch up and because there may be some small chain 21 PFAS that you could pick up. 22

MS. AMICO: Okay. And then I guess just one follow up question to that would be, so is it your intention when you do the exposure assessments to store the samples of what you're gathering at that

23

24

25

1 time and then perhaps use it at another time if 2 there is more technology that can test for other 3 things? 4 DR. BOVE: Absolutely. 5 MS. AMICO: Okay. And I don't know -- have -are we clear if our blood has been stored here at б 7 Pease and if that's something you folks will have 8 access to? 9 DR. BOVE: This is a --10 DR. PAVUK: Yeah. We've been talking with Dr. 11 Chan and there are some blood samples so we are in 12 negotiations of that the participants will be reconsented so that we could potentially use those 13 14 stored bloods. That's the plan. 15 MS. AMICO: Okay. So we do know they're saved 16 There have been some that have been 17 DR. PAVUK: 18 saved, yes. 19 MS. AMICO: Okay. But then there's a matter of 20 re-consenting --21 DR. PAVUK: Yes. 22 MS. AMICO: -- to allow ATSDR contractor to --23 DR. PAVUK: Right. And that's part of that's 24 re-planning on that. 25 MS. AMICO: Okay, very good. Thank you.

1 DR. CIBULAS: Okay, let me just ask before we 2 take another look at our agenda which we've totally 3 blown out of the water which is just fine, let me ask on the phone if there is anybody who has a 4 5 question at this time, recognizing that we're going to get into a little bit more about the protocol in 6 7 a couple of minutes, but is there anybody on the 8 phone that has something right now that they would 9 like to ask? All right. So let's go ahead. 10 They have a question in the back, DR. PAVUK: Bill. 11 12 DR. CIBULAS: Well we need to go through the 13 action items, right? 14 They have a question in the back. DR. PAVUK: 15 DR. CIBULAS: Go ahead, ma'am, come on to the 16 microphone. 17 CDR MUTTER: There's a microphone at the very 18 end. 19 MS. McCURRY: I brought in --20 DR. CIBULAS: Would you identify yourself? 21 MS. McCURRY: My name is Anne McCurry, my 22 husband was Edward Sherman and he was a firefighter 23 at Pease in the '60s and his job was to basically go 24 in the area where the well is and they would dump, I 25 have the information here, dump all the chemicals,

1 anything that was burnable, into that spot and light 2 it up. And my husband had to walk in twice a week 3 and put the fire out and he's dead. But this is a 1984 assessment of my husband's well which is the 4 5 one in Newington under the roadway and this assessment in 1984 says his well was highly 6 7 polluted. And the lawyer that I went to said that 8 he had so many toxins in his system that he couldn't 9 nail it down to the fire foam. I mean, he was just 10 completely full of toxins and I have a specimen from 11 my husband which sounds gross, but I was really 12 upset the way he died and everything that was going I found this and I read it. I was very upset 13 on. 14 because in 1984 they knew the chemicals in the well, 15 they knew all about it and it was supposed to be cleaned up back then and look at how long ago that 16 17 And it takes a long time to get results from was. the well. Just like 9/11 it's in your body and it's 18 19 also in the ground forever. I mean forever. I 20 don't care how much you clean it up, I went to 21 biology teachers and it just doesn't go away. And 22 you know, I wouldn't come here without proof, but I 23 do have the Pease records from 1984 and that was my 24 husband's well and they said it was highly 25 contaminated and it's still that way. He died of

cancer, bile duct cancer. They couldn't nail it down, they did test his body and everything and he was full of toxins like you wouldn't believe. But he did have fire foam.

DR. CIBULAS: I was just consulting with my colleague here and wondering if your specific well would've been part of the health consultation work that's going on --

9 CAPT SOMERS: No, that was a well here on the 10 Pease Tradeport?

1

2

3

4

5

6

7

8

11 MS. McCURRY: That's the well -- that site is 12 the one that is contaminated, absolutely, and it's 13 the one they worked on to clean it up, but it was his duties to put the fire out on the Newington Road 14 15 between Newington and Greenland. All the vegetation 16 there is dead now. But that is -- he used to take 17 me there because he got so sick from putting these 18 out and he was in an asbestos suit. But we went 19 there and he would say this is where I put these 20 fires out, and it was all black grass like nothing ever grew there again, nothing. The trees are dead, 21 vegetation is dead. I mean, it's -- I'm -- I don't 22 23 even care about money or a lawsuit, I just want to 24 know why wasn't it cleaned up in 1984. It doesn't 25 go away by itself, it's in the ground and it's there

1 for good and people were drinking from that well. DR. CIBULAS: Well, Tarah wants to say 2 3 something and then maybe subsequently afterwards you can meet with our regional. 4 5 CAPT SOMERS: Yeah, I can come and talk to you about the work that agents are doing on the health 6 7 consultations we have on site and look at your report. You might be better off talking to the 8 9 Environmental Protection Agency folks who are 10 overseeing the cleanup of the base and have overseen 11 past cleanups of the base, they might have more information. 12 13 MS. McCURRY: Oh, I know. I went on the bus 14 tour. We never did go to the site but --15 We can -- I can get you in CAPT SOMERS: Yeah. 16 contact with someone who might have more answers so 17 we can talk about that. Sure. MS. McCURRY: 18 The whole thing is --19 DR. BOVE: No, that's fine. I'll just say that there was contamination of the public water system 20 21 there of the Haven well in particular. 22 MS. McCURRY: Yeah. 23 DR. BOVE: It's a trichloroethylene which is a 24 solvent and --25 MS. McCURRY: Yeah, they list everything that

1 was dumped in there, if it was --2 DR. BOVE: -- yeah, and --3 MS. McCURRY: -- it if was burnable it went in. 4 DR. BOVE: -- and I'm sure there were other 5 things dumped just like would happen at Camp Lejeune and other military bases. There's a lot of б 7 chemicals, it depends on what part of the base we're talking about. So but we're focused here on these 8 9 PFAS chemicals, the perfluorinated substances and so 10 and AFFF foam. And so --11 MS. McCURRY: Well, that was definitely there 12 because he had to put it out. 13 DR. BOVE: -- that was there too. Yeah, yeah. 14 But there were other things that your husband 15 probably was exposed to as well. MS. McCURRY: Yeah, it's all listed in here 16 17 what they dumped into the well. This is an official 18 document, not mine. Installation Restoration 19 Program Record Search for Pease Airforce Base. 20 CAPT SOMERS: Do you want to come and give me 21 your information and I can --22 MS. McCURRY: Yeah. 23 CAPT SOMERS: -- try to get you some 24 information? 25 MS. McCURRY: Sure.

DR. CIBULAS: Thank you, ma'am. We appreciate your sharing --

1

2

3

4

24

25

MS. McCURRY: I just want to let you know because I was there a long time ago.

DR. CIBULAS: So Jamie has reminded me the CAP 5 6 likes to hear the community concerns early into the 7 meeting. So let's just -- let's ask if there is 8 anyone else out in the audience right now that has 9 anything that they would like to bring to the 10 attention of the Agency and the CAP. We can come 11 back if you don't, but please, I mean this is, in a 12 way as I think as we move further along into the 13 study and things and we start advertising and 14 marketing more what's going on, I think we'll be 15 getting a bigger audience coming to the meetings and 16 things and sharing more concerns. So but please, 17 that's part of this meeting also. So if there's 18 anything, please let us know. 19 So shall we move to the action items, Jamie? 20 We can.

CDR MUTTER:

21 DR. CIBULAS: Okay. Let's go ahead and move to 22 the action items from the last meeting and then from 23 there we'll go with the protocol.

> CDR MUTTER: May we take a break first, because one of the action items Tarah is going to answer --

1 DR. CIBULAS: Okay. 2 CDR MUTTER: -- and she's otherwise engaged so 3 it might be a good time for a 10-minute break, if 4 that's okay. 5 DR. CIBULAS: Okay. 6 CDR MUTTER: Okay, sorry. 7 DR. CIBULAS: All right, let's take -- let's 8 take a quick 10 minutes. We're way behind schedule. I want to make sure we have lots of time for the 9 protocol. Let's come back at 7:30, see if that is 10 doable and we'll take a 10-minute break. 11 Thanks 12 very much. 13 (Break, 7:22 till 7:31 p.m.) 14 DR. CIBULAS: All righty. 15 CDR MUTTER: I don't know where we are now. DR. CIBULAS: Well, we're going to do the 16 17 action items and we are going to check to see if our 18 members are still with us on the phone. Should we do that? 19 20 CDR MUTTER: Sure. 21 DR. CIBULAS: Let's just make sure the phone 22 lines are still working properly as -- are our CAP 23 members who have joined us on the phone still with 24 us? If I hear from one that'll be good enough. 25 UNIDENTIFIED SPEAKER: Yeah, I'm here.

1 DR. CIBULAS: There you go. Very good. So 2 it's 7:31 and let's go ahead and go through the 3 action items and we have six or seven of them as I recall and Jamie Mutter is going to lead us through 4 it. Jamie. 5 ACTION ITEMS FROM JANUARY 2018 CAP MEETING б 7 CDR MUTTER: Thank you. So the first action item is for ATSDR and it says, Commander Mutter 8 stated that ATSDR would let the CAP know what data 9 10 were needed in order to revisit testing the old 11 water, also stating that ATSDR would provide a justification for not testing the old water in the 12 13 tank. And earlier this week I sent out a reply 14 email with an attachment; that was on Tuesday. Are 15 there any questions about that email? Basically, 16 we're still trying to get data. 17 DR. CIBULAS: So it's not a dead end. 18 CDR MUTTER: No. 19 DR. CIBULAS: We've got some information and 20 we're still looking into whether or not that may 21 provide --22 CDR MUTTER: Yes. 23 DR. CIBULAS: -- an important source of 24 information. 25 CDR MUTTER: Correct.

