

C O N T E N T S

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1 and my son was impacted. He went to daycare on Pease
2 and I was working there when I was pregnant with him.

3 MS. AMICO: My name is Andrea Amico, and I am a
4 founder of Testing for Pease and my two small children
5 and my husband were exposed to the contaminated water
6 here at Pease.

7 CDR MUTTER: Hi. My name is Jamie Mutter, and I'm
8 the CAP coordinator at ATSDR.

9 CAPT SOMERS: My name is Tarah Somers. I'm the
10 regional director for ATSDR Region 1.

11 DR. CIBULAS: Good afternoon. I'm Bill Cibulas.
12 I'm the acting director of the division of toxicology
13 and human health sciences. This is my second CAP
14 meeting, and I'm happy to be here.

15 DR. BOVE: This is Frank Bove. I work at ATSDR.
16 I worked on the feasibility assessment.

17 MR. SHEEHAN: Jared Sheehan. I represent Pease
18 Development Authority.

19 MS. MCNAMARA: Kim McNamara, the City of
20 Portsmouth health officer.

21 MR. OSGOOD: And I'm Russell Osgood with the
22 Portsmouth fire department.

23

24 **ACTION ITEMS FROM MAY 2017 CAP MEETING**

25 DR. BREYSSE: Fantastic. So I'd like to turn now

1 to Commander Jamie Mutter to review the action items
2 from the May 2017 CAP meeting.

3 CDR MUTTER: Thank you. So the first action item
4 we have is for the U.S. Air Force, and it was the CAP
5 requested the draft language that the Air Force prepare
6 to support ATSDR when requesting funding from Congress.
7 I did receive that from Colonel Costantino. I think we
8 decided that you'll send that out to the CAP directly
9 tomorrow or the next day, whenever I can get him the
10 distribution list, since I'm traveling tomorrow. Okay?

11 The next one is for the New Hampshire Department
12 of Human Health -- I don't know that abbreviation.
13 Human Health Service --

14 UNIDENTIFIED SPEAKER: Health and Human Services.

15 CDR MUTTER: Health and Human Services, thank you.
16 Should've just said the abbreviation and been done with
17 it. The CAP requested the New Hampshire DHHS check if
18 the blood samples from the 2015 blood testing are still
19 being stored or if they have been discarded. Sir, do
20 you --

21 UNIDENTIFIED SPEAKER: We have them all frozen and
22 stored in, in Concord.

23 CDR MUTTER: Okay. And for the transcriptionist,
24 he said, that they have them frozen and stored in
25 Concord. Thank you, sir.

1 The next action item is for ATSDR. A CAP member
2 requested that updates on ATSDR's plans and progress on
3 the national PFAS study are included on any future
4 agenda, and that has been done. It's on tonight's
5 agenda, and we can continue that going forward.

6 The next one's for ATSDR. ATSDR will provide the
7 CAP with the Agency's position education materials.
8 These materials are available on our Pease -- our PFAS
9 website, and they were also sent to the CAP on
10 August 18th as a follow-up.

11 The last action item is: ATSDR will continue to
12 move forward with developing a Pease study, preparing a
13 protocol and questionnaire, and I think that might be
14 on the agenda later. Sir, do you want to address that
15 now or later on the agenda?

16 DR. BOVE: At present we're working on the
17 questionnaire. We're borrowing from the C8 study and
18 also some studies we've conducted as well on other
19 exposures. So the questionnaire's moved along. We
20 were also working on the consent form, again, based
21 somewhat on the C8 studies but also on other work that
22 we've done. And we've been looking at neural
23 behavioral test batteries that we might want to
24 consider using in any national study. And that's where
25 we're at at this point.

1 Also we're working on the protocol itself. We're
2 basically taking a lot of what's in the feasibility
3 assessment and turning that -- because it was pretty
4 far along. It's a -- almost as a protocol, so we're
5 taking a lot of that out of the feasibility assessment
6 and making a protocol out of it. So we are in the
7 process of developing that protocol, so that's the
8 extent we're at right now. We're also looking to see
9 what comes about with the possible legislation too, so
10 that'll have an impact on also our thinking. But
11 whatever we do we will present it to you as a draft for
12 your comments.

13 DR. BREYSSE: Is that it for the action items?

14 CDR MUTTER: That's it, yes, sir.

15 DR. BREYSSE: Well, that didn't take long.

16 CDR MUTTER: No, it did not.

17 DR. BREYSSE: So I'm looking at agenda items that
18 maybe we can dispose of without some of the outside
19 experts in particular, and maybe we can have a
20 discussion about the PFAS website.

21
22 **ATSDR PFAS WEBSITE DISCUSSION**

23 DR. BREYSSE: I understand there are some
24 concerns. Would somebody like to articulate those
25 concerns, to start the discussion?

1 MS. DAVIS: Was this in regard to the email that I
2 sent, Jamie?

3 CDR MUTTER: Yeah. I think there were a couple of
4 emails sent about the topic.

5 MS. DAVIS: Okay. So I had sent an email because
6 I had seen an article online that was discussing the
7 ATSDR comments about -- so basically it was 3M, which
8 is one of the producers of PFAS chemicals, quoting
9 ATSDR and the CDC as refuting health effects of these
10 chemicals. And they were taken from the website for
11 ATSDR and the CDC, and it was basically saying, you
12 know, according to the CDC, you know, there are no
13 known health effects. So I mean, I understand we can't
14 prevent 3M from doing things like that but our concern
15 is that maybe the language is a little too careful from
16 ATSDR, and that, more and more, that that is going to
17 happen. And we actually had an example of that brought
18 up at the national conference, when Emily Corwin had
19 discussed passing along the story to a fellow
20 journalist because she wasn't able to work on the local
21 issues around here anymore. And he had gone to the CDC
22 website and, like he said, why are you worried about
23 these chemicals? The CDC says that there's no
24 conclusive health effects. And she had to like
25 basically educate him because he had already written it

1 off as not an issue.

2 DR. BREYSSE: Yeah, so that's unfortunate, and I
3 looked at this issue carefully. So first of all I'll
4 start off by saying we welcome scrutiny of things we
5 put on the Web. I can tell you we have a complex
6 webpage. There's different groups posting components
7 that relate to one another. There can be some old
8 stuff there. And so please, you know, look at, with a
9 jaundiced eye, at what we put on the webpage. We're
10 constantly reviewing it. If there's concerns like this
11 we want to hear about it.

12 MR. DALY: May I just make a point? The CDC has
13 not included the C8 peer-reviewed 800-page report done
14 on the DuPont facility in West Virginia. And in there
15 they mention 3M, ^, and two other companies.

16 DR. BREYSSE: Sir, could you introduce yourself?

17 MR. DALY: My name is Geoff Daly. I'm from
18 Nashua, and I'm involved right now with the Merrimack
19 PFOA, PFOS in the water system of the towns, including
20 Nashua now. And I'm sorry if the Air Force is not
21 doing its due diligence. The C8 report has been around
22 since the mid-90s.

23 DR. BREYSSE: Yes, we cite the C8 report. We
24 don't include the report on the website. Is that your
25 concern, the whole report?

1 MR. DALY: It should be on the website, sir.

2 DR. BREYSSE: We can look into that. If there's a
3 link -- we'll look into -- and --

4 MR. DALY: The CDC site and the EPA site, and it's
5 linked.

6 DR. BREYSSE: But it's not on the ATSDR site; is
7 that what you're saying?

8 MR. DALY: Yeah.

9 DR. BREYSSE: Okay. Well, that's -- we can look
10 into that.

11 MR. DALY: That's a mistake, and especially when I
12 learn that you guys have been at this for two years.

13 DR. BREYSSE: Thank you. But the, the issue -- I
14 think I've looked at the material you sent, and
15 unfortunately it's -- people can cherry-pick stuff out
16 of context, and that's part of what's happening here.
17 So we're -- in a section we're talking about medical
18 monitoring. We say that we don't know enough to
19 establish a level at which health effects are known to
20 occur in terms of blood lead levels. That doesn't mean
21 health effects don't occur. But like -- as you all
22 know, if you have a blood test for most things of
23 medical significance, there are ranges that you can
24 fall in that are acceptable and ranges that, if you're
25 outside of that range, it's unacceptable. We don't

1 have a safe range of PFAS in blood that clinicians can
2 refer to right now in order to, in a very black-and-
3 white way, interpret the results.

4 And so when we say there's currently no
5 established PFAS level which health effects are known
6 nor is there a level that predicts health problems in
7 the blood, we think that's a true statement, but they
8 could take that out of context and say, therefore CDC
9 says there's no health effects but that's not what we
10 say. But we will look very carefully to make sure that
11 the context of that is stronger.

12 And so that's an example, I think, unfortunately
13 where somebody could take our stuff out of context.
14 But at its face value, that's a true statement, but it
15 shouldn't be used to make the case that there are no
16 health effects. It just means we don't have an
17 exposure response-dose response value that would allow
18 us to predict how much disease occurs at how much blood
19 PFAS that allows us to create a clinical range that can
20 be used. And so I think maybe there might be an
21 opportunity to clarify that more on our webpage, and we
22 will look at that.

23 MS. AMICO: I just want to add to that, that a lot
24 of us attended a conference in Boston, and had the
25 opportunity to collaborate with a lot of other

1 community members experiencing the same contamination.
2 And there were several members there from the
3 Pennsylvania community, and they brought to the
4 attention of us a slide show that was presented by a
5 member of ATSDR in Warminster, and essentially using
6 our blood testing data in their presentation to say why
7 biomonitoring wasn't being suggested in Warminster.
8 And so I had sent an email to ATSDR saying I was
9 concerned about how -- I felt like these slides that
10 this ATSDR member presented in Pennsylvania was really
11 kind of a direct contradiction to our feasibility
12 assessment that had just come out saying our levels
13 were elevated and we're recommending health studies or
14 saying that health studies are feasible. And so I
15 guess to kind of just echo what Alayna is saying and
16 use this as another example, that I think it's critical
17 that, you know -- I think ATSDR is being seen as a
18 leader here. I think a lot of states are deferring to
19 you guys as to what to do and, you know, how to answer
20 people's questions, and it's imperative that the
21 information is consistent and it's balanced and that
22 it's not trying to minimize information but it -- you
23 know. So I think that's just an example that I found
24 kind of upsetting, that pretty big inconsistencies
25 between different members of ATSDR, and that I think,

1 you know, that shouldn't happen.

2 DR. BREYSSE: Yeah. So I thank you for that. And
3 as we started down this road we had people -- so first
4 of all, I want to remind people to use the microphones
5 and say your name before speaking for the
6 transcriptionist. And if you're in the audience
7 there's a microphone at the end of the table. But for
8 now I think we're going to wait for the audience stuff
9 until there's a period of time when we have questions
10 from the audience. We'll make sure that we reserve
11 that time. But for now I think we're talking to the
12 CAP.

13 But we have, I think, a situation now where we've
14 asked all the SMEs across the country in any region to
15 centralize the presentations they're making and their
16 interpretations they're making so we can do exactly
17 what you said; we can standardize this. We'll make
18 sure we do it. So we make sure when there's data that
19 are being displayed the data are up-to-date and most
20 current. And we want to make sure that we're making
21 similar judgments about what the science means. And so
22 the office of science now is in charge of making sure
23 that we coordinate all those presentations we have on
24 our webpage. A slide bank now that have been approved
25 for people to use, and hopefully we'll get better at

1 that. But thank you for that observation.

2 MS. AMICO: Sure.

3 DR. BREYSSE: So it looks like we got some new
4 people joining us. Why don't we just wrap up the
5 introductions, those of you who just came in? We
6 started with some of the more, you know, administrative
7 items. Hope you didn't mind. Just to move along.
8 But, Laurel?

9 DR. SCHAIER: Hi. I'm Laurel Schaider. I'm a
10 research scientist at Silent Spring Institute.

11 DR. CLAPP: I'm Dick Clapp, retired professor of
12 epidemiology at BU's School of Public Health.

13 DR. DURANT: Hi. I'm John Durant. I'm a
14 professor in the department of civil and environmental
15 engineering at Tufts University.

16 MR. SULLIVAN: Hi. I'm Mark Sullivan. I own a
17 business here at Pease Tradeport for the last 11 years,
18 Seacoast Asset Management. Glad to be here. Thank
19 you.

