U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry

Board of Scientific Counselors Meeting
June 5-6, 2018
Atlanta, Georgia

Record of the Proceedings

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Executive Summary

The U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a meeting of the Board of Scientific Counselors (BSC) on June 5-6, 2018 at the CDC Chamblee Campus in Atlanta, Georgia.

MEETING OVERVIEW

The Designated Federal Officer (DFO) conducted the meeting in accordance with all rules and regulations of the Federal Advisory Committee Act. The DFO verified that the voting members and *ex-officio* members constituted a quorum for the BSC to conduct its business on both days of the meeting. The DFO announced that BSC meetings are open to the public and all comments made during the proceedings are a matter of public record.

The DFO reminded the BSC voting members of their individual responsibility to identify potential conflicts of interest with any of the published agenda items and recuse themselves from participating in or voting on these matters. None of the BSC voting members publicly disclosed any conflicts of interest for the record. The DFO called for public comment at all times noted on the published agenda for the June 5-6, 2018 BSC meeting.

The participants welcomed three new members to their first BSC meeting: Drs. Babafemi Adesanya, Marilyn Underwood, and Joey Zhou (*ex-officio* member for the U.S. Department of Energy [DOE]). Certificates of appreciation were presented to three outgoing BSC members whose terms ended on June 2, 2018: Drs. Deborah Cory-Slechta, Kim Dietrich, and Sharron LaFollette.

NCEH/ATSDR DIRECTOR'S UPDATE

The NCEH/ATSDR Director covered several topics in the update to the BSC.

- The NCEH reorganization was officially approved on January 1, 2018 and includes the same, unchanged Division of Laboratory Sciences (DLS) and the new Division of Environmental Health Science and Practice (i.e., a consolidation of the former Division of Emergency and Environmental Health Services and Division of Environmental Hazards and Health Effects). The proposed ATSDR reorganization was submitted to and is pending approval by CDC leadership at this time. The proposal calls for dissolving the two current ATSDR divisions (Division of Toxicology and Human Health Sciences and the Division of Community Health Investigations) and establishing a new ATSDR Office of the Director (OD) and three new program offices: Office of Innovation and Analytics, Office of Community Health Hazards Assessment, and Office of Capacity Development and Applied Preventive Sciences. Separate strategic plans for NCEH and ATSDR will be developed after the leadership is officially appointed.

- The fiscal year (FY) 2018 budget for the U.S. Department of Defense (DoD) included a one-year Congressional appropriation of $10 million to support per-/polyfluoroalkyl substances (PFAS) health-related activities conducted by NCEH/ATSDR. NCEH/ATSDR will collaborate with federal partners and award subcontracts to conduct these activities. NCEH/ATSDR OD is interested in the BSC exploring the possibility of forming a new PFAS Workgroup to provide external, ongoing advice and guidance on its new PFAS health studies.
- ATSDR drafted ToxProfiles™ for four PFAS chemicals. After the Office of Management and Budget approves the risk messaging of these documents, ATSDR will release the draft PFAS ToxProfiles™ for public comment, make revisions based on proposed changes that are submitted, and publish the final versions.
- Michigan State University (MSU) used its four-year, $14.4 million grant from NCEH/ ATSDR to develop, launch, and implement the Flint Registry. As part of this initiative, MSU established the "Flint Lead Free" Workgroup to oversee specific activities in the community, such as eliminating lead service lines, removing lead-based paint from housing, replacing old brass fixtures in homes, and analyzing lead levels in soil. The workgroup's ultimate goal is to closely collaborate with the community, nonprofit organizations, and agencies at multiple levels for Flint to become the first lead-free city by 2022 and serve as a model for the nation.
- NCEH and ATSDR received level funding in their FY2018 budgets. NCEH also received new funding of $17 million for the Lead Program.

CDC'S 2017 HURRICANE RESPONSE AND RECOVERY EFFORTS

The NCEH/ATSDR Office of Environmental Health Emergency Management presented an update on CDC's response and recovery efforts for the 2017 hurricane season: Hurricane Harvey in Texas; Hurricane Irma in the U.S. Virgin Islands (USVI), Puerto Rico, and Florida; Hurricane Maria in Puerto Rico and USVI; and Hurricane Jose in New England. CDC's specific role and responsibilities in the 2017 hurricane response and recovery efforts were in the areas of drinking water, facility assessments, health communications, and mold remediation/carbon monoxide exposure.

NCEH/ATSDR received supplemental funding of $50 million in March 2018 to specifically address environmental health (EH) issues related to the hurricanes. NCEH/ATSDR will award these funds to jurisdictions and non-governmental organizations in June 2018 to support hurricane recovery efforts in the affected states and U.S. territories.

PREVIOUS BSC GUIDANCE

Responses were presented to the guidance the BSC provided during the November 2017 meeting. NCEH/ATSDR OD described the current status of the new workgroup that was established with representation by the NCEH/ATSDR BSC and the CDC Office of Infectious Diseases BSC to provide recommendations on vector-borne disease prevention and control.

NCEH and ATSDR programs presented point-by-point responses to the recommendations the BSC made on three key presentations during the November 2017 meeting: (1) CDC's noise-induced hearing loss activities; (2) the NCEH National Environmental Public Health Tracking Network; and (3) the ATSDR National Amyotrophic Lateral Sclerosis Registry.

PFAS HEALTH STUDIES

ATSDR presented its proposed design, methodology, and approach for the PFAS proof of concept study that will be conducted as a short-term project at the Pease, New Hampshire site

and completed within two years. The findings from the proof of concept study will inform the design, development, and implementation of the PFAS multi-site health study that will be conducted as a long-term project at eight DoD sites and completed within five to seven years.

BIOMONITORING OF PFAS IN CHILDREN

DLS presented an overview of its biomonitoring methods of PFAS in children. DLS developed the first nationally representative sample of PFAS exposures in children based on a random sub-sample of children 3-11 years of age (of approximately 33 percent of children within this age range in the 2013-2014 National Health and Nutrition Examination Survey (NHANES)). DLS filled the gaps in PFAS data on children by using 639 serum samples that previously were analyzed to measure cotinine levels as part of the 2013-2014 NHANES.

DLS's rigorous study methods were designed to quantify 14 PFAS biomarkers using isotope-dilution mass spectrometry. DLS's study suggested widespread exposure to several PFAS chemicals among children 3-11 years of age. The four major PFAS chemicals that are most frequently detected and have the highest concentrations were identified in all samples.

DLS has completed analyses of 3,050 samples from the NHANES 2015-2016 cycle for six neonicotinoid biomarkers (e.g., four parent compounds and two metabolites). These analyses included NHANES data on children three years of age and older. DLS currently is in the final stages of the quality assurance/quality control process related to the biomonitoring quantification for this new class of pesticides. DLS anticipates submitting a paper describing the analytical method used to quantify the six neonicotinoid biomarkers to the CDC clearance process by July 30, 2018.

DLS found that several new methods proposed and evaluated to measure glyphosate biomarkers and six dialkylphosphates were not sufficiently stable or robust. If ongoing efforts are not successful to correct these problems, DLS will terminate this area of research in early July 2018 and will advance to developing a method only for glyphosate (without the dialkylphosphates). DLS will publish its biomonitoring methods and results from analyses of the NHANES samples in peer-reviewed journals.

CITIZEN SCIENCE PROJECT

ATSDR presented an overview of its new Citizen Science Project. Community members will receive training, tools, and other materials to build skills in conducting environmental sampling and collecting data. As part of this initiative, ATSDR will pilot the Low-Cost Sensor Project for a period of three years for community members to gain experience in operating low-cost sensors, performing outdoor ambient air sampling, and gathering data on particulate matter.

ATSDR acknowledged the data quality issues and other limitations related to low-cost sensors, such as a lower level of precision and accuracy; restricted use for select contaminants or media only; and uncertainty regarding the ability of these new technologies to produce data that are acceptable for public health decision-making.

STATISTICAL INFERENCES IN ENVIRONMENTAL EPIDEMIOLOGY

NCEH/ATSDR presented an overview of its ongoing efforts to improve the evaluation of scientific evidence collected from environmental epidemiological studies with small sample sizes. Based on the published literature, NCEH/ATSDR proposes to shift from the traditional practice of relying on the p-value and apply alternative statistical approaches, such as using estimation (e.g., a 95 percent confidence interval) rather than testing, the Bayes Factor, and the likelihood ratio test.

These approaches have greater capacity to examine the effect and might be a better judge of the evidence rather than solely relying on the use of the p-value. Due to the limitations of small sample sizes in environmental epidemiological studies, NCEH/ATSDR formed a workgroup of epidemiologists and statisticians to develop a statistical guidance document to assist scientists in better presenting and explaining their data without relying on the p-value.

TRIBAL ACTIVITIES AND PROGRAMS

NCEH/ATSDR presented an overview of its activities and programs that are conducted in four major categories to support tribal communities: (1) site-specific activities to evaluate potential hazards; (2) collaborative research and studies with tribes; (3) EH programs and initiatives in collaboration with tribal communities; and (4) laboratory support to tribal communities. NCEH/ATSDR's next steps to advance EH activities in Indian Country include its initial planning efforts to convene an Environmental Tribal Health Summit in 2020.

UPDATES BY THE BSC *EX-OFFICIO* MEMBERS

- The National Institute of Environmental Health Sciences, National Toxicology Program highlighted the peer reviews that recently were completed or will soon be completed in 2018. Key findings were presented for the Draft Technical Report on Cell Phone Radio Frequency Radiation and the Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity (CLARITY-BPA) Core Study Research Report.
- DOE reported that its Office of Environment, Health, Safety, and Security (OEHSS) supports radiation health effect studies. OEHSS celebrated the 70th anniversary of the Radiation Effects Research Foundation (RERF) and the 50th anniversary of the U.S. Transuranium and Uranium Registries (USTUR) in 2018. The RERF aims to foster the health and welfare of Japanese atomic bomb survivors. The study is based on a binational agreement between the United States and Japan. The USTUR studies the biokinetics and internal dosimetry of actinides (uranium, plutonium, and americium) in former U.S. nuclear workers who volunteer portions of or their entire bodies for scientific use posthumously. DOE takes pride in supporting the longest-running international and domestic radiation health effect research program and sponsored celebratory activities.

CURRENT BSC GUIDANCE

The BSC provided extensive input over the course of the meeting in response to NCEH/ATSDR's presentations and updates. The BSC also answered NCEH/ATSDR's key questions on the next steps in its new programs and activities, including the upcoming PFAS health studies; the Citizen Science Project and the three-year pilot of the Low-Cost Sensor Project; and statistical inferences in environmental epidemiology.

The BSC went on record with its formal support of NCEH/ATSDR's efforts to advance beyond the confines and familiarity of using the p-value as the sole metric to judge scientific evidence. The BSC also unanimously approved a motion for NCEH/ATSDR to implement vigorous planning efforts for the 2020 Environmental Tribal Health Summit. Moreover, the BSC proposed several agenda topics for future meetings, particularly periodic updates to track the progress of the new EH activities that NCEH/ATSDR presented during the current meeting.

The next BSC meeting will be held the first week in December 2018. NCEH/ATSDR OD staff will poll the BSC members by email to determine their availability and confirm the date.

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BOARD OF SCIENTIFIC COUNSELORS MEETING
June 5-6, 2018
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Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a meeting of the Board of Scientific Counselors (BSC). The proceedings were held on June 5-6, 2018 in Building 106 of the CDC Chamblee Campus in Atlanta, Georgia.

The BSC is a Federal Advisory Committee that is chartered to provide advice and guidance to the Secretary of HHS, Director of CDC, and Director of NCEH/ATSDR regarding program goals, objectives, strategies, and priorities in fulfillment of the agencies' mission to protect and promote persons' health. The BSC provides advice and guidance to assist NCEH/ATSDR in ensuring the scientific quality, timeliness, utility, and dissemination of results. The BSC also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents to fulfill its mission to protect America's health.

Information for the public to attend the BSC meeting in person or participate remotely via teleconference was published in the *Federal Register* in accordance with Federal Advisory Committee Act regulations. All sessions of the BSC meeting were open to the public (*Attachment 1: Participants' Directory*).

June 5, 2018 Opening Session: Welcome, Introductions, and Agenda Review for Conflict of interest Topics

William Cibulas, Jr., PhD, MS
Acting Director, ATSDR Division of Toxicology and Human Health Sciences (DTHHS)
BSC Designated Federal Officer (DFO)

Dr. Cibulas opened the floor for introductions and confirmed that the 16 voting members and *ex-officio* members in attendance constituted a quorum for the BSC to conduct its business on June 5, 2018. He called the proceedings to order at 8:37 a.m. and welcomed the participants to the first day of the BSC meeting.

Dr. Cibulas noted that BSC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters. None of the BSC voting members publicly disclosed conflicts of interest for any of the items on the June 5, 2018 published agenda.

Dr. Cibulas announced the recent retirement of Dr. Bonnie Richter, the former *ex-officio* member for the U.S. Department of Energy (DOE). Dr. Joey Zhou, a Senior Epidemiologist in the DOE Office of Domestic and International Health Studies, has replaced Dr. Richter as the BSC's new *ex-officio* member for DOE.

Dr. Cibulas asked the participants to join him in welcoming Dr. Zhou and two other new BSC members to their first meeting. Dr. Babafemi Adesanya is the Operations Manager of Corporate Environmental Risk Management in Tucker, Georgia. Dr. Marilyn Underwood is the Director of the Environmental Health Division of the Contra Costa County Health Services Department in Concord, California.

Melissa Perry, ScD, MHS, BSC Chair
Professor and Chair of Environmental and Occupational Health
Professor of Epidemiology, Milken Institute School of Public Health
The George Washington University School of Medicine and Health Sciences

Dr. Perry also welcomed the participants to the first day of the BSC meeting. She informed the new members that the BSC performs a valuable advisory function by providing external objective assessments of NCEH/ATSDR's portfolio of environmental public health (EPH) activities. Moreover, NCEH/ATSDR leadership and program staff thoughtfully consider the BSC's guidance and formal recommendations and take every opportunity to apply the BSC's input whenever possible.

Dr. Perry also informed the new members that the BSC meeting agendas are structured for NCEH/ATSDR to present its ongoing EPH activities and highlight other relevant environmental health (EH) issues in the field. However, a significant amount of time is set aside for the BSC to discuss each presentation and provide critical input. She encouraged the new members to be fully engaged in the BSC''s advisory process.

NCEH/ATSDR Director's Update

Patrick Breysse, PhD, CIH
Director, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Breysse covered several topics in the NCEH/ATSDR Director's update to the BSC.

NCEH/ATSDR REORGANIZATION

The NCEH/ATSDR Office of the Director (OD) launched the reorganization as part of a strategic planning process to resolve inefficiencies in the existing infrastructure. The NCEH reorganization was officially approved on January 1, 2018 and includes the same, unchanged Division of Laboratory Sciences (DLS) and the new Division of Environmental Health Science and Practice (DEHSP) (i.e., a consolidation of the former Division of Emergency and Environmental Health Services and Division of Environmental Hazards and Health Effects). The merger of all NCEH programmatic activities into DEHSP will generate organizational efficiencies, cost-savings, and synergies across similar program areas. NCEH/ATSDR OD expects to appoint and announce the new DEHSP Director in the near future.

The "Reimagine HHS" Initiative was launched for federal agencies to review their current programs and activities; reconsider and re-envision their traditional approaches to conducting business; and identify areas to implement more efficient, effective, and impactful strategies. NCEH/ATSDR OD used the Reimagine HHS Initiative as an opportunity to develop and submit a proposal of a new ATSDR organizational structure to CDC leadership with two key components. First, the two current ATSDR divisions (DTHHS and the Division of Community Health Investigations [DCHI]), will be dissolved due to their overlapping responsibilities. Second, a "one-ATSDR" environment and culture will be promoted with the establishment of three new offices that will be more empowered and interactive than the traditional divisions.

- The proposed "Office of Innovation and Analytics" (OIA) will focus on new and creative approaches for ATSDR to review, analyze, and utilize data to increase the accessibility and availability of emerging science by programs in the field. OIA will provide programs with new and innovative methods, processes, and tools to monitor networks, collect geographic information system (GIS) data, conduct toxicological modeling, create disease registries, and perform surveillance activities.

- The proposed "Office of Community Health Hazards Assessment" (OCHHA) will focus on ATSDR's Congressional mandate to respond to hazardous waste sites and spills of toxic materials in communities. Under its Congressional authority, ATSDR conducts public health assessments/consultations (PHAs/PHCs), detailed exposure investigations (EIs), in-depth health studies, and complex epidemiologic research. OCHHA will take a more aggressive approach to investigate exposure issues at sites, clearly translate these outcomes, and conduct PHAs in impacted communities across the country. OCHHA and OIA will collaborate internally within ATSDR to use existing electronic health records to conduct PHAs in a more rapid, effective, and efficient manner.

- The proposed "Office of Capacity Development and Applied Preventive Sciences" (OCDAPS) will focus on efforts to further develop and strengthen ATSDR's core abilities and increase the emphasis on preventive science. ATSDR's Congressional mandate primarily calls for reactive responses to impacted sites, but past experiences and lessons learned will be translated and applied to implement preventive practices. For example, ATSDR published data from its "Choose Safe Places for Early Care and Education" initiative. This effort provides proactive guidance on siting early child care and education programs to reduce children's risk of being exposed to dangerous chemicals during their care. For this initiative, OCDAPS's role will be to encourage state partners to adopt and implement ATSDR's recommendations as a preventive measure to ensure that child care programs are not sited near industrial, hazardous waste, or other dangerous areas. OCDAPS also will provide leadership at ATSDR by analyzing lead levels in soil and

reporting the results to communities that submit samples. OCDAPS will expand ATSDR's successful pilot of this project. Moreover, OCDAPS will develop and implement new and creative strategies to improve community engagement during all phases of ATSDR's site investigations.

ATSDR's proposed reorganization is pending approval by CDC leadership at this time. In the interim, NCEH/ATSDR OD is exploring the best process to align staff positions and activities in the three new offices. For example, ATSDR conducts PHAs and PHCs primarily with data collected by the U.S. Environmental Protection Agency (EPA). However, EPA's datasets for the regulatory remediation of sites are not ideally suited for ATSDR's public health mandate. The tremendous growth of new environmental monitoring methods and sensor technologies will allow ATSDR to conduct environmental measurements and collect data with approaches that are less expensive, more efficient, and more strongly focused on public health.