DR. CIBULAS: Yeah.

1

2 CDR MUTTER: Yep. Okay, so moving on, the next 3 action item is also for ATSDR. ATSDR was asked if there was a timeline or a plan as to how it is 4 5 spreading the word about physician materials and guidance and if so could ATSDR share that with the 6 7 CAP. Capt Somers responded, there is nothing 8 official but ATSDR can write up a timeline and 9 summary of methods to be used to announce the 10 materials to share with the CAP. 11 CAPT SOMERS: So I can talk about this now, but 12 it might be better to tie it into the health 13 consultation discussion because we're going to go 14 over our plan for releasing those health 15 consultation documents and we are trying to tie in 16 some physician outreach or clinician outreach around 17 the time we're releasing those documents so that way when our documents go out and people read them if 18 19 they have questions for their clinicians, hopefully 20 we've also done some effort to get more information 21 to clinicians. So do you want me to go over all --22 should we --23 CDR MUTTER: We'll wait. 24 CAPT SOMERS: Okay, we'll wait. 25 CDR MUTTER: We can wait on that --

| 1 | CAPT SOMERS: So we'll circle back. |
|----|---|
| 2 | DR. CIBULAS: Good. |
| 3 | CDR MUTTER: Okay, wonderful. Thank you, |
| 4 | Tarah. Okay. So ATSDR will provide a short write |
| 5 | up to the CAP about the role of OMB, what decisions |
| 6 | it makes and what decisions are made elsewhere. |
| 7 | That was shared with the CAP, I believe, on March |
| 8 | 1^{st} , so if you need me to resend that please let me |
| 9 | know, otherwise it should be in your email. |
| 10 | The last action item for ATSDR is a CAP member |
| 11 | asked if they would get to see DoD comments made |
| 12 | during the data validation phase. Dr. Breysse |
| 13 | answered that we will ask DoD if we can share the |
| 14 | comments but it is not a decision he can make. We |
| 15 | did ask DoD and the comments were shared earlier |
| 16 | this week with the CAP. |
| 17 | DR. CIBULAS: I've got to go back to the OMB |
| 18 | thing just for one second. We're not going to go |
| 19 | through the steps again, but I want to assure you |
| 20 | we're putting the best people we have on our team |
| 21 | and our individual who's working with Marian and |
| 22 | Frank on the OMB issue is, in my opinion, she may be |
| 23 | the best expert in all of CDC on working with OMB. |
| 24 | So I just want to assure you we're doing everything |
| 25 | we can to put the best people on this team to make |

1 this go as well as it could possibly go. Go ahead. 2 CDR MUTTER: Thank you. So the last two action 3 items are for the Air Force. The first one, a concern was expressed regarding the public health 4 5 risk posed by the volume of water in the storage tank. A CAP member proposed a discussion about 6 7 potential discharge of the water to protect the land 8 surrounding the tank. Col Costantino will talk to 9 Jared Sheehan about specific information regarding 10 the tank, so I'll... 11 DR. CIBULAS: Colonel. 12 COL COSTANTINO: Sure. Yeah, so during or 13 after the meeting the request was made to kind of 14 discuss it outside of the CAP because it was more of 15 an environmental response type question. So I've 16 been providing, Jared did give me information on the 17 tank, the condition of the tank, the lines were pulled out, the last date that the tank was in use 18 19 which was like 1999 by Pan Am or something like that 20 and it was for a deluge system. So I received that 21 question, received information from him, talked to

24 25

22

23

our own folks about what we know about the tank and

the history of it. We sent it off to our legal team

and asked authority questions like we have to do

every time. We got some response back from that.

In the meantime we got another question from the Pease Development Authority related to a similar type request that will impact our response to this and so that was my last update a couple of weeks ago was I've got to sort through question one because that's going to impact question two and that's what I'm working on right now. And essentially it all boils down to what we're being asked is to address water that's not drinking water, right? That's the basic fundamental question is what about the water in the tank, what about surface water, other things like that. So we're work -- it's a complicated, difficult question. We're working through it and 14 I'll continue to give updates through email as I get 15 them. 16 CDR MUTTER: Thank you. So the last action

item we have for tonight is Col Costantino stated he would provide the correct contact person in the Department of Justice to answer questions regarding the lawsuit back to the CAP.

21 COL COSTANTINO: Right. So I provided that 22 info. You shared that Jamie or ...

23 CDR MUTTER: You know what sir, I did not re-24 share that.

25

1

2

3

4

5

6

7

8

9

10

11

12

13

17

18

19

20

COL COSTANTINO: Okay.

1 CDR MUTTER: I apologize. 2 COL COSTANTINO: They may already have it. 3 CDR MUTTER: They should re -- they should already have it if you want to --4 5 COL COSTANTINO: It's Wyn Hornbuckle was the It was the name I think we had provided 6 name. 7 earlier. A bit of confusion from that office about 8 whether or not the initial response we got back was 9 they -- they're not an office that is set up to 10 handle inquiries from the public or citizens. Ι 11 don't know if they talk to their leadership or talk 12 to someone. They normally only handle media 13 inquiries was the initial response we got back. We 14 followed up with them a couple more times, they said 15 they will take any questions from the public, they 16 will receive those questions. 17 CDR MUTTER: Thank you for that update, sir. 18 So that concludes the action items, sir. 19 PEASE PROTOCOL UPDATE 20 DR. CIBULAS: Very good. Any questions on any 21 of the action items? Okay. So we're going to talk 22 about the Pease protocol now and that will lead us 23 into a little discussion about the multi-site study. 24 And I'll remind you that there will be more than 25 this short opportunity to provide any comments on

the protocol. But if you have some in the next week we would certainly love to entertain them and with that I'm going to turn it over to Frank and Marian to go ahead and walk through this.

1

2

3

4

5 DR. BOVE: Well, just quickly, it's based on 6 the feasibility assessment. So a lot of it you'll -- is -- should be familiar to you. And so I don't 7 8 know, I think it'll be good given where we are with 9 the agenda, do we hear questions or comments from --10 with the -- instead of us going through it, unless 11 you want us --12 DR. PAVUK: Do you want us to just --13 DR. BOVE: -- unless you want us to do that. 14 DR. PAVUK: Do you want us to just -- do you 15 want us just to short -- to go and shortly like 16 overview what we're going to do at Pease? 17 DR. BOVE: Yeah. I mean, what would you --MS. AMICO: I think that could be --18 19 DR. PAVUK: Would you like to hear that? 20 MS. AMICO: -- helpful, especially for people 21 that may watch this video after the fact, if you could give us a brief rundown --22 23 DR. PAVUK: Okay. 24 MS. AMICO: -- that could be helpful. Thank 25 you.

1 DR. PAVUK: All right. Okay, so basically what 2 we're proposing to do at Pease is Pease PFAS health 3 study would be the first part of a multi-site study. So we propose as a proof of concept for a multi-site 4 5 health study and we propose to conduct a cross 6 sectional study that would recruit a sample of 7 children and adults that participated or are 8 eligible to participate in the 2015 biomonitoring 9 conducted by New Hampshire Health, Department of 10 Health and Human Services. So the overall -- the 11 goal at Pease is to enroll at least 350 children 12 ages four to 17 and 1000 adults over 18 years old. 13 Those eligible needed to work, lived on, or attend 14 childcare at Pease Tradeport or former Pease Air 15 Force Base or live in a home near Pease that was served by PFAS contaminated water in or before 2014. 16 17 So the main goals of the study are two-fold, one to evaluate the procedures and the protocols in order 18 19 to identify issues that need to be addressed before 20 embarking on multi-site study. And second, to 21 examine association between measured and 22 historically reconstructed serum levels of PFAS including PFOA, PFOS and PFHxS and other PFAS 23 24 compounds and selected health outcomes that I'll 25 discuss later. So the adult and children study in

this proof of concept study at Pease will also include a small group of reference, 100 for adults and 175 for children. We have focused or based on our review of scientific literature we decided to look at several health outcomes and biomarkers of clinical biomark -- clinical and health effect biomarkers. So in children we are going to look at changes in lipids, impaired renal function, thyroid functions, differences in sex hormones and sexual maturation, immune response and neural behavioral outcomes. We also will look at -- we will contrast the PFAS serum concentration with hyperclosteremia, hyperosmia, obesity and fatty liver disease.

1

2

3

4

5

6

7

8

9

10

11

12

13

14 In adults there's a number of outcomes, health outcomes are similar. We'll also look at 15 16 cardiovascular disease, changes in lipids, changes 17 in renal function and the kidney disease, changes in liver biomarkers, thyroid hormones. And in addition 18 19 to those outcomes we'll also look at osteoarthritis 20 and osteoporosis, endometriosis in women and also 21 autoimmune disease.

To be able to evaluate those health outcomes we propose to also do the medical -- to do the review of participants' medical records review and also some school records for children. To compliment the

self report and medical records review, there'll be extensive -- there'll be extensive battery of clinical and health effect biomarkers that will cover the general -- general groups of diseases of interest, as I mentioned. So there'll be panels on lipids, panels on thyroid hormones, panels on sex hormones, panels on a response to vaccine, autoimmune disease, cytokines and a number of other biomarkers as listed in the protocol.

