

Pease Community Assistance Panel (CAP) Meeting Minutes January 11, 2018

CAP Members present: Andrea Amico, Lindsey Carmichael, Michelle Dalton, Alayna Davis, Rich DiPentima, Sen Martha Fuller Clark, Jared Sheehan, Mark Sullivan, Stefany Shaheen

CAP Members absent: Robert Harbeson, Kim McNamara, Russell Osgood, Shelley Vetter

CAP Technical Advisors present: Dr. Courtney Carignan, Dr. Rick Clapp, Dr. Laurel Schaidler

CAP Technical Advisors absent: Dr. John Durant, Tim Stone

Agency for Toxic Substances and Disease Registry (ATSDR) Representatives: Dr. Patrick Breyse, Dr. Bill Cibulas, Dr. Frank Bove, CAPT Tarah Somers, CDR Jamie Mutter

U.S. Air Force, Office of the Deputy Assistant Secretary for Environment, Safety, and Infrastructure: Col Joseph Costantino

Opening:

- Dr. Patrick Breyse addressed the speculation about CDC/ATSDR not being permitted to use certain words. He read the statement given by CDC Director, Dr. Brenda Fitzgerald: “The assertion that HHS has 'banned words' is a complete mischaracterization of discussions regarding the budget formulation process. HHS will continue to use the best scientific evidence available to improve the health of all Americans. HHS also strongly encourages the use of outcome and evidence data in program evaluations and budget decisions.”

Action Items from previous CAP meeting

Action Item 1 (ATSDR): ATSDR will review its PFAS website and see if a link to the C8 report can be added.

Response: The ATSDR PFAS website includes a link to the C8 Health Panel website. It can be found on the Additional Resources page.

Action Item 2 (ATSDR): ATSDR will review its PFAS webpage and consider clarifying the language regarding PFAS and health effects.

Response: ATSDR, which regularly reviews the content on its PFAS website to ensure the information is current and accurate, recently revised this content to address concerns raised at the August Pease CAP meeting.

Action Item 3 (ATSDR): ATSDR will determine if extracting “old” water from Pease Tradeport would help establish historical levels.

Response: ATSDR invited its Water Modeling team to the December CAP meeting for a discussion. At this time, the team has reached out to the City of Portsmouth and informally

submitted a request for any daily/monthly supply well pumping records for 1994–2002. The informal request will be followed shortly by a more formal request.

Comments:

- CDR Mutter stated that ATSDR would let the CAP know what data were needed in order to revisit testing the “old water.” She also stated that ATSDR would provide a justification for not testing the “old” water in the tank.
- A concern was expressed regarding the public health risk posed by the volume of water in the storage tank. A CAP member proposed a discussion about potential discharge of the water to protect the land surrounding the tank. Col Costantino will talk to Jared Sheehan about specific information regarding the tank.

Action Item 4 (ATSDR): ATSDR will determine if it can help the Pease community or the state with educating physicians on medical monitoring.

Action Item 5 (ATSDR): ATSDR will explore other ways to share information for physician education, i.e., consulting with Kim McNamara or the NH Board of Medicine.

Response: CAPT Somers spoke to Kim McNamara (Portsmouth Health Department) and Dr. Ben Chan (NH Department of Health and Human Services). ATSDR has materials for these chemicals online for physician education, and is trying to determine internally how to better promote the materials, to let physicians know that they can go to the ATSDR website and get CEUs for physician education. Dr. Chan said there will likely be an NH Medical Association meeting at which the Association will provide guidance to NH clinicians on assisting patients exposed to these contaminants. ATSDR has discussed with Dr. Chan the possibility of having ATSDR present materials it has already developed so the Association is aware of them and can decide if it wants to endorse these or create new materials.

Comments:

- CAP member recommended that ATSDR review products completed in the Community Advisory Board. There was education for physicians and a webinar as well.
- ATSDR was asked if there was a timeline or a plan as to how it is spreading the word about physician materials and guidance; and if so, could ATSDR share that with the CAP? CAPT Somers responded there is nothing official, but ATSDR can write up a timeline and summary of methods to be used to announce the materials to share with the CAP. She thought the meetings with the medical society would be a good way to target NH.

Action Item 6 (ATSDR): ATSDR will provide the CAP with the link for the online PFOA and PFOS continuing education.