NCEH/ATSDR OD is aware that ATSDR has not fulfilled all aspects of its Congressional mandate over time. ATSDR has maintained a small staff and a flat budget over the past 20 years, but its mandate to investigate new chemicals, sites, and EH concerns has continued to increase each year. For example, ATSDR's new investigations of per-/polyfluoroalkyl substances (PFAS) have rapidly grown from approximately two to more than 30 sites over the past six years. Despite the emergence of PFAS or other new hazardous substances, however, ATSDR must continue to address lead and other legacy exposures at existing sites.

NCEH/ATSDR OD recognizes that ATSDR is a powerful agency with a critical mandate to protect communities from harmful health effects related to exposure to natural and manmade hazardous substances. As a result, a new ATSDR OD will be a key component of the reorganization to provide ongoing scientific consultation to Dr. Breysse and oversee the day-to-day management of support staff. Recruiting efforts are underway to identify and appoint a new ATSDR Associate Director.

Formal NCEH and ATSDR strategic plans will be developed after the leadership is officially appointed. The two new strategic plans will replace the existing NCEH/ATSDR Strategic Plan to fully address differences between the NCEH and ATSDR missions and programs. However, NCEH and ATSDR will retain their internal partnership on common EPH issues. For example, ATSDR public health assessors and NCEH Lead Program staff will continue their long history of close collaboration and coordination at hazardous waste sites with lead.

PFAS HEALTH-RELATED ACTIVITIES

PFAS includes a group of over 5,000 chemicals that are water-soluble and of various carbon lengths. The chemistries and carbon lengths of PFAS have been modified, but these chemicals are still being manufactured. Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are the two most notable PFAS legacy compounds. PFOA and PFOS are no longer used in the manufacture of consumer products, but these chemicals are strong, extremely stable, and do not readily break down in the environment. Most notably, PFOA and PFOS have tremendous biological and environmental half-lives on the order of decades.

ATSDR is addressing community concerns related to PFAS at multiple sites across the country: Alabama, Alaska, California, Colorado, Massachusetts, Michigan, New Hampshire, New York, Pennsylvania, and Washington. The current literature includes a wealth of PFAS data from animal *in vivo*/*in vitro* research and environmental studies. However, ATSDR has been unable to answer the two most common questions that communities ask at each PFAS site. First, "Should

my family stop drinking PFAS-contaminated water and use an alternate water supply?" Second, "What are the specific health effects if my family has been drinking PFAS-contaminated water for decades?"

ATSDR has been honest and transparent in its communications with communities regarding the lack of solid data on the long-term human health effects from PFAS. Limited data from human health studies and toxicological studies on PFAS indicate that these chemicals potentially have a tremendous health risk and impact nearly every organ system in the human body (e.g., immune, cardiovascular, and reproductive systems as well as the kidneys and liver). Moreover, cancer potentially is another adverse endpoint from PFAS.

ATSDR has been using its PFAS investigations at sites as opportunities to inform communities of other aspects of the federal response to PFAS exposures. For example, EPA measures PFAS in source water as part of its newest Unregulated Contaminant Monitoring Rule (UCMR). However, the UCMR does not include PFAS measurements in tap water. At this time, hundreds of millions of Americans are drinking PFAS-contaminated water. In addition to water, other PFAS exposure pathways include food containers, waterproof leather, and the use of aqueous firefighting foam (AFFF) on military bases and in fire departments.

EPA published a long-term health advisory value in 2016 that established a lifetime exposure threshold at 70 parts per trillion for PFOA/PFOS combined or one of the chemicals alone. Since that time, NCEH/ATSDR OD has received hundreds of calls and letters from diverse stakeholders, including Congressional leadership and staff, state legislators/policymakers, state health officials, and state water quality directors. Dr. Breysse's position was that PFAS will continue to be one of the most significant EPH challenges over the next decade.

ATSDR recognizes that communities increasingly have become more vocal in terms of the need for federal agencies to conduct additional PFAS human health studies to fill existing data gaps, particularly at sites near military bases. Moreover, the media produces approximately five news articles each week on PFAS and/or ATSDR's involvement at these sites. In response to strong community advocacy and the high level of media coverage, Congress passed legislation in the fiscal year (FY) 2018 budget that authorized the U.S. Department of Defense (DoD) to fund NCEH/ATSDR to conduct a national multi-site PFAS human health study and perform exposure assessments (EAs) in communities of concern at eight DoD sites.

The DoD FY2018 budget included a one-year Congressional appropriation of $10 million to support PFAS health-related activities. Efforts are underway to facilitate the interagency transfer of the $10 million appropriation from DoD to NCEH/ATSDR before the current fiscal year ends on September 30, 2018. In the interim, NCEH/ATSDR OD already has outlined a methodology to conduct these activities.

The detailed EAs will be performed at eight DoD sites to better understand PFAS exposures in impacted communities. Rigorous criteria will be applied to select the eight DoD sites (e.g., the magnitude and length of time of PFAS exposures at the site; characteristics of the exposed population at the site; and a simple versus a complex drinking water system at the site).

The PFAS Exposure Assessment Technical Tool (PEATT) that ATSDR created to help state, local, tribal, and territorial health departments conduct PFAS biomonitoring and EA activities will be extensively used at the outset of this initiative. Similar to the National Health and Nutrition Examination Survey (NHANES), however, the PEATT data from the EAs will be generalized at a

broader population level to allow for the review and analysis of PFAS trends over time and comparisons of PFAS exposures between communities. Key findings from the detailed EAs will be used to launch the national multi-site PFAS human health study and recruit participants.

Other aspects of NCEH/ATSDR's methodology are summarized as follows. As the DoD contractor, NCEH/ATSDR will award a series of subcontracts to CDC-approved contractors to conduct the PFAS health-related activities. NCEH/ATSDR will closely collaborate with EPA, particularly on the collection of PFAS data from the sites.

NCEH/ATSDR also will coordinate these efforts with the National Institute of Environmental Health Sciences (NIEHS) in accordance with the Congressional legislation. For example, NIEHS is funding several investigator-initiated PFAS projects and recently awarded a grant to Colorado State University to conduct an EA. As a result, NCEH/ATSDR might select Colorado Springs as one of the eight DoD sites to conduct its EA. Discussions are underway for NCEH/ATSDR and NIEHS to develop and release a joint Notice of Funding Opportunity (NOFO) for PFAS health-related activities beyond the national multi-site human health study.

In addition to exploring an appropriate methodology and design for the detailed PFAS EAs and the national multi-site PFAS human health study, NCEH/ATSDR OD also has been discussing the value of the BSC establishing a new PFAS Workgroup. The workgroup would be charged with providing external, ongoing advice and guidance on NCEH/ATSDR's new PFAS health-related activities. If the BSC agrees and takes a formal vote to approve the establishment of the new workgroup, NCEH/ATSDR OD will take the necessary administrative and logistical actions to provide support.

PFAS TOXPROFILES™

ATSDR has a Congressional mandate to produce ToxProfiles™ for hazardous substances that are found at National Priorities List sites. The major intellectual contribution of the ToxProfile™ is the distillation of these data into minimum risk levels (MRLs) to identify health effects. ATSDR uses MRLs as screening values during its investigations at hazardous waste sites to identify chemicals that warrant additional attention.

The MRLs that ATSDR and its state partners have used for decades are similar to EPA's reference doses. However, a higher or lower threshold for the same chemical can be attributed to the public health role of ATSDR's MRLs versus the environmental protection role of EPA's reference dose. Differences between ATSDR's MRLs and EPA's reference dose also can be a result of the timing of publishing these thresholds with newer versus older data.

ATSDR drafted ToxProfiles™ for four PFAS chemicals: perfluorononanoic acid (PFNA), PFOA, PFOS, and perfluorohexane sulfonic acid (PFHxS). However, concerns were raised by political leaders, the media, and the general public regarding the potential for confusion. ATSDR's MRLs for PFOA and PFOS were found to be lower and more conservative than EPA's current long-term health advisories for the same chemicals.

During several initial discussions and extensive data reviews with federal partners (e.g., the Office of Management and Budget [OMB], DoD, and EPA), NCEH/ATSDR provided a clear rationale to justify differences between ATSDR's MRLs and EPA's long-term health advisories for PFOA and PFOS. Most notably, ATSDR's MRLs were based on the use of newer data from more recent studies. These initial discussions resulted in NCEH/ATSDR attending a meeting in February 2018

with a larger group of six federal agencies to coordinate a government-wide response to PFAS exposures.

The federal partners agreed to implement a common health communications approach and utilize uniform language to describe these thresholds. ATSDR drafted risk messaging to more clearly articulate the meaning of its PFOA and PFOS ToxProfiles™. After OMB approves its risk messaging, ATSDR will release the draft PFAS ToxProfiles™ for public comment, make revisions based on proposed changes that are submitted, and publish the final versions.

EPA recently hosted a PFAS summit with representatives from all states and U.S. territories. During the summit, EPA announced its plans to develop a PFAS standard and coordinate all of its PFAS-related activities through the Office of Water. However, several states used the EPA summit as an opportunity to express their concerns with ATSDR's use of the ToxProfiles™ as the basis to draft the MRLs for PFOA and PFOS. As a result, multiple states are developing their individual health standards for both regulatory and non-regulatory purposes.

FLINT REGISTRY

NCEH/ATSDR awarded a four-year, $14.4 million grant to Michigan State University (MSU) to develop, launch, and implement the Flint Registry (https://www.flintregistry.org). The registry is designed to monitor community residents who were exposed to lead-contaminated water from the Flint Water System from 2014-2015 and provide linkages to programs to minimize their health effects from lead. The services that are being offered to the Flint community include nutrition, early childhood education, and behavioral consultation. Moreover, the Centers for Medicaid & Medicare Services expanded Medicaid eligibility to include children up to 21 years of age who were exposed to lead in the Flint Water System during the period of exposure.

As part of the Flint Registry, MSU established the "Flint Lead Free" Workgroup to oversee specific activities in the community, such as eliminating lead service lines, removing lead-based paint from housing, replacing old brass fixtures in homes, and analyzing lead levels in soil. The workgroup's ultimate goal is to closely collaborate with the community, nonprofit organizations, and agencies at multiple levels for Flint to become the first lead-free city by 2022 and serve as a model for the nation.

FY2018 NCEH/ATSDR BUDGET

Cuts were proposed in the FY2018 budget for ATSDR and several NCEH programs, including the Environmental Public Health Tracking Network and the Climate and Health Program. In CDC's actual appropriation for FY2018, however, the NCEH programs and ATSDR received level funding.

NCEH received new funding of $17 million for the Lead Program in the FY2018 budget. The $17 million appropriation restores the Lead Program budget to the same funding level prior to the severe cut in 2012. However, the new resources are still not sufficient for NCEH to aggressively conduct activities in communities across the country with significant lead problems that are equivalent to those in Flint, Michigan. Overall, NCEH/ATSDR OD is pleased that its FY2018 budget was appropriated with level funding rather than cuts. NCEH/ATSDR OD currently is identifying its EH funding requests for inclusion in CDC's FY2019 and FY2020 budgets.

Dr. Breysse concluded his update by thanking the BSC for continuing to provide NCEH/ATSDR with excellent guidance. He emphasized that the BSC's expertise, insights, and perspectives have consistently challenged NCEH/ATSDR to refine its portfolio of EPH activities to improve EH

issues for communities across the country. He also noted that the BSC's input has helped NCEH/ATSDR to address complex environmental issues with broader political and social implications.

BSC DISCUSSION: NCEH/ATSDR DIRECTOR'S UPDATE
Dr. Breysse provided additional details on the following topics in response to specific questions by the BSC members.

- International research on PFAS, such as studies from China and Germany, that can be used to inform ATSDR's research on PFAS in the United States.
- The ongoing partnership between NCEH/ATSDR and the NIEHS National Toxicology Program (NTP) to evaluate PFAS exposures.
- The specific aspects that will be involved in the biomonitoring component of the PFAS EAs at the eight DoD sites.
- The capacity of other laboratories across the country to use the PEATT to conduct PFAS biomonitoring and EA activities.
- The social responsibility or obligations of industry to address PFAS exposures (e.g., ongoing negotiations for DuPont to fund a large PFAS human health study in a West Virginia community and the recent settlement by 3M with the state of Minnesota to address PFAS contamination issues).

Dr. Perry noted that two overviews on PFAS are scheduled on the agenda. She confirmed that the BSC members would revisit Dr. Breysse's update on PFAS after these presentations, particularly to provide guidance on PFAS biomonitoring, epidemiologic issues, and EAs.

Before opening the floor for the next agenda item, Dr. Cibulas announced that the terms of three BSC members ended on June 2, 2018: Drs. Deborah Cory-Slechta, Kim Dietrich, and Sharron LaFollette. The participants joined Dr. Cibulas in applauding the three outgoing members for their outstanding service to the BSC and NCEH/ATSDR over the past three years. Certificates of appreciation signed by Dr. Breysse and Dr. Robert Redfield, the CDC Director, were presented to the three outgoing members.

CDC's 2017 Hurricane Response and Recovery Efforts

CAPT Renée Funk, DVM, MPH&TM, MBA, DACVPM
Associate Director for Emergency Management
NCEH/ATSDR Office of Environmental Health Emergency Management

Dr. Funk presented an update on CDC's response and recovery efforts for the unusually active 2017 hurricane season. The frequency and intensity of storms have been greater than usual. Of the 13 named storms in 2017, seven developed into hurricanes. The storms in August and September 2017 included Hurricane Harvey in Texas; Hurricane Irma in the U.S. Virgin Islands (USVI), Puerto Rico, and Florida; Hurricane Maria in Puerto Rico and USVI; and Hurricane Jose in New England. If two additional storms had occurred, 2017 would have been in the top 15 most frequent/intense hurricane seasons since 1851.

The 2014 Klinger, *et al.* study documented multiple issues that are affected by power outages during extreme events. These impacts were particularly magnified in Puerto Rico and USVI due to prolonged power outages on the two islands. In general, the public health consequences of disasters in communities include damage to key public health and preventive services, damage

to healthcare facilities and services, damage to the environment, increases in morbidity and mortality, and population displacement. In particular, the major impacts of the 2017 hurricane season included drowning, carbon monoxide poisoning, displaced residents, power loss, contaminated drinking water, damaged/destroyed infrastructures, non-functional clinics and hospitals, affected medical and public health staff, and mold in homes and buildings.

CDC activated Emergency Support Function (ESF) 8, "Public Health and Medical Services," to guide its response to the 2017 hurricane season. HHS is the overall lead for ESF 8, while CDC is the lead for the public health aspects of ESF 8. However, CDC partners with other HHS operating divisions, other federal agencies, and state, tribal, and local governments to fulfill its core functions. Moreover, ATSDR is extensively involved in EPA's leadership role for ESF 10, "Hazardous Materials."

CDC grouped its response efforts for the 2017 hurricane season into three major functions. The epidemiology and health surveillance function included mortality tracking, shelter and syndromic surveillance, and technical assistance (TA) to state/local health departments. The EH function included coordination of public and private water systems, vector control, mold remediation and carbon monoxide exposure, and occupational health issues. The communications function included the dissemination of timely and accurate information, tracking of news and social media postings, control of rumors/inaccurate information, and messaging to partners and community residents.

After the CDC Emergency Operations Center was activated on August 30, 2017, over 700 CDC staff supported the 2017 hurricane response. As of May 18, 2018, the total number of completed CDC deployments included 200 staff in Puerto Rico, 92 staff in USVI, and 55 staff in Texas. CDC's specific role and responsibilities in the 2017 hurricane response are summarized below.

DRINKING WATER

CDC's drinking water role and responsibilities in an emergency response are to address public health issues. Responders are provided with potable drinking water while working in evacuation shelters, federal medical shelters, joint field offices, and other office environments. Technical support on issues related to regulated and unregulated water systems is provided to EPA, the Federal Emergency Management Agency (FEMA), the U.S. Army Corps of Engineers, and state and local partners.

Support is provided for the disinfection and testing of non-transient, non-community water systems that supply water to federally-funded facilities and serve sensitive populations (e.g., patients in hospitals/clinics, children in daycare facilities, and seniors in elderly care facilities). Support is provided for safe and effective home water treatment for families who lack household wells, potable municipal water systems, or bottled water. Support is provided for the disinfection and testing of unregulated household wells.

CDC learned two major lessons during the 2017 hurricane response in terms of drinking water. First, CDC's role in safe drinking water during an emergency response should be clarified. Second, EH service programs should be built that are capable of responding to water disruptions. To achieve this goal, current records should be maintained on the number of public water system connections in each community; the number and locations of wells and other non-regulated systems; and the number and locations of septic systems and small wastewater treatment facilities.

FACILITY ASSESSMENTS

CDC conducted facility assessments in Puerto Rico and USVI. The standardized assessment tool that was developed for healthcare facilities included questions on the capabilities of operational units, bed census, structural damage, and the need for medical services and medical supplies. The initial assessment of a subset of hospitals and clinics was followed by a tiered approach that included 14 high-priority hospitals and 16 high-priority clinics. A total of 69 hospitals and 186 clinics were included in the facility assessments in Puerto Rico.

CDC learned three major lessons during the 2017 hurricane response in terms of facility assessments. First, an appropriate organizational framework is needed for complex or extreme events, such as the hurricanes in Puerto Rico and USVI. The framework should include experienced, multidisciplinary public health teams.

Second, standardized methods and tools should be used immediately after a disaster to collect critical data. This approach will facilitate follow-up assessments to determine the status of public health capabilities throughout the disaster response cycle. Third, disaster response agencies should closely collaborate on developing a portfolio of PHA tools and establishing methods and operational criteria to support and implement in the early phase of the disaster response.

MOLD REMEDIATION/CARBON MONOXIDE EXPOSURE

CDC conducted in-depth training sessions, hosted webinars, and released health communication materials to provide guidance on addressing problems with mold after a flood. For example, people who are unable to dry their homes, furniture, and other personal property within 24-48 hours after a flood should assume that mold is growing in their residences. Most notably, the absence of air conditioning limited the ability of community residents in Puerto Rico and USVI to rapidly dry their homes. Moreover, mold can be readily observed or smelled on clothing, drywall, furniture, cardboard boxes, or books, but unseen fungus also might be behind or hidden under other items (e.g., carpet, cushions, or walls).