20 DR. BREYSSE: So is there anybody who has not been
21 introduced or introduced themselves yet? I think we
22 got everybody. So we've done welcome and
23 introductions. So I'll speed it along by saying
24 welcome. We finished the action items from the last
25 CAP meeting, and we moved to the discussion of the

1 website because I thought that's something that -- the
2 issues were raised by the CAP members who were here,
3 and I thought we could address those pretty quickly.

4 So if there's any -- if there's no issues, what
5 I'd like to do is move on to probably something that's
6 going to take the biggest amount of time we have
7 tonight, and that's the discussion of the feasibility
8 assessment.

9
10 **FEASIBILITY ASSESSMENT DISCUSSION**

11 DR. BREYSSE: We got comments back from you, and
12 we'd like to discuss those comments with you and have a
13 discussion about that issue. Probably before we start
14 I should probably say, so as you know, there are
15 efforts to get resources to ATSDR to do a national
16 study. And as I said last time that, if we got
17 resources, a study at Pease, along the lines of what we
18 propose as a feasibility assessment, might make a good
19 place to start as a pilot, and we still feel that way.
20 I just want to make sure I mention that.

21 Now, I have to be careful because we have no money
22 for a national study and I can't commit to anything,
23 but certainly we're down the road a good ways with you,
24 and so if we were to embark on something like that I
25 think it would make sense to start with some, for lack

1 of better phrase, low-hanging fruit, since we now have
2 a study design in hand and we have a history here and
3 we have a relationship here. We know more about the
4 history of the contamination. So that's still what
5 we're thinking but I just want to be clear that that's
6 not a -- an expression of an overt commitment on our
7 part, because obviously I can't commit to something
8 that doesn't exist yet in terms of the resources that
9 might support a national study. So any questions about
10 that? So that's the context now. Oh, yes?

11 MS. MCNAMARA: Can you speak to the difference
12 between --

13 DR. BREYSSE: Can you just give your name?

14 MS. MCNAMARA: Oh, Kim McNamara, Portsmouth Health
15 Department. Can you speak to the benefits of doing a
16 smaller pilot study here in Portsmouth versus the power
17 of a national study?

18 DR. BREYSSE: Well, the power of the national
19 study, as you'll see as part of the discussion we get
20 to today, is that there are huge sample size issues for
21 a number of the important endpoints that we'd like to
22 investigate, such that we're going to need to recruit
23 larger samples of people, a larger number of people,
24 than we can get by just studying this community.

25 The other benefit of a national study is one of

1 the things we'd like to have is ranges of exposures
2 that allow us to look at the full range of some things
3 that are very high to things that are pretty moderate
4 to things that are maybe on the lower end of the
5 distribution, again, so we can understand what that
6 exposure/response relationship is.

7 So there's lots of reasons why a national study
8 will allow us to expand the endpoints that we look at,
9 and that'll be part of the discussion we have right now
10 because some of the comments we got back was: How come
11 we can't look longitudinally? How come we can't
12 include some other endpoints? If we can do a national
13 study we'll be able to consider some of those things,
14 because we don't feel we have enough statistical power
15 in terms of the number of people we can recruit here to
16 look at some of those endpoints.

17 Plus what we're proposing here, if you
18 recognize -- you remember, is a cross-sectional study
19 as a pilot study. It helps us think about what
20 instruments we use to collect data. It helps to ask
21 questions about what's feasible in terms of
22 recruitment. It helps us think about how the --
23 readily we can collect large numbers of samples from
24 people, how willing they are to produce those samples,
25 what kind of exposure data do we need to make all this.

1 So there's a lot of things that we can think about in a
2 context of a pilot which will inform a national study.
3 Does that answer your question?

4 MS. MCNAMARA: Yes. Thank you.

5 DR. BREYSSE: So I'd like to now turn it over to
6 Dr. Bove who is going to review the comments you
7 submitted, and begin a discussion about our response.

8 DR. BOVE: So several CAP members provided
9 comments. Actually we tried to boil them down into a
10 smaller amount and it still took 15 pages,
11 single-spaced, so we have -- we've got plenty of
12 comments actually.

13 One of the things I want to say though is most of
14 the comments are relevant to a protocol, which is
15 actually not bad at all because that's our next step in
16 both developing a pilot and developing a national
17 study. But I think also the feasibility assessment was
18 written in a way that it almost looked like a protocol,
19 so it -- maybe that's why a lot of the comments were
20 that way. So I'm going to focus on those comments
21 first because that's the multitude of the comments.

22 And first -- oh, by the way, on the issue of pilot
23 versus a national study, what we're thinking about at
24 this point is that the pilot would include all the
25 endpoints that we would include in a national study,

1 and so it would actually pilot all the aspects of a
2 national study, so endpoints that were not feasible to
3 study at Pease alone or -- we're possibly able to study
4 there but more likely we would need more of those two
5 tiers in the feasibility assessment, we would look at
6 all those endpoints. We wouldn't -- you know, since
7 we're collecting, we want to collect enough blood to
8 look at all those endpoints in a national study; we'd
9 want to do the same thing at Pease.

10 So that -- and also the -- one of the key
11 questions and comments was will we look at the full
12 spectrum of PFAS chemicals? The feasibility assessment
13 focused a lot on PFOS and PFHxS, and that was because
14 at Pease the source was AFFF, and those were the two
15 contaminants that were the highest in the Haven well
16 and also highest in the serum and also elevated
17 compared to NHANES, so that's why we focused on those
18 two. That didn't mean we weren't interested in any of
19 the others; it just meant that we wanted in particular
20 to look at PFHxS because of the dearth of studies that
21 have looked at the health endpoint -- the health
22 effects of that chemical.

23 So what we intend to do, in any national study and
24 in any pilot at Pease, is to look at as many PFAS
25 chemicals as possible to analyze, and to actually

1 archive blood so that if, in the future, if we have
2 better ability to analyze additional PFAS we would do
3 that as well. And also we're thinking about as well
4 urine samples that could analyze certain PFAS chemicals
5 as well. So we're thinking about all that for the
6 protocol. So that question was raised -- that comment
7 was raised: Are you going to evaluate the full
8 spectrum of PFAS, and we will evaluate as many as we
9 can possibly analyze with the idea that we would, in a
10 consent form, ask the participant if it is okay to
11 archive their blood to look at additional PFAS at a
12 later date, once the technology --

13 DR. BREYSSE: Can I just add something? So it's
14 important to recognize that this is a huge problem, in
15 that there are upwards of a thousand different members
16 of this family. So when you say you're going to look
17 at all the chemicals, we're not going to look at all of
18 them but we're going to look at the ones that we have
19 strong analytical methods for right now. And the lab,
20 as Frank said, is developing new analytical methods.
21 As they do we will -- we have the -- we'll preserve the
22 right to look at those chemicals as well, but we have
23 to focus on the things that we can measure for now.

24 DR. BOVE: Right. Now, this wasn't actually
25 brought up, I don't think, in one of the comments, but

1 our focus has -- because the -- because the feasibility
2 assessment was focused on Pease, we were focused on
3 AFFF and the chemicals that are -- that get into the
4 drinking water from the use of AFFF, and I think that
5 that may also be how our national study might focus,
6 but we haven't made any decisions yet on that. So just
7 keep that in mind, that we're still very much
8 interested in AFFF as a source of drinking water
9 contamination nationwide.

10 So another group of comments dealt with the
11 outcomes that we were going to evaluate or should
12 evaluate, and a number of them were listed actually in
13 the feasibility assessment. Either they were listed as
14 ones we could do at Pease, ones that we possibly could
15 do at Pease but probably would need more sites, and
16 ones that were not feasible at all at Pease alone but
17 would require a national study or at least multiple
18 sites. And so again, as I said earlier, we will try to
19 involve -- look at all those endpoints or as many of
20 those as we possibly can within a pilot study as well
21 as in a national study.

22 So some of the outcomes mentioned were endocrine
23 disruption, endpoints like fertility, thyroid function,
24 sex hormones. There's -- there were some comments
25 about whether it was worth it to look at neural

1 behavioral outcomes, and I think there is, particularly
2 I'm interested in the executive function and
3 attention that are part of attention deficit-
4 hyperactivity disorder. And so I think there -- it's
5 important to look at that, and we're looking at
6 batteries that will look at that.

7 Other outcomes that were important, that were
8 stressed, were immune system endpoints such as asthma.
9 Fevers was brought up. Atopic dermatitis, antibody
10 response to vaccines. Many of these were mentioned in
11 the feasibility assessment. What wasn't mentioned as
12 much because the focus of the feasibility assessment
13 was on Pease were birth outcomes such as birth weight,
14 miscarriage, preterm birth. Also effects to the
15 mother, pregnancy-induced hypertension, and so on. We
16 didn't really evaluate those at Pease because we didn't
17 think it was really possible to look at those.
18 However, in a multisite study you could. So we'll
19 leave that -- those outcomes open, and that really
20 depends on what sites we can include in the study, and
21 then to see if it's feasible to look at some of those
22 outcomes as well.

23 MS. DALTON: Excuse me for one second. This is
24 Michelle Dalton. Can you explain as to why you don't
25 think it's feasible? Is it regarding numbers?

1 DR. BOVE: Yeah.

2 MS. DALTON: Okay.

3 DR. BOVE: Yeah, yeah. Yeah, I mean, it may be
4 feasible to look at birth outcomes in a different type
5 of study altogether. I was thinking for example if a
6 whole town, a large town, was exposed, residential
7 exposure, let's say, and we have a comparison town, and
8 you can look at it over many years, you could look at
9 birth weight possibly and maybe even particular birth
10 defects. Again, it would depend on the size of the
11 town and how many people were exposed, and so on, so
12 these are tough endpoints to look at.

13 Similarly with childhood cancers, because they're
14 so rare that it's very hard to look at them unless you
15 have a large population exposed. So it may not be
16 feasible to do that, even in a multisite study. On the
17 other hand it may occur that there may be, as I said,
18 populations exposed where the whole town or whole city
19 is exposed or a couple of cities could be cobbled
20 together. And then it might make sense. So we're not
21 ruling it out; it's just that it's going to be
22 difficult to look at.

23 Other endpoints that were mentioned were chronic
24 diseases such as cardiovascular disease and
25 hypertension. And then coming out of the conference,

1 it was already mentioned, that occurred two months ago,
2 one of the biomarkers that was mentioned there was
3 fatty liver biomarkers and some novel biomarkers, and
4 we're looking into that as well as a possibility. It
5 looked from the studies I've seen, you don't need a
6 large population to evaluate that. I was trying to do
7 a sample size calculation, could not really do one very
8 effectively, but the studies I've seen involve rather
9 small populations, certainly a Pease-sized population
10 would be feasible for that biomarker, and certainly if
11 we expand it to other sites. So these are endpoints
12 that might make sense, and we're going to be evaluating
13 them as well. So those are the -- on the outcome side.
14 Are there any questions about outcomes and issues
15 there?

16 MS. DAVIS: In regard to the childhood cancers,
17 would -- if we do have more numbers because we're
18 bringing in other communities, would it be limited to
19 certain cancers or would it be a general childhood
20 cancer? I mean, how would you figure out which ones
21 you're going to focus on?

22 DR. BOVE: Well, I use -- well, I mean, usually we
23 focus on leukemia, in particular acute lymphocytic
24 leukemia, and brain cancer, are the two that we often
25 focus on.

1 DR. CLAPP: Those are the big ones. Those are the
2 two biggest.

3 DR. BOVE: Yeah.

4 DR. BREYSSE: Two biggest in terms of the most?

5 DR. CLAPP: Childhood --

6 DR. BREYSSE: Childhood cancers, the most frequent
7 childhood cancers.

8 DR. BOVE: Yeah. Not necessarily because they're
9 more likely to be related to these chemicals, because
10 we really don't know, but because they're the biggest.
11 So trying to look at all childhood cancers as a group
12 is not a good idea because there are very different
13 cancers with different etiologies, so we try to at
14 least focus on particular ones. But still it would be
15 difficult to look at those unless you have a large
16 population and follow them quite a long time or over
17 time. So it's not out of the realm to look at these.
18 It's just that they're extremely difficult.

19 MS. DAVIS: So would you -- I mean, I'm not sure
20 how you go about the process so I mean, would you
21 take -- look at the registry for all the communities
22 that are involved for any type of cancer in children,
23 and see if there's a higher incidence for certain
24 types, or is that going backwards, or?