Response: Link was sent to CAP on 11/29/2017, when the final action item list was distributed.

Action Item 7 (U.S. Air Force): US AF agreed to answer Mr. Geoff Daly's questions on water filtration offline.

Response: This response was completed on October 2, 2017.

Action Item 8 (U.S. Air Force): US AF will check to see if the answers to Mr. Geoff Daly's questions can be shared with the Pease CAP.

Response: Received info from Col Costantino and CDR Mutter forwarded to CAP on 11/29/2017.

Pease Protocol Update:

- Dr. Bove said that ATSDR is basing the Pease Protocol on the Pease Feasibility Assessment. The hypotheses ATSDR is thinking about exploring in the protocol are the same as in the Feasibility Assessment. There are 10 study hypotheses for children and roughly the same amount for adults that ATSDR would like to explore. If other sites are included in a multi-site study, those sites would have different scenarios that ATSDR would have to incorporate into questionnaires and ATSDR's approach to exposure assessment.
- Dr. Cibulas stated the Pease Protocol is just completing Division clearance and will be sent to ATSDR's Office of Science to initiate the external peer review process. Dr. Bove along with at least one other author, Dr. Marion Pavuk, who is a MD and PhD epidemiologist at ATSDR, have been working on this document.
- ATSDR Office of Science oversees the external peer review process and ensures the best reviewers are chosen to review the document. Generally, the peer reviewers come from academia and are required to sign a no-conflict-of-interest document. The external peer review process generally takes 2-4 weeks. Dr. Cibulas anticipates the document will complete external peer review around March 2018, and then ATSDR will share the document with the CAP. He also stated that ATSDR would have to go through IRB/OMB before the study can begin, a process which would take a minimum of 6 months. ATSDR is doing everything possible to expedite the process. Dr. Breyse stated that he could not comment on possible language in legislation to bypass the role of OMB.
- Dr. Cibulas indicated that no one outside of ATSDR has reviewed the research protocol, including DoD.
- A CAP member raised a concern that the process is going too slowly, asked how the community can help to accelerate the process, and asked for more resources. Dr. Breyse stated that ATSDR will keep the CAP apprised of the status of the document.
- A CAP member asked if a representative from OMB should be invited to join a CAP meeting. Dr. Breyse stated that he would be reluctant to invite OMB because it is not a part of the study planning process. OMB has a separate role: to make sure the work coming out of the federal government is good science and not burdensome to the citizens. ATSDR will provide a short write up to the CAP about the role of OMB, what decisions it makes, and what decisions are made elsewhere.
- A CAP member asked why the protocol is taking so long if it is similar to the Feasibility Assessment. Dr. Bove stated that ATSDR has to come up with two different questionnaires (child and adult) as well determine what the cost would be for the different laboratories for each item we are discussing. Also, ATSDR is exploring some of the neurobehavioral tests discussed in the Feasibility Assessment but wants to expand this in the protocol. In addition, the review process takes time. The protocol had to be repackaged into OMB-required format. The consent forms also had to be changed as there were new rules for IRB. However, none of this changed the scientific

approach as written in the Feasibility Assessment. The protocol might change depending on whether it is a stand-alone study at Pease or whether Pease is part of a multi-site study. This would change how recruitment is done, and that is not addressed in the Feasibility Assessment.

- There was discussion on how the recruitment might change for a Pease-only study vs a multi-site study. Dr. Bove stated that in the Feasibility Assessment, 350 exposed children and 175 unexposed children were discussed. It also stated that 1,500 adults exposed and 1,500 adults unexposed would be in the study. ATSDR may not need that many unexposed from Pease. If ATSDR does a multi-site study, other sites will bring in people with varying levels of exposure, maybe less than Pease, maybe higher than Pease, and so on. ATSDR has to come up with criteria for selection of sites, which will be peer reviewed as well. That would determine, to some extent, how we recruit at each site. At Pease, it makes sense to recruit mostly with people who have already been through the biomonitoring program in order to have two blood samples: one closer to the time of exposure and one several years later. That data would be useful to evaluate. ATSDR may not be able to get the blood samples from the earlier testing but would know the results.