HEALTH COMMUNICATIONS

CDC responded to the health communications needs of affected communities, key partners, stakeholders, and healthcare providers during the 2017 hurricane season. For example, the "8 Tips to Clean Up Mold" fact sheet was widely distributed and posted on the CDC.gov website. Outreach and communications activities to clinicians during the 2017 hurricane season included five "blast" calls and newsletters as well as two health advisory network notices that reached approximately 1 million clinicians within 90 minutes of dissemination. Engagement of and outreach to the public during the 2017 hurricane season included over 1,000 social media posts with a reach of over 11 million people through Twitter and over 4 million people through Facebook.

CDC distributed generator safety materials with several simple messages. "Carbon monoxide is an odorless, colorless gas that can cause sudden illness and death if inhaled." "Generators and other gasoline, propane, natural gas, or charcoal-burning devices should never be used inside or outside near an open window." "Carbon monoxide detectors always should be used with generators."

The generator safety materials resulted in over 1 million views on the CDC.gov website, including the disaster, mold, hurricane, carbon monoxide, and flood web pages. CDC's outreach to emergency preparedness information consultants included 15 newsletters, 7 announcements, and 3 calls that reached over 49,000 subscribers. CDC distributed approximately 3.3 million

materials, including fact sheets, handouts, flyers, and children's coloring books. CDC-INFO (i.e., CDC's National Contact Center) responded to over 500 inquiries related to the 2017 hurricanes.

CDC ensured that its health communications materials were widely accessible through multiple formats and included simple, easily understandable language. Moreover, CDC disseminated health communications messaging through radio announcements in the U.S. territories. In addition to providing guidance on public health and EH issues related to the hurricanes, CDC also addressed mental health issues in its health communications materials.

HURRICANE RECOVERY FUNDING

CDC is shifting its focus from response to recovery efforts for the 2017 hurricane season. Most notably, Congress approved disaster relief supplemental funding of $89.3 billion in the FY2018 HHS budget. HHS will use these resources to continue conducting activities with states and U.S. territories that were impacted by the hurricanes and other disasters in 2017. In accordance with the Congressional language, HHS allocated $200 million of its appropriation to CDC to address the public health aspects of the disaster response and recovery efforts in affected communities.

Of CDC's $200 million appropriation from HHS, NCEH/ATSDR received supplemental funding of $50 million in March 2018 to specifically address EH issues. NCEH/ATSDR will use the funds to address three key priority areas in the recovery phase: EH assessments, EH services, and monitoring of the health impact of affected communities. NCEH/ATSDR also will coordinate efforts with state and territorial health departments to align the three priorities with their individual needs. Moreover, NCEH/ATSDR will use CDC's existing CRISIS NOFO and other funding mechanisms to allocate the funds. NCEH/ATSDR plans to award funds to the jurisdictions and non-governmental organizations (NGOs) in June 2018.

BSC DISCUSSION: CDC'S 2017 HURRICANE RESPONSE AND RECOVERY EFFORTS

Dr. Funk provided additional details on the following topics in response to specific questions by the BSC members.

- CDC's key lessons learned in engaging states and U.S. territories in the 2017 hurricane season.
- CDC's ongoing efforts to clarify its EH and public health role in safe drinking water during an emergency response (e.g., serving on a new workgroup with EPA and conducting activities under the new water sector of the FEMA recovery structure).
- Lessons learned from the multidisciplinary hurricane response and recovery efforts targeted to vulnerable populations, such as children, that CDC can apply to inform future hurricane seasons.
- The potential role of CDC and/or its federal partners in tracking the economic impacts of hurricanes, such as time off from work or family-specific implications.
- Activities at the federal level to respond to the psychological trauma or other mental health effects of hurricanes (e.g., leadership by the Substance Abuse and Mental Health Services Administration; CDC's funding of Suicide Prevention Programs in affected jurisdictions; and the establishment of interagency workgroups to address mental health issues related to disasters).
- CDC's process to closely monitor the distribution of medications and pharmacy supplies during hurricanes.

- Areas in which NCEH/ATSDR's FY2018 supplemental funding will be used to improve emergency preparedness, response, and recovery capacity at the local level in Puerto Rico and USVI, such as hiring experienced EH and health communications staff.
- NCEH/ATSDR's collaboration with George Washington University and the implementation of other activities to track hurricane-related mortality in Puerto Rico, such as the provision of guidance on accurately counting and capturing "primary" and "secondary" hurricane-related deaths.

BSC GUIDANCE
Dr. Perry noted CDC's existing expertise to track hurricane-related mortality. She advised CDC to consult with the NCEH Climate and Health Program to conduct scenario preparedness, planning, and modeling projections of mortality in future hurricanes.

NCEH/ATSDR Program Responses to BSC Guidance

William Cibulas, Jr., PhD, MS
Acting Director, ATSDR/DTHHS
BSC DFO

Dr. Cibulas made several introductory remarks for the benefit of the new BSC members. This update is a standing agenda item for NCEH/ATSDR to present its responses to the BSC's guidance from the previous meeting. This recurring agenda item also allows the BSC to track and monitor whether its guidance is or is not reflected in NCEH/ATSDR's programs, research or activities.

Dr. Cibulas noted that the current agenda item would include an update by NCEH/ATSDR OD and responses by individual NCEH/ATSDR programs to the BSC's guidance on three key presentations from the November 2017 meeting: (1) CDC's noise-induced hearing loss (NIHL) activities; (2) the NCEH National Environmental Public Health Tracking Network; and (3) the ATSDR National Amyotrophic Lateral Sclerosis (ALS) Registry.

Yulia Carroll, MD, PhD
Acting Associate Director for Science, NCEH/ATSDR

Dr. Carroll reminded the BSC of its formal recommendation to establish a new workgroup to provide guidance on CDC's vector management and pesticide recommendations. Due to the representation of both the NCEH/ATSDR BSC and the CDC Office of Infectious Diseases (OID) BSC, the new workgroup will serve as CDC's first cross-center/institute/office (CIO) advisory body.

Dr. Carroll reported that NCEH/ATSDR and CDC/OID leadership finalized a five-page, "charter-like" document to clearly define the role and function of the workgroup, including its membership, key activities, and administrative tasks. She highlighted the key components of the document.

Workgroup Membership
- Co-chair (Dr. Melissa Perry), alternate co-chair (Dr. John Meeker), and 4 members proposed by NCEH/ATSDR leadership
- Co-chair and 4 members proposed by OID leadership
- NCEH/ATSDR and OID DFOs

Workgroup Goals and Strategies

- Develop and evaluate vector-borne disease prevention and control tools
- Clarify CDC's role in monitoring human exposures and adverse health effects subsequent to pesticide applications
- Establish a strong vector control public health workforce
- Improve risk communications for vector-borne diseases
- Enhance collaborations between public health, organizations, academia, and other groups

Dr. Carroll concluded her update by announcing that efforts are underway for the workgroup to convene its first meeting in June 2018.

Dr. Perry reminded the BSC that the new cross-CIO workgroup was established because CDC was required to make judicious and thoughtful decisions on pesticide spraying and other critical issues during the national response to the Zika virus. Due to the rapidly evolving nature of the Zika outbreak, however, CDC had to quickly make decisions and issue recommendations without soliciting independent guidance from external EH experts in the field. For example, CDC's earliest guidance documents on the Zika virus would have benefitted from EH expertise on the potential health effects and long-term environmental impacts of pesticide spraying.

Overall, Drs. Meeker and Perry were excited and honored to serve on CDC's first cross-CIO workgroup. As members of the NCEH/ATSDR BSC, they made a commitment to ensure that equal attention will be given to both the EH and infectious diseases aspects of vector-borne diseases and pesticide application.

Dr. Breysse confirmed that he looked forward to updates by the new workgroup during future BSC meetings. In terms of a broader, structural context, he hoped the experiences, lessons learned, best practices, and role of the workgroup as CDC's first cross-CIO advisory body would be compiled and replicated as an agency-wide model. Most notably, he saw multiple benefits of the NCEH/ATSDR BSC increasing its presence on and contributing its EH expertise to advisory groups of other CDC CIOs.

John Eichwald, MA
Audiologist, NCEH/ATSDR Office of Science (On Detail)
Centers for Disease Control and Prevention

Mr. Eichwald thanked the BSC for providing outstanding guidance to CDC on its portfolio of NIHL activities during the November 2017 meeting. The BSC's comments and suggestions on the future direction of these efforts were particularly helpful because NCEH/ATSDR and its internal CDC partners are conducting the NIHL activities with no formal funding mechanism in the FY2018 budget. The responses to the BSC's guidance on CDC's NIHL activities are set forth in the table below.

PRESENTATION: CDC'S NOISE-INDUCED HEARING LOSS ACTIVITIES	
BSC Guidance	**CDC Response**
Gather and publicize NHANES data that demonstrate key trends in hearing decrements over time.	CDC is continuing to collect and analyze NIHL data from NHANES cohorts of adolescents to determine key trends over time. A comparison between the 2005-2006 and the 2007-2010 NHANES cohorts of adolescents showed an increase in the prevalence of

PRESENTATION: CDC'S NOISE-INDUCED HEARING LOSS ACTIVITIES	
BSC Guidance	**CDC Response**
	hearing damage from noise-induced exposure among both males and females. However, a slightly higher prevalence of hearing damage was observed in females than in males. Based on its analysis of data from the most recent NHANES cycle, CDC estimates that 1 in 6 adolescents have hearing damage due to noise exposure. Because the 2015-2016 NHANES cycle focused on adults only, CDC likely will not report updated data on trends in hearing damage from noise-induced exposure among children and adolescents until 2020-2022.
Use existing media relationships to raise public awareness of NIHL, particularly since the dramatic increase in the continuous use of ear buds is contributing to deteriorated hearing among individuals in younger age groups.	CDC has expanded the focus of its NIHL activities in older adults to include younger populations, their parents, and schools. CDC uses its website and social media platforms, particularly Facebook and Twitter, to raise public awareness of NIHL in youth. In celebration of World Hearing Day on March 3, 2018, CDC launched several activities to educate youth and their parents on NIHL. These activities had a potential global reach of over 2.4 million people within one week of dissemination. CDC also targeted activities specifically to youth in recognition of "Better Hearing and Speech Month" in May 2018. CDC will maintain the focus of its NIHL activities on youth during "National Protect Your Hearing Month" in October 2018.
Strengthen the important role and partnership of the National Institute of Occupational Safety and Health (NIOSH) in CDC's NIHL activities.	NIOSH is a member of CDC's intra-agency NIHL Workgroup and serves as a critical partner in these efforts. CDC sponsored a Public Health Grand Rounds in June 2017, *It's Loud Out There: Hearing Health Across the Lifespan*. Data from the Grand Rounds were compiled and published in the *Morbidity and Mortality Weekly Report* (*MMWR*) in March 2018. Dr. William Murphy of NIOSH served as the lead author of the *MMWR* article. NIOSH sponsored a panel presentation during a conference of the Acoustical Society of America in May 2018.
Replicate the "Buy Quiet" initiative for non-occupational settings to encourage manufacturers to design quieter lawnmowers, machinery, and other equipment that are used in the home.	CDC would welcome the opportunity to take action on the BSC's guidance, but resources are not available to support this effort. However, CDC's strong interest in the manufacture of quieter tools in non-occupational settings, including portable generators, has led to the development and publication of two fact sheets on the CDC.gov website to raise awareness of this issue. CDC recently released another fact sheet on the danger of air horns, particularly at sporting events.
Identify and obtain commitments from key partners that can play an instrumental role in ensuring the	CDC will collaborate with federal partners and NGOs in the implementation of its guidelines on NIHL and other hearing-related health effects in non-occupational settings. The National Academies of Sciences,

PRESENTATION: CDC'S NOISE-INDUCED HEARING LOSS ACTIVITIES	
BSC Guidance	**CDC Response**
implementation of CDC's new NIHL guidelines in the field. Expand CDC's NIHL intra-agency workgroup to include external federal partners.	Engineering, and Medicine published a report in 2016, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, that was co-funded by CDC, other federal agencies, and the Hearing Loss Association of America. The National Academies will soon reconvene its workgroup of federal agencies stakeholders, and NGOs to develop an action collaborative to implement the 12 recommendations that were highlighted in the report. The workgroup primarily will focus on issuing new guidance to the U.S. Food and Drug Administration (FDA) on the use of over-the-counter hearing aids. However, the workgroup also will be used as an opportunity to promote the four recommendations in the report that were specifically targeted to CDC on improving access to hearing health care. Moreover, CDC and the National Hearing Conservation Association have initiated discussions to explore the possibility of forming a new NIHL task force or workgroup.
Define concrete public health goals and outcomes for CDC's new NIHL guidelines.	CDC is continuing to conduct a systematic review of the scientific literature to support the development of its NIHL guidelines for non-occupational settings. The new guidelines will document a fairly strong association between hearing loss and cardiovascular disease. CDC recently launched a new initiative to review community noise ordinances. Data will be collected from this effort to design a model noise ordinance that will allow communities to provide informed guidance to policymakers in their cities, counties, and regions. CDC will partner with subject-matter experts from multiple disciplines in this activity, such as legal experts from the Network of Public Health Law. CDC expects to complete the systematic review over the next two months. However, the timeline of CDC's standard guidelines development process (including revisions, peer reviews, clearance, and publication) can range from one to five years. Materials on the interim NIHL activities will be regularly posted on the CDC.gov website, such as the audio recording and slide sets from the NIHL webinar that CDC hosted in May 2018.

CAPT Fuyuen Yip, PhD, MPH
Section Chief, Environmental Public Health Tracking Program
NCEH Lead Poisoning Prevention and Environmental Health Tracking Branch
Centers for Disease Control and Prevention

Dr. Yip thanked the BSC for providing excellent guidance to NCEH on the Tracking Network during the November 2017 meeting. NCEH particularly appreciated the BSC's suggestions on

expanding the scope, reach, and data variables of the Tracking Network. The responses to the BSC's guidance on the Tracking Network are set forth in the table below.

PRESENTATION: NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING NETWORK	
BSC Guidance	**NCEH Response**
Ensure that users at the graduate/postgraduate level can access and utilize Tracking Network data.	In accordance with the current NOFO, all Tracking Network grant recipients must partner with local colleges and universities. Based on this requirement, several grant recipients have made presentations and given live demonstrations of the Tracking Network to undergraduate- and graduate-level classes. NCEH developed online modules of the Tracking Network in 2013 that are designed for college-level instruction. The topics covered by the modules include EPH tracking and the use of Tracking Network data. NCEH's new training modules will be incorporated into the Tracking Network in 2018.
Separate the 20 content areas of the Tracking Network by populations, routes of exposure, and outcomes to promote hypothesis-driven research.	NCEH agrees that the Tracking Network should be used to link environmental and health data in one platform to generate hypotheses and address research questions. The 20 content areas of the Tracking Network currently are organized in three major categories: environmental exposures and hazards, associated health outcomes, and population characteristics and vulnerabilities. In its ongoing efforts to expand the Tracking Network, NCEH will attempt to take action on the BSC's guidance and organize the data by routes of exposure. In the interim, granular and contextual data on routes of exposure are included in the "About the Data" and the "Indicators and Data" sections of the Tracking Network.
Expand the grant recipients to include at least one tribal nation to collect EH data on tribal communities.	NCEH agrees that taking action on this suggestion is extremely important. NCEH currently funds three Tribal Epidemiology Centers in the Great Lakes, Northwest, and Southwest regions of the country. The tribal grant recipients are paired with the Tracking Network grant recipients to achieve three major goals: (1) build tribal epidemiologic capacity and expertise, particularly in the area of surveillance; (2) provide additional resources to tribes; and (3) collect data to identify tribal EH priorities and conduct projects to address these specific needs. The tribal grant recipients published a paper in the September/October 2017 edition of the *Journal of Public Health Management & Practice* to highlight their current efforts with their Tracking Network partners.
Expand the heart disease content area to include hypertension and stroke and also divide this content area into three subcategories: ischemic	Hospitalizations and heart attacks currently are included as categories in the heart disease content area of the Tracking Network. Heart disease mortality includes a further breakdown of ischemic heart disease mortality and heart attack mortality. NCEH will continue to collaborate with its grant recipients, data

PRESENTATION: NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING NETWORK	
BSC Guidance	**NCEH Response**
heart disease, heart failure, and arrhythmia.	stewards, and other partners to identify opportunities to include additional data in the Tracking Network for the heart disease content area based on the BSC's guidance. However, NCEH's process of adding new variables to the Tracking Network involves evaluating the appropriateness of the proposed data element from an EPH perspective and determining whether indicators can be developed to effectively measure the data element.
Measure health-related quality of life issues, such as the stress of community residents who lose their homes and personal belongings due to wildfires.	NCEH is in the final stages of developing an online tool for the Tracking Network to identify populations that are at risk for wildfire smoke hazards in real-time and produce real-time vulnerability assessments. Data for the wildfire tool will be integrated with the Tracking Network's existing standardized health and environmental data. NCEH published the design, methodology, and other aspects of developing the wildfire tool in the *Science of the Total Environment* earlier in 2018. After the wildfire tool is launched in the fall of 2018, NCEH will determine whether data are available to take action on the BSC's guidance to measure health-related quality of life issues due to wildfires. After its implementation in the field, NCEH will solicit advice from the BSC on the use of the wildfire tool to better inform state and local partners.
Use data collected from Florida to address similar mold and carbon monoxide issues that were caused by hurricanes in Texas and Puerto Rico.	Hurricanes and other large-scale events provide additional opportunities to use the Tracking Network as a major platform to share publicly available information on post-disaster exposures. For example, Tracking Network grant recipients collect and submit data to NCEH on carbon monoxide poisoning, hospitalizations, and emergency department visits following a disaster. NCEH places all of these data in the public domain. Disaster-related data collected by health departments are owned by the respective state and are not publicly available. However, NCEH partners with its funded state health departments to include their private disaster-related data on the Tracking Network public portal. NCEH currently is developing a new Environmental Health All-Hazards Disaster module that will be included in the Tracking Network. NCEH also expects to place data from the new module in the public portal. NCEH will present an update on the new module to the BSC in late 2018 or early 2019.
Review state and local regulations and evaluate the role of the Tracking Network in decreasing EH exposures or reducing health outcomes.	NCEH will continue to highlight the important role and significant impact of the Tracking Network on informing public health decision-making and policy development. Most notably, "public health action" is a key performance indicator that NCEH tracks and monitors

PRESENTATION: NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING NETWORK	
BSC Guidance	**NCEH Response**
	for all Tracking Network grant recipients. For example, grant recipients are measured on the extent to which their tracking data and resources have informed or influenced public health decision-making. NCEH published a supplement in the September/October 2017 edition of the *Journal of Public Health Management & Practice* that featured various public health actions of multiple Tracking Network grant recipients. NCEH currently is developing an evaluation framework for the entire Tracking Network at national, state, and local levels. NCEH plans to use the new evaluation framework to capture and report the successes of more Tracking Network grant recipients in the future. NCEH will continue to select and feature key public health actions of the grant recipients as success stories on the Tracking Network.
Incorporate National ALS Registry data into the Tracking Network portal to provide an additional rich source of data on environmental risk factors and exposures.	NCEH will take action on the BSC's suggestion. NCEH's next steps will be to consult with ATSDR staff to identify opportunities to integrate the Tracking Network and National ALS datasets.