1

2

3

4

5

б

7

8

9

10 So that information will be complimented, every 11 participant will take questionnaire, both adults and children. Children will also undergo extensive 12 neurobehavioral battery testing, it will take about 13 14 two hours. Some questions will be answers by the 15 parents as well as children. The important 16 component with the PFAS compounds is in addition to 17 measured levels of PFAS in serum is to attend and 18 conduct historical reconstruction of serum levels based on measured levels and also based on water 19 20 modeling given the information on water system. As 21 we mentioned several times before, the Pease study 22 will be part of larger multi-site study and the data 23 will be integrated into the larger system. We are 24 proposing or expecting that the multi-site study 25 will enroll about 6000 adults and 2000 children that

1 would provide sufficient sample size to study health 2 outcomes, not only those that are more prevalent, 3 but also those that may be more rare and that require a larger sample sizes. So just for those of 4 5 you, just a note, for those of you that had a chance to look at the proposed number of biomarkers and 6 7 health outcomes that we're going to look at, this is 8 a list that we want to get approved so that we can 9 do all of this if the funding is available to fund 10 some of those. Some of those tests are fairly 11 expensive and it will be really -- some of those 12 tests will depend on the level of funding that we'll be able to receive. As we have mentioned before, we 13 14 will be storing samples. Each of the participants 15 will have opportunity to provide consent to have a 16 store sample that we can analyze later. So even if 17 the funding is not available after immediate conduct of the study, some of those analytes or clinical 18 19 biomarkers can be measured at a later point. 20 DR. CIBULAS: Frank, you want to add anything 21 or? DR. BOVE: No, I'm fine. 22 23 DR. CIBULAS: Okay. So we can see if there's 24 any questions here or if not we -- Andrea, please go 25 ahead.

MS. AMICO: So you mentioned that folks that participate in the biomonitoring could be eligible to participate in the study. What if we have people that didn't participate in that initial round of biomonitoring but met, you know, were drinking the water at Pease prior to the Haven well shutting down in 2014, would those people be eligible for the testing?

1

2

3

4

5

б

7

8

9

DR. PAVUK: Yes, they would also be eligible.

10 MS. AMICO: Okay. And then you talked about 11 the age for children and I know that it's been 12 brought up a few times by community members that have children that are now adults but were exposed 13 14 as children, you know, 20 years ago so they don't 15 quite fit the criteria for either the kids or the 16 adults, so where would -- would those people be 17 eligible to be in a study and if so, where are they 18 being studied, as adults even though they're exposed 19 as kids --20 DR. BOVE: As adults. As adults. 21 DR. PAVUK: They'll be eligible as adults. 22 DR. BOVE: Yeah. 23 MS. AMICO: They would be eligible as adults 24 even if they were exposed 20 years ago --25 DR. PAVUK: Correct.

1 MS. AMICO: -- as children and are no longer 2 children? 3 DR. PAVUK: Correct. 4 DR. BOVE: Well we have a limit on how far back 5 your last exposure was. MS. AMICO: And what limit --6 7 DR. PAVUK: Children. MS. AMICO: -- would that be? 8 9 DR. BOVE: For adults too, don't we? We 10 didn't? 11 DR. PAVUK: Not so much. 12 DR. BOVE: Not so much? I thought it was like 13 10 years --14 DR. PAVUK: For children. 15 DR. BOVE: -- for children only? Well, let me double check that, but I thought there was some 16 17 restriction there. But all right, yeah, yeah. It's 18 -- yeah, it's a 10 years. So if there -- so that's 19 the criteria. So if they --20 MS. AMICO: So that's for children, they --21 DR. BOVE: No, it's for both children and adults. We have a 10 year, because of the half-life 22 23 of PFHxS which is from the study done at Ronneby was 24 somewhere around five years. So you know, so that's 25 arbitrary, we can change that. But that's -- right

now that's what we're thinking about is recruiting from those who participated in the biomonitoring as the first cut and anyone who was eligible to be in that biomonitoring, so that would include both children and adults at this point.

MS. AMICO: Sure.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

DR. BOVE: But we have that -- we wanted to have a cutoff so that we have people with more recent exposures.

MS. AMICO: Yeah. I guess my concern is that so we're now coming -- we're on four years since our exposure and we're talking more than five years before the study even starts. So if we're going only back 10 years we could be cutting down significantly the people that were expo -- that we're going to allow to be in the study. I understand what you're saying and that's something we can add in our comments or whatnot, but --

DR. BOVE: Yeah.

MS. AMICO: -- so then based on what you're telling me, it sounds like people that did drink the water as children 20 years ago would not be able to participate because their exposure was 20 years ago.

DR. BOVE: At this point we're trying to limit it to those who have more recent exposures. Yeah.

1 DR. CIBULAS: We're getting some interference 2 from somebody on the phone, if you could mute your 3 phones, please. Let's keep going, I'm not sure what 4 5 DR. BOVE: Yeah. б MS. AMICO: So can I just ask a recruitment 7 process question, I guess, in the sense that would 8 you -- when you go out recruiting will you put that 9 hard limit on the 10 years or will you recruit, see 10 who you get and then decide or? 11 DR. BOVE: Well again, we're trying to get 12 people with more recent exposure so that the PFAS blood measurements will be relevant. And but that 13 14 could be relaxed. If we don't get one -- if we 15 start the study in 2019, then that's only five years 16 since the well was shut down. So we are going to 17 get a lot of those people. A lot of those people 18 were exposed up to 2014, if you look at the data 19 from the biomonitoring program. So we're not 20 eliminating anybody from pretty much from that 21 group. MS. AMICO: Yeah, I think my concern would be 22 23 just that the concern is long term health effects 24 too, so if we're only looking at people that were 25 exposed within 10 years are we missing people that

maybe had exposure before that that may have some health effects right now that we could benefit from that knowledge. But I understand what you're saying too. I guess that's just my initial thoughts on it.

1

2

3

4

5

6

7

8

9

10

11

DR. CIBULAS: Let me ask if there's anyone on the phone, I don't want to forget our members on the phone, anybody have a question for our epidemiologists?

Okay. So should we try to summarize what we've learned from external peer review, is that the next step right now?

DR. PAVUK: If you want to I can go over it. DR. CIBULAS: Would that be helpful? I mean, we did bring those to your attention and maybe just briefly sort of give an overall sense of what the peer reviewers had to say, Marian.

17 DR. PAVUK: Okay. So in general we got 18 supportive reviews on overall design methods and 19 analysis planned for the study objectives to address 20 study objective. I think most of the reviewers really liked the extensive number of biomarkers that 21 22 we plan to collect and analyze to investigate the 23 associations between PFAS and health outcomes and 24 also the availability of previous PFAS measurements, 25 hence sampling of the participants of earlier

biomonitoring that will give us comparison levels to points and basic in time. So they thought that the scope and selection of health outcomes and biomarkers in general for adults and children are appropriate, that the test neurobehavioral testing was also appropriate. And they support, they're in general support of the multi-site study sample size of 6000 adults and 2000 children and for the Pease health study of 1000 adults and 350 children. Ι think we stressed in our -- also in our responses that those estimates were really based on the scientific review of literature on the studies that we reviewed, those that needed to be followed up, the health outcomes that may have been found in some studies and were not found in other studies we would still consider that. We consider that the evidence and the knowledge on the associations between PFAS and health outcome is growing and that not -- there are differences between different populations and before different designs in different studies. So I think you may find some of those responses and explanations in the protocol. There were several additions or requests from

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

There were several additions or requests from the reviewers on some aspects of the protocol. They requested and we have expanded the discussion of pharmacokinetic and physiologically based pharmacokinetic modeling and information on historical reconstructions of exposure and response to reviewers. They also felt that recent evidence on diabetes and glycemic outcomes and biomarkers was important to be added to both children and adult study and we have added that information references and biomarkers to our protocol.

1

2

3

4

5

6

7

8

9 They also felt that we should comment a bit 10 more on -- do more advanced literature review and 11 highlighted that some of the studies or some of the 12 designs on a follow up design more than a cross 13 sectional design that some of the health outcomes 14 have not been associated with the outcomes that we 15 plan to study and just make a note of that on liver 16 enzyme, heart disease, glycemic parameters and some 17 kidney function.

18 There were also a number of suggestions that we have responded that we have not accepted suggestions 19 20 from external peer reviewers. One large area of 21 comments focused on the design or inclusion of the 22 study of pregnant women and infants into the Pease 23 or multi-site study. We have responded in that 24 request that a design of the study would have to be 25 changed that such study to include sufficient number

of pregnant women and infants would have to be a separate study that would require a different design, different focus and we believe that we are not in a position to properly address and conduct such study at this point. I want to note that -and I trust at this point this funding at least six such cohorts such as VR project, ATCO, consortium so there's a number of studies that look at pregnant women, infants pair that look into exposure of PFAS's in add-on or in some other ways. There were some other suggestions also to include autism, include antibodies and autoimmune disease, measuring other chemicals or mixture of chemicals in the confounding at this point, doing more in urine, doing clinical tests that really are difficult to do in community settings such as liver imaging, body plethysmography, and some other suggestions that would be either very expensive or not feasible in a community setting unless done in the medical center. We were also asked to consider whether we want to include sites not from the point of view whether

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

to include sites not from the point of view whether they are military or non-military, but one of our requirements is to have at least some measurements that are higher than lifetime limits as proposed by EPA and we do things that the contamination in water

1 should be documented and exceed that limit so we 2 have not gone with that suggestion. 3 I think that is in short is a summary of the major comments that they may have made. We are 4 5 happy to discuss some other comments that you may have noticed. Thanks. 6 7 DR. CIBULAS: Go ahead, Dick. 8 DR. CLAPP: There were a couple of comments 9 about taking the cross sectional data and trying to 10 make a piece of it longitudinal, could you talk 11 about that? 12 DR. BOVE: Well, we're going to collect Social 13 -- well, we have to make a justification for it, but 14 we're going to collect Social Security Number and 15 use that as a way of at least having the option of 16 doing a longitudinal follow up with these people. 17 DR. PAVUK: Yeah. I think, you know, it's very desirable to have that kind of component for any 18 19 environmental study of this magnitude. What we 20 cannot necessarily propose at this point is that we 21 do not have the cohort established. So we're 22 proposing as a first step really to establish a 23 cross sectional cohort which can act as a baseline 24 for any later efforts. I should say up front that 25 any of such efforts are many, many times more

expensive than conducted multi-site study or study at Pease so that's why those efforts are rare. For example, the C8 projects, West Virginia, Ohio, have not been able to fund -- to find funding for the follow up of their fairly rich and substantial cohort or even subparts of that cohort to this day.

