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
December 12-13, 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 December 12-13, 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 December 12-13, 2018 BSC meeting.

The participants were asked to welcome three new BSC members: Dr. Paloma Beamer (University of Arizona); Dr. Daniel Hryhorczuk (University of Illinois at Chicago); and Dr. Joan Rose Michigan State University).

NCEH/ATSDR DIRECTOR'S UPDATE

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

- The NCEH/ATSDR Director is continuing to meet with the CDC Director to propose environmental health (EH) topics to include in CDC's three new priorities: (1) the national opioid epidemic; (2) disease elimination with a specific focus on HIV and tuberculosis; and (3) global health security. The elimination of lead as the source of hazardous exposures to children was proposed for inclusion in Priority 2, while activities and products that have a global impact were proposed for inclusion in Priority 3.
- The NCEH/ATSDR Office of the Director (OD) reviewed and reinforced NCEH/ATSDR's center-wide priorities:
    - Safe drinking water
    - Children's EH issues (e.g., asthma and lead)
    - Expansion of ATSDR's overall capacity
    - Emerging changes in data collection and dissemination
    - Retention of and continued investment in the NCEH Division of Laboratory Sciences (DLS) as a worldwide resource

- ATSDR, EPA, and the U.S. Consumer Product Safety Commission launched the Federal Research Action Plan to investigate problems with recycled tire crumb rubber (TCR) that is used on playing fields and playgrounds. Concerns were raised that ongoing exposure to recycled TCR could cause cancer. The federal partners will complete the TCR exposure assessment, collect additional data in early 2019, and publish the FRAP report in the spring of 2019.
- NCEH/ATSDR received new funding in fiscal year (FY) 2019 from the HHS appropriations to support the revision of the current Cancer Cluster Investigation guidelines.
- The cross-center Vector-Borne Diseases (VBD) Workgroup, with leadership by the NCEH/ATSDR BSC and the CDC Office of Infectious Diseases (OID) BSC, is being used to foster collaborative opportunities with CDC centers that have a potential role in the risks and benefits of VBD control.
- ATSDR has made tremendous progress in applying its new funding to conduct a variety of per-/polyfluoroalkyl substances (PFAS) health-related activities.
- The FY2019 NCEH budget was appropriated at an essentially flat funding level, but the FY2019 ATSDR budget has not yet been appropriated. NCEH/ATSDR OD has made preparations for ATSDR in the event of a government shutdown.
- NCEH/ATSDR welcomed its new leadership: Dr. Christopher Reh (ATSDR Associate Director) and Dr. Erik Svendsen (Director of the NCEH Division of Environmental Health Science and Practice).

CROSS-CENTER VBD WORKGROUP

The BSC Chair presented the first update by the Cross-Center VBD Workgroup. The presentation included the workgroup's membership, charge, specific tasks, and major activities completed to date; key outcomes from the workgroup's three teleconference meetings convened to date; and the workgroup's input provided to NCEH/ATSDR and CDC/OID.

PREVIOUS BSC GUIDANCE

NCEH and ATSDR programs presented point-by-point responses to the input the BSC provided on three key presentations during the June 2018 meeting: (1) ATSDR's Proof of Concept Study/ PFAS Multi-Site Health Study; (2) ATSDR's Use of Citizen Science for Assessment of Health Risks; and (3) NCEH/ATSDR Activities with Tribes and Tribal Programs.

ATSDR TOXPROFILES™

The ATSDR Division of Toxicology and Human Health Sciences presented a comprehensive update on its ToxProfiles™. The key topics in the presentation included:

- ATSDR's legislative mandate and rigorous methodology to develop the ToxProfiles™
- The systematic literature review of toxicological studies and human epidemiology studies
- ATSDR's redesign to modernize the content, format, and organization of the ToxProfiles™ based on input by partners, stakeholders and other users
- ATSDR's achievements in increasing the impact and reach of the ToxProfiles™ to diverse audiences (e.g., policy, public health, and academic/scientific sectors)
- The status of two highly anticipated ToxProfiles™ for PFAS and glyphosate

FEDERAL ACTION PLAN TO REDUCE CHILDHOOD LEAD EXPOSURES AND ASSOCIATED HEALTH EFFECTS

The NCEH/ATSDR Office of Priority Projects and Innovation presented the draft Federal Lead Action Plan (FLAP), including the proposed vision and mission statements, goals, key priorities,

timeline, and overall process. The President's Task Force on Environmental Health Risks and Safety Risks to Children proposed four goals for the FLAP: (1) reduce children's exposure to lead sources; (2) identify children in high-risk communities and improve their health outcomes; (3) communicate more effectively with stakeholders; and (4) support critical research areas. The draft FLAP will be finalized and published on December 20, 2018.