Multi-Site Study

- Language passed by Congress authorizes funding for a five- to seven-year study that includes multi-sites across the country looking at health endpoints. There is appropriation language that is in Congress right now but has not yet been passed. ATSDR has language that authorizes it to work with the DoD and coordinate with NIEHS to do a study but does not yet have funding.
- Dr. Breyse stated that he is not making any formal commitments about a multi-site study. ATSDR does not have the capability to do a multi-site study without appropriations along those lines. ATSDR has been cautious about making any specific plans public in a way that might create an expectation that it cannot fulfill if funding does not come through. However, Dr. Breyse stated that ATSDR is committed to doing work in the Pease community and is going to honor that commitment.
- ATSDR has begun planning for what a multi-site study will look like and developing site selection criteria. ATSDR has a study team in place, discussing how to translate what was learned in the Feasibility Assessment into a larger protocol that will include people from other sites, a larger cohort.
- The language also includes specification that we start by doing a preliminary exposure assessment at eight sites to help characterize the exposure at those sites.
- That data could provide input into possible site selection criteria, which will look at a range of exposures and sufficient sample size across all the different communities to fill the need.
- ATSDR has not reached out to any other communities as possible participants in a multi-site study, but has heard from many communities across the country about their willingness to participate. ATSDR is already working in many of these communities, in some cases, supporting health studies and working with the state. For example, Michigan has requested money to do a PFAS study. ATSDR wants to work closely with the state to ensure its study is consistent with what ATSDR plans to do. ATSDR has offered technical support for the study, if needed.
- ATSDR reached out to NIEHS to coordinate and make sure we maximize our combined resources.
- If a multi-site study were to occur, it is mandated that ATSDR start with the exposure assessment at eight DoD sites. ATSDR has an exposure assessment protocol in place, so it would be prepared to quickly implement the protocol. ATSDR needs to know factors such as who was exposed, how long they were exposed, and at what levels were they exposed. Those are all questions ATSDR will be able to explore in this exposure assessment phase, which will be able to provide

groundwork for the recruitment of a cohort. That does not mean that all eight sites will be part of a multi-site study.

- Dr. Breyse stated that ATSDR would likely not come to Pease to do an exposure assessment because ATSDR already knows more about the Pease community than about most other communities. ATSDR would like to invest those resources in communities where less is known about their exposures.
- Dr. Breyse stated that there might be some changes to the Pease Protocol if Pease were included as part of a multi-site study. Dr. Breyse reiterated that he is not making any commitments that Pease will be a part of the multi-site study at this point, but he is acknowledging and honoring ATSDR's commitment to work with the Pease community on a health study.
- Dr. Bove stated that if Pease is part of the multi-site study, the biggest impact would be on recruitment. For example, if other sites are included, the size of the recruitment, varying levels of exposure, and different mixtures of PFAS might differ from what was in the Pease Feasibility Assessment.
- Dr. Breyse stated that ATSDR will still work with DoD as the funding is going to come through the DoD as it is currently written right now.
- Dr. Breyse explained that ATSDR is shifting from calling the study a national study to calling it a multi-site study because "national study" implies that the whole country will be participating. The whole country is not going to participate, so "multi-site study" is a more accurate description. ATSDR will select enough sites to address the critical hypotheses that we described before.
- Members of the CAP expressed disappointment if Pease is not included in a multi-site study as there are many exposed children and that is an area where more research is needed.
- A CAP member stated that to specify exactly where the federal funding is going right now, before the appropriation is signed, could ultimately jeopardize the funding. The way in which the proposal was submitted for a national study was by design, to try to build political support for the study. There are going to be multiple sites, we don't know which will be chosen yet, and it is to our advantage that that uncertainty exists because we would prefer senators and members of the house to be supportive of the study because their states may also be affected.
- In reference to a multi-site study, a CAP member stated that every community and site do not need to be included if we do a good enough multi-site epidemiological study. The data can be extrapolated globally to other sites.
- Dr. Breyse stated there is a lot of public/political interest in what ATSDR is trying to do right now, and ATSDR is trying to navigate that complexity and address the concerns at Pease at the same time.
- Dr. Cibulas described the peer review process. ATSDR has a requirement for external peer review that is written into the Superfund legislation.
 - Program submits proposal/product/study to the Office of Science for peer review
 - The Office of Science will identify 3–7 peer reviewers (the Program can suggest peer reviewers). The Office of Science must identify the best independent reviewers to ensure that the study is scientifically valid and evidence based.
 - Time frame is usually 2–4 weeks.
 - We ask the peer reviewers to sign confidentiality and a no-conflict-of-interest paper.
 - The peer reviewers are paid an honorarium for their time.
 - ATSDR will send the peer reviewers a series of questions, i.e., "Is the hypothesis correct?"
 - The reviewers will send back advice and guidance to the Office of Science, which will then send the peer review comments to the Program.
 - The Program will address the comments.