DR. CIBULAS: Andrea.

1

2

3

4

5

6

7

8

9

10

11

12

13

25

MS. AMICO: Yeah, I just had a clarifying question in terms of the study for women, pregnant women and children. You said there's six cohorts going on right now, obviously independent, and they are looking at PFAS contamination in those cohorts or they are not?

14 DR. PAVUK: Yes, they are. I mean, six of 15 those, I mean, they were not designed necessarily to 16 study PFAS exposure, but since they had stored serum 17 they were able to measure PFAS in the stored serum 18 and are evaluating how the outcome and publishing on 19 those currently. So if you type in VIVA or ECHO 20 cohort or consortia you can find some of those 21 results. 22 MS. AMICO: Okay.

23DR. PAVUK: And we cite some of those in our24protocol as well.

DR. BOVE: Right. But just keep in mind that

1 they weren't chosen because of the exposure to PFAS, 2 so they would probably have levels that would, like 3 NHANES levels of exposure mostly. DR. PAVUK: Right. They were not studying the 4 5 sites where there was any documented exposure --DR. BOVE: But still --6 7 DR. PAVUK: -- for most part. 8 MS. AMICO: Okay. And can you just elaborate a 9 little bit on who these peer reviewers are just so 10 the community knows who were these people that 11 reviewed this document and made these comments? DR. PAVUK: Do we want to handle it? 12 13 DR. CIBULAS: Okay. Yeah. No, it's okay to 14 release the names of peer reviewers. 15 DR. PAVUK: Yeah, those are academics 16 professors that are involved in research on PFAS or 17 held outcomes for environmental contaminants. 18 DR. CIBULAS: So I went through the peer review 19 process last time, as you recall. It's -- we -it's run by our Office of Science. When a program 20 21 has the need for peer review, the program has an 22 opportunity to suggest names because they know what 23 they need most. Right, I need an epidemiologist, I 24 need a good environmental epidemio -- you know, 25 statistician or whatever. So the program will

generally send suggestions forward but there's sort of a firewall between the program and the Office of Science and the Office of Science then will choose the actual peer reviewers. But as he said, they're generally academics, they sign no conflict of interest forms and they're generally experts in their fields. But again, you know, we can release names if there's a reason to do so, but they are experts in their field. Yeah, we can certainly do that.

1

2

3

4

5

б

7

8

9

10

11 And I wanted to make just a quick sidebar 12 comment. You know, in my 32 years of government 13 experience I have never seen the federal family 14 galvanized around an environmental health issue like 15 this. In -- there are 15 federal agencies that are 16 working different angles of this every day. In 17 February we had a two-day federal information exchange in Washington where the goal is to try to 18 19 come up with a federal research strategy on PFAS. 20 Hundreds of people, we invited states also to join 21 us, government officials. In two weeks EPA is 22 hosting a national summit where they're bringing 23 leaders from federal agencies and states to come 24 forward and talk about what are the issues and how 25 can we all work better together on this. So it is

1 really amazing to see what's going on. EPA put out 2 a notice of award last week with \$2,000,000 going 3 out for monies to do tox testing on PFAS. And so I just, it's amazing to really see this and, you know, 4 5 we are really trying hard to look at these issues and see what we can -- how we can best help 6 7 communities that are suffering, so. 8 So any other questions or comments on the Pease 9 protocol and/or peer review comments? Again, please 10 if you have comments get them to us in the next week 11 or so and we'll try to incorporate those in this 12 current draft version before it starts the process 13 of HHS and clearance. 14 MULTI-SITE STUDY UPDATE 15 DR. CIBULAS: So the next thing on the agenda, 16 Marian and Frank, was just some additional 17 information on the multi-site study, so. 18 DR. BOVE: I think the question we got, I 19 think, from -- who did we get it from, John? We get it from John Durant or did we get it from --20 21 CDR MUTTER: Andrea's question? 22 DR. BOVE: No, no, about the -- how we're going 23 to do the exposures. 24 DR. CIBULAS: Oh, okay. 25 MS. AMICO: It came from both of us.

1 DR. BOVE: Okay. 2 MS. AMICO: Our conversation, yeah. 3 DR. BOVE: So, can you give me an idea? 4 MS. AMICO: Yeah. We just wanted ATSDR to 5 spend a little bit of time talking about how you're going to estimate the PFAS exposure through water б 7 modeling at the different sites. 8 DR. BOVE: Okay. DR. DURANT: I also, if I could jump in, my 9 10 understanding was, forgive me if my understanding is 11 wrong, that the service centers would be done ultimately at the new site, so if you could talk 12 13 about that I would be happy to hear more. Thank 14 you. This is John Durant. 15 DR. BOVE: Yeah, actually I just missed -- I 16 missed what he said because Jamie was saying 17 something to me. 18 DR. PAVUK: Just tell him to repeat. 19 DR. CIBULAS: Make sure we're talking about what's happening at Pease too in addition to the 20 21 multi-site study. 22 DR. BOVE: Right, right, right. Actually, I'm 23 going to talk about what's happening at Pease first. 24 So we have a PHA that is not released yet, right? 25 MS. AMICO: The health documentation?

DR. BOVE: Yeah.

1

2

MS. AMICO: Yeah.

3 DR. BOVE: Right. So there's been some modeling done and what they basically -- the first 4 5 step is to historically reconstruct the 6 contamination levels in the distribution system. 7 Okay. And so what we have is well data when the 8 contamination was occurring and then we have 9 distribution samples after the well was shut --10 after the Haven well was shut down. So what has 11 been done so far is to get information about the 12 well logs, the production of each of these supply 13 wells and try to go back in time as far back as we 14 can have data on these well production logs. So 15 what we had so originally was dated from 2003 on, 16 monthly well logs for Haven, what are the other two 17 names of the wells? 18 MS. AMICO: Smith and Harrison.

DR. BOVE: Yeah, right, yeah. And so based on that, based on the April 2014 sample data we could then make a simple estimate. It's kind of a black box type of model. You simply assume that the water comes out of the treatment plant and goes uniformly through the whole system so that pretty much everyone's getting the same amount of contamination

1 at the same time because the water is all mixed. 2 And all you need to know then is how much each well 3 is producing and what proportion of the system, so it's a very simple calculation. And so based on 4 5 that the health assessment which will -- the health assessment will provide that information to you. 6 7 I'm not going to give it to you now, but that's one 8 simple thing that can be done. And then based on 9 the April 2014 contamination level and assuming that 10 the contamination that's been there for quite a 11 while and it's pretty much reached a steady state 12 you can then back calculate based on that and have a rough estimate of what the contamination might've 13 been all the way back to say 20 -- 2003. 14 Beyond that, it starts getting a little fuzzy. So that's -15 16 - so that's one approach to the historical 17 reconstruction. Okay. That's the simplest thing 18 you can do. Okay? And recently we were able -- the 19 city of Portsmouth found hard copies of well logs from, I think it's from '94 through '97, so daily 20 well logs in a hard copy with some months missing, 21 but during that period. So right now we have to 22 23 look at, we have data from 1994 to '97, almost 24 complete monthly data. Then we have data from 2003 25 on, monthly data. And then we have, I think, annual

1 data in the middle years, 1998 to 2002. And I think 2 there's some missing data from one of those years so 3 it's not complete. We'd like to have complete monthly data going all the way back to the start of 4 5 the Tradeport, but at least we have that. Okay. 6 Now, you can do more sophisticated modeling if 7 you get more information on the -- from the Air 8 Force, for example, on how much AAAF (sic) was used 9 on a routine basis --10 DR. DURANT: They should have the model. What 11 kind of model are you talking about, are you talking about ground water models or --12 13 DR. BOVE: Not yet. 14 DR. DURANT: -- distribution models, what 15 models are you talking about? 16 DR. BOVE: Well in this case it's a simple 17 mixing model so you don't have to use EPA net or 18 anything like that, okay? So for Pease, which is 19 all the water goes to a treatment plant, mixed 20 together and out and you just need to know the 21 demand and you need to know the -- how much the 22 wells are producing. So for the simple mixing model, so --23 24 DR. DURANT: So when you say models, do you 25 just mean for hand calculating?