CANNABIS AND PUBLIC HEALTH

The CDC Office of the Deputy Director for Non-Infectious Diseases presented an overview of CDC's public health role in addressing marijuana. CDC identified public health concerns related to marijuana use in several areas: chronic diseases, vulnerable populations (particularly pregnant and breastfeeding women), youth access, injury prevention, product safety and environmental health, and mental health, substance abuse, and dependence.

CDC has no official mandate or funding to address public health concerns related to marijuana use, but three major activities are being conducted to support states in their initiatives on the public health outcomes of marijuana use: (1) collect and disseminate data to states to strengthen their understanding of trends in marijuana use; (2) share accurate information with the public from evidence-based sources and experts; and (3) translate complex science into simplified messaging and guidance documents for the public.

CDC/ATSDR OPEN DATA POLICY (ODP)

NCEH/ATSDR presented the CDC/ATSDR ODP on Public Health Research and Non-Research Data Management and Access that became effective on January 26, 2016. The purpose of the ODP is to ensure public access to federally funded public health data. The key topics in the presentation included:

- Definitions of "public health data" and "personally identifiable information"
- The "public release," "restricted release," and "no release" data access levels
- Specific requirements for the NCEH/ATSDR ODP
- Confidentiality and privacy protection protocols, laws, regulations, and policies for open data activities

PFAS COMMUNITY OF PRACTICE (COP)

ATSDR presented an update on its PFAS health-related initiatives, including new funding of $20 million to conduct PFAS research; planned and future PFAS studies; and the new PFAS CoP design. From October 2018-October 2023, ATSDR will implement exposure assessments at eight selected sites, community engagement and communications activities, the PFAS Proof of Concept Study, and the PFAS Multi-Site Health Study. ATSDR described other PFAS initiatives that might be conducted in collaboration with internal and external partners.

ATSDR highlighted five key goals that have been established to achieve the overarching objective of the new PFAS CoP to facilitate collaboration, coordination, knowledge sharing, and problem-solving among public health professionals. All PFAS initiatives in the CoP will be linked to eight existing and new NCEH/ATSDR products. ATSDR presented an organizational chart to illustrate the PFAS CoP staffing structure, including the ATSDR leads for the cross-cutting functional roles and the ATSDR technical officers for ongoing PFAS-related activities.

UPDATED CDC CANCER CLUSTER INVESTIGATION GUIDELINES

NCEH/ATSDR presented an overview of the CDC Cancer Cluster Investigation Guidelines, including the background and history of these investigations and CDC's approach to update the

current guidelines. NCEH/ATSDR's role in CDC's cancer cluster investigations is to (1) develop guidance for state/local health departments (SHDs/LHDs) with a specific focus on residential and community settings and (2) provide technical assistance to SHD/LHDs. The current guidelines are being updated to explore new concepts and methods in science and technology:

- advances in cancer genomics;
- new statistical methods, software, and tools to improve spatial and temporal analyses of cancer cases; and
- new methods to better understand exposure pathways in the evaluation of potential cancer clusters.

To update the guidelines, NCEH/ATSDR formed an internal steering committee and is proposing the establishment of a new BSC Cancer Cluster Guideline Workgroup. Subject-matter expertise will be provided in the fields of cancer, community engagement/communications, epidemiology, geospatial science, policy development, statistics/spatial statistics, toxicology, and exposure assessment. Input will be gathered from the published and "grey" literature, the general public and community members, SHDs/LHDs, individual subject-matter experts, and the BSC. NCEH/ ATSDR established a two-year timeline from FY2019-FY2021 to complete the update of the CDC Cancer Cluster Guidelines.