Other PFAS Health Activities

- ATSDR developed the PFAS Exposure Assessment Technical Tools (PEATT) and wanted to evaluate and validate the toolkit in a couple of communities to see what the states are capable of doing and where they may need ATSDR's technical assistance. ATSDR is working through the Association of State and Territorial Health Officers to ask states to apply to get resources (monetary) to do this PEATT. ATSDR will select two states through that process.
- Colorado got funding through NIH/NIEHS, which has a mechanism to fund grants that are time sensitive, usually smaller grants. Upon receiving the grant, CO called ATSDR, so ATSDR is talking with them. ATSDR hopes that CO will use the PEATT so there will be another opportunity to test the toolkit, independent of our funding.
- NY state did statistically based biomonitoring in one of the communities in upstate NY, associated with a company not a military site. ATSDR is anxious to get the PEATT utilized in communities. It is important for ATSDR to identify any barriers to PEATT; that is why we are aggressively pursuing this. ATSDR will then have eight other sites to use if this appropriation comes through based on the authorization language.
- ATSDR is not involved with the blood testing in Newburgh, NY, but the state of NY touches base with ATSDR on occasion. NY is one of our Cooperative Agreement states, so it is using money we provide to do ATSDR-related work to do the blood testing. That is part of this funding we provide to certain states.
- A CAP member asked if there were any other states that ATSDR is aware of that haven't been discussed yet. Dr. Breyse answered that there are communities in almost every state in the country that are dealing with PFAS. Approximately 29 sites between ourselves and our partners are actually investigating community exposures to PFAS chemicals in the water. However, not much biomonitoring is happening; that is why ATSDR is trying to push the PEATT. ATSDR needs to know of any barriers states encounter so it can adjust the technical assistance provided.
- A Technical Advisor asked if ATSDR gets a recommendation from the science community to have another type of PFAS mixture, but if you are limited to DoD sites, would these all be AFFF contaminated sites or would there be an option in the multi-site study to bring in a different contamination source?
- Dr. Breyse stated that ATSDR is waiting on General Counsel from DoD and CDC to sort through what the wording might mean in terms of our flexibility in looking at non DoD sites. DoD isn't the only place using firefighting foam.

Document Sharing Discussion:

- Dr. Breyse stated that he would like to commit to sharing documents with the CAP at the same time they are shared with DoD. However, when DoD gets a document, often it is in a preliminary draft phase and DoD must verify the data and timelines within the document are correct. At this stage, ATSDR is not ready for the public at large to see the draft. For example, in a health consultation, the conclusions may change throughout the process.
- It was decided that the CAP and Technical Advisors would self-select who would like to see a document based on the content and type of document. The CAP members who would like to review a document will be asked to sign a confidentiality agreement that states that they would not share the document more broadly. However, the CAP wanted to ensure that they could share possible concerns with the rest of the CAP, without sharing the document itself.

- A CAP member asked if DoD also had to sign a confidentiality agreement. ATSDR responded that DoD does not sign a confidentiality agreement, but it is not uncommon to share a document for internal use.
- Once a document is cleared through the Agency, ATSDR would normally share it with you willingly. We are now talking about documents that are pre-cleared.