1 DR. BOVE: Yeah, you could probably calculate 2 this by hand, yeah. Yeah, it's a simple mixing 3 model. Yeah. Okay. And you can -- and it's a useful model to use in this case because of the 4 5 situation at Pease. It would not be useful in a situation like Warminster or some of these other 6 7 systems where you can't assume that there's uniform 8 concentration throughout the system, okay. So I'm 9 just talking about Pease right now. And you could -10 - in order to figure out if you wanted to know when 11 the contamination first reached the well, which I don't think we need to know that in this case 12 because we can assume the contamination reached the 13 14 well before the Tradeport opened, but if you needed to know that and we needed to know that, for 15 16 example, at Camp Lejeune, then you have to have, as 17 I said, more information on the source of the contamination. So you'd have to know more 18 19 information on AFFF use, how often it was used, the 20 amounts, any extraordinary events like accidents, like fires that -- you know, that had to be used and 21 so on and so forth. So you'd have to have a history 22 23 of that source, right? And then -- then the next 24 step would be you can go either way. One is to get 25 a lot of information on the hydrogeology of the area

1 with monitoring well data if they had it and they 2 probably do from remediation work over time. And 3 get some parameters about the flow of ground water That's a more -- that's a sophisticated 4 and so on. 5 We did that at Camp Lejeune. But we also model. used another model which basically was a black box 6 7 model which just said that basically used 8 information on when the contamination in the Camp 9 Lejeune well stopped and the data after that and was 10 able to back calculate using a very sophisticated 11 math to estimate what the contamination was before 12 that without having to get all this information 13 about hydrogeology, about the source concentration. 14 And it turned out, because we were looking for a 15 quick way to do this, it had taken so long, the 16 water modeling at Camp Lejeune, and we were able to 17 do this -- use this approach. It's called the, if I 18 have it in front of me. I'm not going to go into it 19 in detail because if you need that kind of detail 20 you need to have some of our water modeling people 21 here. But I know it's called the linear control 22 model and we were able to predict very well what the 23 more sophisticated model did and in a much shorter 24 period of time. So there are possibilities like 25 that. But it may be all that's necessary is to

actually use this simple mixing model that I mentioned before which is just with the information you have on how much each well produced, the water demand for the system, you can -- and assuming that April 2014 is pretty representative of the kind of contamination that was going on before that, you can have a pretty good idea of what the historical data was. Okay. So that's the first step.

1

2

3

4

5

6

7

8

9 So there's the simple mixing approach. There 10 is a very hard sophisticated approach getting 11 information on hydrogeology and using several models that are available for that and we have all this 12 13 stuff that if you go to our Camp Lejeune website you 14 can see what we used and the models we used for that 15 approach. And then there's this linear control 16 model that actually was developed by the Georgia 17 Tech people and it was a simple model and could get 18 it done quickly. So those are different approaches. 19 So that's -- so let's assume now that we have a 20 historical reconstruction of the contamination and 21 so what's the next step? The next step is to go from there to what's in your blood. Okay and 22 23 there's what the C8 study did was basically another 24 black box model. Here's your whole body, right, and 25 the volume. You get the drinking water exposure

coming in and it being excreted using the half-life, whatever half-life information going out and that's what you have. And that's the basis for the C8 models, that's also the basis for the Bartels PFOA calculator which is online, I think. I haven't used it. Same thing, same approach.

7 The people at NIEHS and I think did -- looked 8 at a two compartment models so this is a one 9 compartment model. A two compartment, mother, child 10 to look at breast feeding and exposures to the 11 fetus, so they had a two compartment model, a little 12 more sophisticated than this one compartment model. 13 And then you can have a multi-compartment for each tissue, liver, kidney, so on and so forth. 14 15 Pancreas, all the way down or whatever you have 16 information on. And that -- that's been done too 17 with PFOA and PFAS, and I think they tried it with 18 PFHxS and it wasn't very successful.

1

2

3

4

5

6

So again, so there's the simple approach that was done at C8, right, which is the black box. Your drinking water contamination exposure here, with information on how much you drank, you know, so you can make it, you know, which is what Bartels calculator incorporates. And then some parameter of excretion based on the half-life information that

you have, which we have in the literature and so on, so it's an easy approach. And as I said, there's a calculator for PFOA, probably works pretty well.

1

2

3

4

5

6

So I don't know if that answers your question, but that's -- that exhausts what I know, I'll just put it that way.

7 DR. CIBULAS: Well I think that's a good final 8 point there, because as Frank mentioned and as you 9 already know, we have a really great team of experts 10 at ATSDR that assisted with the Camp Lejeune 11 modeling and they're going to be working as part of 12 this team also to help us here. And you know, we're 13 also looking to put together another group of 14 advisors, experts to assist and be able to provide constant advice throughout the conduct of our 15 studies. So we're making sure we have the right 16 17 expertise that can provide --

18 DR. BOVE: Right. But if you have any 19 particular questions about, and again you can go to 20 our Camp Lejeune website and we have detailed documents about all these including a whole document 21 which I have here actually, on this linear control 22 23 model which was that black box model I mentioned. 24 But and then if you still have questions after that, 25 you can contact our water modeling people

themselves.

1

2 DR. DURANT: I appreciate your taking the time 3 to explain the process. I think you did a good job of kind of outlining in broad strokes there. I do 4 5 have some more questions and so who on your team should I approach if I need to know a little bit б 7 more about the details of the methodology? CDR MUTTER: This is Jamie. You can work with 8 9 me and I'll get you in contact with the right 10 people. 11 DR. DURANT: Okay. Thanks, I appreciate it. 12 DR. CIBULAS: Is there anything else? 13 DR. DURANT: Is it correct that the methods you 14 outlined are going to be applied at Pease? 15 DR. BOVE: Well, again we have to decide and we 16 haven't sat down with the water models and hashed 17 this out yet. Again, they've approached this using 18 the simple mixing model and if they feel that that 19 is sufficient we may just go with that. But I think 20 that what we, in any case we're going to be asking 21 the Air Force for the information I just said and any data they have, any PFAS sampling they've done 22 23 and go from there. Given that there's been 24 remediation work done there and there's been work 25 done in the '80s around trichloroethylene so there

1 probably is some information historically on ground 2 water flow and the characteristics of the aquifer, 3 so on and so forth that might be useful if we wanted to go down the route of being a little bit more 4 5 sophisticated. But you know, we know from our own experience that it does take a long time to do this б 7 modeling work and getting all the information, the 8 data discovery took a long time at Camp Lejeune and 9 we can't really do that at these sites, both at 10 Pease and any of the other sites we decide to 11 include in the multi-site study. So we're going to 12 have to figure out ways to streamline the process. 13 And as I said, there is one way that Georgia Tech developed that worked very well in a situation where 14 15 there were 80 some wells going -- coming online and going off line over a 30 some year period with 16 17 several contamination sources and so on. And the 18 approach, the simple approach which I mentioned 19 actually worked pretty well. So that's where we're 20 at now, but we're open for, again, suggestions and you know... But I think at Pease, given the simple 21 -- it's a simple situation. Much -- more -- simpler 22 23 than let's say, as I said, a place like Warminster 24 or some other water system where there are wells 25 that are serving particular areas, you have

purchased water coming in and so on. So a more complicated system, maybe even the system is cut in half with part getting purchased water and part not and so on. So at Pease it's so much easier.

1

2

3

4

5

б

7

8

9

DR. CIBULAS: A question down there. Laurel.

DR. SCHAIDER: Hi, this is Laurel Schaider. I had a question about what if you could comment on the information that you get from the blood testing versus this kind of reconstructed exposure. Like how would you use both of those kinds of information 10 11 and then also getting back to Andrea's question 12 about people who maybe went to preschool on the Tradeport and then are more than 10 years out from 13 14 that could you rely on this kind of reconstructed 15 exposure for those people where the blood testing 16 might not be that reliable a measure of exposure. 17 DR. BOVE: Okay. So refresh my memory now what the first question was. 18

DR. SCHAIDER: Well, what do you learn from --19 20 DR. BOVE: Oh, all right, okay. Yeah, right. 21 DR. SCHAIDER: -- previous exposure --22 DR. BOVE: Right. 23 DR. SCHAIDER: -- beyond what you get from the 24 blood testing. 25 DR. BOVE: Yeah. Well first of all the blood

1 testing that was done for the biomonitoring program 2 that the health department did will be very useful 3 for calibrating any models we do. And then the blood we get now when we do this will also be useful 4 5 for that purpose. So we'll be able to see if we can predict, how close we can predict the current blood 6 7 levels as well as the past blood level. So that's a 8 rich amount of data that can be used. The -- so 9 that's how, you know. So we can use the -- we can 10 analyze the effect biomarkers and use the current 11 blood sample. For those endpoints where there isn't 12 an issue with what they call reverse causation or 13 confounding, for example, if you use -- if you look at kidney endpoints, you know, they could affect 14 15 your PFAS level so it could, you know, you don't 16 know which way the arrow is going and they're having 17 this issue debate about whether one particular kidney biomarker is reverse causation or not and a 18 19 lot of people in the literature seem to think it is 20 and the people I'm talking to in my own agency think man, maybe not or maybe not entirely. So there's, 21 22 you know. But because there's that question that's 23 why historically reconstructing and predicting the 24 blood levels is important because that won't be 25 affected by your kidney issue.

So for those endpoints where you don't have this issue you can use everything, anything you want. For those biomarkers that could affect your PFAS blood level that's where the historical reconstruction serum levels are important. That's what they did in the C8 and showed that it made a difference. So that's your first question.

1

2

3

4

5

6

7

8 The second question goes back to Andrea's 9 question about long term effects, right? And first 10 of all, some of the adults will have been exposed 11 quite a long time at the Tradeport so there will be 12 people with that lengthy exposure. They just have 13 to -- the most recent exposure can't be 10 years ago or more than 10 years ago. But I'm sure that there 14 15 are a lot of people who went through the 16 biomonitoring that worked at PFAS -- at Tradeport 17 for quite a long time and were exposed to PFAS in 18 the drinking water for a long time. So that's the 19 first thing.