Kevin Horton, DrPH, MSPH
Chief, Environmental Health Surveillance Branch
ATSDR/DTHHS

Dr. Horton presented background information on the National ALS Registry for the benefit of the new BSC members. In response to the enactment of new Congressional legislation in October 2008 that directed CDC to create a population-based ALS registry for the United States, ATSDR launched the National ALS Registry in October 2010. With the exception of Massachusetts, however, no states required ALS to be a notifiable or a reportable disease. As a result, ATSDR faced a daunting task of identifying cases throughout the country for a non-notifiable, non-reportable disease.

ATSDR addressed this challenge by implementing the National ALS Registry with a two-pronged approach: (1) collect epidemiologic information on ALS patients from large national databases and (2) identify ALS patients through a web portal registration system. ATSDR's other key achievements include the publication of four annual reports in the *MMWR* on the prevalence of ALS in the United States, including the upcoming release of the most recent report in the fall of 2018.

ATSDR administers 17 different online risk factor surveys to gather information on multiple topics from ALS patients, such as their occupational, military, and trauma histories. ATSDR launched the National ALS Biorepository in January 2017 to collect biospecimens from ALS patients, including blood, urine, saliva, brain tissue, cerebrospinal fluid, and bone tissue. Due to the linkage of the risk factor survey information and the biospecimens, the National ALS Registry is the only dataset in the world that integrates epidemiologic and biospecimen data. This rich data source is

available to researchers for various purposes, such as the recruitment of patients for ALS studies and clinical trials.

Dr. Horton thanked the BSC for providing extremely helpful and thoughtful guidance to ATSDR on the National ALS Registry during the November 2017 meeting. The responses to the BSC's guidance are set forth in the table below.

PRESENTATION: NATIONAL AMYOTROPHIC LATERAL SCLEROSIS REGISTRY	
BSC Guidance	**ATSDR Response**
Expand the question on "occupational history" in the ALS risk factor survey to collect more detailed information on specific types of metal exposures.	ATSDR collects urine, blood, and serum specimens for the National ALS Biorepository to measure exposures to 15 different metals, including lead, mercury, and beryllium. ATSDR links the biospecimen data (e.g., lead levels in blood) and the risk factor survey information (e.g., occupational history) of ALS patients. These integrated datasets are made available to external researchers. However, ATSDR cannot take action on the BSC's suggestion to expand the "occupational history" question in the ALS risk factor survey without deleting an existing module. For all federally funded research, OMB restricts the burden of data collection through surveys or other instruments to 90 minutes. In its research protocol, ATSDR informed OMB that ALS patients could complete all 17 online risk factor surveys in approximately 90 minutes.
Ensure that the National ALS Registry has the capacity to provide data on changes in ALS diagnosis practices or patterns to identify differences in the rates of disease over time.	ATSDR has included a longitudinal survey module in the National ALS Registry to examine and capture data on the progression of disease in an individual patient over time. For example, the module is designed to track the periods of time between the patient's ability to walk and confinement to a wheelchair and/or the patient's ability to speak and loss of speech. The clinical module in the National ALS Registry tracks the period of time between the patient's onset of symptoms and the exact date of the ALS diagnosis. ATSDR provides these data to neurologists to assist in tracking ALS patterns over time.
Code information that is provided for the "lifetime residential history" in the ALS risk factor survey with GIS to identify common issues.	ATSDR agrees with the BSC's guidance regarding the tremendous potential to incorporate GIS data into the National ALS Registry. ATSDR is leveraging the expertise of its Geospatial Research, Analysis, and Services Program (GRASP) to achieve this goal. ATSDR recently published a paper to emphasize the need to improve access to ALS care in state-of-the-art clinics, particularly in rural areas. The paper demonstrated ATSDR's use of its GRASP data to overlay ALS cases across the country with multidisciplinary specialty clinics. External researchers also have expressed an interest in overlaying ATSDR's GRASP data with their existing maps to determine

PRESENTATION: NATIONAL AMYOTROPHIC LATERAL SCLEROSIS REGISTRY	
BSC Guidance	**ATSDR Response**
	whether exposure to cyanobacteria from algae blooms potentially can cause ALS.
Maintain information in the National ALS Registry on the typical amount of time between the patient's initial signs/ symptoms and first neurological diagnosis versus the definitive ALS diagnosis.	The National ALS Registry is designed to capture multiple data points from enrollees, including the date of first symptom onset and the date of ALS diagnosis. ATSDR is collaborating with pharmaceutical companies to conduct clinical trials of new ALS medications with patients who are enrolled in the registry. ATSDR also conducts direct outreach, widely publicizes the registry, and encourages enrollment by meeting with pharmaceutical companies and attending ALS conferences to speak with patients and neurologists.
Compare the demographics of National ALS Registry participants to the subset of participants who donate biospecimens to the National ALS Biorepository.	The demographics of these two groups are the same because patients who donate samples to the National ALS Biorepository are required to enroll in the National ALS Registry. ATSDR has developed and implements a rigorous sampling scheme to ensure that the biospecimens are representative of ALS patients in diverse geographic areas of the country.
Maintain data on ALS patients who are not enrolled in the registry because these cases can serve as a control group.	The National ALS Registry and registries for other diseases, such as cancer and birth defects, typically are not developed with control groups due to the high cost of this type of design. However, external researchers who submit applications to ATSDR to use the registry data for studies likely will have access to control groups. ATSDR also advises researchers to conduct their ALS studies with a paired match design by using NHANES data as a control group.
Ensure coordination and linkages between the National ALS Registry and the Camp Lejeune registry of volatile organic compounds (VOCs) in drinking water.	The National ALS Registry captures data from enrollees on their military history because military personnel and veterans are twice as likely as civilians to develop ALS. ALS cases in the registry can be linked to the Camp Lejeune registry of people at the site who were impacted by VOCs in drinking water. However, ATSDR will first need to obtain Institutional Review Board approval to cross-reference the two datasets. ATSDR's health studies and modeling at Camp Lejeune found an excess of ALS cases at this site.

BSC DISCUSSION: NCEH/ATSDR'S RESPONSES TO PREVIOUS BSC GUIDANCE

NCEH/ATSDR OD and program staff provided additional details on the following topics in response to specific questions by the BSC members.

- The extent to which the National ALS Registry will be able to focus on health effects that were linked to trichloroethylene exposure at Camp Lejeune.

- Specific questions that are asked during NHANES hearing tests, such as the use of ear buds and other exposures to noise for adults (10 or more hours per week) and children (five or more hours per week).
- NCEH's ongoing activities or future plans to expand the Tracking Network to collect and report data, disseminate risk communication messaging, and provide support for volcanoes, particularly to assist the state of Hawaii.
- The status of the FY2018 budget for the Tracking Network, particularly since a significant $9 million cut was proposed.
- ATSDR's upcoming publication in the summer/early fall of 2018 on ALS mortality data from 2011-2014.
- The inclusion of the universal "ALS Functional Rating Scale" in the National ALS Registry that serves as an ALS severity measure.

BSC GUIDANCE

The BSC thanked NCEH/ATSDR OD and the program staff for continuing to provide detailed responses to its guidance in a timely manner. Several BSC members made additional comments and suggestions for NCEH/ATSDR to consider in its ongoing efforts to improve the NIHL activities, Tracking Network, and National ALS Registry.

- CDC should engage the Federal Aviation Administration (FAA) as an additional federal partner in conducting its NIHL activities. In direct response to increased Congressional pressure, the FAA will soon launch new initiatives to aggressively address noise pollution in airport communities across the country. Ms. Condon offered to provide Mr. Eichwald with contact information for FAA officials who are involved in this effort.
- In its new initiative to design a model noise ordinance, CDC should limit its review of existing local noise ordinances to those that have a demonstrated record of effectiveness. Most notably, some ordinances that are only documented in writing have not been enforced to achieve an impact on or make positive changes in the community.
- Media reports increasingly are being released that characterize the habitual and chronic use of ear buds and other listening devices, particularly among children, as a public health concern. CDC should leverage the national interest in this issue as an opportunity to align its NIHL messaging and activities with those of pediatric organizations.
- NCEH and ATSDR should consult with their grant recipients in Massachusetts in the ongoing effort to integrate the Tracking Network and National ALS Registry datasets. Most notably, Massachusetts is the only state in the nation that has created and maintains a population-based ALS registry. These discussions should focus on determining the extent to which the Massachusetts ALS registry dataset at the state level is accurate and complete compared to the ATSDR ALS registry dataset at the national level.
- ATSDR should engage the BSC in a thoughtful discussion to weigh the advantages and disadvantages of deleting an existing module in the ALS risk factor surveys to allow for the expansion of the "occupational history" data variable. This approach also will address the BSC's previous suggestion for ATSDR to collect more detailed information on specific types of metal exposures for the National ALS Registry. For example, ATSDR reported that urine, blood, and serum specimens are collected for the National ALS Biorepository to measure exposures to 15 different metals, including lead, mercury, and beryllium. However, ATSDR also should prioritize the measurement of exposures to other essential metals, such as iron, copper, and zinc. Most notably, the accumulation of iron in the brain is extensively implicated in multiple neurodegenerative diseases, including ALS.

NCEH/ATSDR thanked the BSC for providing additional guidance on the NIHL activities, Tracking Network, and National ALS Registry. Responses to the BSC's input on these three programs by NCEH/ATSDR OD and program staff are summarized below.

- Dr. Breysse provided background information on CDC's NIHL activities for the benefit of the new BSC members. NCEH/ATSDR and other CDC CIOs formed an internal workgroup in direct response to a request to address NIHL in non-occupational settings. A budget was not provided to support this effort, but the workgroup of motivated CDC/ ATSDR staff identified internal resources and developed a strategic plan to achieve a significant public health impact on NIHL. For example, the workgroup produced a manuscript with NHANES data to document the strong risk associated with hearing loss and increased susceptibility to depressive symptoms in elderly women. The manuscript recently was accepted for publication and recommends additional screening for depressive symptoms among women with high-frequency hearing loss.

- Dr. Carroll explained that the bulk of the data CDC has collected to date from its systematic review of the scientific literature on environmental exposures to noise is related to highway and airport traffic pollution. CDC is using these data to demonstrate an association with cardiovascular diseases and stress.

- Mr. Eichwald confirmed that CDC is exploring strategies to address the BSC's suggestion on targeting its NIHL messaging and activities to the pediatric community to broaden outreach to children. For example, CDC has been discussing the possibility of sponsoring another Public Health Grand Rounds on non-auditory effects. CDC has proposed to brand the new grand rounds as "Noise: The New Secondhand Smoke Public Health Issue."

- Dr. Horton made a number of follow-up remarks in response to the BSC's additional guidance on the National ALS Registry.
    - ATSDR and Massachusetts recently engaged in a discussion to begin making comparisons and identifying gaps in cases between the ATSDR ALS registry dataset at the national level and the Massachusetts ALS registry dataset at the state level. ATSDR also will leverage its strong relationship with the NCEH Environmental Health Tracking Branch to integrate the National ALS Registry and the Tracking Network datasets.
    - ATSDR measures exposures to copper and zinc in biospecimens that are collected for the National ALS Biorepository. However, Dr. Horton will follow-up with staff to determine whether iron also is one of the 15 metals that are measured.
    - The BSC offered to assist ATSDR in expanding the "occupational history" data variable in the ALS risk factor surveys while still complying with OMB's data collection restrictions. Drs. Breysse and Horton proposed two key options to achieve this goal. First, ATSDR could determine the total number of enrollees who have completed the ALS risk factor surveys and use an incomplete survey to pilot the expanded "occupational history" data variable. Second, NIOSH has developed matrices that list occupational exposures by job title. ATSDR can extract a wealth of information from the NIOSH matrices without asking additional questions or exceeding OMB's 90-minute data collection limit. ATSDR uses the North American Industry Classification System (NAICS) to code occupations for the registry. ATSDR can translate and extrapolate the NAICS codes for the NIOSH coding system to assign occupational exposures from the matrices to specific job titles.

ATSDR's Proof of Concept Study/PFAS Multi-Site Health Study

Marian Pavuk, MD, PhD
Senior Epidemiologist, ATSDR/DTHHS

Dr. Pavuk presented an overview of the ATSDR PFAS proof of concept study at the Pease, New Hampshire site (Phase 1) that will inform the design, development, and implementation of the PFAS multi-site health study (Phase 2). The 2018 National Defense Authorization Act and the 2018 Omnibus appropriations provided two new opportunities for ATSDR to conduct PFAS activities.

- Statistically-based PFAS biomonitoring EAs will be performed at no less than eight current or former DoD sites. The EAs will be designed to include measurements of PFAS in serum and urine as well as limited environmental sampling in dust and tap water. New funding of $10 million was allocated to ATSDR in FY2018 to complete the PFAS EAs as a short-term project within two years.
- The design and development of the multi-site PFAS health study will be informed by data that are collected from the PFAS biomonitoring EAs. New funding of $10 million is expected to be allocated to ATSDR in FY2019 to complete the multi-site PFAS health study as a long-term project over the next five to seven years. ATSDR potentially could receive additional funds to support this effort in subsequent years.

PHASE 1: PROOF OF CONCEPT STUDY

ATSDR will conduct a cross-sectional study at the Pease, New Hampshire site as the proof of concept for the multi-site PFAS health study. Pease International Tradeport is a former U.S. Air Force base that had used AFFF since the 1970s. In 2014, one of the three wells that served the Pease community showed elevated levels of PFOS. These levels were above EPA's provisional health advisory.

A large biomonitoring study that the New Hampshire Department of Health and Human Services (NHDHHS) conducted in 2015 with over 1,500 participants served as a major driving force for ATSDR to launch its feasibility assessment. ATSDR published the feasibility assessment in November 2017 on potentially conducting drinking water epidemiological studies at the Pease site in the future.

ATSDR reviewed epidemiological studies that evaluated the health effects of PFAS exposures. ATSDR's report of its literature review and calculations of sample sizes concluded that cross-sectional epidemiological studies of children and adults would be feasible at one site only (e.g., Pease) and for certain health endpoints only (e.g., lipids and kidney function). ATSDR determined that the sample size would be insufficient for other health endpoints, such as thyroid, liver, and immune functions as well as autoimmune diseases. These efforts highlighted the need for a multi-site PFAS health study.

The primary goals of the Pease proof of concept study will be to (1) evaluate procedures and test study protocols to identify any issues that need to be addressed before launching the multi-site PFAS health study and (2) examine associations between measured and historically reconstructed serum levels of PFAS (including PFOA, PFOS and PFHxS) and selected health outcomes.

A sample of children and adults who participated or were eligible to participate in the NHDHHS biomonitoring program at Pease in 2015 will be selected and recruited. The eligibility criteria will include people who worked at, lived on, or attended a childcare facility at the Pease Tradeport or Pease Air Force Base before June 2014. Efforts will be made to enroll at least 1,350 people in the Pease proof of concept study (e.g., 350 children 4-17 years of age and 1,000 adults 18 years of age and older). A small control group of approximately 100 adults and 175 children who were not exposed to PFAS-contaminated water at the Pease site will be recruited as well.

ATSDR's research protocol for the Pease proof of concept study was externally peer reviewed and currently is undergoing the OMB and Institutional Review Board approval processes. The health outcomes that will be analyzed in the study will include measurements of PFAS as well as extensive health biomarkers of lipid, cardiovascular, liver, kidney, thyroid, glycemic, and immune functions. The children's component of the study will include an evaluation of neurobehavioral parameters. The results from the Pease proof of concept study will be compiled into a database that will be used to achieve the overall goal of the multi-site PFAS health study to analyze health outcomes related to PFAS exposures from contaminated drinking water.

PHASE 2: MULTI-SITE PFAS HEALTH STUDY

ATSDR will conduct the multi-site PFAS health study at eight DoD sites that were impacted by PFAS-contaminated drinking water from both public and private wells. The cross-sectional study design will include multiple locations and separate evaluations of children 4-17 years of age and adults 18 years of age and older. The following criteria will be considered for the sites that are included in the multi-site PFAS health study:

- Documented past or present PFAS drinking water concentrations at the tap that are above the current EPA lifetime health advisory for PFOS/PFOA (i.e., 70 parts per trillion) or PFAS serum biomonitoring results indicating levels above the NHANES serum levels for PFOS and/or PFHxS
- Data on drinking water systems or private wells at the site
- Data on the size and sampling frame of the study population
- Human biomonitoring data on PFAS from previous studies

Based on a review of the scientific literature to determine health outcomes of interest, ATSDR estimates that the sample size of the multi-site PFAS health study will include 8,000 participants in total (e.g., 2,000 children and 6,000 adults). The study participants will be categorized as "referent/low," "medium," or "high" based on measured or modeled serum concentration levels of PFAS compounds. The study will be designed to collect and analyze multiple data endpoints in the following categories.

Health Outcomes

Children and Adults

- Lipids
- Cardiovascular
- Kidney function/disease
- Liver function/disease
- Thyroid
- Immune function

Children Only
- Sex hormones/maturation
- Neurobehavioral
- Vaccine response

Adults Only
- Osteoarthritis/osteoporosis
- Endometriosis
- Autoimmune disease

Biomarkers
- Total cholesterol, low-/high-density lipoprotein, and total triglycerides
- Uric acid and creatinine
- Thyroxine and thyroid-stimulating hormone
- Glucose, insulin, glycosylated hemoglobin, auto-antibodies, C-peptide, and pro-insulin
- Alanine transaminase, γ-glutamyltransferase, direct bilirubin, and cytokeratin-18
- Immunoglobulin A, E, G, and M
- Testosterone, estradiol, sex hormone-binding globulin, follicle-stimulating hormone, and insulin-like growth factor
- Cytokines and adipokines

Questionnaire Data
- Demographics
- Water consumption and residential history
- Medical history and family history of disease
- Occupational history[1]
- Reproductive history in women

Neurobehavioral Testing of Children
- Wechsler Abbreviated Scale of Intelligence
- NEPSY-II® (core tests only)
- Connors' Kiddie Continuous Performance Test
- Strengths and Difficulties Questionnaire (administered to parents)
- Behavior Rating Inventory of Executive Function (administered to parents)

ATSDR will conduct a historical reconstruction of serum PFAS concentrations by using water contamination data to estimate the half-lives and elimination rates of this compound to inform physiologically-based pharmacokinetic (PBPK) modeling. This approach will enable evaluations of exposure lags and vulnerable periods as well as statistical analyses that can be controlled for reverse causations. At Pease and other sites with previous biomonitoring data, children and adult studies might be used to evaluate changes in PFAS concentrations over time.