PEDIATRIC ENVIRONMENTAL HEALTH SPECIALTY UNIT (PEHSU) PROGRAM

ATSDR presented an update on the PEHSUs, including their function, clinical expertise, major accomplishments, and value to environmental public health (EPH), health care, and communities. ATSDR and the U.S. Environmental Protection Agency (EPA) co-fund and jointly established the PEHSUs in 1998 to address undiagnosed causes of illnesses associated with toxic contamination of homes where children and others became ill after two reported events. The BSC was asked to provide input on opportunities to enhance the PEHSU Program and build stronger partnerships.

UPDATES BY THE BSC *EX-OFFICIO* MEMBERS

- The National Institute of Environmental Health Sciences (NIEHS), National Toxicology Program (NTP) described the recent publications and upcoming peer review meetings for its technical reports, monographs, and other studies. NTP launched its strategic realignment to refine its vision and mission statements, enhance the translation toxicology pipeline, and implement heath effect innovation initiatives. NTP developed more rapid screening tools for its new Developmental Neurotoxicity Data Resource. NIEHS awarded multiple intramural and extramural grants via various funding mechanisms. NIEHS is continuing to focus on its birth cohort studies. Ongoing activities by the Office of Health Assessment and Translation include a literature-based assessment of immune effects; a collaboration with EPA on the "Rapid Evaluation and Assessment of Chemical Toxicity" (REACT) study; and two-year cancer bioassay data on perfluorooctanoic acid.

- The U.S. Department of Energy (DOE) described its support of both domestic and international radiation health studies. In 2018, DOE 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 is an epidemiological study of Japanese atomic bomb survivors that is implemented under a binational agreement between the United States and Japan. The RERF is the longest running international radiation health effects research program, while the USTUR is the longest running domestic radiation health effects research program. DOE described USTUR's

contributions to the scientific literature by presenting a series of published reports and special issues.

- EPA reported that the Office of Research and Development (ORD) created its 2019-2022 Strategic Research Action Plans with a focus on approximately 52 different research areas. EPA is conducting several PFAS-related projects and is partnering with NTP on some of these efforts. ORD created a library of approximately 500 PFAS compounds that can be made available to external researchers. EPA will release its PFAS Management Plan, including the ORD Research Strategy, in January 2019. EPA expects to release a broader dataset on these efforts in the fall of 2019. Based on the findings, EPA will design targeted *in vivo* studies.

- The National Institute for Occupational Safety and Health (NIOSH) reported that the Firefighter Cancer Registry Act of 2018 was passed in July 2018. The legislation requires CDC to develop and maintain a voluntary registry of firefighters and specify the number and types of fires that each firefighter attends. The registry data will be used to enhance knowledge and understanding of the prevalence and incidence of cancer among firefighters. NIOSH is leading this effort for CDC.

CURRENT BSC GUIDANCE

The BSC provided extensive input over the course of the meeting in response to NCEH/ATSDR's presentations and updates.

- Develop and disseminate a "marketing" package for external stakeholders to more widely publicize NCEH/ATSDR's programs; articulate the relevance of these activities in day-to-day EH practices in the field; and serve as outside champions and stewards of NCEH/ ATSDR's impressive EPH portfolio.
- Engage NCEH's 19 Safe Water Program grant recipients in a pilot project to develop, test, distribute, and evaluate standardized safe water guidelines. Use the outcomes of the pilot to (1) scale-up new safe water protocols and procedures at the national level and (2) apply NCEH's new national standards on universal sampling of private wells to ensure that people are not unduly exposed to contaminants.
- Consider the following topics as emerging issues for NCEH/ATSDR to address:
    - Health effects of increased air pollution caused by wildfires
    - National epidemic of colon cancer in young adults based on environmental rather than genetic factors
    - Studies on noise pollution in occupational settings and noise pollution as a mortality factor in non-occupational populations (e.g., the elderly, residents of urban cities, and hospital patients)
    - Research on prolonged exposure to "blue light" pollution late at night
    - Climate and health
- Widely publicize the ATSDR Citizen Science Project, such as posting a podcast on the NIEHS website.
- Engage a diverse group of partners at the outset of the planning efforts for the 2020 Tribal EH Summit, including federally funded tribal groups and academic institutions that closely collaborate with tribes.
- Engage new audiences, adopt other forms of systematic review, post marketing videos, and test methods to disseminate data through mobile devices to further increase the reach and impact of the ToxProfiles™.