Pease Public Drinking Water Health Consultation Update

- CAPT Somers outlined the process for a health consultation.
 - ATSDR will get the data
 - ATSDR will write a draft health consultation
 - The health consultation will be sent to whomever provided the original data for data validation
 - The document would then be sent through the ATSDR internal clearance process
 - The document is put out for public comments where everyone in the community can see the document and anyone has an opportunity to provide comments to ATSDR
 - ATSDR will release the final health consultation. The comments received during the public comment period will be included and addressed in the final document.
- If you would like to review the Health Consultation for data validation, it would be helpful to have reviewers from the CAP/Technical Advisors who know what data are out there to ensure ATSDR did not miss any.
- Dr. Breyse stated that the draft version of the health consultation has recently been shared with DoD for data validation. DoD comments are due by February 2, 2018 and ATSDR has not received any comments or questions to date.
- This health consultation has conclusions on community health effects that might be modified based on the feedback received.
- CDR Mutter will send an email to the CAP members and Technical Advisors to see who would like to review the health consultation for data validation purposes. CDR Mutter will then send a confidentiality statement and once it is signed and returned, distribute the document to the CAP.
- A CAP member asked if they would get to see DoD comments made during the data validation phase. Dr. Breyse answered that we will ask DoD if we can share the comments, but it is not a decision that he can make.
- A CAP member asked why the health consultation has already been shared with DoD before bringing this up to the CAP, given the prior history with the Feasibility Assessment? CAPT Somers stated that ATSDR has two divisions. The Division of Community Health Investigations (DCHI) produces health consultations, and The Division of Toxicology and Human Health Sciences (DTHHS) produced the Feasibility Assessment. The CAP process doesn't happen at most sites where DCHI is writing health consultations, so ATSDR was following its normal process for a health consultation. DCHI has very little experience working with a CAP and was not initially aware the document should be shared with the CAP for transparency.
- A CAP member asked for an example of where the polluter (not DoD) would get a health consultation before a community. CAPT Somers responded that sometimes a city or state can be a Primary Responsible Party (PRP), or polluter. For example, the city will allow a school to be built on a contaminated site. The city is often involved with collecting data, even as the PRP. The city, often involved in the cleanup process, would then get to see the document at the data validation stage.
- A CAP member asked if there was a way to ask and receive information using a third party so the process remains unbiased. Dr. Breyse answered that DoD is not responsible for saying what the health effects are. DoD is responsible only for helping ATSDR confirm that it has all the data and the correct timeline. ATSDR is not looking for comments on the assessment process (exposure pathway, dose, etc.) or conclusions. It is looking for DoD to confirm data.

- A CAP member asked how a health consultation relates to a health study and if they influence each other in any way.
- Dr. Breyse stated that often, ATSDR is addressing concerns in a community with a well-established contaminant, lead for example. We would not need to do a health study to show that lead is harmful, as there are established data and a threshold for lead. The challenge ATSDR faces with PFAS is not knowing how to interpret what the health effects are because of insufficient data. There is enough information to suggest a range of things that could go wrong, so ATSDR cannot tell you that if your body burden is below some level, it is not a concern. When ATSDR does not have enough information or data on a substance, it will shift to a health study. Dr. Breyse stated, as the head of the Agency, ATSDR does not do a lot of health studies, in part because ATSDR has often established contaminants with established risk levels, and also because they are very expensive and time consuming. ATSDR is undergoing a reorganization with strategic planning to shift its resources so that it can do more health studies and primary health investigations. ATSDR thinks it can do that moving forward because it now has access to electronic health records and other data in a way it didn't before. Dr. Breyse continued that there could be an initial assessment, the public health consultation. If the health consultation identified some gaps that need to be addressed, ATSDR would like that to go into an exposure investigation, and health study. However, not every site is going to have an exposure investigation or health study.
- A CAP member asked if the health consultation for Merrimack, NH is contingent on the Pease Health Consultation. CAPT Somers stated that a decision was made internally to use the Pease Health Consultation as a "model" to work out the process for PFAS contaminants. ATSDR has discussed how to handle a cumulative chemical exposure, how to quantify the exposure in a way that a health call can be made and determine if a population is at risk from the exposure. Any subsequent documents will use the methodology agreed upon in the Pease Health Consultation. The work at the other sites is not on hold as ATSDR is still gathering data, doing some calculations to get to some of those exposures and determining possible daily dose to people. In this case, because these contaminants are less well known, some are concerned about how to convey that exposure so that community members can understand it, understand what their potential health risk might be, and decide what actions to take. ATSDR has done a lot of preliminary work; it is waiting on that final wordsmithing to ensure clear communication to the community.
- The timeframe for a health consultation depends on many factors such as when we get the data, number of contaminants, and exposure pathways. Multiple contaminants through multiple pathways mean that the health consultation will take longer. Dr. Breyse said he hoped the Pease Health Consultation will be released in under 6 months.
- A CAP member asked how a community that does not have a CAP participates in the health consultation process. CAPT Somers indicated that it differs by site. When there is a public comment version to share with the public, ATSDR will typically put it on the ATSDR website and put press releases in the local papers to let the community know the document is available to review. The document is made available online and also in local libraries, where people don't have access to the internet. ATSDR will also hold a public meeting or attend another meeting (i.e., DES) that is already set up. ATSDR tries to base its actions on the community and make sure members know the document is there and have the ability to comment on it.