Dr. Pavuk concluded his presentation by asking the BSC to provide guidance on the Pease proof of concept study and the multi-site PFAS health study in response to four key questions.

1. Are the methods and general approach of the PFAS health studies appropriate?

[1]Responses to the occupational history question will be used to exclude firefighters who used AFFF and workers who were involved in the production or use of PFAS compounds.

2. Should any additional health outcomes be analyzed in the PFAS health studies?
3. Are the proposed neurobehavioral tests appropriate? Should any other tests be included?
4. Does the BSC have recommendations on prioritizing any particular measurements or tests if funding is not available to conduct all of the proposed analyses?

BSC DISCUSSION: PFAS HEALTH STUDIES

Dr. Pavuk provided additional details on the following topics in response to specific questions by the BSC members.

- ATSDR's plans and specific mechanisms to report the results of the Pease proof of concept study to the participants.
- The degree of uncertainty in ATSDR's PBPK modeling of historically reconstructed serum levels of PFAS and whether these estimates have been subject to external peer review.
- Specific data sources that ATSDR will use to historically reconstruct serum levels of PFAS in children and adults.

BSC GUIDANCE

The BSC commended ATSDR for proposing the PFAS health studies with a solid design, a thoughtful approach, and a rigorous methodology. Several BSC members provided guidance to enhance and strengthen the the PFAS health studies in response to some of ATSDR's key questions.

Question 1: Methods/General Approach

- ATSDR will implement the PFAS health studies with a cross-sectional design. At the time of recruitment, ATSDR should ask the participants about their willingness to be contacted in the future in the event that cohort investigations are conducted.

Question 2: Additional Health Outcomes

- Evidence increasingly is being documented in the literature on the association between prenatal effects of exposures to environmental chemicals and the risk for disease in adults. ATSDR should use this emerging body of research as an opportunity to explore prenatal exposures *in utero*. Most notably, analyses of this health outcome would serve as a powerful addition to the design of the PFAS health studies. To support this effort, ATSDR should intentionally recruit, select, and include pregnant women in the studies. ATSDR also should take action on the BSC's strong recommendation to focus on other indicators of reproduction beyond hormones. These analyses can be performed by collecting sperm samples from the male study participants. Moreover, ATSDR should expand the data collection questionnaire to gather additional information on the time to pregnancy and difficulties with infertility (i.e., the number of unsuccessful attempts to become pregnant).
- Cancer malignancies should be included as an additional health outcome to analyze in the PFAS health studies.

Question 3: Neurobehavioral Tests

- ATSDR will administer the core NEPSY-II® tests to children 4-17 years of age who are enrolled in the PFAS health studies. The core NEPSY-II® tests are shorter than the full set of neuropsychological tests in this series, but are still overly burdensome for children. As a result, ATSDR should further minimize the burden of the core NEPSY-II® tests by only administering the attention and executive function subtests. For example, technology allows children as young as four years of age to easily and fully complete the eight-minute

tests of the Cambridge Neuropsychological Test Automated Battery (CANTAB) within 90 minutes. Based on its design as an "iPad game," children have a high rate of completing the CANTAB. Moreover, ATSDR should only engage well-trained and experienced neuropsychologists due to the complex and difficult nature of administering the NEPSY-II® to young children.

Dr. Pavuk thanked the BSC for providing extremely helpful guidance for ATSDR to consider in its ongoing efforts to refine the overall approach, design, and methodology of the PFAS health studies. His responses to the BSC's input are summarized below.

- ATSDR is interested in expanding the cross-sectional design of the Pease proof of concept study to analyze other health outcomes in the full study population or a subset of the enrolled sample. However, ATSDR cannot support additional study designs, such as cohort investigations, without additional funding.
- The BSC's current guidance is well aligned with the external peer review panel's previous recommendations for ATSDR to enroll pregnant women in the PFAS health studies to focus on *in utero* outcomes and effects. However, the input to establish separate cohorts of women and infants is far beyond the scope of the PFAS health studies and would not be feasible for ATSDR's proposed study design and approach. To address this issue, ATSDR has made strong efforts to apply recent research findings and develop the data collection questionnaire to capture as much information as possible on PFAS-related reproductive outcomes at the Pease site. Moreover, ATSDR is aware of approximately six different cohort studies that are underway with pregnant women to focus on PFAS exposures *in utero*. ATSDR plans to identify collaborative opportunities to integrate its PFAS health studies with the external PFAS cohort studies. Dr. Breysse added that ATSDR has initiated discussions to explore the possibility of using NIEHS's existing risk cohorts and forming an interagency collaboration to focus on PFAS-related reproductive outcomes in the future.
- ATSDR welcomes the opportunity to take action on the BSC's suggestion to include cancer malignancies as an additional health outcome in the PFAS health studies. However, the enrolled sample will not have sufficient size and power to analyze cancers that have been linked to PFAS, such as testicular, kidney, and pancreatic cancers. To address this issue, ATSDR is exploring the possibility of replicating the Camp Lejeune model for the PFAS health studies by leveraging existing cancer registry data for DoD sites.
- The BSC noted that the core NEPSY-II® tests are shorter than the full series, but will still be overly burdensome for children 4-17 years of age. ATSDR agrees with the BSC's input and might shorten the timeframe of the neurological testing component of the PFAS health studies to decrease the burden. Most notably, ATSDR is continuing its rigorous review of this issue to provide OMB with fairly precise estimates on the feasibility and burden of collecting data from young children. ATSDR also agrees with the BSC's other suggestion on the neurological testing component of the PFAS health studies. ATSDR will include specific language in its notice of a new contract to ensure that highly qualified, educated, and experienced clinical psychologists submit proposals to administer the core NEPSY-II® tests.

DLS's Biomonitoring of PFAS in Children

Antonia Calafat, PhD
Chief, Organic Analytical Toxicology Branch
NCEH Division of Laboratory Sciences
Centers for Disease Control and Prevention

Dr. Calafat presented an overview of DLS's biomonitoring of PFAS in children. Exposures that influence children's health begin before conception and continue through adolescence. Exposures during childhood might affect health later in life, but limited data have been generated on exposures among young children.

PFAS is a family of chemicals that have been produced since the 1950s. Important changes in the manufacture of PFAS were introduced in the 2000s. PFAS persist in the environment, but a number of these chemicals also are persistent in humans. Human exposure to PFAS is widespread because of the presence of these chemicals in industrial and consumer products, diet, dust, and contaminated drinking water. Evidence is documented in the literature that shows associations between PFAS and select adverse health effects in humans.

DLS has a long history of using NHANES data to better understand and determine the specific factors that affect exposure to PFAS in the general population. Most notably, DLS published its first methods paper on PFAS in 2004. From the 1999-2000 to the 2013-2014 NHANES cycles, DLS has analyzed thousands of serum samples from NHANES participants to measure several short- and long-alkyl chains PFAS. For 2013-2014 NHANES, PFOS and PFOA were measured as isomers.

DLS's data showed that changes in manufacturing practices after 2003 contributed to significant declines in concentrations of certain PFAS. For example, the geometric mean of PFOS concentrations has decreased by 83 percent since the 1999-2000 NHANES cycle (or from approximately 30 to approximately 5 parts per billion). However, the reduction in the geometric mean of PFOA concentrations has not been as dramatic over the course of the NHANES cycles because this chemical was produced for a much longer period of time than PFOS. Moreover, the geometric mean of PFHxS concentrations has had the smallest decrease of these three PFAS chemicals, partly because of the longer half-life of PFHxS in the body.

DLS recognizes the relevance of PFAS data in children because of the critical need to gather data that are representative of the pediatric population in the United States. Most notably, children are not "small adults." PFAS data previously were collected only for adolescents and adults 12 years of age and older as part of NHANES. Moreover, the volume of blood serum for NHANES children under 12 years of age was extremely limited. As a result, no NHANES data on PFAS exposures in children were available to compare with concentrations of PFAS-contaminated water at the Pease, New Hampshire site in the pediatric population.

DLS developed the first nationally representative sample of PFAS exposures in children based on a random sub-sample of children 3-11 years of age (of approximately 33 percent of children within this age range in the 2013-2014 NHANES cycle). DLS filled the gaps in PFAS data on children by using 639 NHANES serum samples that previously were analyzed to measure cotinine levels in children 3-11 years of age. The demographics of the NHANES cohort included children in the 3-5 and 6-11 age groups with breakdowns by sex and race/ethnicity (e.g., Hispanics and non-Hispanics). Higher concentrations of certain PFAS in non-Hispanics than in Hispanics likely

were associated to a variety of factors, such as specific exposure pathways, socioeconomic status, and lifestyle.

DLS's rigorous study methods were designed to quantify 14 PFAS biomarkers using isotope dilution mass spectrometry. The limit of detection was 0.1 ng/mL for all PFAS chemicals. The statistical analyses used NHANES sampling weights to determine descriptive statistics for each biomarker. Geometric means were calculated only for PFAS chemicals detected in more than 60 percent of the samples. The multivariable linear regression models included the children's age group, sex, race/ethnicity, and either body mass index or household income.

DLS's study showed widespread exposure to several PFAS chemicals among children 3-11 years of age. The four major PFAS chemicals that are most frequently detected and have the highest concentrations (e.g., PFHxS, PFOS, PFOA, and PFNA) were detected in all samples. Other PFAS chemicals were detected less frequently at a range from 0-53 percent. Based on serum concentrations from 2013-2014 NHANES, geometric means and 95th percentiles of the four major PFAS chemicals were relatively stable or increased with age in the age groups of 3-5, 6-11, 12-19, and 20 years and older.

To strengthen the rigor and power of its study, DLS compared data on children 3-11 years of age from the 2013-2014 NHANES cycle with the findings of eight other studies that also measured PFOS, PFOA, PFHxS, and PFNA in children's blood. The eight children's studies covered various project periods (ranging from 1994-2010) and focused on multiple age groups of children (ranging from 0-18 years of age). Moreover, the eight children's studies were conducted in diverse jurisdictions across the country, including Boston, California, Cincinnati, San Francisco, and Texas. DLS's cross-study analysis showed that background exposures of PFOS, PFOA, PFHxS, and PFNA occurred in young Americans.

Overall, DLS's collection and analyses of NHANES data demonstrated that this tremendous and powerful dataset can provide valuable information on ongoing exposures in the U.S. population to select environmental chemicals, including PFAS. Although the NHANES study design could not address all public health issues, DLS's biomonitoring of NHANES data supported and contributed to public health. Different studies and research approaches are needed, but DLS will continue to use NHANES data as a key resource to identify additional biomarkers of PFAS.

DLS used NHANES data to develop the first nationally representative dataset of baseline exposures to PFAS in young children 3-11 years of age. This dataset will be extremely useful in identifying whether exposures in other populations are higher or lower than background exposures. DLS's study showed that exposure to PFAS is still ongoing and concentrations of PFAS are similar among adults, adolescents, and children, including children who were born after changes were made to PFAS manufacturing practices in the early 2000s. DLS observed differences in PFAS concentrations by sex, race/ethnicity, and age. These factors will play a role in identifying sources of exposure and emphasizing the important need to support future studies that focus on the environmental fate and transport of PFAS chemicals.

Dr. Calafat reminded the BSC that during the November 2017 meeting, she presented an overview of DLS's efforts to develop biomonitoring methods for new classes of pesticides. She provided an update on these activities. DLS has completed analyses of 3,050 samples from NHANES 2015-2016 for six neonicotinoid biomarkers (e.g., four parent compounds and two metabolites). These analyses included NHANES data on children three years of age and older.

DLS currently is in the final stages of the quality assurance (QA)/quality control process related to the biomonitoring methods for this new class of pesticides. DLS expects to report the NHANES data to the CDC National Center for Health Statistics (NCHS) by July 30, 2018. DLS also has been drafting and revising a paper to provide a detailed description of the methodology that was used to analyze the NHANES samples. DLS anticipates submitting the paper to the CDC clearance process by July 30, 2018.

DLS's data have clearly shown that for the six neonicotinoid biomarkers, emphasis should be placed on the metabolites rather than the parent compounds. Most notably, the non-detection of the parent compounds suggests that the parent compounds might not be adequate biomarkers for background exposures. After CDC clears these data for release to the public, DLS will be in a better position to determine potential public health actions for these chemicals.

DLS found that several new methods proposed and evaluated to measure glyphosate biomarkers and six dialkylphosphates were not sufficiently stable or robust. If ongoing efforts are not successful to correct these problems, DLS will terminate this area of research in early July 2018 and will advance to developing a method only for glyphosate (without the dialkylphosphates). DLS already has obtained approval from NCHS to measure glyphosate in NHANES samples. DLS will publish its biomonitoring methods and results from analyses of the NHANES samples in peer-reviewed journals.

BSC DISCUSSION: BIOMONITORING OF PFAS IN CHILDREN

Dr. Calafat provided additional details on the following topics in response to specific questions by the BSC members.

- The current capabilities and expertise of other laboratories to produce accurate measurements of PFAS.
- The extent to which DLS will be able to rely on other laboratories to meet the increased demand for biomonitoring of PFAS in children.
- The possibility of using DLS's study with NHANES data to pilot new research with sufficient rigor and power to detect diseases or health effects from PFAS exposures in children.
- Emerging PFAS chemicals, such as GenX, that DLS currently is measuring in urine samples from NHANES.

BSC GUIDANCE

The BSC emphasized the critical importance of the NHANES biomonitoring repository. The BSC also commended DLS on its well-designed approach of using residual serum samples from NHANES to determine exposures to PFAS in young children.

Ms. Witherspoon announced the release of several studies by the National Institutes of Health (NIH) that reported adverse health effects from PFAS exposures in infants, including low birth weight and reduced vaccine response. She was pleased that DLS used NHANES data to develop the first nationally representative dataset of PFAS exposures in children 3-11 years of age. However, she advised DLS to also use the NIH studies to inform future research in this area on infants.

Public Comment Period

Dr. Cibulas read the following comment into the public record that was submitted in writing by an unidentified member of the public.

"The fact is that we need standardization because the hurricane that just damaged is going to happen more and more frequently. The projections for climate change certainly include ever increasing violent storms, so your lingering over this last one for ages doesn't at all prepare you for the next one, which will come very soon. Clearly, we are in the age of frequent storms and failing to have a procedural manual doesn't help the United States at all."

Use of Citizen Science for Assessment of Health Risks

LT Brad Goodwin, PhD
Scientist Officer, ATSDR/DCHI

Dr. Goodwin presented an overview of ATSDR's new Citizen Science Project. ATSDR defines "citizen science" as scientific activities that are conducted by members of the general public in collaboration or association with ATSDR's trained scientists as a federal partner. ATSDR's role in citizen science is to provide guidance and use data that are generated by citizen scientists to identify actions to protect public health.

Citizen science provides an opportunity for citizen scientists to support ATSDR's site-specific activities, including PHAs, PHCs, EIs, health education, community involvement/engagement activities, and recommendations to protect public health. Most notably, citizen scientists can provide leadership in collecting and interpreting data and engaging community members in the assessment process.

ATSDR's EIs are designed to collect data in communities. Environmental data are gathered to monitor air, water, and soil. Biological monitoring is conducted to detect concentrations of contaminants in blood, hair, and urine. The key goals of EIs are to address health concerns; determine whether people are being exposed to hazardous materials at concentrations that might harm their health; identify and fill data gaps with the collection of biased samples; and determine actions to protect public health.

The major challenges associated with EIs include time-consuming, resource-intensive data collection efforts. From receiving a request from the community and reporting the findings, for example, one year is the average timeframe for ATSDR to complete an EI. Moreover, extensive resources are needed for ATSDR to deploy staff to the field and establish monitoring capabilities.

ATSDR is conducting a technology evaluation to identify the advantages and disadvantages of using low-cost sensors to support citizen science. On the one hand, the cost of low-cost air quality sensors can range from $200-$300, while the price of ATSDR's state-of-the-art equipment exceeds $10,000. These instruments are capable of identifying "hot spots" in distributed monitoring networks and generating valuable information for the overall assessment process. Low-cost sensors also provide an opportunity for communities to develop resources by assisting external groups in designing and implementing projects independently.

On the other hand, ATSDR is concerned about data quality issues with these new technologies. Due to the lower level of precision and accuracy, low-cost sensors can only be used for select contaminants or media only. Moreover, the extent to which low-cost sensors can produce data that are acceptable for public health decision-making is still uncertain.

ATSDR will soon launch a new "Low-Cost Sensor Project" within the Citizen Science Project. The goals of this initiative are three-fold. First, community members will be engaged in environmental sampling activities to build trust and provide perspectives on their exposures in real-time. Second, commercially available, low-cost sensors will be utilized. Third, various tools will be developed to support environmental sampling in three areas: (1) guidance on the selection of sensors and project design; (2) training materials on the deployment, operation, and maintenance of sensors; and (3) data processing and visualization tools to facilitate rapid turnaround times for data analyses and communication of results.

The potential users of low-cost sensors are diverse. For example, ATSDR can use these instruments for screening purposes and EIs. State/local health departments and community groups also can use low-cost sensors for data collection. For example, ATSDR recently received a petition request to conduct an EI from a community near an asphalt plant and a gravel quarry, but no data were available at this site to identify potential health effects. To address this issue, the community could use low-cost sensors and submit the data to ATSDR for review and consideration. Alternatively, ATSDR could minimize its resources at the outset by using low-cost sensors to conduct initial screening and generate baseline data in the community. ATSDR could then use these data to decide whether a larger investment of staff and resources is warranted at the site.