But the other thing is we can't look at everything and you can't look at everything effectively. And I think that if we can look at this cohort that we establish longitudinally, we can start picking up some of those chronic diseases. The other thing is so we can look at these kinds of

1 diseases in other ways. We can, as I said, in New 2 Jersey when we looked at -- back in the old days we 3 looked at trichloroethylene, we looked at other solvents, we looked at trihalomethanes in drinking 4 5 water and looked at leukemia non-Hodgins lymphoma, we looked at the mortality in the past in these 6 7 kinds of studies. You know, you can look at -- at 8 Lejeune we looked at mortality. So you can look at 9 other populations and look at some of these 10 diseases. You don't have to do everything in one 11 study. This study is focusing right now in the 12 cross sectional study on changes in these kind of 13 biomarkers. And so it's looking for subtle changes, 14 subtle differences, that's why you need a larger -large population to some extent and that's sort of 15 16 the goal of this effort. It's not trying to answer 17 all the questions because no study can do that. So that's how we're feeling at this point and that's 18 19 why we wanted to have a cut off. And we're going to 20 get pushed back anyway, both OMB and the peer 21 reviewers will want and our IRB will want some kind 22 of cut off where you're saying okay. And so we have 23 to do it and we're going to base -- want to base it 24 on exposure and so we'll base it on what we know 25 about the half-life and assume that those people

much further the blood sample we're taking now is not going to be as informative. We can try to predict it -- we can try to predict it. I guess I haven't been sitting close to this microphone. We can try to predict it, but I think we're going to have harder and harder time as we go further and further back to try to predict it without more recent -- without a blood sample that's recent that is somewhat reflective of the contamination.

10 DR. PAVUK: I think just to simplify one of the 11 points that Frank was making, our first really our 12 first line of recruitment will be for people that 13 participated in the biomonitoring. So for adults or 14 children that basically includes all of those people 15 that were in there. And as you know, there was no 16 such restriction for biomonitoring on those 10 years 17 for last exposure so there are about 1400 plus 18 adults in that --

DR. BOVE: More than that now.

1

2

3

4

5

6

7

8

9

19

20 DR. PAVUK: -- more than that now probably, so 21 let's say 1500 so to be able if we are able to 22 achieve with the sample size of about 1000 people 23 from that group we'll do that. But we cannot expect 24 necessarily that they'll be, you know, your 25 community is concern is interested to participate.

We know from experience that actually getting people coming, you know, to study office at the time when, you know, the study is available, people are available, this is not exactly the same thing. So really that eligibility criteria will only be applied to those that are outside of the biomonitoring part. And I do think that there may be some push backs on that either from OMB or IRB and there may be opinions on whether that is not a little bit too restrictive, but at the same time we think that the size of biomonitoring sample is large enough to have enough people really from our initial effort and that's where our focus will be initially. DR. CIBULAS: Lindsey. MS. CARMICHAEL: Yeah, I had a quick question

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 about the modeling. So I'm wondering if you can 17 help clarify, is the modeling that's going to be 18 done static modeling like that might use something 19 like a spreadsheet or is it more of a dynamic simulation type of model that's going to be built? 20 21 DR. BOVE: Dynamic, simulation. 22 MS. CARMICHAEL: Okay. Thank you. 23 DR. PAVUK: Also, on that part I think --24 DR. BOVE: Whoa, whoa, whoa. The -- one other 25 The simple mixing model is -thing.

MS. CARMICHAEL: That's just a calculation. DR. BOVE: -- it's static, I don't use those terms but it's not based on simulations but I -- but the -- I think that any of the other modeling, the pharmacokinetic model would use simulations.

1

2

3

4

5

6

7

8

And certainly the black box model that I talked about for the linear control model has quite a bit of simulation involved.

9 DR. PAVUK: I just wanted to note on that point 10 that I think you need to look at those -- there are 11 really two parts to it and one is the measured level 12 of serum, the current one, and the other part is the 13 modeling that really in a sense completely ignores 14 what your actual level may be. So the uniqueness of 15 or uniqueness or usefulness of Pease situation is 16 that we do have more than one point of PFAS 17 measurements to validate those models. So you have 18 a number of studies that use a number of approaches, 19 one in multiple part models that really base the 20 exposure levels or calculate those in all sorts of 21 dynamic modeling using a lot of variables and a lot of assumptions and come with some sort of number. 22 23 But a lot of those models have no way to really 24 validate the group of people they're looking at and 25 we have really an advantage here that have a sample

1 from 2015 or '16, then we'll have sample from 2019 2 or 2020 and we'll be able to see like how good or 3 how our models really approximated this recent exposure and will be less about the exposure further 4 5 back in the past. But it still gives us some point of reference that most of the other sites probably 6 7 will never have. So hence we're focusing on Pease first. 8 9 MS. CARMICHAEL: Makes sense. Thank you. 10 PEASE HEALTH CONSULTATIONS UPDATE 11 DR. CIBULAS: Great. So I suggest, if there's 12 no objection, let's move on to the health 13 consultations. We're not that far off of our agenda 14 time frame. 15 CDR MUTTER: You got us back on track. 16 DR. CIBULAS: Tarah. 17 CAPT SOMERS: All right. So I'm Tarah Somers, 18 I'm with ATSDR in our Boston office. So just so we 19 can review again, I think we've gone over this 20 before but just one more time. So there are two 21 health consultations, there's one for the Pease 22 public drinking water system, so we're calling that 23 like the public drinking water system and then 24 there's a second document that's a health 25 consultation that focuses on the private wells that

have contamination. So those are ones that off the Tradeport that are being used largely in private residences. So there's two health consultations and then there's a third document which supports the public drinking water system health consultation that is the water modeling report and this is the one that Frank was just referencing a few moments ago that is a mixture model, if you will. I'm not the model expert so I don't want to mischaracterize it, but it's -- it is basically what it did is it looked at the levels that were identified and then said well if this well has been pumping this much into the system then this would be the amount you would get, you know, when you go to the tap. It's a pretty simple water model.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 So that supports the public drinking water 17 health consultation because when you do a health 18 consultation you have to estimate what people's 19 exposure was as they were drinking the water. And 20 in this case that's how we can estimate when people 21 went to their tap how much they were being exposed So that report is -- we're deciding now if it's 22 to. 23 going to be released entirely as a separate report 24 or if it's going to be added onto the health 25 consultation almost like a very big appendix, if you

will. So those are the three things that we will have coming out.

1

2

3 For the public drinking water health consultation that was given to Air Force and the CAP 4 5 members for data validation draft, we got comments The authors of the report have addressed all 6 back. 7 the comments in the document. They made changes if 8 changes needed to be made. They updated things. 9 All the comments were considered and that version 10 that has the comments addressed is now in our 11 clearance process, I know, back in clearance, and we 12 hope to get that out, we're targeting by the end of 13 the fiscal year would be when we would like to have 14 it out. And this is what I need to talk to some of 15 the CAP about is when we release documents we always try to have a public process. So these documents 16 17 when they're released they will be considered public 18 comment documents so they will go out to the public 19 and everybody anywhere will have a chance to send 20 comments to ATSDR. So when we do that we do like to try to -- rather than just stick them up on a 21 22 website which people may never visit because they 23 don't know a document's been released, we do try to 24 go out to communities and have, you know, public 25 availability sessions or in some cases we present to

like a town, city council or a select board or a board of health. It depends on what the community wants. And we have some ideas we would like to tell the CAP about so we can get your feedback so if you think if this is a good plan. So our draft plan for the -- I was going to start with the public drinking water consult because the two documents, the public one and the private well, although we're trying to get them both out the door roughly the same time, there's a little bit of lag with the private drinking water one. So although I would like them to come out rather concurrently, there might be a little bit of time between. So I'll start with the public drinking water one.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15 So the public drinking water health 16 consultation, what we would like to do is what we 17 call public availability sessions where we have people from ATSDR and it'll probably be me because 18 19 I'm in the Boston office and the two authors of the 20 document come and since it's the public drinking 21 water system for Pease Tradeport, it would likely be 22 at the Tradeport, maybe even in this room or if they'll let us have the space. So we'll be here at 23 24 the Tradeport and people can come and ask us 25 questions about the reports. And we thought because

1 the Tradeport exposures were largely, you know, 2 working exposures we would have our availability 3 sessions so we could stagger it so we could have morning hours so if people wanted to come before 4 5 work we could have, you know, noon time hours, if people have lunch breaks and then we could do after 6 7 work hours to capture as many people as we can 8 knowing that people don't live like right here. So 9 after -- if you just did after work you might end up 10 losing a bunch of people who are available during 11 the day. So we could stagger, you know, maybe over 12 two days. We could do like a morning and afternoon and evening. We can kind of be flexible on how that 13 works, but that was our idea for doing the public 14 15 health consultation for the public drinking water. 16 I'm trying to make sure I'm getting them straight. 17 And we would use the CAP and to help us spread the word at the Tradeport that we would be available for 18 19 these sessions. We would obviously, you know, make 20 sure the childcare centers are aware so if, you know, you have parents that want to come ask us 21 22 questions we would -- I know there's a group right 23 on the Tradeport that has all the, I forget its 24 name, I'm sorry, that has all the businesses that 25 work on --

MS. CARMICHAEL: Tenants Association.