25 DR. BOVE: No. Well, again -- well, if you know

1 that the whole town was exposed you could actually use
2 a registry like that. Otherwise you'd have to do a
3 study to find out who -- and, and you could use the
4 registry for that purpose, in a sense. I mean, you
5 could divvy up the town into parts that were exposed,
6 unexposed, and you might be able to do that. It really
7 depends on how -- what geographic unit the registry
8 gets down to, what the exposure situation is. Does it
9 fit -- is it easy to characterize particular areas as
10 exposed and unexposed. So there's some of the ways to
11 do it.

12 You could do a case control sample of a registry,
13 and look and see if the cases are more likely to have
14 lived in areas where the exposures occurred. So there
15 are a number of approaches. All of them, though, are
16 going to be difficult with -- unless you have a large
17 population. In this case a large population exposed,
18 not just a large population. So but that isn't --
19 we're not saying we're not ruling it out; I'm just
20 saying these are some of the difficulties we have to
21 grapple with in doing it.

22 MS. DAVIS: So would what I was describing be a
23 case control exposure method?

24 DR. BOVE: That's one approach to it, yeah. Yeah.
25 So in the case, for example, of Woburn, which Dick can

1 talk more about, that's the approach that was taken, to
2 see if the -- in that case there were about 19, I
3 think, weren't there at some point?

4 DR. CLAPP: Twenty-one.

5 DR. BOVE: Twenty-one, that's right, close, cases
6 and to see where they resided and whether the wells,
7 the two wells that were contaminated, served the areas
8 of more of the cases than the controls. So that's,
9 that's how it was done there. And still -- and, and
10 Woburn was -- there was a good portion of Woburn that
11 was exposed, and the town was big enough and it could
12 be followed over a long period of time, so you could
13 get that many cases and look at it. Still, you had
14 small numbers of cases to evaluate. So I think the
15 study was great, but, you know, because of the small
16 numbers you had wide confidence intervals, and so on.
17 And so, you know, there's some uncertainty. So and
18 this is just the difficulty you have with any of these
19 rare outcomes, like, you know, specific birth defects
20 or childhood cancers.

21 DR. BREYSSE: So can I pause for a minute?

22 (pause for audio issues)

23 DR. BOVE: As I was trying to say, if you look at
24 the literature there are no studies as far as I know
25 that have looked at childhood cancers, and that's

1 because of the difficulty. And there are very few have
2 looked at specific birth defects, and all of them have
3 been so small that it's really been hard to interpret
4 them, so this has been the problem. So if we can find
5 enough population to study these, we'd like to add
6 something to the literature since there's very little,
7 if any. But it is difficult.

8 MS. AMICO: Can I just add a comment to that?
9 Andrea Amico. I don't know if you folks are aware but
10 we do have a rare pediatric cancer cluster here on the
11 seacoast of two rare cancers, so obviously there's been
12 no environmental link to it, but it's certainly a
13 concern of a lot of people, and it makes me wonder if
14 we're going to look at that, if we can maybe look at
15 those cancers in other sites. You know, like there's
16 rhabdomyosarcoma and pleuropulmonary blastoma. And we
17 also have seen increased levels of brain cancer, or
18 central nervous system cancers, on the seacoast, so I
19 guess I just want to put that out there. You know, I
20 don't know if any of these children are -- have been
21 exposed at Pease or their parents were exposed at
22 Pease; I have no idea. But if we are seeing that
23 cluster here, if that's something, when we look at
24 other sites maybe we look at the cancer -- those cancer
25 incidences in kids at those other sites too.

1 DR. BOVE: Well, this is maybe off the topic, but
2 the first thing to do is to find out from those --
3 where those cases -- where the pregnancy occurred for
4 those cases, where the child was up to one year of life
5 at least. That would be important just to ask those
6 particular questions, and see if, if they were located
7 at Pease or had anything to do with PFAS exposures or
8 any other particular exposure, so that -- in any
9 cluster investigation I think that would be the first
10 step to take. Anyway, but that's for another topic.

11 So -- okay, so those are the endpoints that were
12 discussed in the comments, and I think we're interested
13 in all the -- all the endpoints that were raised. The
14 question is which ones are possible to study, even with
15 a national study, and which ones aren't, and so we'll
16 continue to move in that direction, to include as many
17 of them as possible.

18 Another issue raised was the inclusion criteria
19 for the children study, the adult study, military,
20 civilian worker studies, and so on. And so we had
21 initially proposed that the age range would be four to
22 16 for the children study. There's no reason why we
23 couldn't expand that to 17. And then the adult study
24 would be 18 and over. The other way -- move though to
25 include three-year-olds poses some difficulties. So

1 we're not ruling it out but the difficulties we were
2 thinking about are, one, it may be difficult to recruit
3 them. The second issue would be the amount of blood
4 we'd want to get to look at a lot of these endpoints
5 may be too much to ask for a three-year-old. It may be
6 too much to ask for a four-year-old as well. And the
7 third issue would be, related to the second, is what
8 endpoints are feasible to evaluate in a three-year-old
9 versus the older children? And we're thinking here
10 about some of the neural behavioral endpoints. There
11 are batteries that go to look at age four and higher,
12 such as ones that look at executive function and
13 attention, that we're looking at, but don't include
14 three-year-olds; they start at four.

15 So these are some of the issues we were thinking
16 about when we used that age limit. We're still open to
17 expanding it. I don't think it would add too many to
18 the Pease population. So those are the issues.
19 Whether it's easy to recruit them or more difficult to
20 recruit three-year-olds; it may be difficult to recruit
21 four-year-olds too. The amount of blood we're asking,
22 so that we can look at a whole range of endpoints, and
23 whether for particular endpoints you can actually
24 evaluate three-year-olds effectively. Okay? So.

25 MS. AMICO: This is Andrea. Can I ask a question?

1 How much blood would you be asking for?

2 DR. BOVE: Well, we were talking about -- let's
3 see if I can remember. For the children study -- it's
4 been a while since I looked at this. We were looking
5 for four teaspoons, or 20 milliliters. So in the New
6 Hampshire blood sampling, I can't remember, I think it
7 was just one teaspoon, if that much. Is Dr. Chan
8 around?

9 DR. CHAN: Yeah. It was between like one half to
10 one milliliter.

11 DR. BOVE: Oh, so it was even much smaller than
12 that. Yeah, so it was just enough to look at the PFAS
13 chemicals. So we're asking for quite a lot more. It
14 may not -- again, we may have difficulty getting this
15 from a four-year-old too. These are supposedly the
16 amount that NHANES tries to get from children. Whether
17 they actually do is -- you know, may vary. That's also
18 why, for a long time, the age range where they analyzed
19 PFAS chemicals was 12 and above. Now they've actually
20 looked at younger children, so they're able to look at
21 that. So they are able to get blood -- enough blood
22 for at least to look at a range of PFAS chemicals. So
23 anyway, that's the issue. It's just we're asking for a
24 lot more blood than was done for the New Hampshire
25 blood testing, okay?

1 Any other -- any questions about the children
2 study?

3 As for adults, one of the -- several of the
4 comments, I think, were what about those who attended
5 daycare at Pease and are now 18 or over? And it's
6 certainly possible to include them. Our concern would
7 be that, if you're 18, say, next year, your last -- the
8 last time you might have been exposed, say at age five
9 or six, we're talking about a long period now since the
10 last -- your last exposure, so that could make a
11 difference in terms of trying to estimate what your
12 historical serum levels were. And looking at your
13 serum levels now, after 13 or more years since you were
14 last exposed, may not be very helpful. So that's why
15 we're a little concerned about doing that, versus
16 people who had more recent exposures at Pease, in the
17 last three, four, five years. So those are the issues
18 there.

19 And again, I think that what you have to remember
20 is you don't have to include everyone in a study. You
21 need to include those who can provide the most
22 information in a study. So that -- so leaving people
23 out of the study doesn't mean that the study isn't
24 relevant to them. In fact it might be very relevant to
25 them. It's just that it may not be effective to study

1 them, given the length of time since their last
2 exposure, so.

3 MS. DAVIS: This is Alayna Davis. So my question
4 about -- you said that their serum levels might have
5 reduced by the time we get around to studying them.
6 What about PFHxS which has the longest half-life? And
7 we want more information on that one. I mean, the
8 half-life is about seven to nine years, so for an
9 18-year-old, you know, they've only had like two cycles
10 of reducing.

11 DR. BOVE: Right, right. I mean, that's true. So
12 for PFHxS there's a long half-life. That's still,
13 though, a long period of time since their last
14 exposure. So we're not ruling it out; I'm just saying
15 that these are the considerations. So we could
16 include --

17 DR. BREYSSE: I think the challenge is for the
18 historical reconstruction, when we look at what's in
19 the blood today and predict what it was in the past.
20 The closer that blood measurement today is to when the
21 exposure occurred in the past, the stronger that
22 prediction will be. And so something that occurred,
23 you know, ten, 12 years ago is just going to be --
24 there are a lot more uncertainty around trying to
25 calculate back to what the exposure was, recognizing

1 that they do have two half-lives, that it's probably
2 dropped, or something on -- of that order. So it
3 doesn't mean, as Frank said, that it's not worth
4 looking at, but it's just sometimes that uncertainty
5 is -- creates more of a challenge than we would gain by
6 including them in a study.

7 DR. BOVE: Okay. And then there was a comment
8 that, what about those exposed in utero or during
9 breastfeeding after the Haven well was shut down, so
10 after 2014, May 2014? And that's, partly depends on
11 when we would start the study. If we started the
12 study, the pilot, in 2018 they wouldn't be old enough.
13 They wouldn't fit the four- to 16-year group. If we --
14 if the study started later than that it's possible to
15 include them but we would again have to figure out how
16 to estimate their serum levels when they were exposed,
17 and this might be difficult, more difficult than, say,
18 if we -- if for those who were exposed to the drinking
19 water itself or when the -- when the water was
20 contaminated. It's not impossible, again, and so this
21 is something we'll think about. But if we start the
22 study in 2018 they wouldn't be old enough to fit the
23 age range.

24 So then the next issue was military and civilian
25 workers, and we had a whole section of the feasibility

1 assessment that tried to address that, and we realized
2 that we couldn't just do it at Pease but that doesn't
3 mean we're not interested in studying them. And we
4 think we can identify at least some other bases where
5 PFAS-contaminated drinking water occurred that are
6 possible candidates for inclusion, along with Pease, in
7 such a study. So we still have work to do though in
8 identifying those sites, determining what the water
9 situation was at those sites, how far back the use of
10 AFFF was, and so on. And so there's still a whole
11 number of steps to do that, but we could look at
12 those --

13 One of the things we proposed, or at least
14 discussed in the feasibility assessment, was a study
15 that is similar to what we're doing at Camp Lejeune,
16 where we looked at mortality and cancer incidence, but
17 instead of just Camp Lejeune it would be several sites.
18 There are military sites, many military sites, that
19 have used AFFF, but not many of them actually had
20 contaminated drinking water on site. So there are
21 sites that could be unexposed in that sense. And
22 actually the issue would be which ones had contaminated
23 drinking water and can we characterize that over time.
24 So that's, you know, something we'll be focusing on as
25 well. We're interested in studying those workers and

1 the military personnel. So that's those issues.

2 And then there was a discussion -- there was a
3 couple of comments about comparison populations, and in
4 the feasibility assessment we mentioned Portsmouth, the
5 city of Portsmouth, residents there as a possible
6 comparison population. There was some concern that
7 there was PFAS contamination in one of the wells at
8 least in the Portsmouth water system.

9 Our understanding is that the levels there would
10 be so low it would be below the -- any of the standards
11 that have been set, even in New Jersey or any other
12 state, but that -- but, and again, before we would
13 choose a comparison population we'd want to make sure
14 that it was unexposed so that the levels would have to
15 be way below -- a non-detect basically or, or similar
16 to being non-detect so that we would feel comfortable.
17 So we haven't set on a comparison population either,
18 for Pease or for any other site that we were going to
19 include, okay? So if Portsmouth is not suitable we'll
20 try to find a comparison population that's similar to
21 the Pease population in all other aspects we can
22 possibly think of except for the exposure. Okay? So
23 that's where we're at with that.

24 So we're going to do -- we'll do some more work to
25 characterize the Portsmouth system. At this point we

1 think that the levels were such that it could be
2 considered unexposed. But, you know, we're still
3 looking into that. Yeah?

4 MS. MCNAMARA: Kim McNamara, Portsmouth Health
5 Department. I'm not sure if I misunderstood but if
6 almost all people carry these chemicals in their blood
7 system how would you find a population that's non-
8 detect, or are you talking about the water supply?