- Shift from the old lead model (e.g., children as an indicator) to a broader focus (e.g., elimination of lead sources in the environment) in the FLAP.
- Promote the recent accomplishments of DLS to encourage CDC's development of a new marijuana research agenda at the federal level.
- Include a new policy in the ODP that will allow for a screening protocol or a protective barrier prior to the public release of any data.
- Ensure collaboration and outreach on a broader scale in the PFAS health-related initiatives:
    - Include partnership language in the Notice of Funding Opportunity for the PFAS multi-site health study
    - Encourage collaboration with national coalitions and advocacy organizations that have existing relationships with communities affected by PFAS
    - Use CDC's Facebook and Twitter pages to post webinars on the ongoing PFAS activities
- Widely market the PEHSUs and engage professional associations to support this effort; conduct a systematic evaluation of the entire program; and disseminate the PEHSU evaluation report to the public.

The BSC agreed by consensus to establish a new Cancer Cluster Guideline Workgroup. The new members were identified; the new chair will be designated at a later time; and the workgroup will regularly present updates to the BSC.

The BSC Chair led the members in a review of topics that were proposed to be placed on the agendas of future meetings. The next BSC meeting will be held in approximately June 2019. 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
December 12-13, 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 December 12-13, 2018 in Building 106, Conference Room 1B, at 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*).

December 12, 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 17 voting members and *ex-officio* members in attendance constituted a quorum for the BSC to conduct its business on December 12, 2018. He called the proceedings to order at 8:39 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 December 12, 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 asked the participants to join her in welcoming three new BSC members, but she noted that Dr. Beamer was unable to attend the current meeting. The affiliations of the new BSC members are highlighted below.

- Paloma Beamer, PhD; Associate Professor of Environmental Health Sciences, Mel and Enid Zukerman College of Public Health, University of Arizona
- Daniel Hryhorczuk, MD, MPH; Professor Emeritus, Center for Global Health, University of Illinois at Chicago
- Joan Rose, PhD; Homer Nowlin Chair in Water Research, Michigan State University

Dr. Perry informed the new members that the BSC plays an important role as an external advisory body at the federal level. Most notably, the BSC provides sound guidance and expertise on both persistent and emerging problems in NCEH/ATSDR's environmental health (EH) programs and activities as well as in its overall environmental public health (EPH) portfolio.

On the one hand, the BSC goes on record with its strong support and approval of NCEH/ATSDR's proposed, ongoing, and/or new EH activities. On the other hand, the BSC members apply their EH experiences in the field as academicians, practitioners, and policy leaders to provide NCEH/ATSDR with constructive input and pose critical questions when needed. Overall, the NCEH/ATSDR leadership and program staff give thoughtful consideration and provide detailed responses to the BSC's feedback, guidance, and perspectives.

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.

COLLABORATION BETWEEN CDC AND NCEH/ATSDR LEADERSHIP

Dr. Robert Redfield was named as the new CDC Director in March 2018. Since his appointment, he has established three key priorities for CDC to address: (1) the national opioid epidemic; (2) disease elimination with a specific focus on HIV and tuberculosis (TB); and (3) global health security. EH was not explicitly mentioned in any of the three priorities, but Dr. Breysse described opportunities to include this topic in his recent briefings with Dr. Redfield.

Priority 2 will address the elimination of infectious diseases (e.g., HIV and TB). However, EH can be included in this topic by focusing on the elimination of lead as the source of hazardous exposures to children. Because this issue strongly resonated with Dr. Redfield, Dr. Breysse was asked to provide additional details at a future briefing on launching a national effort to eliminate lead hazards from all environmental pathways, including water, housing, and transportation.

Priority 3 will address global health security through an infectious disease lens (e.g., the Ebola and Zika viruses). However, EH can be included in this topic by focusing on activities that have a global impact, such as the importation of consumer products from other parts of the world to the United States; transmission of air quality problems from China to the United States; and migration of wildfire smoke between the United States and Canada. Dr. Breysse confirmed that he looks forward to continuing to meet with Dr. Redfield and promoting NCEH/ATSDR's EH expertise to support CDC's new priorities.