ATSDR will pilot the Low-Cost Sensor Project with particulate matter sensors in air. ATSDR agreed to take this approach because particulate monitors are commercially available, further along in their development, and easy to use. The processes and tools that are developed for particulate matter monitoring over the course of the three-year pilot project will be applied to other media and contaminants in the future.

ATSDR will provide citizen scientists with extensive guidance on ambient air sampling and data collection of particulate matter. The EPA *Air Sensor Guidebook* will be distributed to provide a framework on designing a citizen science air monitoring project and identify performance requirements for multiple data uses, including regulatory purposes, communications, and increased awareness. ATSDR will establish performance requirements for public health decision-making and also will evaluate and compare co-located monitoring data from current reference methods and data from low-cost sensors.

ATSDR will conduct a literature review to identify existing monitors that meet its established performance criteria. Meteorological monitoring equipment will be included in this effort to account for potential interferences, such as relative humidity. ATSDR will initiate the instrument testing process by purchasing low-cost particulate monitors and deploying these sensors alongside equipment that traditionally is used in EIs. An evaluation will be performed to compare the ease of using low-cost versus state-of-the-art technologies and also to assess the quality of the data collected. ATSDR will use the instrument testing process as an opportunity to address three key challenges, including data quality, specific training needs for community members to operate the low-cost sensors, and the potential to produce compromised results (e.g., intentional efforts to generate high or low measurements).

ATSDR will incorporate a comprehensive data analysis component into the instrument testing process. Automated scripts will be developed to perform QA tests on the data and generate warnings if the QA tests fail. Data visualization products, including simple graphics, will be designed to present the results and provide a context for the data. Data will be displayed with health-based standards, health comparison values, and data from other locations in United States. An electronic one-page fact sheet will be generated to clearly explain the meaning of the monitoring results to the community. The fact sheet will provide a straightforward answer to the question that is of most interest to impacted communities: "Could this exposure harm my health?"

ATSDR will launch the community training component by clearly articulating the goals, outputs, and limitations of the pilot project. Materials will be developed and distributed to train community members on installing, operating, and downloading data from the low-cost sensors. The format of the training will be a one-hour distance learning course.

ATSDR has established several key objectives and outcomes for the pilot of the Low-Cost Sensor Project. Community members will install and operate the low-cost sensors, while ATSDR professional staff will operate its standard instruments to collect data for an EI. Professional staff in the field also will directly observe the installation and operation of the low-cost sensors by community members to ensure adherence to ATSDR's training procedures. Testing during the EI will focus on monitoring of training, downloads of data, and dissemination of communication tools.

An evaluation will be performed to determine whether (1) the results from the low-cost sensors were provided to the community in a timely manner and (2) the data were sufficient to inform community members of the meaning of the results in terms of their individual health. A follow-up questionnaire will be administered to community members with several focused questions, such as "How difficult was it for you to use the monitor?" "What was your overall experience?" "How useful was the information you received?" ATSDR will measure the success of the pilot project by comparing data from the low-cost sensors and standard monitors and reviewing feedback on the community questionnaire regarding the ease of using these instruments.

The findings of the Low-Cost Sensor Project potentially can be applied to several areas. ATSDR can use the data internally as a tool to screen sites and evaluate whether an additional investment of resources to support a full EI is warranted in the community. ATSDR, state/local health departments, or community groups can use the data externally to launch low-cost EIs to assess health effects. External groups can use the data to support community-initiated investigations of health concerns.

Overall, ATSDR expects to use data from its new Citizen Science Project to inform public health decision-making and disseminate health messages. Moreover, these data will provide community members with evidence-based information on making personal choices to reduce their environmental exposures and improve their health. Citizen science data also will provide community members with a clear answer on whether exposures detected at the site pose a health risk of concern.

Dr. Goodwin concluded his presentation by asking the BSC to provide guidance on ATSDR's Citizen Science Project in response to four key questions.

1. What are appropriate uses of citizen science data in the health assessment process?

2. What are the best strategies for ATSDR to engage communities that are interested in pursuing citizen science projects?
3. What additional resources could ATSDR leverage to help communities in applying citizen science?
4. What are potential limitations to this approach?

BSC DISCUSSION: ATSDR'S CITIZEN SCIENCE PROJECT

Dr. Goodwin provided additional details on the following topics in response to specific questions by the BSC members.

- The extent to which ATSDR will involve community members at the outset in the planning process of citizen science activities and the development of methods to interpret data.
- The feasibility of ATSDR actually determining whether the data and results from the low-cost sensors were provided to the community in a timely manner, particularly since multiple activities will be conducted at different timeframes over the course of the three-year pilot project.
- The availability of citizen science guidance and tools to state/local health departments and community groups that do not submit a petition to request ATSDR's assistance at a site.

BSC GUIDANCE

The BSC expressed a great deal of enthusiasm and support for ATSDR's new, robust Citizen Science Project. The BSC agreed that EIs are the appropriate product for ATSDR to launch this initiative. Because the project is still in the early stages of development, several members asked ATSDR to present periodic updates to report the ongoing progress. The BSC also provided guidance on the Citizen Science Project in response to ATSDR's four key questions.

Question 1: Appropriate Uses of Citizen Science Data

- ATSDR is launching its Citizen Science Project for the first time, but communities have been engaged in scientific assessments since the 1980s. To inform its ongoing efforts to refine the methodology and approach of the Citizen Science Project, ATSDR should review key lessons learned from these historical efforts and conduct a more extensive literature review.
- NIEHS has been a leader at the federal level in allocating funding to support community-based participatory research (CBPR), but major challenges arose in conducting EIs and analyzing biomarkers with a CBPR approach. Most notably, NIEHS was required to report the results of its funded CBPR projects to families and individual community members without causing confusion or undue concern. In some cases, however, NIEHS had no or limited knowledge of the level of harm from exposures to particular contaminants. ATSDR should explore whether NIEHS's key findings or experiences in addressing these types of issues in its funded CBPR projects can be applied to the Citizen Science Project.
- ATSDR should use its Citizen Science Project to play an important arbitration or mediation role by resolving mistrust between the community and the principle responsible party for the exposure at the site or state government agencies that appear to support industry.

Question 2: Community Engagement

- ATSDR did not identify any particular sites or groups that will be recruited to participate in the pilot of the Low-Cost Sensor Project. The BSC members made three key suggestions for ATSDR to consider in this regard.

- Students from high schools and colleges who are interested or majoring in science should be engaged in the three-year pilot project to perform ambient air monitoring of particulate matter with low-cost sensors.
- EPA has conducted numerous activities with the six Federally Recognized Tribes in Region IV, including the state of Georgia, on appropriately utilizing traditional ecological knowledge (TEK) to inform projects that are conducted from a traditional Western science perspective. The Cherokee Nation and the Poarch Band of Creek Indians are two tribal recipients of EPA grants in Region IV that can serve as resources to provide ATSDR with the expertise of senior citizens in tribal communities. Most notably, tribal elders have an extremely high level of TEK and represent a close-knit community that lives in tribal housing on Indian reservations. ATSDR's use of tribal elders to pilot the Low-Cost Sensor Project likely will result in broad endorsement of the overall citizen science process, the collection of high-quality data, and the implementation of solid community-based research. Mr. McCullers offered to facilitate ATSDR's initial contact and communications with seniors in the Region IV tribes.
- The Low-Cost Sensor Project should be piloted at "non-controversial" sites. Most notably, ATSDR informed the BSC of its concerns regarding the bias, lower level of performance, and data quality issues associated with low-cost sensors. Due to instrumentation issues that are beyond ATSDR's control, every effort should be made to select communities with no additional site-specific issues. Instead, ATSDR should focus on gathering the data, comparing outputs between the community's low-cost sensors and ATSDR's standard air monitoring equipment, and applying lessons learned from the pilot.

Question 3: Additional Resources for Communities

- ATSDR should design and incorporate a workforce development component into the Citizen Science Project that will serve as a long-term, sustainable asset to communities. ATSDR's ability to provide community members, particularly youth, with a new skill set and training to utilize in other areas will be tremendously valuable. For example, citizen scientists can apply their new skills and training from ambient air monitoring of particulate matter to collect data to document the public health implications of compressor stations at sites across the country.
- ATSDR should inform communities that data collected by citizen scientists for EPA's multi-year CBPR project are available on the EPA.gov website. The website can serve as an extremely useful resource for ATSDR's citizen science sites. For example, the EPA.gov website provides links to the CBPR study protocols, interim and final progress reports, journal articles, and publications/presentations.

Question 4: Limitations to the Citizen Science Approach

- ATSDR should design a transparent process to manage community expectations at the outset. In addition to NIEHS, other public health agencies also faced challenges in conducting CBPR projects in the past. ATSDR should engage in candid discussions with its federal partners to compile lessons learned and ensure that problems from previous CBPR projects are not replicated in the Citizen Science Project. For example, ATSDR plans to clearly articulate the goals, outputs, and limitations of the pilot of the Low-Cost Sensor Project as part of the community training component. However, ATSDR should immediately communicate these aspects of the project after the citizen science sites are selected.

- ATSDR should develop effective strategies well in advance of piloting the Low-Cost Sensor Project to address potential problems with the citizen science approach.
    - Unintended consequences or potential harm of providing communities with scientific evidence collected by non-professionals with no training or expertise in air pollution science.
    - The need to establish rigorous, well defined, and transparent criteria to select the citizen science sites that will pilot ambient air monitoring of particulate matter.
    - Limited availability of ground-truthing monitors in most states when the Citizen Science Project is expanded in the future to include VOCs.
    - The need to coordinate citizen science activities with state regulatory agencies in addition to state health departments.
    - The need to identify appropriate comparison levels to evaluate short-term samples collected at the pilot sites instead of using long-term reference concentrations.

Dr. Goodwin confirmed that the BSC's guidance will be extremely helpful to ATSDR during its ongoing planning efforts to launch the three-year pilot of the Low-Cost Sensor Project. In response to the BSC's specific request, he also confirmed that he looked forward to presenting updates on this initiative during future meetings. In the interim, he made a number of comments in response to the BSC's input.

- ATSDR has initiated discussions with its colleagues at NIEHS on potential opportunities to collaborate on interagency citizen science activities. ATSDR also serves on the Federal Community of Practice on Crowdsourcing and Citizen Science. However, ATSDR is limiting the focus of its citizen science activities to environmental monitoring for EIs at this time. ATSDR has not developed an approach to address more complex issues that are associated with community members collecting biological samples.
- ATSDR will only include outdoor ambient air sampling of particulate matter in the pilot of the Low-Cost Sensor Project, but personal sampling might be incorporated when the Citizen Science Project is expanded in the future. However, ATSDR's expanded approach to include personal sampling will depend on the further development of citizen science tools as well as the small size and low cost of monitors.
- ATSDR has not yet developed a process or established criteria to identify sites that will participate in the pilot of the Low-Cost Sensor Project. In its initial discussions, ATSDR raised the possibility of selecting sites where air quality EIs currently are being conducted. If these sites are not appropriate candidates for the pilot project, however, ATSDR will consider the BSC's suggestions to engage high school/college science students and/or senior citizens in tribal communities.
- ATSDR agrees with the BSC's comments regarding the need to address mistrust between the community and state/local governments at some sites. As a federal agency, however, ATSDR cannot serve as an arbitrator or a mediator between two entities. Instead, ATSDR's role in citizen science is to apply its training and expertise to collaborate with the community. As a professional partner, ATSDR will provide the community with a sound rationale if the results of citizen science data differ and will not be used in an EI. For example, ATSDR will be open and transparent in its communications of any problems with the methods, type of instrument, or location of the community's ambient air monitoring of particulate matter. The community can then apply ATSDR's guidance to correct these issues.

Dr. Breysse acknowledged the BSC's guidance to ATSDR to address the limitations of the citizen science approach. He emphasized that ATSDR's Citizen Science Project ideally will increase the rigor and power of community-based environmental sampling and data collection efforts. He noted that community groups across the country are independently conducting environmental sampling with no training materials, tools, or expertise from skilled scientists.

For example, a community group in Pennsylvania that was concerned about hydraulic fracturing operations purchased approximately 100 low-cost sensors and placed the monitors on the front porches of homes throughout the state to perform particulate matter sampling. The community group requested ATSDR's technical expertise to interpret an overwhelming amount of data collected by the sensors (e.g., thousands of "measurement days" at a rate of one minute per measurement). In terms of the problems associated with commercially available low-cost sensors, Dr. Breysse pointed out that the development of newer technologies will improve their overall performance.

Dr. Breysse also noted the BSC's suggestions for ATSDR to apply the lessons learned and experiences from the CBPR projects conducted by its federal partners, particularly EPA and NIEHS. Although all three agencies focus on EH issues, their missions are different. ATSDR's role will be to collaborate with citizen scientists to provide more detailed data, interpret complex environmental sampling results, and inform community members on whether exposures detected at the site are harmful to their health. The Citizen Science Project likely will achieve these objectives because ATSDR scientists typically are deployed to a site to conduct an EI for a maximum of six weeks, but community members can use low-cost sensors to perform environmental sampling for multiple years.

With no further discussion or business brought before the BSC, Dr. Perry recessed the meeting at 3:39 p.m. on June 5, 2018.

June 6, 2018 Opening Session: Welcome-BSC Meeting Reconvenes

William Cibulas, Jr., PhD, MS
Acting Director, ATSDR/DTHHS
BSC DFO

Dr. Cibulas opened the floor for introductions and confirmed that the 17 voting members and *ex-officio* members in attendance constituted a quorum for the BSC to conduct its business on June 6, 2018. He reconvened the proceedings at 8:37 a.m. and welcomed the participants to day 2 of the BSC meeting.

Dr. Cibulas announced that BSC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters. None of the BSC voting members publicly disclosed conflicts of interest for any of the items on the June 6, 2018 published agenda.

Melissa Perry, ScD, MHS, BSC Chair
Professor and Chair of Environmental and Occupational Health
Professor of Epidemiology, Milken Institute School of Public Health
The George Washington University School of Medicine and Health Sciences

Dr. Perry also welcomed the participants to the second day of the BSC meeting. She announced that the BSC members agreed to forego their break in favor of adjourning the meeting earlier than the time on the published agenda. However, she confirmed that this change will not affect the scheduled time of the public comment period.

Statistical Inferences in Environmental Epidemiology

Chinaro Kennedy, DrPH, MPH
Senior Health Scientist, NCEH/ATSDR

Dr. Kennedy presented an overview of NCEH/ATSDR's efforts to improve the evaluation of scientific evidence collected from environmental epidemiological studies with small sample sizes. Scientists traditionally have relied on the p-value to determine the statistical significance of scientific evidence. However, the role of inferential statistics and its reliance on the use of p-value have been a topic of vigorous debate.

Arguments proposed by Greenland, *et al.* and the American Statistical Association (ASA) support the position of using multiple methods to judge evidence obtained from scientific data. Researchers have contended that the erroneous "overreliance" on the use of the p-value as a value tool to judge the "significance" or "non-significance" of scientific evidence might have potentially resulted in discounting important scientific information.

The overarching purpose of environmental epidemiology is to examine the probability that exposure to an environmental risk factor will result in the development of a disease or health condition. A sample of the entire target population is selected and findings from the sample are inferred to a larger population. Inferential statistics are used to examine the probabilities associated with exposure to a risk factor and develop outcomes. Statistical inference is applied to draw conclusions about a population based on findings from the sample.

Dr. Kennedy presented the graphic on the following page to illustrate the difference between the entire population versus the sample.

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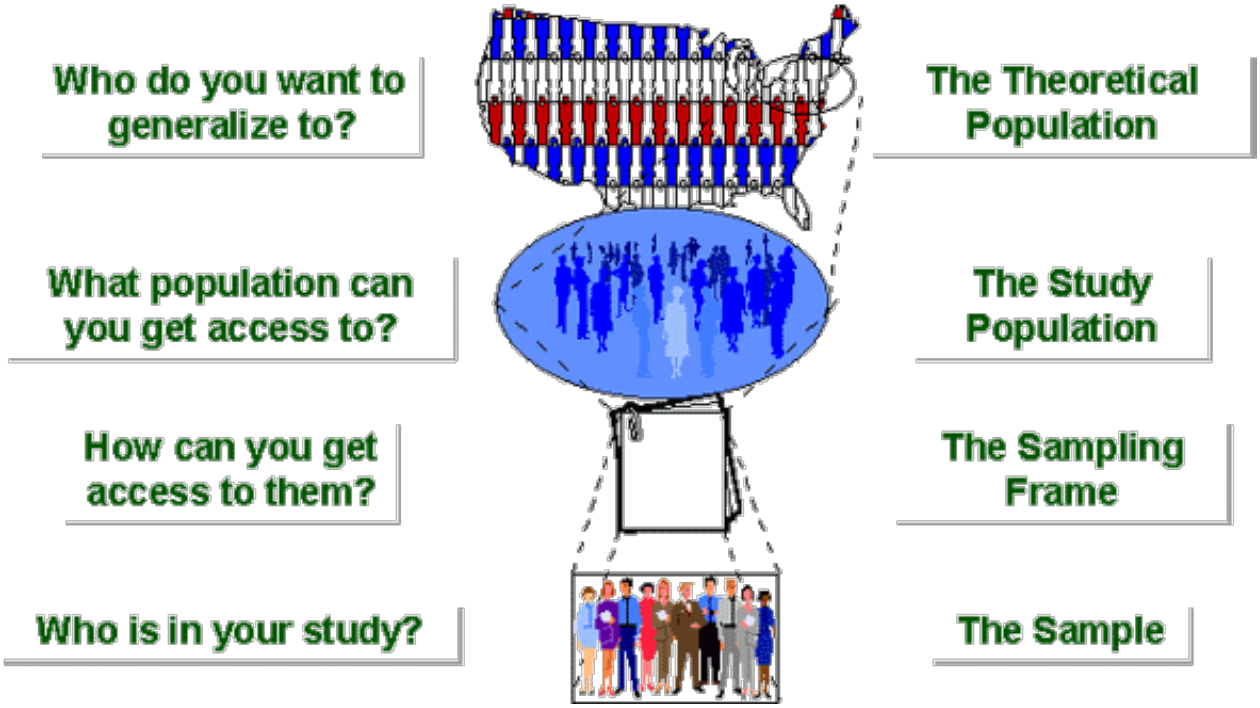

Inferential statistics and resultant statistical tests depend on complex assumptions that are embodied in a given statistical model and serve as the underpinning of the individual method. The model is intended to explain variability in the data if all of the assumptions have been met. However, statistical assumptions cannot be satisfied in all cases due to variability in the sampling methods and exposure assignment, loss or missing information, and violation of the model assumption. In many studies, particularly those that are non-experimental and non-randomized, the ability to satisfy random or independent assumptions is difficult. Moreover, the assumption of a specified association or effect often is hypothesized to be the null due to no difference between the exposed and unexposed groups.