1

2 CAPT SOMERS: -- the Tenants Association, yes 3 that. So we could put information out through the Tenants Association or any other method you have to 4 5 let people know we would be happy to try to use those methods to tell people this is what we plan to 6 7 do, this is when we'll be, this is where we'll be, 8 please come see us. Again, then the document will 9 be available on our website too so people can read 10 it if they want to read it on the web and then they 11 can come talk to us. We'll have fact sheets to go 12 with it. The fact sheet will be a very brief 13 summary of the conclusions, recommendations, a 14 little bit of history because sometimes people don't want to read a whole health consultation, you know, 15 16 they can be kind of thick documents. So we'll have 17 those available. For the public drinking water one 18 we also considered going back and presenting before 19 the Portsmouth their -- what is it called, the 20 select board --MS. CARMICHAEL: City Council. 21 22 CAPT SOMERS: City Council. Because we 23 presented to them, remember, like a long time ago we 24 were there. So we could go back and present to the 25 City Council again at a -- and that would be another

1 way for the public to come and ask us questions and 2 we'd present it to them at their meeting. Sometimes 3 it's easier to tie it into a meeting that's already happening because people might already be attending 4 5 those meetings, so we could work to attend one of б their meetings as well. And as I mentioned, at the 7 same time we would like to try to release some more 8 clinician awareness. Again, we had the meeting that 9 some folks were at with New Hampshire Medical 10 Society. They're having a conference but it's not 11 happening till later in the fall, so that may be, I 12 think, we still would want to have some information 13 on PFAS and that would be really good but it might 14 happen a little bit after our documents are starting 15 to come out so we are working with Michael Hatcher 16 who's in the other division who does clinician 17 education to try to come up with a plan to, I'm not 18 going to call it clinician education at that point 19 because we're probably not going to be out doing 20 actual education to clinicians but at least put out 21 information for awareness so they know some 22 resources clinicians can go to to find information 23 about these chemicals so if a patient comes to them 24 they'll have some resources to turn to. So we'd 25 like to do that about the same time again so if the

1 document comes out and someone has a question and 2 they talk to their provider, their provider has some 3 resources. And we'd like to put the link for providers even on a fact sheet as well. So I 4 5 imagine if people go to their clinician they might take a fact sheet rather than a whole health 6 7 consultation would be my guess, so to have it as 8 available as possible. 9 So that is sort of our plan for the public 10 drinking water health consultation. Do you have 11 some feedback? Yes, Lindsey. 12 MS. CARMICHAEL: Yes. So I --13 DR. CIBULAS: It's Lindsey Carmichael. 14 MS. CARMICHAEL: Oh yeah, sorry, Lindsey Carmichael. So I have a question. 15 CAPT SOMERS: Sure. 16 17 MS. CARMICHAEL: It's related to this and you 18 all might be aware of the fact that there are 19 several municipal wells in Portsmouth that now have 20 tested or have revealed that the same PFAS compounds 21 that were present in the Smith and Harrison and 22 Haven wells, they're showing up in a couple of 23 municipal wells in Portsmouth. And my question 24 because of that and it's a huge concern for the 25 people who are drinking water because if I turn on

1 my tap at home that isn't being filtered, PFAS 2 compounds are coming out of our taps in Portsmouth. 3 So my question, specifically, is what is the criteria for the initiation of the health 4 consultation to be written? So I understand one has 5 been written for Pease Tradeport, there's the 6 7 private drinking well consultation. We have a 8 broader issue that's extraordinarily concerning for 9 the entire municipality. So I'm just trying to 10 understand what that criteria is. 11 CAPT SOMERS: What triggers a health 12 consultation? 13 MS. CARMICHAEL: Yeah. 14 CAPT SOMERS: Oh, that's a good question. So 15 there's several ways health consultations can get 16 triggered. Sometimes so under our mandate through 17 Congress any site that is a Superfund site we have 18 to work on and do a report on, so that's one way but 19 that wouldn't qualify for the access unless it was 20 on site. 21 Sometimes it's at the request of a state, 22 either the health department is usually the one who will request or sometimes it could be another state 23 24 agency that can request. And ATSDR also has a 25 petition process where any community member can

1 petition ATSDR and we'll review the petition and 2 decide if it's something that ATSDR can work on. 3 Generally, for the petition process there has to be data available for us to have to do the assessment 4 5 on or, you know, because we as an agency generally 6 don't go collect our own environmental health data, 7 that's really rare. So some of our sites come in as 8 petitions from community members, so public --9 there's more information about it on the -- we can 10 get you more information. 11 MS. CARMICHAEL: That would be great. Thank 12 you. 13 DR. CIBULAS: Great. 14 CAPT SOMERS: But back to the -- sorry. The 15 thing we're having. If you have suggestions for us, 16 yeah. 17 MS. AMICO: I just want to say that I like the 18 idea of doing the different sessions at different 19 times on Pease. I think that would be very 20 convenient for people that work here. That I know 21 Testing for Pease would be willing to help spread 22 the word about those and I guess in terms of the 23 clinician awareness I think that's a good thing. 24 But if I can just continue to stress that medical 25 monitoring is absolutely needed in our community and

1 I know that that doesn't completely apply to this but it kind of does that, you know, people are left 3 today with questions. And you know, you talk about not clinician education but just awareness and that, 4 you know, anything that ATSDR can do or CDC can do to help give people better guidance about what they 7 can do now to monitor their health would be critical. Because even in the news of the health study breaking so many people are so excited about 10 that but we know that we're not going to have 11 answers to these -- to the things that we're 12 studying here for years. So that still leaves 13 people questioning today what they can do to monitor their health and that's a huge huge need in our 14 community as well as other communities across the 15 16 nation, so I just want to say that during this time. 17 Thank you.

2

5

6

8

9

18 CAPT SOMERS: Yeah. And from my discussion 19 with Michael Hatcher, I know they are working on 20 revising some of the materials we have based on, you know, new information that comes in and some of the 21 22 meeting with the New Hampshire Medical Society folks 23 and also potentially creating some additional 24 materials as the exposure investigations go forward 25 and then the multi-site study moves forward. Ι

think there's an anticipation that this is going to come up, you know --

MS. AMICO: Everywhere.

1

2

3

CAPT SOMERS: -- a lot of places. And so the 4 5 group that works on that kind of clinician education б piece is, you know, trying to be proactive and 7 start, you know, thinking about how to create more 8 materials and how to best reach clinicians which can 9 be a challenge, not just in -- and that's why I'm 10 calling it awareness because it takes a really 11 pretty intensive effort if you're going to do actual 12 like education that then potentially might change 13 practice, right? Like that's different than 14 awareness. At this point probably honestly if one 15 of our documents coming out, awareness is probably 16 what we can agree to try to get done. So I don't 17 want to call it clinician education and then have 18 people be disappointed that we didn't do some big, 19 you know, like day of education. I don't think 20 that's probably going to work, but...

21 So then, can I go into the private well one 22 too, because we have a slightly different plan than 23 for the private drinking water well health 24 consultation. And we felt like because the private 25 drinking water health consultation really affects

1 mostly the homes that have the private wells, we 2 would take a little bit different approach and we 3 would target those homeowners. A lot of them are homeowners, some of them may not be homeowners, but 4 5 the residents who live in the homes where the wells were sampled we have the list of addresses so we 6 7 could target those residents and send them like a 8 letter and do a similar public availability session 9 in a place that they could easily access, maybe in 10 Newington or Greenland and let them come and ask us 11 questions. Make them aware the document's there and 12 then let them come and talk to us. We felt like 13 because it's their residence some people may be 14 hesitant to want to come to a more public meeting 15 and talk about exposures at their home, you know, 16 that's kind of a private issue. So that's why we 17 were going to target them specifically, but then 18 also to open it up to more community members we 19 could do a similar thing where we try to go to, I 20 don't know if they have city councils or select boards for those towns and again present to them 21 22 formally and allow more public to come. And in some 23 towns, honestly, the select boards have said well 24 we'd rather you talk to the Board of Health than the 25 select, you know, we can be flexible in who or what

1 public meetings we go to. But I think we just 2 wanted to, again, try to recognize the sensitivity 3 that some people have had their private wells tested and may not want to stand up in the room and say, my 4 well was tested, you know, so we're trying to do 5 that for them. In the document, just to be clear, 6 7 in the health consultation, addresses are not There's no -- you know, you can't tell from 8 listed. 9 the health consultation people's individual well 10 results, but we can target those homes with a 11 mailing. So that would be our roll-out plan for 12 that document. And again, the CAP might can help in 13 some ways, maybe advertise that because some of the 14 people who live in those homes may also work nearby 15 or in the Tradeport, I don't know, so that would be 16 our second plan. 17 DR. CIBULAS: Tarah, are these roll-out plans at this time committed to paper, are they draft that 18 19 they can be shared and might be easier for the CAP 20 to see? 21 CAPT SOMERS: We have drafts. I can ask if we 22 can share our draft. 23 DR. CIBULAS: Or when you --24 CAPT SOMERS: There's a -- okay, so there's an 25 official roll-out plan that has to get cleared

1 through the agency and my understanding is it may 2 have to go all the way to HHS --3 DR. CIBULAS: Oh. CAPT SOMERS: -- for our roll-out plan. But we 4 have in -- like an internal one for us that's kind 5 of like the steps, you know, it's more just the 6 7 steps in the process we're talking about. 8 DR. CIBULAS: I just thought it might be easier 9 for them to see exactly what steps you --10 CAPT SOMERS: Yeah, I can ask if we can put it 11 down. 12 DR. CIBULAS: -- and they can --13 CAPT SOMERS: Yeah. 14 DR. CIBULAS: Okay. Put that --15 CAPT SOMERS: But if you have thoughts or 16 comments you want to send our way, again, we're 17 targeting hopefully, I guess, it would be this is the other timing issue, if you have strong feelings 18 19 about when is a good time. Like I know sometimes 20 the end of August isn't so good because a lot of people are on vacations, you know. August is a 21 22 popular vacation time in the northeast. And then 23 school starts usually like right around either the 24 week before or week after Labor Day. So maybe we'd 25 avoid like the very end of August to the very

1 beginning of September might be a not so good time. 2 So we could either do maybe aim for early August, if 3 possible, or you know, mid-September time might work, so. I don't know if there's any like days at 4 5 the Tradeport that are better or worse. You might -- if people telework but they're -- any of that 6 information would be helpful to try to make sure 7 8 we're reaching people. 9 UNIDENTIFIED SPEAKER: I think week days are 10 definitely more --11 CAPT SOMERS: Oh, yeah, yeah. Weekdays, yeah, 12 yeah, we'd do week days but, you know, I don't know 13 some places a lot of people telework Monday and 14 Friday so you'd want to target like a Tuesday, 15 Wednesday or, you know, any information is helpful. 16 I hope that helps. 17 DR. CIBULAS: Anybody on the phone have a 18 comment about the health consultations? One more, 19 Andrea? 20 MS. AMICO: Yeah, one more question. Andrea 21 Amico. You talked about this third report, the 22 water modeling --CAPT SOMERS: Oh, yeah --23 24 MS. AMICO: -- that was not sent to the CAP to 25 review, was it?