9 DR. BOVE: Just the water system.

10 MS. MCNAMARA: Okay.

11 DR. BOVE: Yeah. All of us have some background,
12 so the question is what is the additional exposure to
13 drinking water? What does that cause? Okay. Okay,
14 so -- and that's true also for military personnel and
15 sites where, even though they used AFFF, we'll look for
16 those sites where there was no contamination of the
17 drinking water, as, as possible comparison populations,
18 so that they'll be similar to the bases that did have
19 contamination except for the contamination itself,
20 okay?

21 Okay, so a lot of comments about longitudinal
22 studies, the fact that we're just -- at this point we
23 were proposing a cross-sectional study. Actually the
24 military study would be a retrospective cohort study,
25 so that is longitudinal in that sense. But we weren't

1 talking about prospective longitudinal studies of a
2 population, say, children or adults, at this point
3 because we wanted to focus on doing the cross-sectional
4 study first, as a basis for a then-possible future
5 longitudinal study.

6 So this was the approach that was taken in the C8
7 studies. Almost all of them are cross-sectional. Very
8 few were -- they were running out of money, basically.
9 They did a few longitudinal studies but most of the
10 work was a cross-sectional, and that was the basis even
11 for the longitudinal studies that were conducted. So
12 we're not ruling out at all a longitudinal study but we
13 think we need to get our feet wet first and do a cross-
14 sectional study of children and adults with, again,
15 looking at a wide range of endpoints, and then seeing
16 what funding and resources are available to move to a
17 longitudinal approach to that -- those cohorts. So
18 once -- so we'll have a cohort, we'll have archive
19 samples. That's the idea, and then if we can follow
20 those people over time, we'll do that.

21 Okay, and then there was a couple of other
22 comments that dealt with what was the selection
23 criteria for multi-sites, and we're working on, again,
24 sites where there's residential exposures primarily, to
25 drinking water, and the source of the contamination

1 being AFFF at this point; although we're not ruling out
2 any other sites at this point. We're just -- but we
3 are focusing a lot on AFFF primarily.

4 There was talk about case control sampling, how
5 that could be done. We've already discussed there
6 might be a way to look at some of the more rare
7 outcomes. The purpose of doing a case control sample
8 in this situation would be if you could improve the
9 exposure assessment, for example. So when you look
10 at -- when case control samples are often done you can
11 get more information on exposure, on the residential
12 history, and so on that you might not be able to get if
13 you're evaluating a larger population.

14 But in this situation it seemed that the -- that
15 it might not be necessary to do that because we intend
16 to get a lot of information from all the participants
17 in the study. We're going to get serum levels as well,
18 so it's not clear that the exposure assessment would be
19 improved by just doing a case control sample. So
20 again, that's a very effective sampling method. We'll
21 think about it in terms of looking at particularly rare
22 diseases, if that makes sense. But the design we've
23 been thinking about so far and we're pretty much -- we
24 think it's the way to go is similar to what the C8
25 study did, and that would be a cross-sectional study.

1 MS. DAVIS: I have a question.

2 DR. BOVE: Yeah.

3 MS. DAVIS: This is Alayna Davis. So when we were
4 talking about the case control for childhood cancers,
5 do you know what number you would need if it ends up
6 expanding to other populations in order for it to be a
7 valid feasible study?

8 DR. BOVE: I'd have to do a sample size
9 calculation. I know that -- I mean, that's a tough
10 question. In Woburn there were 21 cases. The
11 confidence intervals were wide. So we've learned a lot
12 more than that. So and that's true for -- I did one
13 study in New Jersey where I had 80-some neural tube
14 defects and still ended up with small numbers in the
15 exposed category just because the population that was
16 exposed was small. So you could have a lot of a
17 particular number of cases of a disease but if the
18 percent of that population that's exposed is small,
19 you're going to have trouble, again. So it has to be a
20 sizable population that's exposed, for one thing, and
21 so that, that might be the difficulty.

22 DR. BREYSSE: Plus another challenge is in that
23 approach is that we're learning more and more about how
24 widespread this contamination is every day, and while
25 we know a lot about some areas, there's a lot of

1 contamination around the country we don't know about.
2 So you'd want to make sure that, if you had a case and
3 came from a place where the water hadn't been sampled
4 yet, we might be less -- our ability to find that
5 person as truly as being unexposed might be
6 problematic. There are water systems that are being
7 discovered -- you know, every month we hear one or two
8 more of them -- at ATSDR. And so as the testing
9 expands, and as tests -- water systems that haven't
10 been sampled as part of the EPA unregulated contaminate
11 monitoring rule gets sampled, we're finding exposure is
12 more widespread than you might think just from that
13 sampling.

14 DR. BOVE: Yeah. The UCMR looked large systems
15 and a sample of small systems, so maybe took maybe
16 80 percent of the population roughly, but then there's
17 a large 20 percent or so of many thousand small systems
18 that haven't been tested, so.

19 DR. BREYSSE: And lots of well systems.

20 DR. BOVE: Well, then there's private wells too on
21 top of that, yeah. So that went back to what we talked
22 about earlier, that it is difficult to study these rare
23 endpoints, but, you know, we'll have to see what, what
24 information we get from other sites, what additional
25 testing is done in these small systems and where other

1 sites we may be able to identify that could be included
2 in a national study.

3 There were a lot of questions about historical
4 reconstruction of exposures. What do we mean by
5 physiologically-based pharmacokinetic modeling? And so
6 what we mean by that is that modeling sort of a
7 mathematical technique that looks at absorption of the
8 chemical, how it's metabolized and distributed
9 throughout the body and how it's excreted, and modeling
10 that. And using that information along with the amount
11 of contaminants in the drinking water and also -- to
12 the extent that we can get good information on how much
13 people drank, with all that information, then you can
14 start historically estimating what the serum levels
15 were over time. And if you have a serum measurement
16 currently, you can use that to help calibrate those
17 estimates.

18 So that's -- basically what the C8 study did for
19 PFOA and PFOS. I haven't seen anyone do it yet for
20 PFHxS. I don't know if there's a model yet for that,
21 but we're going to be talking with experts in the field
22 to see what -- what's feasible in terms of historically
23 reconstructing serum levels of PFHxS as well.

24 MS. AMICO: I have a question about that.

25 DR. BOVE: Yeah.

1 MS. AMICO: Andrea Amico. I had emailed a bunch
2 of people from DES EPA, City of Portsmouth, earlier
3 this year. At Wurtsmith Air Force Base they were able
4 to test water in old fire hydrants that hadn't been
5 used for a long time, and that was able to give them
6 some historical levels of PFAS chemicals from the 90s.
7 And I had emailed and asked if there was any sources
8 like that on Pease, that we could look back and see if
9 we knew back in, you know, whatever year what the
10 levels might be, and it sounds like there is
11 potentially one place that they can test, but they
12 feel -- they, meaning DES and EPA -- feel that it's not
13 safe for them or it would cost a large amount of money
14 to safely extract this water, but I don't know if
15 that's something that we should consider as part of our
16 study, if that would be helpful if we could extract old
17 water, and that would give us some historical levels.

18 DR. BOVE: There are some issues with that, and
19 I'm not the person to ask that question -- to answer
20 that question actually, but there are people in my --
21 on our staff that have looked at Wurtsmith in
22 particular and whether those -- that analysis of the
23 hydrants is a good approach to understanding the
24 historical levels of PFAS. So there's some question
25 about that. And I'm -- again, I'm not the best person

1 to answer that. But if it -- and so I will go back and
2 actually ask that question.

3 MS. AMICO: Yeah.

4 DR. BOVE: But we can -- I mean, any historical
5 information you can get on the water system, including
6 how the wells were used and even any sampling data for
7 the particular chemical is useful. So that's on the
8 other side of the coin. So I'm not sure that the
9 hydrant testing is useful or not.

10 MS. AMICO: Okay. Well, I guess just know that
11 there is potentially an older source of water here at
12 Pease. It sounds like it's difficult or would be
13 costly to safely extract the water, but if we feel that
14 it would give us valuable data in terms of prior
15 exposure it's something we should think about.

16 DR. BOVE: Right. Okay.

17 DR. BREYSSE: When did you bring that up? I'm
18 just curious.

19 MS. AMICO: I emailed I think back in January, and
20 I heard about it at a RAB meeting in July, that there
21 is this possible source.

22 DR. BOVE: Yeah. They did test the hydrants at
23 Wurtsmith, yeah. The water had been sitting there for
24 quite a while. Again, that may have had some effect on
25 the levels, so. Okay, so I'm not sure how --

1 DR. BREYSSE: We've got plenty of time.

2 DR. BOVE: We have plenty of time? Okay. Okay.
3 So there were questions, again, on the exposure side of
4 how we would characterize in utero exposures based --
5 occurring in utero and breastfeeding, during breast-
6 feeding, and again, that is difficult. It was done,
7 though, in the C8 study, so it's possible, at least for
8 PFOS and PFOA, so it is possible to do that. And
9 again, we're going to be talking to experts who know
10 how to do this, and see what the situation is with
11 PFHxS, if, if it is feasible.

12 And then there's also the impact of pregnancy,
13 breastfeeding and menstruation on elimination of PFAS
14 and taking that into consideration, and that's -- also
15 would have to be done if you're going to model
16 historically your serum levels, so that has to be taken
17 into account as well.

18 Okay, and then the last thing -- so any other
19 questions about the exposure assessment and issues
20 concerning exposure assessment? No? Okay. And if you
21 think of other issues, 'cause I've gone over a lot of
22 stuff here, we can -- you know, we can discuss them as
23 well.

24 One last thing on -- that has some -- that's more
25 applicable to a protocol is how we would report results

1 to the participant, to the general public about both
2 the study itself, the particular results, both the
3 biomarker results and the PFAS results. And again, we
4 would work with you on that. There are models out
5 there that Laurel can talk -- has -- and her
6 organization has, has developed. So we will work with
7 you to come up with the best way to do that. We didn't
8 address that in the feasibility assessment 'cause
9 that's more of a protocol issue. Okay.

10 So what we -- now, there were a couple of comments
11 on -- that are relevant to the feasibility assessment
12 in particular, and they had to do with sample size
13 calculations, because that's pretty much what the
14 feasibility assessment was -- a good deal of it was
15 about. One was why did we do a 2-to-1 ratio for
16 children and a 1-to-1 ratio for adults? We did that
17 for a couple of reasons. The main reason was that we
18 thought it would be harder to recruit unexposed
19 children. Also there were fewer children that had
20 participated in the blood testing program, so we
21 thought that we would maximize our recruitment effort
22 into getting as many of the exposed children as
23 possible. And so that's why we did that. We could do
24 a 1-to-1 ratio, and we will do those sample size
25 calculations for a 1-to-1 ratio. It won't change the

1 outcome -- the way we've tiered the outcomes but we'll
2 do that.

3 Similarly for adults we could do a 2-to-1 ratio
4 for adults. Again, I don't think it's going to change
5 the tiers that we -- the one -- you know, the
6 likelihood that it could be studied at Pease and, and
7 not likely unless there's a multisite study and
8 definitely not likely those three tiers. We can do --
9 and we'll do those sample size calculations.

10 And then there were a request that we do sample
11 size calculations for the -- to show the sample size
12 calculations for the tier 2 and tier 3 endpoints, and
13 we'll do that. Let me see if there's anything else on
14 that. Yeah, so those will all be in the final
15 feasibility assessment.

16 And then finally, other issues have been raised
17 that aren't really necessarily part of what a protocol
18 would be about or a feasibility assessment would be
19 about. How would the studies be conducted? Can ATSDR
20 conduct these studies? Would ATSDR get other
21 researchers to do these studies? How would that work?
22 And so that's a good question. We haven't really made
23 up our minds on that as far as -- right?

24 DR. BREYSSE: Sorry?

25 DR. BOVE: Okay. How, how the studies will be

1 conducted? Can ATSDR conduct the studies? Do we have
2 the capability ourselves to conduct them? Will we
3 give -- give any money we have to other researchers so
4 that they would conduct the studies instead, how that
5 would work? We haven't made any decisions on that.

6 DR. BREYSSE: Correct. So we're exploring
7 different models to get it done, and no decisions have
8 been made.

9 DR. BOVE: All right. And then the second issue
10 was --

11 MS. DALTON: I have -- excuse me, I have one
12 question. This is Michelle Dalton. Who makes that
13 decision as to whether ATSDR does it or gives it to --
14 is it ATSDR that makes that decision?