Intelligencer article: "Records: Military knew of firefighting foam hazards in 1995."

- Col Joseph Costantino stated that a request for comment on the article was sent to Secretary of Defense. He asked the Secretary of Defense if DoD had provided comment to the article; it had not. In addition, he asked if he could provide a comment at the CAP meeting. He was told that because the article was written based on documents received from a law firm currently suing the

government based on use of AFFF and contamination, he could not provide any comment specific to the article or the lawsuit. Col Costantino stated that he would provide the correct contact person in the Department of Justice to answer questions regarding the lawsuit to the CAP and asked that any questions about the specific article, not the lawsuit, be sent directly to him.

- A CAP member stated she read in the article that DoD knew or potentially knew about the health effects or the environmental implication of AFFF more than 20 years ago, did not stop using the foam, and did not test the surrounding water supplies. She asked how far back did the Air Force know that AFFF was toxic, was building up in the environment, and was getting into water supplies.
- Col Costantino responded that the DoD does not have a core competency in chemical toxicity research and testing, so the DoD doesn't know the answer. Until a few years ago, the DoD wasn't taking any action on it because of lack of information. Twenty years ago, the Air Force did not have information or data telling them that they had to take action.
- Col Costantino stated that for the decades the DoD has been using this material, it has complied with all environmental regulations and health regulations. The DoD is largely a user of the material, follows the published rules and regulations, and has done that for decades.
- A CAP member pointed out that documents show people from DoD knew 20 years ago and did nothing; DoD continued to use it because the regulations weren't there. She asked again if the DoD knew prior to 5 years ago that the chemical was potentially dangerous and going to pollute millions of people across the country.
- Col Costantino answered, "No." He said the Navy manages material for DoD. The DoD puts out specifications that say that it has to put out a fire in a specified amount of time, puts the specifications out to industry, and industry provides a product that can meet those specifications. He stated that the DoD is not the only user of the material, and it has to rely on other federal agencies to help it understand what is and is not a contaminant of concern. That is not its core competency.
- A CAP member stated that she understands Col Costantino said that DoD was following the rules because there were no EPA guidelines in place. However, at that time there were meetings being conducted, and DON members shared information that said that imaging equipment should be used to detect PFAS in groundwater to determine the environmental impact because there were environmental issues, potential toxicity to humans and wildlife.
- Col Costantino stated the CAP member was referring to an EPA study from when EPA came onto an installation and tried a new technology.
- A CAP member stated that a contractor from the Navy decided to wait and see what EPA was going to come up with, instead of determining that they should probably reduce the impact by reducing the use of the product.
- Col Costantino stated that he could not speak for the Navy. He stated that the material is commercially available and the DoD uses it because it is required to save lives, put out fires, and protect our property.
- A CAP member also stated that to serve and protect, you look beyond defense; you look at the impact on U.S. citizens and the people who are serving our country. Col Costantino agreed.

Additional CAP concerns

- CDR Mutter stated that the Pease CAP meets monthly by telephone and two more in-person meetings will be scheduled before the end of the fiscal year (September 30, 2018).
- A CAP member recommended the CAP members meet as a group in the interim between official in-person CAP meetings.
- A CAP member asked if the group can meet in person more often (besides the two that are already planned for this fiscal year). Dr. Breyse said we can discuss the possibility.

- A CAP member suggested that the group should look at video conferencing or something that would allow the group to engage differently than the one-hour monthly telephone call.
- A CAP member read a prepared statement in response to Col Costantino and the Intelligencer article.

Link to the January 11, 2018 Pease CAP Meeting:

<https://www.youtube.com/watch?v=IeMCYtGTHsc&t=5596s>