NCEH/ATSDR PRIORITIES

The NCEH/ATSDR Office of the Director (OD) used Dr. Redfield's announcement of CDC's three new agency-wide priorities to review and reinforce NCEH/ATSDR's center-wide priorities.

- Provision of safe drinking water to the American public
- Children's EH issues (e.g., asthma and lead)
- Expansion of ATSDR's overall capacity, including its scientific expertise, EH impact at sites, and Congressionally mandated role in protecting communities from hazardous waste and materials
- Emerging changes in data collection and dissemination (including the new "Community/ Citizen Science" movement), informatics, surveillance, and quality measures
- Retention of and continued investment in the NCEH Division of Laboratory Sciences (DLS) as a worldwide resource

For the safe drinking water priority, ATSDR is continuing to define its specific role without overlapping or infringing on the regulatory authority of the U.S. Environmental Protection Agency (EPA) to oversee water distribution systems. Because EPA does not regulate small water systems and private wells, ATSDR is focusing its efforts on unregulated drinking water sources. ATSDR's increasing investigations of per-/polyfluoroalkyl substances (PFAS) and harmful algal blooms in drinking water systems are a key component of the safe drinking water priority.

FEDERAL RESEARCH ACTION PLAN (FRAP)

ATSDR, EPA, and the U.S. Consumer Product Safety Commission launched the FRAP to investigate problems with recycled tire crumb rubber (TCR) that is used on playing fields and playgrounds. Most notably, concerns were raised that ongoing exposure to recycled TCR could cause cancer. The federal partners have conducted multiple research projects and other activities under the FRAP to date.

- Recycled TCR samples were collected from playing fields across the country to analyze their chemical composition.
- Materials were obtained from manufacturers that develop recycled TCR to determine their biological relevance or availability in the environment. A draft report of the bioavailability research efforts was developed and disseminated for peer review.
- Air samples were collected to conduct an exposure assessment of volatile organic compounds (VOCs) and semi-VOCs from recycled TCR.
- Biomonitoring was performed to measure the blood and urine of people before and after their extended period of time on playing fields and playgrounds that contained recycled TCR.

The next steps for the federal partners will be to complete the TCR exposure assessment, collect additional data in early 2019, and begin drafting a report on all aspects of the FRAP for publication in the spring of 2019.

CANCER CLUSTER INVESTIGATION GUIDELINES

Community concerns regarding cancer clusters have continued to grow over time. Most notably, the "Strengthening Protections for Children and Communities from Disease Clusters Act" (i.e., "Trevor's Law") was introduced to Congress in 2011. HHS has taken no action on this legislation to date because Congress did not appropriate funding to support expensive disease cluster investigations. If resources are allocated in the future, however, HHS likely will instruct CDC to become more proactive in investigating cancer and other disease clusters.

NCEH/ATSDR has been developing and distributing guidelines for cancer cluster investigations to states since 2012. However, NCEH/ATSDR received new funding in fiscal year (FY) 2019 to support the revision of these guidelines. A presentation of this effort is scheduled on the current agenda for NCEH/ATSDR to obtain guidance from the BSC on its proposed approach.

CROSS-CENTER VECTOR-BORNE DISEASES (VBD) WORKGROUP

The NCEH/ATSDR BSC and the CDC Office of Infectious Diseases (OID) BSC formed a joint VBD Workgroup to address the increase in VBDs in the United States. The workgroup will be used to foster collaborative opportunities with CDC centers that have a potential role in the risks and benefits of VBD control. NCEH/ATSDR's important role on the workgroup will be to contribute its VBD expertise in the areas of toxicology, pesticides, integrated pest management, and rodent control. An update on the recent activities of the VBD Workgroup is scheduled on the agenda.

PFAS HEALTH-RELATED ACTIVITIES

ATSDR received new funding to conduct a variety of PFAS health-related activities. The major activities are summarized below, but a detailed update on NCEH/ATSDR's new PFAS Community of Practice (CoP) is scheduled on the agenda.