15 DR. BREYSSE: Yes, we'll decide.

16 MS. DALTON: Okay.

17 MS. AMICO: Can I ask -- Andrea Amico -- a
18 question about that? What is your experience with
19 conducting a national health study of this nature?

20 DR. BREYSSE: So we have --

21 MS. AMICO: -- in terms of ATSDR doing a study
22 like this?

23 DR. BREYSSE: So we have experience doing national
24 studies, and I'll point to the -- probably the most
25 recent one is the national study of the Camp Lejeune,

1 which requires us to follow people across the country,
2 as the Marines went across the country. What's unique
3 about this is it's going to be site-focused work, and
4 so every site's going to have its unique
5 characteristics. It's going to almost be a collection
6 of five or six mini-independent studies, and so there
7 might be some efficiencies -- and by the way, we're
8 committed to community engagement in each of those
9 communities so we're going to have, you know, community
10 groups across the country engaging with us. And then
11 we're going to probably have a national panel of some
12 kind to help steer things nationally. And so it
13 just -- we're exploring different -- we want to be as
14 efficient as possible. We want to be as timely as
15 possible. We want to get something in the field as
16 quickly as possible. And as we all know there are
17 barriers when you do things as part of the federal
18 government that people not part of the federal
19 government don't share, and so we'll consider what some
20 of those barriers are as well as the efficiency of
21 getting the work done as quickly as -- and as
22 scientifically rigorous as possible.

23 MS. DAVIS: This is Alayna Davis. So one question
24 that I have, and I know that we can't predict this, but
25 is if we solely use ATSDR, what if there are cutbacks

1 and people let go and laid off from the government
2 with, you know, just natural procedures? And then what
3 do we do? We have to replace those? Would it
4 compromise the study? I mean, that's why I think this
5 question comes up, because we're -- you know, we're
6 wondering how much experience there is but we're
7 wondering how much we can see it through to the end.

8 DR. BREYSSE: And so those are all things --

9 MS. DALTON: Without compromising it.

10 DR. BREYSSE: -- those are all things we're going
11 to consider as we plan going forward. So there are
12 many levels of decision-making that will play into that
13 final decision, and staffing and long-term commitment,
14 and -- will all kind of lead into the overall
15 discussion.

16 DR. BOVE: One plug for us is that we do think
17 that community involvement is key to this -- to this
18 national study, and in particular community involvement
19 at each of the sites. So that is, you know, something
20 we feel strongly about, as Dr. Breyse has mentioned.

21 So anyway a second issue that was raised was what
22 kind of actions will result from the studies, what
23 kinds of interventions, in particular medical
24 monitoring was mentioned in some of the comments. And
25 this again wasn't part of the feasibility assessment.

1 It's not clear that it would be actually part of our
2 protocol necessarily either, but these are issues that
3 we'll -- we've been considering all along, medical
4 monitoring and other, so we'll consider that and
5 keep -- continue to consider that.

6 DR. BREYSSE: So we're constantly surveilling the
7 publications, the literature, and as data become
8 available we consider all our recommendations, not just
9 those about medical monitoring as well, so we're
10 constantly evaluating what we know, and when we think
11 we know enough to change our recommendation we'll do
12 it, whether it comes from this study or some other
13 study.

14 DR. BOVE: Right. I don't expect that any actions
15 will come just out of this study but will come out of
16 all the studies that are being conducted, so that we
17 have a firm basis, whatever we do, a firm basis from
18 the input of other studies.

19 Finally the last thing that was mentioned, and
20 it's very important and we'll reiterate it here, that
21 the CAP will review the final version of the
22 feasibility assessment. The CAP will review the draft
23 of the protocol and will see the final protocol and
24 will have input in other -- any other health activities
25 we intend to do, both at Pease and at any of the other

1 sites. The CAPs there will have that similar input, so
2 that -- we're committed to doing that.

3 MS. MCNAMARA: Will the CAP have any input into
4 whether or not ATSDR does do the study? I would think
5 that there would be a lot of confidence in long-term
6 national studies, particularly outcomes that might come
7 from the study if ATSDR actually did the research
8 rather than farming it out to people.

9 DR. BREYSSE: So as we decide, we'll discuss it
10 with you. And like with everything we do, we're happy
11 to get your input and we'll actually be thrilled to
12 kind of hear what you have to say. Anything we do, you
13 know, has to stand the test of the broader support, and
14 we'll communicate that and we'll get your input and
15 hopefully we'll -- whatever path we choose we'll
16 convince you is the right path forward.

17 We will be involved. I don't want to give the
18 impression that this is something that's going to be
19 totally farmed out. That's not going to be the case.
20 It's just a question of what's the best way to get a
21 multisite study into the field, and there are lots of
22 models to do this. NIH does this type of study all the
23 time, so we're going to -- and the CDC, other parts of
24 CDC have done multisite studies before, so we're trying
25 to garner as much sense from these studies about what

1 works, what's successful. And so we'll share that with
2 you without a doubt.

3 MS. MCNAMARA: Okay.

4 DR. BOVE: So I just want to make one more
5 comment, and that is that I really appreciated the
6 comments that we received. They were very good. I
7 think they'll help us steer the protocol, and I think
8 we'll get a better product out of it, so thanks for
9 your comments.

10 MS. DALTON: Frank, I have one question. This is
11 Michelle Dalton. Are we going to be able to receive a
12 copy of all of the comments that were submitted and
13 your responses to those?

14 DR. BOVE: Yeah. There's two ways we can do that.
15 One is what I've done was -- what I've done was
16 actually respond to each person's comments. We can do
17 it that way or probably more appropriately is to group
18 the comments and the responses together, and not
19 attribute it to each particular person. But I've done
20 it both ways so that each comment I received I have a
21 response to. But I got some help from the staff in my
22 office to consolidate the comments and the responses,
23 so I think that's probably what we'll do, and that'll
24 be part of the feasibility assessment.

25 DR. BREYSSE: And just to be clear, I think it's

1 unethetical to ask people for their comments and not
2 respond to them in a meaningful way, so we will do
3 that.

4 MS. DALTON: Okay, thank you.

5 MS. AMICO: I have a question. This is Andrea
6 Amico. In terms of the protocol you said the CAP would
7 see the final feasibility assessment, the protocol of
8 that. Will the community see that, at large, or is
9 that something that'll just be internal to the CAP? I
10 guess my question -- I think I have heard at other
11 meetings that typically a protocol is not made public
12 to the people that you're studying 'cause there could
13 be biases to that, so I'm just curious if you mean just
14 the CAP or if you mean the entire community.

15 DR. BOVE: Well, we -- for Camp Lejeune we've
16 shared reports with the CAP, with the idea that we
17 would get the CAP's feedback, and the idea would be for
18 the CAP to be in touch with the community so that we'd
19 have a good sense of what the community was thinking,
20 but that the CAP would review it and not distribute it
21 to the public. We did that with the water modeling and
22 we did that to some extent with the protocol for the
23 cancer incidence study, and so that's probably the
24 approach we might take, but just for the reasons you're
25 saying.

1 MS. AMICO: Right. Okay. Thank you.

2 DR. BREYSSE: But we would hope you would share
3 the sense of things and the outline of things and the
4 approach with the community, to make sure that we're
5 getting, not just the collective wisdom of this group,
6 but of whoever else might be talking to you as well.

7 DR. BOVE: Yeah, in particular, I mean, the issues
8 around the best way to recruit, the best way to get the
9 word out about the study, any issues that might occur
10 with requesting school records. I know one comment was
11 about could you get school records? Would the parent
12 consent to that, and so on, and so these are issues
13 that you can bring to us from your discussion with the
14 community, and, and see if there are problems with the
15 protocol in that sense.

16 MS. DAVIS: This is Alayna Davis. So I have one
17 question that might be for ATSDR and one for the New
18 Hampshire Department of Health and Human Services. So
19 would it be possible, and I guess the first question
20 would be for Dr. Chan -- have people that have been
21 exposed in Newington as a result of the contamination
22 here on base been able to be blood tested?

23 DR. CHAN: So the blood testing was open to
24 anybody that was exposed on the Pease Tradeport, so I
25 think the answer to your question is yes.

1 MS. DAVIS: Well, they wouldn't -- it wouldn't
2 technically be Pease Tradeport but the site 8 flowed
3 off Pease Tradeport into residences in Newington, and
4 there were three residences --

5 DR. CHAN: The private residences.

6 MS. DAVIS: Yes.

7 DR. CHAN: Yes. We actually reached out to them
8 directly and offered blood testing to them.

9 MS. DAVIS: Okay, so they were eligible.

10 DR. CHAN: They, they were eligible.

11 MS. DAVIS: Okay. So I was just wondering if they
12 could be included in the study also because they were,
13 you know, exposed through Pease, but also they have
14 residential usage which might be different than what
15 Pease is as a business tradeport.

16 DR. BOVE: Yeah, if we do a multisite study, well,
17 most of the people will be exposed residentially.
18 Pease is actually unique in some ways, that the
19 exposures are workplace exposures. So most communities
20 it would be residential exposure, so yes. Yeah.

21 DR. SCHAIER: Hi. This is Laurel Schaider. I
22 was wondering if you could talk a little more about the
23 timeline for turning around the, the next -- I guess
24 the final feasibility plan, for comments, and then the
25 protocol and how that sort of meshes with the timeline

1 for the potential budget that would fund this.

2 DR. BOVE: Yeah, we can turn around the
3 feasibility assessment rather quickly; although we have
4 to go through clearance again for the final document
5 so, but I don't expect any problem, major problems,
6 there. We've already went through most of the big
7 hurdles already, so we've already responded to the
8 comments and any feedback we've gotten here, and so it
9 shouldn't take long at all. And as I said we're
10 working on the protocol, but for that I guess we'd have
11 to see about the legislation?

12 DR. BREYSSE: Yeah. It's tied into the
13 legislation, support for the legislation. We're
14 developing a protocol, as we talked about last time,
15 because I'm always optimistic, and so we want to be
16 ready to go should things fall into place, and so we're
17 not going to wait. And we actually have a work group
18 now that's beginning to talk and plan for the national
19 study, so again we're trying to plan for that. The
20 funding, you know, it's -- you know, this is -- these
21 are unusual times, and I -- you know, I don't care to
22 comment on the timeline for the funding or what's
23 happening in Congress other than recognizing that we
24 have a lot of legislative supporters for this effort,
25 and we'll have to just wait and see how things work

1 out.

2 DR. BOVE: But I would venture to guess that we
3 would have some kind of draft protocols for the next
4 meeting of the CAP, I would say. It depends on when we
5 meet, and going through, again, our -- what we do with
6 a protocol is we, we do have it peer-reviewed by
7 independent peer reviewers, and we do that for all our
8 protocols. And so we would want to do that. Whether
9 we do that before or after having presented to you, I'm
10 not sure how that would work, but at some point in the
11 development of the protocol you will be presented with
12 what we are thinking. It won't be that much different
13 than what you've heard already, and then you'll be able
14 to comment on it. Okay? So I, I would -- our next CAP
15 meeting is what, three or four months from now,
16 roughly?

17 CDR MUTTER: We'll have to talk about it at our
18 next conference call.

19 DR. BOVE: Yeah.

20 CDR MUTTER: Our monthly conference call.

21 DR. BOVE: Yeah, so we could have a draft by then.

22 MS. DAVIS: This is Alayna Davis. So the final
23 protocol, would that have more details on the
24 recruitment so that we can give you some feedback on
25 whether we think that's feasible or not?

1 DR. BOVE: Yes.

2 MS. DAVIS: Okay, thank you.

3 DR. BOVE: Absolutely, yeah.

4 MS. AMICO: This is Andrea Amico. So will you
5 have to go through the OMB process if we get this money
6 through -- you know, through this NDAA and -- 'cause I
7 guess we've heard before that the OMB process can slow
8 things down a little bit or a lot a bit, I guess.

9 DR. BREYSSE: As it stands now we will have to.

10 MS. AMICO: Okay.

11 DR. BREYSSE: And the OMB process can easily add
12 six months to a year and a half, maybe, to the review
13 process.

14 MS. AMICO: Is there any way to go around that?

15 DR. BREYSSE: I think there has to be legislative
16 language that would change that requirement.

17 MS. DAVIS: This is Alayna. So if we do source
18 out the study would that change the OMB process, if say
19 for instance, NIEHS is the primary --

20 DR. BREYSSE: That's one of the things we're
21 talking about, so I don't want to use the word source
22 out, but if we give grants, and, and -- but if we want
23 to have -- as you've said before, there's an interest
24 in having ATSDR stay involved, if we want to stay
25 involved, there's a threshold of involvement that we'd

1 likely exceed that would require OMB approval anyway.
2 So we're exploring all options, but chances are, if we
3 want to have access to the data in any meaningful way,
4 we'll have to go through OMB.