The "study hypothesis" is the targeted assumption on the association or effect. The "statistical hypothesis test" is the statistical method that is used for evaluation. The goal of statistical hypothesis testing is to examine the certainty or uncertainty related to the association or effect. The association typically is hypothesized to be the null, while p-values are used to judge uncertainties.

The fixated use of a p-value ≤0.05 as a measure of statistical significance has been an ongoing topic of debate over time. On the one hand, proponents have argued that the p-value allows for an objective assessment of scientific research evidence. On the other hand, opponents have argued that various assumptions around a given statistical model cannot be wholly satisfied by data. As a result, reliance should not be placed on the p-value. The traditional definition of the "p-value" is the probability of observing differences between the exposed and unexposed samples if the null hypothesis is true. If the p-value is lower, the probability also is lower that chance alone can explain the difference in the sample if no differences are observed in the population.

A better function of the p-value is to determine whether the null hypothesis better explains the data versus an alternative hypothesis. A more contemporary interpretation of the p-value is its use as a statistical summary of compatibility between the observed data and predicted or

expected outcomes if all of the statistical assumptions used to compute the p-value were correct. Moreover, the p-value should indicate the degree to which data conform to a pattern predicted by the test hypothesis (established as the null) and underlying model assumptions. For example, a p-value of ≤0.05 suggests that data are not compatible to the test hypothesis of no difference between the two compared groups or the model assumptions. A p-value of >0.05 suggests that data are compatible to the test hypothesis of no difference between the two compared groups and the model assumptions.

The Bayes Factor should be used to determine whether the null hypothesis is a better explanation of the data compared to the alternative hypothesis. Most notably, one of the key advantages of the Bayes Factor is the ability to incorporate various uncertainties into the models, such as the absence of independent units or a random sample. However, the Bayes Factor is not typically used in environmental epidemiology due to its complexity and the need for a high level of statistical expertise to develop these types of models.

The 2016 Wasserstein and Lazar study reported several limitations of the use of p-value: (1) influenced by small sample size; (2) does not provide evidence of causation, measure the probability that the studied hypothesis is true, or measure the size of the effect or its importance; and (3) does not independently provide a sound measure of evidence regarding the model or hypothesis.

The ASA has proposed alternative approaches to shift from the traditional practice of relying on the p-value, such as using estimation (e.g., a 95 percent confidence interval) rather than testing, the Bayes Factor, and the likelihood ratio test. These alternative approaches also have statistical assumptions, but the methods have greater capacity to examine the effect and might be a better judge of the evidence rather than solely relying on the use of the p-value. NCEH/ATSDR has adopted some of the approaches proposed by the ASA.

The interpretation of statistical tests requires an analysis of the p-value in addition to examining the effect size and confidence intervals; examining the assumptions associated with developing the model and generating results; and evaluating multiple studies to understand the totality of the evidence and identify similar trends.

NCEH/ATSDR acknowledges that reporting environmental epidemiological results to stakeholders is one of the key challenges in using statistical approaches other than the p-value. Although an EH study might be conducted with a rigorous design and methodology, for example, the sample size might be small due to a rare exposure, health outcome, or condition that involves only two cases. Moreover, the data might show an association that is “non-statistically significant.” The traditional knowledge of the p-value and its use pose challenges because these types of findings often are overlooked.

For example, NCEH/ATSDR conducted a case-control study to investigate an association between exposure to an environmental risk factor and the development of two health conditions. The two findings of the study were (1) an odds ratio of 3.78 with the 95 percent confidence interval ranging from 0.99-4.63 and (2) an odds ratio of 1.56 with the 95 percent confidence interval ranging from 0.80-2.50. On the one hand, the first result might be considered to be more meaningful due to the larger effect size and the narrower confidence interval. On the other hand, an argument could be made that both of the results are meaningful.

Overall, NCEH/ATSDR is challenged by, and is requesting the BSC's guidance on, identifying the most effective approach to convey both results to the community. Most notably, NCEH/ATSDR is interested in resolving the ongoing discussion and debate regarding the appropriate time to depend on p-value. For example, the primary role of the p-value is not an issue in randomized, double-blind clinical trials with random allocations of treatment and equal disbursements of confounders between the treatment and placebo groups.

For NCEH/ATSDR's purposes, however, the major role of the p-value is debatable because EH studies typically do not have a large sample size from a defined target population. Although NCEH/ATSDR's well-designed EH studies often generate non-statistically significant p-values, the findings could show elevated risks from rare environmental exposures and health outcomes. Moreover, NCEH/ATSDR's EH studies are implemented with a thoughtful design and a high degree of transparency, but the methods and assumptions might not be satisfactory due to the small sample size.

Dr. Kennedy concluded her presentation by asking the BSC to provide guidance to NCEH/ATSDR in response to two key questions.

1. Does the BSC agree with the approach that NCEH/ATSDR presented regarding alternate approaches to the use of the p-value in judging scientific evidence?
2. What other approaches can be used to present findings to the community when the effect size is greater than 1.0, but the p-value is >0.05?

BSC DISCUSSION: STATISTICAL INFERENCES IN ENVIRONMENTAL EPIDEMIOLOGY

Dr. Perry requested additional details on the epidemiologists, biostatisticians, and other members of the NCEH/ATSDR team who are making efforts to improve statistical inferences in environmental epidemiology and external experts in the broader scientific community who are providing advice to NCEH/ATSDR to reach consensus on this issue.

Dr. Kennedy explained that since December 2017, she has been leading an excellent workgroup of NCEH/ATSDR epidemiologists and statisticians. The six subject-matter experts on the workgroup are developing a statistical guidance document to assist NCEH/ATSDR scientists in better presenting and explaining their data without relying on the p-value due to the limitations of small sample sizes. Dr. Kenneth Rothman was one of the lead authors of the 2016 published paper, *Statistical Tests, P Values, Confidence Intervals, and Power: A Guide to Misinterpretations*. He has been invited to make a presentation to the NCEH/ATSDR workgroup.

The BSC went on record with its formal support of NCEH/ATSDR's efforts to advance beyond the confines and familiarity of using the p-value as the sole metric to judge scientific evidence. Several BSC members provided guidance for the NCEH/ATSDR workgroup to consider while developing the new statistical guidance document for environmental epidemiology.

- The NCEH/ATSDR workgroup will benefit from Dr. Rothman's presentation, but the members of the team also should take advantage of external training opportunities. For example, the Society for Epidemiologic Research and the American College of Epidemiology convene workshops. Other groups also convene workshops on causal inferences at various locations across the country.
- The BSC members offered different perspectives on designing studies with statistical inferences.

    - Dr. Grant advised NCEH/ATSDR to take caution in designing a study from a biased perspective in which the data might show harm. The use of different statistical tests in observational studies is a "dangerous" approach because observational studies cannot show causation. NCEH/ATSDR's use of alternative approaches other than the p-value should include a clear disclaimer that statistical tests should be applied in certain cases only. This strategy will be important because NCEH/ATSDR's statistical methodologies potentially could be misused by others in the scientific community.
    - Dr. Lunn explained that a group of observational studies actually can show causation. For example, the International Agency for Research on Cancer used observational studies to identify most of the known human carcinogens, including smoking.
- Statistical significance plays an important role environmental epidemiology, but NCEH/ATSDR also should analyze other factors in its studies, such as meaningful patterns, biology, and subgroups.
- The statistical guidance document that the NCEH/ATSDR workgroup is developing should advise scientists to apply solid risk communication skills while maintaining rigorous scientific integrity. For example, "insignificant" findings typically are not documented in the literature, but a finding of "no effect" also is an important outcome that should be conveyed to stakeholders.
- The NCEH/ATSDR workgroup should develop the statistical guidance document in close consultation with clinical experts. Most notably, clinicians have experience in disease processes and extensive expertise in applying Bayesian networks in clinical practice, communicating probabilities, and addressing biases. Clinicians also must make risk management decisions for their patients when confidence intervals overlap one, effect sizes are large, and sample sizes are small. Dr. Bernstein offered to provide Dr. Kennedy with contact information for his clinical colleagues who have statistical expertise and can serve as a resource to the NCEH/ATSDR workgroup.

Dr. Breysse clarified that NCEH/ATSDR's proposal is not intended to establish a new statistical foundation. Instead, NCEH/ATSDR's goal is to apply appropriate statistical approaches based on recommendations by ASA and other experts in the field. He added that NCEH/ATSDR's new statistical guidance document will serve as a consistent statistical approach for scientists to convey findings of environmental epidemiological studies with small sample sizes.

NCEH/ATSDR Activities with Tribes and Tribal Programs

Donata Green, PhD, MA
Public Health Analyst
NCEH/ATSDR Office of Policy, Planning and Partnership

Dr. Green presented an overview of NCEH/ATSDR's activities in Indian Country. NCEH/ATSDR has established tribal priorities and goals in four major areas. First, clean water initiatives will be continued across Indian Country. Second, collaborations will be established with tribes to address community EH concerns, identify gaps, and respond to unmet EH needs. Training, TA, and other support will be provided to state, local, and tribal health. Staff will be trained to improve understanding of the best approaches to collaborate with and support tribal communities.

The four primary activities that NCEH/ATSDR conducts to support tribal communities are highlighted below.

SITE-SPECIFIC ACTIVITIES TO EVALUATE POTENTIALS HAZARDS

ATSDR performs site assessments and consultations to evaluate potential hazards at the request of communities. ATSDR's assessments on tribal lands include the Native Village of Savoonga on the Northeast Cape in St. Lawrence Island, Alaska. This military site conducted surveillance and other communications activities from the 1950s to the 1970s. The dwellings are still being used for subsistence hunting, fishing, and gathering, but in the summer months only.

The villagers and other residents have expressed a strong interest in making the seasonal dwellings year-round communities. However, concerns were raised regarding the military's use of certain chemicals (e.g., exposures to polycyclic aromatic hydrocarbons, polychlorinated biphenyls (PCBs), and other pesticides) and their effect on cancer and birth defects. The consumption of fish, grains, and berries as well as the use of soil and surface water in the Northeast Cape were identified as exposure pathways.

ATSDR and the Alaska Department of Public Health coordinated efforts to review data from cancer and birth defects registries. The data review showed that the types of cancers maintained in the registry were not related to the types of chemicals formerly used at the site. Moreover, the rate of birth defects at the site were similar to other areas without these chemical exposures.

ATSDR also conducted a site assessment at the Jackpile-Paguate Uranium Mine in Cibola County, New Mexico. Uranium mining was conducted for approximately 30 years at the site. Of nearly 8,000 acres that were leased, approximately 33 percent were used for mining. The residents raised concerns regarding exposures to uranium and other harmful chemicals. ATSDR's site assessment showed that nearby residents were unlikely to be harmed by current exposures to radiation if their homes were tested and radon abatement systems were properly installed and operated. ATSDR disseminated an advisory with four simple messages to the residents: "Stay away from the mines." "Do not use plant soils, rocks, sand, or water from the mines." "Get proper testing for radiation or radon." "Use public water for drinking rather than private water systems."

ATSDR released a PHC for public comment in November 2017 and held a public availability session in March 2018 to present the results of the site assessment to tribal leaders and community members at the Jackpile-Paguate Uranium Mine site.

COLLABORATIVE RESEARCH AND STUDIES WITH TRIBES

NCEH/ATSDR conducted the prospective Navajo Birth Cohort Study (NBCS) that involved environmental uranium exposure in the Navajo Nation. The study population included over 780 pregnant women and 740 infants. The NBCS was conducted in collaboration with NCEH/ATSDR, the University of New Mexico (UNM), the Navajo Area Indian Health Service, and the Navajo Nation Department of Health. Enrollment of the study population concluded in 2017.

Several programmatic activities were conducted to support the NBCS, such as monthly "Radiation 101" workshops that were offered to the communities in both English and Navajo. In response to a Congressional request in 2007, five agencies formed the "Cross-Federal Workgroup to Address Impacts of Uranium Contamination in the Navajo Nation." The 2008-2012 plan outlined a strategy to better understand and address exposures to uranium. The development of the 2014-2018 plan is underway and will implement concrete action steps to address exposures to uranium, such as

home remediation and increased water infrastructure in mining areas. UNM will conduct one-year follow-up assessments of the NBCS participants and present the results to the Navajo Nation communities.

EH PROGRAMS AND INITIATIVES IN COLLABORATION WITH TRIBAL COMMUNITIES

NCEH/ATSDR implemented the "Climate Ready Tribes Initiative" in 2016 to address climate and health issues faced by indigenous peoples. NCEH/ATSDR is partnering with the National Indian Health Board to provide funding and TA to tribes (e.g., the Blackfeet Nation and the Swinomish Indian Tribal Community) to plan for the potential effects of climate change. NCEH/ATSDR also is collaborating with the Navajo Nation in its Brownfield/Reuse Health Program to redevelop a parcel of land and create a crafts village.

NCEH/ATSDR convened an EH summit in the state of Washington in January 2018 with 88 participants, including tribal elders and tribal/non-tribal public health professionals. The participants represented 17 tribes throughout the state. The key discussion topics of the summit included safe drinking water, the built environment, and food safety.

LABORATORY SUPPORT TO TRIBAL COMMUNITIES

NCEH/DLS provides biomonitoring measurements for collaborator-led studies of exposures to environmental chemicals among tribal groups. For the NBCS, for example, DLS played an instrumental role in analyzing 36 metals and compounds in blood and urine specimens.

The Alaska Native Tribal Health Consortium is leading the Maternal Organics Monitoring Study to analyze an association between exposures to persistent organic pollutants, heavy metals, and radionuclides and developmental, neurological, and immunological effects in newborns. Potential exposures to these chemicals were detected in Alaska Native women due to their diets of fish and marine mammals. DLS provided TA for the study by measuring lipid content, PCBs, perfluorinated compounds, vitamin D, lead, mercury, and other chemicals in biological samples.

NCEH/ATSDR's next steps to advance its activities in Indian Country include its initial planning efforts to convene an Environmental Tribal Health Summit in 2020. NCEH/ATSDR currently is gathering information to outline the context and framework of the summit, determine discussion topics, and identify participants. During a meeting of the NCEH/ATSDR Tribal Workgroup in March 2018, some of the topics presented during the 2018 summit were suggested for the 2020 summit, such as safe water, the built environment, and other safety issues. NCEH/ATSDR welcomes guidance from the BSC on key issues that should be considered in its initial planning efforts.

BSC DISCUSSION: NCEH/ATSDR TRIBAL ACTIVITIES

Dr. Green provided additional details on the following topics in response to specific questions by the BSC members.

- NCEH/ATSDR's approaches to widely publicize, disseminate, and communicate the important and significant findings from tribal public health assessments, consultations, and studies.
- The extent to which datasets from tribal studies are released and available in the public domain.
- The meaning and definition of "Indian Country."

BSC GUIDANCE

- The BSC went on record with its formal support for NCEH/ATSDR to convene the 2020 Environmental Tribal Health Summit. However, several members provided input to ensure that the 2020 tribal summit results in actual change and does not merely serve as another federally sponsored event.
    - The 2018 tribal summit reflected efforts at the federal level by NCEH/ATSDR alone and participation by tribes in the state of Washington only. However, NCEH/ ATSDR should collaborate with and leverage the resources of its federal partners, particularly EPA and NIH, to hold the 2020 tribal summit that is national in scope.
    - Members of external tribal advisory groups should be engaged at the outset of the planning activities for the 2020 tribal summit, including the ATSDR-funded Tribal Public and Environmental Health Think Tank; the EPA-funded National Tribal Toxics Council and the National Tribal Air Association; and the NIH-funded Tribal Advisory Committee.
    - The Alaska Community Action on Toxics hosted the Children's Environmental Health Summit in October 2016 with strong representation by tribal leaders. NCEH/ATSDR should review the recommendations from this event as an additional resource to inform its planning activities. For example, the agenda of NCEH/ATSDR's 2020 tribal summit should include topics that give equal attention to primary, secondary, and tertiary prevention to avoid future environmental exposures on tribal lands. The major product from the summit should be the development of a feasible and realistic action plan with clearly defined roles and responsibilities for the federal agencies, tribes, and NGOs to improve EH issues of tribes.
- NCEH/ATSDR established a priority to train staff to improve understanding of the best approaches to collaborate with and support tribal communities. ATSDR previously funded and supported the Tribal Public and Environmental Health Think Tank. This group developed and presented the "Working Effectively with Tribal Governments" course to various agencies and NGOs. Because ATSDR funded this effort, the materials for the course should be available as a resource to train NCEH/ATSDR staff. The two-day course is extremely effective and extensively covers historical, legal, and cultural issues in Indian Country.
- ATSDR issued the following message in its advisory to residents of the Jackpile-Paguate Uranium Mine in Cibola County, New Mexico: "Do not use plant soils, rocks, sand, or water from the mines." Although ATSDR communicated this message to reduce risk by minimizing exposure, these natural elements are an integral part of Native culture, medicine, religion, and lifestyle. The inability to access these natural elements will have a significant and profound impact on Native populations. ATSDR should consult with tribal leaders to examine the holistic, non-tangible, and non-health impacts that can occur in Native populations as a result of federal restrictions at sites, such as adverse effects on their spiritual and emotional health. Overall, tribal people will not be healthy without healthy and sustainable Native languages, fish, water, air, and cultures.
- NCEH/ATSDR presented its proposal to the BSC to use alternative approaches in its environmental epidemiological studies, such as the Bayes Factor, to shift from the traditional practice of relying on the p-value. The Bayesian approach will be particularly important in NCEH/ATSDR's tribal studies due to the small sample sizes of Native populations.

Dr. Cibulas provided additional details in response to one of the BSC's specific questions. A government-wide initiative was launched two years ago to make all datasets from all federal agencies publicly available. Under this initiative, a transparent data management plan is established at the outset of a new federal study or research project to clearly identify the specific data that will be released and provide a sound rationale if data cannot be shared.

Dr. Breysse thanked the BSC for providing sound advice to NCEH/ATSDR on advancing its activities in Indian Country. Most notably, he agreed that NCEH/ATSDR should not use the 2020 Environmental Tribal Health Summit to only document the participants' recommendations. Instead, the tremendous needs in Indian Country should be identified, prioritized, and addressed with a concrete strategic plan.