- Exposure assessments will be performed at not less than eight sites across the country that have water contamination as a result of military operations, particularly from aqueous firefighting foam (AFFF).
- A multi-site, cross-sectional study of PFAS will be conducted in multiple communities across the country. The study will be designed to analyze clinical outcomes associated with PFAS.
- A PFAS research agenda will be developed that will focus on cancer, reproductive outcomes, more sensitive immunological functions, and developmental outcomes.

NCEH AND ATSDR FY2019 BUDGET

The FY2019 NCEH budget was appropriated at an essentially flat funding level. The FY2019 ATSDR budget has not yet been appropriated. The Department of the Interior allocates ATSDR's funding and is not part of the spending bill that Congress passed. NCEH/ATSDR OD has made preparations for ATSDR in the event of a government shutdown.

NEW NCEH/ATSDR LEADERSHIP

Dr. Christopher Reh recently was appointed as the new ATSDR Associate Director. He introduced himself to the BSC and briefly described his background in both the public and private sectors. He is scheduled to present an update to the BSC on the PFAS CoP, but he planned to make a presentation at a future meeting to describe his vision for ATSDR's new brand, strategic approach, and future direction.

Dr. Erik Svendsen was appointed as the Director of the new NCEH Division of Environmental Health Science and Practice. He would be placed on the agenda for one of the meetings in 2019 to present his first update to the BSC.

BSC DISCUSSION: NCEH/ATSDR DIRECTOR'S UPDATE

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

- NCEH's role in CDC's response to the national opioid epidemic, particularly new funding of $9 million to DLS to improve laboratory methods to measure exposure to fentanyl and fentanyl-like compounds.
- Funding for and the current status of implementing ATSDR's "Choose Safe Places for Early Care and Education" initiative.
- Future activities and products from the collaborative efforts of NCEH/ATSDR, EPA, and the National Institute of Environmental Health Sciences (NIEHS) on the PFAS research agenda, such as newly published PFAS reports from the National Toxicology Program (NTP) in 2019.
- NCEH's ongoing activities to support the 19 Safe Water Programs (SWPs) across the country that are cooperative agreement (CoAg) recipients.

BSC GUIDANCE

- The BSC commended NCEH/ATSDR for its continued public health leadership and application of high-caliber standards to address high-priority EH issues that are important to communities across the country (e.g., safe water, lead, PFAS, and cancer clusters). Moreover, the BSC was pleased that Dr. Breysse is promoting NCEH/ATSDR's EH expertise in these areas directly to the CDC Director. However, the BSC emphasized the need for NCEH/ATSDR to develop and disseminate a "marketing" package. External stakeholders would use these materials to (1) more widely publicize NCEH/ATSDR's programs; (2) articulate the relevance of NCEH/ATSDR's activities in day-to-day EH practices in the field; and (3) serve as outside champions and stewards of NCEH/ATSDR's impressive EPH portfolio. The BSC members suggested potential content to include in the marketing package.
    - NCEH has oversight of the CDC Vessel Sanitation Program (VSP) and establishes health, safety, sanitation, and hygiene standards to prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise ships. In addition to passenger safety, NCEH's standards, guidelines, and investigations

also have increased overall protection in using these vessels for travel and transportation.
    - The general public, and even a large proportion of the public health community, have limited or no knowledge of ATSDR's role as a federal agency, including its overall mission, purpose, and function.

- NCEH should review recent studies to further inform the safe drinking water priority. For example, new research increasingly is being published to document microbial contamination in private wells and linkages to potential sources, such as nearby land use from confined animal feeding operations. Moreover, differences, inconsistencies, and gaps in safe water practices at state and county levels (e.g., sampling of specific contaminants in private wells) have not been adequately addressed to date. As a result, NCEH should engage its 19 SWP grant recipients in a pilot project to develop, test, distribute, and evaluate standardized safe water guidelines. NCEH could then use the outcomes of the pilot to scale-up new safe water protocols and procedures at the national level. NCEH's new national standards on universal sampling of private wells also could be used to ensure that people are not unduly exposed to contaminants.