5 DR. BOVE: That would be true of NIEHS too. And
6 if you -- again, if you give out grants one of the
7 things you'd like to have with the national study is
8 uniformity in the way the data's collected -- all the
9 procedures uniform. And so if you'd give grants to
10 different researchers you can't guarantee that, so
11 that's one drawback to giving out grants. That's a
12 reason why you'd want to have one entity making sure
13 that everything's done the same way, whether it was
14 NIEHS or ATSDR or whoever. If it's the federal
15 government we have to go through OMB. That's the
16 requirement.

17 MS. AMICO: Is there anything we can do now to
18 start that process? You know, is there anything we can
19 start working on or submitting or? We're not --

20 DR. BOVE: Well --

21 MS. AMICO: -- we're just not far enough along
22 yet?

23 DR. BOVE: Having the protocol developed, going
24 and having it peer-reviewed, having it -- however
25 approval, all that needs to happen before it goes to

1 OMB, so yes, getting through that process, all those
2 steps, which aren't -- shouldn't take too long, would
3 be important to do. And then the OMB process -- the
4 OMB process could be shorter than six months. It's
5 just that we've also had experience with a year or more
6 as well, so we've had both kinds of experiences, quick
7 turn-around and long turn-around, and it may have to do
8 with what -- how OMB feels about the legislation
9 itself; who knows. But we can have it ready for OMB,
10 you know, and go through those hoops so that might help
11 shorten the process, so we'll work on it that way.

12 SEN. FULLER-CLARK: Senator Martha Fuller-Clark,
13 just follow-up. If you've been able to package the
14 protocol and it's been accepted, reviewed and so forth,
15 and all the entities are on board, does that mean that
16 you might have a chance of getting it through the OMB
17 faster?

18 DR. BREYSSE: Not necessarily.

19 DR. BOVE: Not necessarily.

20 SEN. FULLER-CLARK: Not necessarily.

21 DR. BOVE: Not necessarily, but at least it will
22 be -- it'll be ready -- you know, the clock will start,
23 you know, sooner. That's the idea.

24 SEN. FULLER-CLARK: Okay.

25 DR. BREYSSE: So the steps are, you know, internal

1 peer review, external peer review, not necessarily in
2 this order, human subjects review, OMB review. And I
3 include you all as part of the external peer review.
4 But the external peer review's also going to be the
5 scientific panel that we talked about before.

6 DR. BOVE: Yeah.

7 MS. AMICO: So am I understanding correctly though
8 that the legislation could be written in a way where
9 OMB would not be needed?

10 DR. BREYSSE: So I'm afraid I'm not going to
11 comment on that --

12 MS. AMICO: Okay.

13 DR. BREYSSE: -- right now. It's really -- I
14 think we just have to be careful. We can't comment on,
15 on legislation that's going to affect what we do.
16 That's just a line we can't cross.

17 So any other questions about the feasibility
18 assessment discussion? If not we're kind of right on
19 time for a break. So why we don't we take a ten-minute
20 break? Come back at 7:40.

21 (Break, 7:30 till 7:40 p.m.)

22 DR. BREYSSE: Where all good CAP members should be
23 in their seats.

24 **QUESTIONS FROM AUDIENCE**

25 DR. BREYSSE: Well, there's questions from the

1 audience. So we have 20 minutes or so for the
2 questions from the audience. What I'd like you to do
3 is say your name, and use that microphone at the end of
4 the table. Questions or comments.

5 MR. DALY: Geoff Daly from Nashua. One thing that
6 has not come up tonight is what have you in place in
7 and around Pease and Newington to filter the existing
8 water that will pass the EPA Clean Water Act?

9 DR. BREYSSE: So I can't comment on that, but if
10 the Air Force would like to talk about efforts to
11 provide water filtration it might be more appropriate.

12 COL COSTANTINO: Yeah, I -- let me try to scoot up
13 here a little bit. Colonel Joe Costantino, United
14 States Air Force Office of the Deputy Assistant
15 Secretary. Can you be more specific? Can you help
16 me --

17 MR. DALY: We know a number of wells within the
18 Newington area are contaminated.

19 COL COSTANTINO: Private, residential wells.

20 MR. DALY: Yes. And then you've got wells here on
21 the site.

22 COL COSTANTINO: Right.

23 MR. DALY: Those wells must be feeding your own
24 site system. What are you doing to filter that water
25 to make sure it meets EPA Clean Water Act?

1 COL COSTANTINO: So you're asking about discharge
2 standards, right? Meeting discharge --

3 MR. DALY: In other words you're drawing it from
4 your well --

5 COL COSTANTINO: Right.

6 MR. DALY: -- distributing it. How are you making
7 sure it meets --

8 COL COSTANTINO: Well, so I'll take it for a
9 follow-up, but my answer is everything that's being
10 done on the tradeport is in conjunction with the
11 regulator, so every action we're taking, any systems
12 that we're putting in and any discharges that are made
13 are approved by the regulatory agencies that we're
14 working with. I can give you more specifics at a later
15 time but that's what I can tell you right now.

16 MR. DALY: So New Hampshire DES is still
17 recommending that you use granulating activated carbon
18 to filter the water?

19 COL COSTANTINO: We -- that granulated activated
20 carbon is being used to filter for drinking water, yes.

21 MR. DALY: And how long has it been operating and
22 how many changes of carbon have you had to undertake in
23 the past three years?

24 COL COSTANTINO: Right. So some of that work is
25 actually subbed out to the City of Portsmouth, and

1 they're actually doing pilot studies, and I -- so I
2 defer to --

3 MR. DALY: Pilot studies still?

4 COL COSTANTINO: To do exactly what you're asking,
5 to test and answer those questions that you're
6 proposing.

7 MR. DALY: Well, there are many military bases,
8 and one of them Dr. Bove mentioned was Camp Lejeune,
9 the most contaminated military site in the nation.
10 They've got children and officers and military
11 personnel down there who have died over the past 17
12 years, and they put activated carbon in, and it failed
13 miserably. You spend hundreds of millions of dollars
14 and it's still not cleaned up. So why are we still
15 studying? Why don't you go out into the industry,
16 where there are experts in this type of micro-
17 filtration? It's terrible. You've got a public system
18 here. You've got a gentleman here with a business, and
19 you're exposing him to contamination.

20 The people in Newington, yes, they've got wells
21 but those wells, they know, were contaminated from your
22 base. We've got a situation in Manchester airport
23 right now. You've got a situation just up the road in
24 Brentwood. You probably know about it, Chief. Triple
25 AF has contaminated numerous wells in Brentwood, where

1 they have their firefighting demonstration system.

2 I mean, we've got to stop this. We've got to be
3 open and transparent. If you've got a system running
4 here in Pease, let's know about it. Let the public
5 know about it.

6 DR. BREYSSE: So we can have as a report back at
7 our next meeting an assessment of the water technology,
8 clean-up technology?

9 COL COSTANTINO: What I'd recommend is we have
10 another public forum called a restoration advisory
11 board.

12 MR. DALY: I've been through that.

13 COL COSTANTINO: Right. Right.

14 MR. DALY: And got nowhere.

15 COL COSTANTINO: That's where the questions can be
16 better asked.

17 MR. DALY: Do I go to submit a FOIA?

18 COL COSTANTINO: I'll be glad to take all of your
19 questions and answer them --

20 MR. DALY: I appreciate that.

21 COL COSTANTINO: -- to the (indiscernible) so we
22 can -- no, I'll be glad to take all of your questions.
23 I'm just -- I didn't know if you were at the RAB. I
24 wanted to offer that up to make sure you knew that it
25 existed.

1 MR. DALY: Yeah. Because, you know, Dr. Bove and
2 Dr. Breysse said six months, 18 months to get the
3 protocol organized. In the meantime people are still
4 consuming the water, still being exposed.

5 COL COSTANTINO: People are not consuming water
6 above EPA's health advisory.

7 MR. DALY: Seventy parts per trillion lifetime
8 exposure.

9 COL. CONSTANTINO: Correct.

10 MR. DALY: Lifetime. And if you go on to their
11 website, which is slowly being taken down, people have
12 put questions up: If I continue to consume the water
13 will I still be affected? The answer came back no, but
14 you've got Johns Hopkins, Yale University, UCLA saying,
15 wait a minute; it's bioaccumulative. If you've got it
16 in your liver or kidney, or something like that...
17 There's a young man in Merrimack right now that's got
18 stage 4 thyroid cancer. He moved from the Midwest.
19 Within one year he went to stage 4. His well was
20 measured at 288 parts per trillion. He's now dying.
21 Twenty-four years old. And we cannot allow this to
22 happen.

23 DR. BREYSSE: Thank you, sir.

24 MR. DALY: Okay? But I'll get you all your
25 information and I'll email you accordingly. Thank you.

1 COL COSTANTINO: Very good. Thank you.

2 DR. BREYSSE: Any other questions or comments from
3 the community members that are present? Hearing none,
4 we'll move on to update on future health studies, which
5 we touched base on a little bit as we went through the
6 review of the feasibility assessment and as my
7 introductory comments.

8

9 **UPDATE ON FUTURE HEALTH STUDIES**

10 DR. BREYSSE: So as everybody's aware, there are
11 potential plans afoot to fund a national study, and as
12 I said before, we're moving forward with our initial
13 planning phases to think about what that could be and
14 what the best way to move forward with that is. And as
15 we get anything more concrete to say we'll share it
16 with you, but for now we're just exploring options.

17 We're looking to an external group of scientific
18 experts to help inform what we say, which we would
19 normally do at a protocol developing phase as well.
20 And so we're going to look to potentially this pilot
21 effort here at Pease to help inform that study, and I
22 think that's probably about all we can say about the,
23 the study at this point. And we appreciate the support
24 for us that you guys have expressed here today and
25 elsewhere as well in terms of our efforts.

1 MS. AMICO: Can I ask a question? Andrea Amico.
2 Can you talk a little bit about what you envision these
3 others sites? Are you planning to set up CAPs at these
4 other sites or -- and how, how would we all stay
5 connected?

6 DR. BREYSSE: So there will be CAPs at these
7 sites. It's our philosophy that we don't study
8 communities; we collaborate with communities to address
9 health concerns, and that requires developing a
10 relationship with the community, maintaining that
11 relationship, getting input, partnering with the
12 community. And the best way to do that is through a
13 community assistance panel, such as we have here, at
14 least if there's going to be a long-term commitment to
15 a study. So let -- I want to be clear that we engage
16 with communities all the time in ways that don't
17 involve a community assistance panel, but when we have
18 a long-term arrangement or engagement envisioned that's
19 when we want to make sure we do that. So we will have
20 a CAP at all the local sites, and we'll have probably a
21 national CAP that represents -- have representatives
22 from each of those local CAPs, to help make sure that
23 efforts across communities -- or at least you all know
24 what the community concerns are across the country as
25 well so that we can integrate that, in a sense. So

1 it'll be a bit of a challenge. We've never done that
2 before. We've had individual CAPs before. We've never
3 had a pooled CAP such as we'd likely have for this
4 case.

5 MS. AMICO: Where are you at in the CAP process
6 with any of these other sites? Have you --

7 DR. BREYSSE: We have no other CAPs right now. So
8 we haven't chosen the sites yet. One of the things
9 that's part of the protocol development is we have to
10 think about what the characteristics of a site are that
11 would allow us to recruit sites. And we're just at the
12 nascent stages of that thinking right now. So until we
13 get sites identified and communities engaged, that's
14 the point at which we'll constitute CAPs. And if the
15 funding comes through we will put money aside for
16 community assistance panels and supporting community
17 assistance panels, so some of the resources will go to
18 support that effort.

19 SEN. FULLER-CLARK: Senator Martha Fuller-Clark.
20 Could you explain a little bit more about how you're
21 going about identifying those sites and choosing one
22 site over another site?

23 DR. BREYSSE: I can't, because we haven't
24 developed the criteria yet. And so I think we need
25 to -- we're getting a little bit ahead of the game.