1 CAPT SOMERS: Correct. So that document 2 doesn't go to data validation draft. It's going to 3 come out as a public comment document because it's not being sent to the Air Force for data validation 4 5 draft, so it doesn't have that step in the process. 6 MS. AMICO: So when will the CAP get to see it? 7 CAPT SOMERS: When it becomes a public... 8 MS. AMICO: Okay. 9 CAPT SOMERS: When everyone can comment on it. 10 MS. AMICO: Okay. 11 CAPT SOMERS: And you've already gotten some 12 idea that it was -- that water modeling report was 13 used in the health consultation to help determine 14 the exposure that was in the health consultation. 15 So although you haven't seen the water modeling 16 report, you've kind of seen the effect of the water 17 modeling or does that make sense, but because it's not going to the Air Force for a data validation 18 19 draft, there -- it's just going to go to a public 20 comment. 21 MS. AMICO: Thank you. 22 CAPT SOMERS: Sure. 23 BOARD OF SCIENTIFIC COUNSELORS MEETING IN ATLANTA 24 DR. CIBULAS: Okay. So I can be real quick on 25 the next action item, Board of Scientific Counselors

Meeting in Atlanta. I understand that, you know, somebody saw our Federal Registry notice and had a question just what this is, so the Agency gets advice from a lot of different ways, right? So one of them is that most agencies and even centers like our center has a federal advisory committee that is chartered and meets twice a year. I happen to be the designated federal official for our Board. We have a meeting coming up June 4^{th} and 5^{th} . One of 10 the topics will be an update by Marian to talk a 11 little bit about what's happening with the protocol 12 and what's going to happen at Pease and hopefully 13 eventually in the multi-site study and so this group 14 is generally academics, members of state and local 15 health departments. We get an industry person every 16 once in a while. A whole range of expertises and 17 they're chartered and with us for at least three years and then we rotate. And it's just another 18 19 mechanism by which we obtain advice. This group is broader in perspective, you know,

1

2

3

4

5

6

7

8

9

20 21 it's not just focused on PFAS, it's focused on all 22 of NCEH and ATSDR programs. And again, we have --23 it's a public meeting, you can listen in and if you 24 have any more questions I'm happy to answer any 25 questions. But we have a meeting coming up. Is

that sufficient for right now? Is there --

1

2

3

UNIDENTIFIED SPEAKER: Is it video-taped or just recorded in any way?

DR. CIBULAS: It is not video-taped. We do get 4 5 transcription, we put the minutes up so you can go 6 to our website right now and see the minutes from 7 all previous meetings. But as I said, it's -- we 8 take programs to our Board and get advice on, you 9 know, they like to get involved early so that their 10 advice actually is meaningful rather than late in 11 the process where it's too late. But they meet 12 twice a year, and it's good for Dr. Breysse to be 13 able to say, I've taken this to our Board of 14 Scientific Counselors and they support us moving 15 forward. So he uses it in that fashion and it's worked out well for him. Suzanne Condon who was 16 17 here earlier is a member of our Board. She was 18 former assistant commissioner of health for 19 Massachusetts, the State of Massachusetts. So I'm 20 glad to come back and talk more about what happened 21 at that Board meeting if that would be helpful. 22 UNIDENTIFIED SPEAKER: Sure. 23 CAP CONCERNS 24 DR. CIBULAS: Sure. Okay. So we have 15 25 minutes left and let's get to any CAP concerns that

1 anybody has and anybody just wants to bring to our 2 attention at this time. Dr. Clapp. 3 DR. CLAPP: Yeah, this is really a general question. I understand that there's an acting head 4 of the CDC right now, Dr. St. John? 5 DR. CIBULAS: Acting head of CDC? 6 No, Dr. 7 Redfield is the Director of the Centers for Disease 8 Control. 9 DR. CLAPP: Oh. 10 DR. CIBULAS: Dr. Robert Redfield. He's been 11 with us for about a month now. DR. CLAPP: The interim is over with. 12 The interim is over. Yeah, he 13 DR. CIBULAS: 14 came on board about a month ago. He's a 15 distinguished career in HIV, infectious diseases. 16 He's big on opioids, not big on environmental 17 health. What a surprise for a director of CDC. So 18 he'll be counting on Pat and others to help him with 19 the environmental health issues, but he is on board 20 full time. 21 UNIDENTIFIED SPEAKER: What was his name? 22 DR. CIBULAS: Robert Redfield. It's sort of 23 funny because he looks a little like Pat and we've 24 been making fun of it. So we put a picture of Pat 25 up and Rob and Pat -- well, I think the funniest

1 thing is probably a dozen and a half people have 2 welcomed Pat to the agency, thinking that he's Dr. 3 Redfield. Who else, anybody else? Go ahead, Andrea. 4 5 MS. AMICO: A question. Will the DoD's 6 comments on the protocol be made available to the 7 CAP? 8 DR. CIBULAS: You want to answer that, Joe? 9 COL COSTANTINO: Which --10 DR. CIBULAS: So we have sent the protocol to 11 the CAP and to you at this time. 12 COL COSTANTINO: I don't think we're providing 13 any comments on that. 14 DR. CIBULAS: Okay. Very good. Okay, Laurel. 15 DR. SCHAIDER: Yeah. I just wanted to follow 16 up on the private well health consultation and 17 you'll be having some outreach sessions with people 18 in that area who rely on private wells and I didn't 19 -- I don't know much about the proportion of people 20 in that area whose wells were tested, but I could 21 imagine like it was very well specific, these wells 22 were over, these wells were under. And unlike in 23 the public well situation where everyone had the 24 same water, the private well results seem very 25 heterogeneous, some people had high and some people

1 had low. So if I were living here and I had a 2 private well and my well hadn't been tested, I think 3 I would not know what to make of the results and I might want my own well to be tested. So I was 4 5 wondering if there would be any opportunities for б other wells in that area to be tested or if everyone 7 had already had the opportunity to participate. I 8 just wonder what your message would be for people 9 whose well hadn't been tested. 10 CAPT SOMERS: Yeah, that's a good point. Ι 11 believe that the testing was all done through New 12 Hampshire DES with the Air Force, so I can -- I 13 personally don't know the answer, but I'll find out 14 like with the --15 DR. SCHAIDER: I know you didn't do the 16 testing, I just --17 CAPT SOMERS: Yeah, I'll find out what the --18 DR. SCHAIDER: -- people might want to get 19 their well tested now if they --20 CAPT SOMERS: -- if they now have a new 21 concern. I think they were pretty -- they tried 22 pretty hard to get folks to test their wells. But 23 yeah, there's always people who don't want to and 24 that's fine; it's their private, you know, property, 25 you can't make people test it. So that's good. And

we can ask them like how many potentially, you know, there could be that didn't get tested that would now maybe ask that. The authors of the document probably know because they've been more intimately familiar with it, but off top of my head I don't know.

WRAP-UP/ADJOURN

1

2

3

4

5

б

7

8

9

10

DR. CIBULAS: Is there anyone on the phone who has a question or comment or a concern they want to bring up at this time?

11 Well, I'm looking around the room and I Okay. 12 don't see anything else at this time so again, I 13 guess, in the way of a wrap up we do have some 14 action items that we've recorded and we'll get back 15 with you on those. I want to reiterate what we said 16 at the beginning. I mean, we're really excited now, 17 where we're entering a new stage, we're moving 18 forward, monies are in hand. We've got a plan, 19 you're a big part of that plan and, you know, Dr. 20 Breysse is, you know, is engaged as any director has ever been on a project that I've ever seen. So you 21 22 know, you can count on him holding us to milestones 23 and bringing the right people on board to make sure 24 that this is the best science that we can do. So 25 any last comments or anything? Well, let's call it

| | | 130 |
|----|---|-----|
| | | |
| 1 | a success and let's call an end to the meeting. | |
| 2 | Meeting's adjourned. Thank you very much. | |
| 3 | (Proceedings concluded, 9:00 p.m.) | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | | |
| 20 | | |
| 21 | | |
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | | |
| | | |

1 2

CERTIFICATE OF COURT REPORTER

STATE OF GEORGIA COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Master Court Reporter, do hereby certify that I reported the above and foregoing on the day of May 10, 2018; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither relation nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 10th day of June, 2018.

<u>Steven Ray Green, CCR</u> STEVEN RAY GREEN, CCR, CVR-CM, PNSC CERTIFIED MERIT COURT REPORTER CERTIFICATE NUMBER: A-2102