Dr. Breysse noted that the national lead problem in non-tribal communities can be used as a model in Indian Country. For example, the first step in developing the National Lead Strategy was for each federal agency to list its ongoing lead initiatives. The separate inventories of lead activities will be integrated to allow the federal partners to identify duplicative efforts, determine gaps, and better understand the challenges, unmet needs, and economic impact associated with lead. This model of interagency coordination and collaboration to respond to significant lead problems in Flint, Michigan and other communities throughout the country should be replicated to address EH issues on tribal lands.

Action	Description
Chair's call for a vote	Based on the BSC's discussion and Dr. Breysse's follow-up remarks, Dr. Perry entertained a motion for the BSC to formally approve NCEH/ATSDR's implementation of vigorous planning efforts for the 2020 Environmental Tribal Health Summit. The motion includes the BSC's guidance for NCEH/ATSDR to use the summit as an opportunity to develop a solid action-oriented EH strategic plan on tribal lands and not convene the summit merely as an information sharing event.
Outcome of the vote	**The motion was unanimously passed by 15 BSC voting members.**
Next steps	Dr. Kennedy will periodically present updates to the BSC on NCEH/ ATSDR's planning activities for the 2020 Environmental Tribal Health Summit, including collaborations with federal partners and the engagement of tribes and other external groups.

Dr. Breysse acknowledged the existing gap between the budget constraints of the federal agencies and the need to address significant EH issues on tribal lands. The development of a solid interagency strategic plan will be a necessary first step in building political will to generate additional resources to address unmet needs. He confirmed that NCEH/ATSDR will take action on the BSC's formal recommendation to use the 2020 Environmental Tribal Health Summit to develop an interagency strategic plan in collaboration with federal partners. Because EH issues, needs, and concerns in Indian Country can differ among individual tribes, states, or regions, efforts will be made to create the strategic plan to have the broadest reach, the greatest impact, and the highest level of effectiveness.

As a new member, Dr. Adesanya questioned the practical implications of the BSC formally approving NCEH/ATSDR's planning activities for the 2020 Environmental Tribal Health Summit in light of Dr. Breysse's comments regarding limited resources at the federal level. Dr. Perry

clarified that regardless of federal budgets or funding levels, the BSC's advisory role is to contribute its external expertise to provide sound guidance on NCEH/ATSDR's portfolio of EH research and other activities. NCEH/ATSDR then reviews the BSC's guidance and determines whether action can be taken with its current funding and other available resources.

As Special Government Employees (SGEs), Dr. Perry explained that the BSC members are not permitted to offer advice or influence decisions related to the cooperative agreements, contracts, or other funding mechanisms of NCEH/ATSDR's programs and projects. In its guidance to the HHS Secretary, CDC Director, and/or NCEH/ATSDR Director, however, the BSC is authorized to make overarching statements, such as the critical need for additional funding, resources, attention, and support to increase NCEH/ATSDR's flat budget over the past 20 years.

Dr. Perry also emphasized that the BSC members retain their rights as private citizens while serving as SGEs. Individual BSC members, as private citizens with no affiliation to the BSC, are free to communicate with their political leaders at local, state, and national levels to advocate for ongoing or increased Congressional support of NCEH/ATSDR's EH activities.

Updates by the BSC *Ex-Officio* Members

Dr. Cibulas informed the BSC that Dr. Wayne Cascio (EPA *ex-officio* member) and Dr. Douglas Trout (NIOSH *ex-officio* member) were unable to attend the meeting. He opened the floor for the remaining *ex-officio* members to present their updates to the BSC.

Ruth Lunn, DrPH, MS
Director, Office of the Report on Carcinogens
National Institute of Environmental Health Sciences

Dr. Lunn reported that NTP, including the Office of Health Assessment and Translation (OHAT), recently completed or will soon complete several peer reviews in 2018.

Topic	Status
RECENTLY COMPLETED PEER REVIEWS	
Draft Technical Report on Cell Phone Radio Frequency Radiation (RFR)	Peer review completed: March 26-28, 2018
Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity (CLARITY-BPA) Core Study Research Report	Peer review completed: April 26, 2018
UPCOMING PEER REVIEWS IN 2018	
Draft NTP Monograph on Long-Term Neurotoxicity of Acute Sarin (OHAT)	Internal draft completed; peer review/public meeting scheduled
Draft Report on Carcinogens (RoC) Monograph on *Helicobacter pylori*	Internal draft/public comment completed; letter review scheduled
Draft NTP Monograph on Developmental Neurotoxicity of Fluoride (OHAT)	In progress

Topic	Status
Draft RoC Monograph on Night Shiftwork and Light at Night	Internal draft completed; peer review/public meeting scheduled
Draft NTP Monograph on Gestational Hypertension with Traffic-related Air Pollution (OHAT)	In progress

The peer review was completed of the draft technical reports for NTP's cell phone RFR 28-day pre-chronic and two-year toxicology and carcinogenicity studies in Sprague Dawley rats and B6C3F1 mice. The most prominent health effects were injury to the right ventricle of the heart, cardiac schwannomas, and gliomas. NTP is finalizing its conclusions and will present these results at the BSC meeting on June 20, 2018. NTP's communication plan to disseminate the final results to the public will include press releases, fact sheets, and targeted messaging.

Follow-up studies have been proposed for NTP's cell phone RFR study to generate several key outcomes. First, changes observed in the chronic bioassay will be further characterized. The mechanisms of RFR-induced toxicity will be investigated, including DNA damage or repair, the role of heat, and changes in gene expression. Second, RFR-induced effects on physiology and stress will be further evaluated to understand their potential role in injury. Third, the studies will be expanded to include newer and evolving technologies.

The core CLARITY-BPA study is designed as a two-year perinatal and chronic study that will be conducted with the Good Laboratory Practice (GLP) approach at the FDA National Center for Toxicological Research. Several effects, such as mammary gland tumors, were detected in some arms of the study, but no dose-response was observed. For the CLARITY-BPA grantee studies, 14 academic investigators will focus on a range of molecular, structural, and functional endpoints that typically are not assessed in guideline-based, GLP-compliant research. Data from the grant recipient studies are expected to be publicly available by August 2018. A report with an integrated interpretation of datasets, findings, and publications will be peer reviewed and released in 2019.

NTP's PFAS research under its Rapid Evaluation and Assessment of Chemical Toxicity (REACT) Program includes over 75 chemicals. The study design includes four major components: (1) quantitative structure-activity relationship modeling to inform the selection of *in vitro* models and assays; (2) *in vitro* screening of multiple endpoints; (3) *in vitro* to *in vivo* extrapolation, grouping of PFAS chemicals, and follow-up *in vivo* tests if needed; and (4) toxicological studies on GenX chemicals.

NTP is conducting *in vivo* testing on seven PFAS chemicals that involves 28-day toxicity rat studies to compare short-and long-chain PFAS chemicals. This series of studies is available at (https://ntp.niehs.nih.gov/results/path/index.html). Data from NTP's two-year studies on PFOA will be available in 60 days. The peer review of these studies will be completed in 2019. NTP will present an update on its synthetic turf/recycled tire crumb rubber (TCR) research at the BSC meeting on June 20, 2018.

Joey Zhou, PhD
Senior Epidemiologist, Office of Domestic and International Health Studies
U.S. Department of Energy

Dr. Zhou reported that the DOE Office of Environment, Health, Safety, and Security supports radiation health effect studies. He was pleased to announce that 2018 marked the 70th anniversary of the Radiation Effects Research Foundation (RERF) and the 50th anniversary of the U.S. Transuranium and Uranium Registries (USTUR). The RERF aims to foster the health and welfare of Japanese atomic bomb survivors. The study is based on a binational agreement between the United States and Japan.

The USTUR studies the biokinetics and internal dosimetry of actinides (uranium, plutonium, and americium) in former U.S. nuclear workers who volunteer portions of or their entire bodies for scientific use posthumously. DOE takes pride in supporting the longest-running international and domestic radiation health effect research program and sponsored celebratory activities.

Dr. Zhou explained that his attendance at the current BSC meeting primarily was as an observer. In his new role as the *ex-officio* member for DOE, he confirmed that he would present a more substantive update at the next BSC meeting.

Public Comment Period

No members of the public provided comments for the BSC's consideration.

BSC Discussion of Future Agenda Topics

Dr. Perry led the BSC in a review of topics that were proposed to be placed on the agendas of future meetings.

Presenter	Agenda Topic
Dr. John Meeker Dr. Melissa Perry	First update by the joint workgroup of the NCEH/ATSDR and CDC/OID BSCs on vector-borne disease prevention and control.
Dr. Marian Pavuk	Periodic updates on ATSDR's PFAS proof of concept study at the Pease, New Hampshire site and the PFAS multi-site health study.
Dr. Melissa Perry	BSC's facilitated discussion and guidance to NCEH/ATSDR on the development of a sampling scheme or study design that will allow for PFAS biomonitoring data to be generalized at a broader population level. ➢ Dr. Breysse confirmed that an update on the PEATT will be presented at the next BSC meeting. ATSDR developed the PEATT as a statistical sampling frame to obtain a representative sample of PFAS exposures.
Dr. Antonia Calafat	Update on DLS's ongoing efforts to publish data from the neonicotinoid and glyphosate biomarkers with NHANES samples.
Dr. Brad Goodwin	Periodic updates on ATSDR's Citizen Science Project, including the three-year pilot of the Low-Cost Sensor Project.
Dr. Chinaro Kennedy Dr. Melissa Perry	BSC's external peer review of and formal recommendations on NCEH/ATSDR's new statistical guidance document for environmental epidemiological studies.
Dr. Donata Green	Periodic updates on NCEH/ATSDR's planning activities for the 2020 Environmental Tribal Health Summit.

Presenter	Agenda Topic
ATSDR/DTHHS Staff	Update on the use of TCR on playgrounds and playing fields. ➢ Dr. Breysse reminded the BSC that NCEH/ATSDR, EPA, and the U.S. Consumer Product Safety Commission launched a joint investigation of TCR and analyses of TCR samples. The report of this interagency effort will be presented at the next BSC meeting.
NCEH/DLS Staff	The potential role of recreational marijuana use in increasing tobacco smoking. ➢ Dr. Breysse announced DLS's development of tools to assess THC levels in marijuana biomarkers and e-cigarettes. DLS will present an overview of these laboratory studies at the next BSC meeting.
NCEH/ATSDR OD	Overview of NCEH/ATSDR's plan to comply with the government-wide initiative to make all datasets from all federal agencies publicly available and the impact of this mandate on NCEH/ ATSDR's lead research and studies on other toxic exposures. ➢ Dr. Breysse's understanding was that the OMB rule only applies to the EPA regulatory process. He did not believe that "all federal agencies" are required to make all of their datasets publicly available. ➢ Dr. Cibulas confirmed that OD will clarify this issue while drafting the agenda for the next BSC meeting and determine whether the OMB rule also applies to NCEH/ ATSDR.
ATSDR Staff	Overview of the National Pediatric Environmental Health Specialty Unit Program.
Dr. Patrick Breysse	Update on ATSDR's ToxProfiles™ development process. ➢ Dr. Breysse suggested this topic for the next BSC meeting due to the recent scrutiny of and the concerns regarding the differences between ATSDR's draft ToxProfiles™ for four PFAS chemicals and EPA's long-term health advisories for the same PFAS chemicals.

In his role as the BSC DFO, Dr. Cibulas will ensure that the following information is disseminated.

- As an action item to the NCEH/ATSDR Director's update by Dr. Patrick Breysse, the BSC members will be provided with links to the draft ToxProfiles™ for PFNA, PFHxS, PFOA, and PFOS when the public comment period is announced.
- As an action item to Mr. John Eichwald's update on CDC's NIHL activities, Ms. Suzanne Condon will provide contact information for FAA officials who are addressing noise pollution in airport communities across the country.
- As an action item to Dr. Brad Goodwin's overview of ATSDR's Citizen Science Project, Mr. Ralph McCullers will facilitate the initial contact and communications with elders in the Region IV tribes who can serve as resources to pilot the Low-Cost Sensor Project.
- As an action item to Dr. Chinaro Kennedy's overview of NCEH/ATSDR's alternative approaches to statistical inferences in environmental epidemiology, Dr. Aaron Bernstein will provide contact information for his clinical colleagues who have statistical expertise.

Closing Session and Adjournment

The participants engaged in several rounds of applause in recognition of the key individuals who continue to play an instrumental role in convening extremely successful and productive BSC meetings.

- Dr. Perry was applauded for continuing her outstanding leadership as the BSC Chair and applying her excellent skills in moderating discussions of complex topics to ensure that NCEH/ATSDR is provided with the necessary external guidance to inform its next steps and future directions as the nation's leader in EPH.
- The BSC members were applauded for continuing to interrupt their busy professional careers and personal lives; attend each meeting; and contribute their valuable time, expertise, and support to improve NCEH/ATSDR's portfolio of EPH programs, research, and activities.
- Ms. Shirley Little, Ms. Amanda Malasky, and other NCEH/ATSDR OD staff were applauded for their ongoing commitment to planning and organizing the BSC meetings and overseeing the logistical arrangements for each individual member.

The next BSC meeting will be held the first week in December 2018. NCEH/ATSDR OD staff will poll the BSC members by email to determine their availability and confirm the date.

With no further discussion or business brought before the BSC, Dr. Perry adjourned the meeting at 10:30 a.m. on June 6, 2018.

CHAIR'S CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date	Melissa Perry, ScD, MHS Chair, NCEH/ATSDR Board of Scientific Counselors

Attachment 1: Participants' Directory

BSC Members Present

Dr. Melissa Perry, Chair
Dr. Babafemi Adesanya
Dr. Aaron ("Ari") Bernstein
Dr. Darryl Brown
Ms. Suzanne Condon
Dr. Deborah Cory-Slechta
Dr. Kim Dietrich
Dr. Roberta Grant
Dr. Sharron LaFollette
Joyce Martin, Esq.
Mr. Ralph McCullers
Dr. John Meeker
Dr. Devon Payne-Sturges
Dr. Marilyn Underwood
Ms. Nsedu Witherspoon

BSC Member Absent

Dr. Kenneth Aldous

BSC *Ex-Officio* Members Present

Dr. Ruth Lunn
National Institute of Environmental Health Sciences, National Toxicology Program

Dr. Joey Zhou
U.S. Department of Energy

BSC *Ex-Officio* Members Absent

Dr. Wayne Cascio
U.S. Environmental Protection Agency

Dr. Douglas Trout
National Institute for Occupational Safety and Health

Designated Federal Officer

Dr. William Cibulas, Jr.
Acting Director, ATSDR Division of Toxicology and Human Health Sciences

NCEH/ATSDR Director

Dr. Patrick Breysse

CDC/NCEH/ATSDR Representatives

Lina Balluz
Antonia Calafat
Yulia Carroll
Shirley Ding
John Eichwald
Alisha Etheredge
Renée Funk
Brad Goodwin
Donata Green
Mahad Gudal
James Guest
Olivia Harris
James Holler
Kevin Horton
Ryan Jackson
Chinaro Kennedy
Peter Kowalski
Jorge Lazo
Shirley Little
Amanda Malasky
Moiz Mumtaz
Marian Pavuk
James Pirkle
Angela Ragin-Wilson
Von Roebuck
Perri Ruckart
Tara Serio
Pamela Wigington

Lynn Wilder
Fuyuen Yip
Mina Zadeh

Member of the Public

Suzanne Triplett
(RTI International)

Attachment 2: Glossary of Acronyms

Acronym	Definition
AFFF	Aqueous Firefighting Foam
ALS	Amyotrophic Lateral Sclerosis
ASA	American Statistical Association
BSC	Board of Scientific Counselors
CANTAB	Cambridge Neuropsychological Test Automated Battery
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CIO	Center/Institute/Office
CLARITY-BPA	Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity
DCHI	Division of Community Health Investigations
DEHSP	Division of Environmental Health Science and Practice
DFO	Designated Federal Officer
DLS	Division of Laboratory Sciences
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DTHHS	Division of Toxicology and Human Health Sciences
EAs	Exposure Assessments
EH; EPH	Environmental Health; Environmental Public Health
EIs	Exposure Investigations
EPA	U.S. Environmental Protection Agency
ESF	Emergency Support Function
FAA	Federal Aviation Administration
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FY	Fiscal Year
GIS	Geographic Information System
GLP	Good Laboratory Practice
GRASP	Geospatial Research, Analysis, and Services Program
HHS	U.S. Department of Health and Human Services
MMWR	*Morbidity and Mortality Weekly Report*

Acronym	Definition
MRLs	Minimum Risk Levels
MSU	Michigan State University
NAICS	North American Industry Classification System
NBCS	Navajo Birth Cohort Study
NCEH/ATSDR	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NCHS	National Center of Health Statistics
NGOs	Non-Governmental Organizations
NHANES	National Health and Nutrition Examination Survey
NHDHHS	New Hampshire Department of Health and Human Services
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIHL	Noise-Induced Hearing Loss
NIOSH	National Institute of Occupational Safety and Health
NOFO	Notice of Funding Opportunity
NTP	National Toxicology Program
OCDAPS	Office of Capacity Development and Applied Preventive Sciences
OCHHA	Office of Community Health Hazards Assessment
OD	Office of the Director
OEHEM	Office of Environmental Health Emergency Management
OEHSS	Office of Environment, Health, Safety, and Security
OHAT	Office of Health Assessment and Translation
OIA	Office of Innovation and Analytics
OID	Office of Infectious Diseases
OMB	Office of Management and Budget
PBPK	Physiologically-Based Pharmacokinetic
PCBs	Polychlorinated Biphenyls
PEATT	PFAS Exposure Assessment Technical Tool
PFAS	Per-/Polyfluoroalkyl Substances
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PHAs	Public Health Assessments
PHCs	Public Health Consultations
QA	Quality Assurance
REACT	Rapid Evaluation and Assessment of Chemical Toxicity
RERF	Radiation Effects Research Foundation
RFR	Radio Frequency Radiation
RoC	Report on Carcinogens

Acronym	Definition
SGEs	Special Government Employees
TA	Technical Assistance
TCR	Tire Crumb Rubber
TEK	Traditional Ecological Knowledge
UCMR	Unregulated Contaminant Monitoring Rule
UNM	University of New Mexico
USTUR	U.S. Transuranium and Uranium Registries
USVI	U.S. Virgin Islands
VOCs	Volatile Organic Compounds