1 We're trying to think of this, as I said, think this
2 through in advance of any potential funding, but we're
3 talking about potential funding right now, and so we
4 don't want to get too far ahead. I don't want to
5 commit to what the appropriate criteria are for a site,
6 other than to say, you know, we're looking for sites
7 that will allow us to do a large study as efficiently
8 as possible. We're looking for sites that have a range
9 of exposures. We're looking for sites where we think
10 we can characterize what the historical levels were in
11 the water as efficiently as possible. And we're going
12 to target enough sites to get a sample size that Dr.
13 Bove will calculate, or, or some other epidemiologists
14 will calculate, in terms of the numbers of people we
15 would need, you know, to, to reach the endpoints we're
16 trying to look at. So I can't even commit to the
17 number of sites we'll have right now or what the
18 characteristics of those sites are.

19 SEN. FULLER-CLARK: Thank you.

20 MR. SULLIVAN: Might it be possible -- I know it
21 might be not your jurisdiction, but to get the results
22 of that conversation that's going to happen after the
23 fact between this gentleman and this officer -- 'cause
24 it intrigued me, his comments, and --

25 DR. BREYSSE: You mean for you guys?

1 MR. SULLIVAN: Yeah. Please. I don't know who
2 we'd ask for that.

3 DR. BREYSSE: Any reason why that can't be shared
4 with the CAP more broadly?

5 COL COSTANTINO: I mean, I'd have to have it
6 checked, legal, but I don't think there was anything he
7 was asking that I wouldn't be able to share.

8 DR. BREYSSE: Okay, thank you.

9 MS. AMICO: Can I just ask one more follow-up?
10 So -- how do I want to phrase this? Is there the
11 potential that where you haven't set up these other
12 CAPs yet and you don't even have the criteria, that
13 could slow down our process at all? If, if we get the
14 funding. Because we're a pilot, we can move forward
15 even if they're not organized yet.

16 DR. BREYSSE: Yes.

17 MS. AMICO: Okay.

18 DR. SCHAIER: Hi, this is Laurel Schaider. I was
19 wondering if you could talk about the process of
20 picking the external advisors and does the CAP weigh in
21 on who those external advisors would be?

22 DR. BREYSSE: So right now what the process is, I
23 ask my office of science to constitute an external
24 review panel. And beyond that I don't know where they
25 are exactly. So we have an office of science, and I

1 know the PFAS study team's probably -- generates some
2 names. We can -- there's no reason why we can't ask
3 you guys for recommendations if you want to provide
4 some.

5 Recognize, though, that, if we do choose a grant
6 route, and you thought you might want to apply for the
7 money, you probably shouldn't be one of the external
8 advisors at that point, if you know what I mean. Just
9 in case.

10 So we can't -- we have to be careful that any
11 discussions we have publically would not give a
12 competitive advantage to one institution, should we go
13 that route. Everybody has to be on equal footing. If
14 not, having been on the grant-writing side before, you
15 know it's -- you don't like to think that somebody has
16 a leg up that you don't have.

17 Any other questions? So we already did the
18 website discussion. So we're a little bit ahead of
19 schedule, which is not a disaster because I did notice
20 that that Redhook Brewery was just down the road when I
21 drove in again tonight.

22
23 **CAP CONCERNS**

24 DR. BREYSSE: But now we have a CAP concerns, if
25 you want to raise any concerns that we haven't already

1 talked about.

2 MS. AMICO: This is Andrea Amico. I think I just
3 want to continue to stress at every meeting, I know
4 it's come up at other meetings, the desire from the
5 community to have some type of medical monitoring
6 program in place and just understanding is that
7 something you think that could be part of this national
8 study or be something that is developed, or where ATSDR
9 stands on medical monitoring, because even if we do get
10 the study that is different than medical monitoring in
11 that not everyone's going to participate in the study,
12 but people today want to know what they can do to
13 monitor their health and protect their health, so.

14 DR. BREYSSE: Yeah, so the study will inform any
15 decisions about future medical monitoring. And the
16 types of tasks we're going to be doing are tasks that
17 could also be done in a clinical setting, but it's not
18 designed to develop medical monitoring protocols per
19 se.

20 But we do give advice about medical monitoring,
21 and I'm trying -- I don't know if I brought it with me.
22 And, and we recommend, you know, for example, we
23 reference the C8's medical screening recommendations.
24 But we don't take a stand on whether people should
25 do -- get medical monitoring or not, if I remember

1 correctly. Sorry, I'm just trying to see if I can put
2 my hands on it.

3 So we say health effects associated with PFAS --
4 this is in our -- one of our fact sheets; I wish I knew
5 which one -- but just for example, we say health
6 effects associated with PFAS are not specific because
7 they can be caused by other factors. There are no
8 guidelines to support laboratory testing to monitor
9 PFAS health concerns at this time. However, if a
10 patient is concerned about -- this is guidance to
11 physicians -- is concerned about PFAS exposure,
12 discussing routine cholesterol screening can reassure
13 the patient that his or her concerns and some other
14 possible health effects can be screened based on these
15 symptoms. Then we go on to talk about other things,
16 and we actually mention the C8 guidelines, if they want
17 to look at those.

18 So it's probably not as strong as you would like,
19 if you should get monitoring. So we don't say medical
20 monitoring is advised. We don't say it's not advised
21 either at this point. I think we're just trying to
22 stay a little agnostic until we feel more strongly.

23 Once we make a recommendation at CDC, that's a big
24 deal. And a recommendation like that would have to be
25 vetted and peer-reviewed rigorously across the agency.

1 And I wouldn't propose something for it if I didn't
2 think we would get successfully through that process.
3 And right now the science is probably not strong enough
4 to be the basis of a CDC medical monitoring
5 recommendation. For example, I sat through last year
6 and watched what CDC went through to make
7 recommendations about opioid prescription, and it's a
8 very serious recommendation at that point when CDC puts
9 their name behind it.

10 MS. AMICO: Well, I guess I -- my response would
11 be that this issue's only getting bigger. We're only
12 seeing more people exposed and that it's something I
13 hope that the CDC continues to pay attention to
14 because, whether it's difficult or not, it's the
15 reality of the people that have drank this water, that
16 we face that question every day. When I look at my
17 kids I wonder every day: Are you going to be okay?
18 You know, you're sick again; is it because you drank
19 the water? You know, so I understand it's a
20 challenging process but I want you to understand, from
21 a mom of kids that have drank this water, that I really
22 want to know what I can do now to keep them safe and,
23 and not just wait until it's not a difficult task or
24 it's -- you know. I think we need to err on the side
25 of caution here, and that's one of my frustrations is

1 that I feel like we give the chemicals a benefit of the
2 doubt; we don't give public health the benefit of the
3 doubt when it comes to these chemicals.

4 DR. BREYSSE: And I understand that frustration.
5 I will say that a year or so ago we actually had a
6 recommendation in writing that said we don't recommend
7 medical monitoring, so at least, you know, we've taken
8 a step to a more neutral posture at this point, so
9 that's, I think, a partial success.

10 MS. AMICO: I think the other thing I'd like to
11 say too is that our community experiences a variety of
12 responses from healthcare providers, just here in New
13 Hampshire, you know. Some providers are much more open
14 to medical monitoring on an individual patient and are
15 willing and then we have other people that are really
16 hitting barriers, with their providers saying, I will
17 not provide medical monitoring for you. I've read what
18 the guidelines are, and I just don't think we need to
19 do that, anything other than your routine annual exams.
20 And people aren't comfortable with that, and they're
21 frustrated with that. And that's the other thing; we
22 need something more streamlined, I guess, that why can
23 I get medical monitoring for my children but somebody
24 else can't? And that's something we're facing quite a
25 bit here in New Hampshire.

1 DR. BREYSSE: I understand, and that's important
2 that we hear that, and we'll be as aggressive as we can
3 about reevaluating our recommendations as the science
4 evolves.

5 MS. DALTON: This is Michelle Dalton. I also
6 wanted to just piggyback on what Andrea was saying,
7 that my family was actually one of those families that
8 was denied any type of blood testing for my son. He
9 was in utero exposed when I was working on Pease, and
10 then after, breastfed. He attended daycare. He has
11 high levels of these contaminants in his blood. And
12 just recently I went for his annual exam and was
13 talking with the physician, and the physician said
14 basically I needed to educate him on what these
15 chemicals were and the C8 health study and what their
16 potential health effects were.

17 Long story, short, we had about an hour
18 conversation that kind of turned into debating over
19 whether or not we should be monitoring for these types
20 of, you know, potential health effects. And in the end
21 he said, I'm going to review all of the materials from
22 ATSDR, from New Hampshire DHHS, and I will give you a
23 call. He called me a few days later and said, no, I'm
24 not going to recommend them because I'm going off of
25 what the recommendations are from higher-ups.

1 DR. BREYSSE: Was he aware of the C8 study medical
2 monitoring --

3 MS. DALTON: I did tell him the C8 study of
4 medical monitoring, and his response to me, off the --
5 you know, off the side, was he needed to make sure that
6 that was a legit website because he had never heard
7 about it before. So.

8 DR. BREYSSE: I think it's -- you could really
9 reasonably reassure him it's not illegitimate.

10 MS. DALTON: That's what I was trying to tell him,
11 but anyway, so I was denied. My son was denied any
12 type of, you know, future monitoring. And what really
13 got me was that the amount of time that he took
14 debating and researching and pushing back other
15 patients and making them late for their appointments
16 probably cost more money than him writing the script
17 and saying, okay, I understand, you know, your
18 concerns. This is -- you know, here's the blood slip
19 to do this, or the lab slip to do it. And so his
20 decisions were based off of the physician guidance.

21 MS. DAVIS: This is Alayna Davis. So I've had the
22 same experience when I went to my physician and
23 actually produced my son's blood level results, and
24 then followed up with them to say, could you please,
25 you know, have a conference with me about this. It

1 wasn't as long a conversation as Michelle's, and it
2 pretty quickly went to the annual exam will cover it.
3 The New Hampshire Department of Health and Human
4 Services doesn't make any recommendations regarding
5 this and we aren't going to do anything additional.

6 So the State's stance has been clearly stated at
7 several different meetings across the state, not just
8 Pease, that they don't believe that the C8 evidence is
9 conclusive enough to warrant any additional monitoring.
10 So I'm not sure if you're aware of that, but it is a
11 struggle that the community has here. It's a struggle
12 that the Merrimack community and other surrounding
13 communities that have contaminations have, and so
14 that's why we keep coming back to you on this, because
15 the State itself is not supporting this cause for us,
16 and so we need to turn somewhere else where we can get
17 that authority to decide that this would be valid.

18 DR. BREYSSE: I understand, and it's important to
19 hear the frustrations you're having.

20 MS. AMICO: And then can I ask, what is ATSDR's
21 position on the C8 health study? Is it you view it as
22 a valid scientific study? And, and also what are your
23 thoughts on the medical monitoring tool that came out
24 of that study?

25 DR. BREYSSE: So I don't think we -- as a policy

1 we comment on the validity of any one individual study.

2 DR. BOVE: I mean, the -- it's a group of studies;
3 it's not just one study. And the three people who
4 reviewed the literature -- and they not only reviewed
5 the C8 studies but also the occupational studies that
6 have been conducted, studies done in other countries
7 and so on. So they looked at all the evidence at the
8 time and came up with a decision as to whether there
9 was a probable link with the exposures at -- the PFOA
10 exposures in particular, at -- in the C8 area and a
11 whole bunch of endpoints. And so the probable link
12 meant greater than 50 percent, or more likely than not,
13 similar to what we tried to do at Camp Lejeune.

14 So it's -- you know, it's not -- it was done
15 because of a legal court case, true, but that really
16 has nothing to do with the actual assessment. The
17 assessment was done in the usual way assessments are
18 done, looking at all the evidence from all the studies,
19 including the C8 studies, and coming up with a
20 difficult, oftentimes, decision as to whether the
21 evidence was from all those studies reached a more
22 likely than not level.

23 I don't think they felt that any of them was
24 conclusive, such like TCE and kidney cancer, but they
25 did -- several endpoints were reached that level that

1 it was more likely than not in their opinion. So
2 that's -- that's how it should be described, as a group
3 of studies, but the assessment done by the three panel
4 scientists was an assessment of all the evidence that
5 was available at the time.

6 MS. DAVIS: And this -- this is Alayna Davis
7 again. So I just want to point out for those that
8 don't know this, that the reason why we look at the C8
9 study, I mean, for many reasons, as we're looking at it
10 for guidance, is because that study studied 69,000
11 people for PFOA at 50 parts per trillion for as small
12 amount of time as a year. And the Haven well, when it
13 was shut down, was 350 parts per trillion. That's
14 seven times the level that the C8 study was studied.
15 So if they're finding probable links at the 50 parts
16 per trillion for as little a time as a year, and the
17 people at Pease were exposed for several years, decades
18 even, in some -- probably for some people, that's a
19 huge concern.