Update by the Cross-Center Vector-Borne Diseases Workgroup

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 provided background information on the VBD Workgroup for the benefit of the new BSC members. During the January 2017 BSC meeting, NCEH/ATSDR OD presented an update on CDC's Zika response, including its decisions regarding vector management and pesticide recommendations. NCEH/ATSDR OD also presented a proposal for the BSC to establish a new Zika Workgroup. Due to the need for external guidance and expertise from both EH and infectious disease perspectives, however, a recommendation was made to form a broader VBD Workgroup with representation by both the NCEH/ATSDR and CDC/OID BSCs.

During the June 2018 BSC meeting, NCEH/ATSDR OD presented the charter for the new VBD Workgroup. The workgroup serves as CDC's first cross-center advisory body. In terms of its membership, the workgroup is equally represented by a co-chair and an alternate representative from the NCEH/ATSDR and CDC/OID BSCs. Drs. Perry and John Meeker serve in these roles for the NCEH/ATSDR BSC. The workgroup members include external experts from around the country who have experience in entomology, epidemiology, and occupational health. Federal staff from both centers serve as the DFOs.

In general, the VBD Workgroup is charged with reporting to the NCEH/ATSDR and CDC/OID BSCs regarding specific questions that impact the agency's overall efforts to detect, prevent, and respond to VBDs. In particular, the workgroup is tasked with evaluating the goals and strategies of CDC/ATSDR on five key issues.

1. Develop and evaluate VBD prevention and control tools, including conducting a public health assessment of the safety, efficacy, and feasibility of available and innovative vector control methods. In particular:

- develop and conduct public health evaluations of novel control methods;
- model the most effective tactics for prevention and response;
- determine the relative effectiveness of non-pesticidal tools (e.g., traps and genetically modified vector populations) for public health use; and
- develop strategies for the collection and use of data on vectors and pathogens.

2. Clarify the role of CDC and ATSDR in monitoring human exposures and adverse health effects subsequent to pesticide applications through surveillance, biomonitoring, and epidemiologic investigations.

3. Establish a strong public health workforce in vector control, including developing a cadre of public health entomologists and providing targeted training for state and local health departments. In particular, develop, maintain, and improve day-to-day mosquito control programs to ensure appropriate infrastructure is available during outbreaks and to improve responses and decrease the need for emergency measures

4. Improve overall risk communications for VBD, with emphasis on balancing risks between vector control methodologies and disease transmission, in transparent and clear language and with proactive community engagement.

5. Enhance collaborations between public health organizations, academia, and industry that are aimed at developing new and strengthening existing VBD prevention and control strategies, including better assessment of the risks of particular vector control strategies.

The activities of the VBD Workgroup to date are highlighted as follows. The first teleconference was held in July 2018 to establish the workgroup membership, review the specific tasks, identify key issues from NCEH/ATSDR and CDC/OID, and discuss the timeline to complete activities. The second teleconference was held in October 2018 for both centers to present their 2018 strategic plans for discussion by the workgroup. The third teleconference was held in November 2018 to discuss three key topics: the workgroup's progress to date; the workgroup's tasks and additional comments by the centers; and areas of expertise within both centers. The workgroup noted that the release of a report is pending by the HHS Tick-Borne Disease Workgroup.

The VBD Workgroup members acknowledged that VBDs are increasing in the United States with more disease agents and more people at risk. However, the United States is not fully prepared to address these risks. The presentations of the NCEH/ATSDR and CDC/OID strategic plans and the workgroup's subsequent discussions have helped staff from both centers to better appreciate opportunities for collaboration. Most notably, the workgroup identified common themes in both centers:

- Training and workforce development, including the CDC Vector-Borne Disease Regional Centers of Excellence (COEs) and the NCEH online training modules
- Communications and the need for clear, coordinated messaging, particularly during emergencies
- Characterization of state and local health departments as the "customer"
- Common interests in rodents as reservoirs or vectors of disease
- Concerns regarding the importation of exotic mosquito and tick vectors of disease

The VBD Workgroup provided valuable comments to NCEH/ATSDR and CDC/OID, particularly on the VBD Regional COEs. For example, the COEs are giving considerable attention to the health effects, follow-up, and surveillance of aerial spraying campaigns. The workgroup identified unique expertise in both centers that is relevant to VBD. For example, NCEH has expertise in the toxicology of pesticides, integrated pest control, rodent control, and control of dog ectoparasites, while OID has expertise in tick-borne diseases.