20 And so I mean, for people that don't know that,
21 that's why we keep going back to the C8 study. I mean,
22 it was a large population. It was peer reviewed. Yes,
23 it was the result of a legal settlement, but both
24 sides, both the prosecuting side and the defense side,
25 had to decide on these epidemiologists and these

1 scientists, and they had to both agree on whether that
2 was a valid approach, and the people that they chose
3 were okay. So I just wanted to give that as additional
4 feedback.

5 DR. BREYSSE: Any additional CAP concerns?

6 MS. DALTON: One additional follow-up. This is
7 Michelle Dalton. Following up to what Alayna said
8 earlier, is there anything that ATSDR can do to help
9 our community or our state in terms of educating the
10 physicians or making a stance on whether or not we need
11 medical monitoring?

12 DR. BREYSSE: So can I explore that with our staff
13 when we go back, and, and get back to you?

14 MS. DALTON: Absolutely.

15 DR. BREYSSE: It might not be a role we could
16 play, but we support a group called the pediatric
17 environmental health specialty units, and their job is
18 to interact with the medical community on pediatric
19 health issues and translate science into medical
20 decisions. So --

21 CAPT SOMERS: We also have -- this is Tarah
22 Somers, ATSDR -- there is an online program. It's for
23 physicians and practitioners to get continuing
24 education credits, to talk about PFOA and PFOS and the
25 contaminants. Again, it doesn't come out and say these

1 are the medical tests you as a provider should do. It
2 doesn't do that. It follows more similarly the fact
3 sheet guidance to physicians, but it does give them the
4 background on the contaminants, and they get continuing
5 education credit which is important to a lot of
6 providers. So that is available online right now.
7 It's up there. It's been there for six months or so.

8 MS. DALTON: Yeah. I think the background
9 information is certainly helpful, but in terms of
10 either making a stance or making recommendations as to
11 what our providers can do to help us, 'cause we're
12 running into roadblocks.

13 MS. DAVIS: Tarah, can you provide the CAP with
14 that link to how the physicians can sign up for that?

15 CAPT. SOMERS: Yeah, sure.

16 MS. DAVIS: Because I'm not sure physicians are
17 even aware of that.

18 CAPT SOMERS: Yeah. And I mean, it's challenging,
19 certainly, to target like every physician's office in
20 any area, 'cause there's like lots. I know the State,
21 New Hampshire, Department of Health and Human Services
22 has tried to put out information to local physicians.
23 Maybe we could go through the local health department.
24 Kim McNamara, maybe she has other resources to push out
25 more locally, you know, rather than state level,

1 locally. We can explore that with her, but it is
2 available.

3 SEN. FULLER-CLARK: So Senator Martha Fuller-
4 Clark. We do have the New Hampshire Board of Medicine,
5 and I don't know to what degree this discussion has
6 taken place with them, but I think that would be
7 another avenue. It would be worth exploring.

8 CAPT SOMERS: We can look into that. I got it.

9 DR. BREYSSE: Okay. Anything else?

10 MR. DALY: Yeah, Geoff Daly. I know we've just
11 talked about drinking water. One of the things the CDC
12 has been looking into, has not come up with any firm
13 decisions, and that is aerosolized water vapor from
14 showers and hot baths opening up the pores of the skin.
15 These particles are down in the nano range, into the
16 angstrom range in fact, and therefore through the skin
17 will percolate, if it's hot. And they're possibly
18 thinking about a warning of taking hot showers, steamy
19 showers, and breathing in the moisture. Especially
20 youngsters. I had a son who loved hot showers. He's
21 now asthmatic, and we live in Nashua. So that's
22 something I think that should be part of your protocol
23 testing. Were the people exposed to hot showers and
24 hot baths during the period of time here at Pease and
25 in the Newington area?

1 DR. BREYSSE: Thank you for the suggestion.

2 MR. DALY: It's very important.

3 DR. BREYSSE: All right.

4 MS. DALTON: I actually have one other question.
5 Sorry to hold you up; I know you want to get to
6 Redhook.

7 DR. BREYSSE: No. No, no, no. No. That was a
8 joke.

9 MS. DALTON: This is Michelle Dalton. It's
10 actually a question for Dr. Chan. Earlier you had
11 mentioned that the blood samples from the 2015 testing
12 were being stored. What about the testing after 2015
13 and the samples that are currently being taken?

14 DR. CHAN: Yes. We're still holding those as
15 well.

16 MS. DALTON: Great. Thank you.

17 DR. BREYSSE: Great.

18 MS. AMICO: I'm sorry, one more thing.

19 DR. BREYSSE: Don't apologize.

20 MS. AMICO: Andrea Amico. I just want to ask
21 about, you know, we kind of talked a lot about the
22 three-year-olds, the four-year-olds, the -- you know.
23 I just want to know that, you know, if someone had a
24 three-year-old we wouldn't turn them away, if they want
25 them to be part of the study, and like can you describe

1 a little bit more about if people do want to be part of
2 the study but they're maybe in between these awkward
3 age cut-offs that we have. Would we turn someone away
4 because of just an age or would we consider them, if we
5 understood their exposure and what they may bring to
6 the study? For example, like I'm thinking of some
7 people with children that were here 20 years ago, and
8 they're adults now but -- you know. So how, how can we
9 make sure these people are part of the study?

10 DR. BOVE: Well, the protocol would be to find the
11 age inclusion so we would have to stick with that, and
12 it would be based on what's the best population to
13 study most effectively. So yes, they would be turned
14 away. I mean, part of the recruitment would be to make
15 sure that people knew what the age of inclusion is. So
16 again, you know, we didn't study everybody at Lejeune
17 either, but the endpoints that we evaluated and the
18 results that we gathered for the mortality study and
19 the overall assessment pertained to all the Camp
20 Lejeune Marines and other service people who were on
21 the base, so even if they're not in the study the
22 results of the study were important to them, and
23 they're getting compensation actually because of that.
24 So you don't have to be in the study to benefit from
25 the study.

1 The C8 study did look at -- it had 69,000, but if
2 you look at the actual studies that were done it's a
3 smaller, not much smaller, but it's not every one of
4 those 69,000 are in the studies. So but the results
5 pertained to all of them.

6 So we would have to make it clear in any
7 recruitment that we do that this is the age range. And
8 to make it clear in any of the media and public
9 information we put out that the results of this study
10 will be important for all who were exposed, not just
11 the people in the study.

12 MS. AMICO: And where do you see kids that were
13 here 20 years ago at daycare but now they're adults?
14 Where do they fall into this? Would they just not be
15 eligible to be part of the study or would they be under
16 adults now, but they were exposed as children?

17 DR. BOVE: We have to think about that. Again,
18 'cause we're concerned about whether we could actually
19 characterize their exposures historically.

20 MS. AMICO: I get that --

21 DR. BOVE: Because if we get a serum level now,
22 can we -- I mean, and this is a question for the expert
23 panel that we'll be putting together, because we want
24 to have experts not only on the endpoints but we want
25 to have experts on the modeling of the exposure in

1 particular. And so this would be a question for their
2 consideration too. So we're not going to just base it
3 on what we think.

4 MS. AMICO: Okay. I think they're a valuable
5 population to look at, if you have adults now that were
6 exposed 20 years ago at daycare. For me as a mom, I'm
7 like I want to know what's going with those, those
8 people now.

9 DR. BOVE: Right.

10 MS. AMICO: That's going to provide me a lot of
11 information. So even if they can't be part of this
12 study how do we still talk to those people or capture
13 information from them?

14 DR. BOVE: Well, one of the reasons --

15 MS. AMICO: Not as part of a study but something
16 that's meaningful to you guys.

17 DR. BOVE: Well, one of the reasons we want to
18 look at civilian workers and military personnel is that
19 they did have this exposure 20, 30 years ago. And then
20 look and see if we can find particular cancers and
21 causes of death among them, that would stand out. So
22 that would look at those endpoints.

23 The endpoints we're talking about in the children
24 study and the adult study at Pease and other sites
25 would inform that as well. You know, more recent

1 exposures and particular endpoints. So all this stuff
2 will be important to anybody who was exposed regardless
3 of when they were exposed, I would say.

4 MS. AMICO: Okay. And I guess, kind of leading on
5 to that would be -- and I think I've asked this
6 question before, but do you guys create any type of
7 registry where people can report to you, you know,
8 health effects they may be having, even if they're not
9 part of a study? Does ATSDR keep track of that data in
10 any way or if people are willing to give that
11 information to you?

12 DR. BREYSSE: So we don't normally set up
13 registries like that. And we're currently not planning
14 on doing that. We think we need to invest in a
15 carefully designed study that has cohorts of people
16 defined, based on criteria that we think are most
17 valuable, to provide the most meaningful information
18 that we think we can.

19 DR. BOVE: However, what we could use is maybe a
20 ongoing mailing list. If we want to follow people over
21 time, and one of the things we'll ask in the consent
22 and -- I mean in the questionnaire is: Is there a
23 person or a couple of people that we can contact who
24 will know where you are, so that we can -- if we want
25 to follow these people over time and re-interview them,

1 and maybe even get an additional blood sample, or
2 whatever, that we'll be able to track them down. So in
3 that sense we would -- it's not a registry, that's what
4 you're talking about, but we would probably need to set
5 up something so that we can continue to track people
6 over time.

7 MS. DALTON: This is Michelle Dalton. Even if a
8 registry isn't something that you typically do, is
9 there a way to do that for this study?

10 DR. BREYSSE: I don't know the answer to that
11 right now but historically we've tried to do that in
12 the past, before I came on board, and the efforts were
13 found to be fraught with difficulty. And based on the
14 resources it took to do it and maintain it the decision
15 was that they're probably not the most valuable way
16 that we can approach these health concerns. Now, what
17 Frank was talking about was, for the people in the
18 study, if we do it right we can build in the
19 opportunity for coming back to them over time, to
20 follow them and so on. In a sense a cohort is a small
21 registry, if you want to think of it that way. And
22 those are people that we'll have very detailed
23 information on about their exposure, their exposure
24 history, their health history, so we know to contact
25 them over time, will probably provide us a unique

1 opportunity to look at the health history of the people
2 exposed that we know a lot about.

3 DR. DURANT: Could I just ask -- follow on to
4 Andrea's question? This is John Durant. So with the
5 adults, how do you propose to quantify their historical
6 exposures, going back in time? Just briefly, what are
7 your -- what's the approach?

8 DR. BOVE: Well, we would probably use something
9 similar to what the C8 study did. But again this is
10 something we would -- we want to have an expert panel
11 to actually discuss this with us. But what the C8
12 study did was they did have PBPK modeling of the PFOA
13 and PFOS, so they had those models to use. And then
14 with the -- they also had to estimate historically the
15 water contamination levels, so that was additional
16 modeling that had to be done for that, which we've done
17 at Lejeune, so we have some -- and at Toms River, to
18 some extent, so we have some experience doing that.
19 The PBPK modeling, we have some experience but not with
20 PFOA and PFOS, so we'd have to develop that expertise,
21 and again, with other researchers in the expert panel
22 that would be able to do that. So with those two
23 pieces plus any information we get from the
24 participant, him- or herself, about their water
25 consumption, and then their serum level from the --

1 which is what the C8 study used for calibration
2 purposes. So that's set.

3 DR. DURANT: So it would be individualized?

4 DR. BOVE: Yeah, yeah. Right, that's the easy way
5 to put it, yeah.

6 DR. BREYSSE: Thank you all very much. I love
7 coming up here.

8

9

10 (Whereupon the meeting was adjourned at 8:25 p.m.)

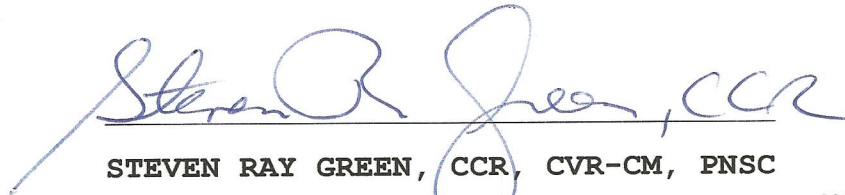
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I further certify that I am neither relation nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 26th day of Sept., 2017.

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