The workgroup will begin focusing on Task 3 by discussing workforce development in vector control. The workgroup began its initial focus on Task 4 with an in-depth discussion on risk communications. Most notably, the importance of notifying the public about CDC's endorsement of control strategies to be used was emphasized. Strategies to better coordinate messaging during emergencies were considered as well.

Dr. Breysse thanked Dr. Perry for her comprehensive update on the VBD Workgroup's recent activities. He asked the BSC to use the discussion period to provide input on emerging EH issues that NCEH/ATSDR should consider addressing at this time. Due to the proliferation of microplastics in the environment, for example, NCEH/ATSDR acknowledges that additional research is needed on the ecological and human health impacts of these materials in water, food, and consumer products.

BSC GUIDANCE: EMERGING EH ISSUES FOR NCEH/ATSDR

The BSC supported NCEH/ATSDR's potentially new focus on microplastics. The BSC noted that multiple organizations in the United States and other countries are committed to the removal of a wide variety of plastics from oceans. If a decision is made to address microplastics in the environment, the BSC advised NCEH/ATSDR to collaborate with these groups. In response to Dr. Breysse's request for input, the BSC proposed other emerging EH issues that NCEH/ATSDR should consider at this time.

- NCEH should conduct additional research to strengthen the existing scientific evidence base on the health effects of increased air pollution caused by wildfires. For example, the most recent wildfire season in California resulted in unprecedented, prolonged exposure to smoke at greater distances from the fires. The lack of science caused local health officials to provide the public with conflicting messaging and unclear guidance on the use of N95 respirators, air filtration in commercial buildings and private homes, and other air pollution issues.
- The cluster of colon cancer in young adults is a national epidemic. Because environmental rather than genetic factors are the cause of the colon cancer cluster, ATSDR should develop a ToxProfile™ to better understand and assess exposures in this population.
- NCEH should leverage its existing partnership with the National Institute of Occupational Safety and Health (NIOSH) to conduct a study on the dangers of noise pollution, such as repeated alarms in health care settings. Research conducted in Boston and London showed that noises at levels well below the Occupational Safety and Health Administration standard are causing cardiovascular events. Additional studies also are needed to assess noise pollution as a mortality factor in non-occupational populations, particularly among the elderly, residents of urban cities, and hospital patients.
- Prolonged exposure to "blue light" late at night (i.e., the typical light emitted from cell phones, computers, televisions, and other electronic devices) can lead to an increased risk for various chronic diseases. For example, the Nurses' Health Study reported that night-shift nurses who were exposed to blue light had more opportunities for a disruption to their circadian rhythm. Moreover, no research has been conducted to date on the

impact of blue light pollution on the developing brains of children. Most notably, insomnia, fatigue, and other detrimental effects on the sleep cycle have been reported in a large proportion of children who are exposed to blue light late at night and have a clinical diagnosis or symptoms of attention deficit hyperactivity disorder. Blue light pollution is both an occupational health issue for night-shift workers as well as a community issue for children and residents of urban cities.

- The detrimental effects of human activities on the environment and other ecosystems potentially are irreversible. Most notably, the Intergovernmental Panel on Climate Change has stated that these issues must be addressed over the next 15 years. Moreover, the impact of human activities on the environment is a major threat to the health of the entire planet. Instead of NCEH continuing to address climate and health as an EH topic alone, this issue should be promoted at a higher level and included in the global health security priority that Dr. Redfield has established for CDC.
- The Fourth National Climate Assessment in 2018 was released with rigorous scientific evidence. NCEH administers the CDC Climate and Health Program and also should use its strong body of evidence to issue clear, bold statements, but with more emphasis on the "health" component. For example, (1) "Climate change and extreme weather events directly impact the health of Americans." (2) "The increased use of renewable energy sources and decreased use of coal will result in a dramatic reduction in air pollution. These changes in the U.S. energy system will generate significant health benefits to Americans." Overall, NCEH is commended for its "courage" in continuing to address climate and health, particularly since this issue has virtually no political will, support, or federal funding.

NCEH/ATSDR leadership provided follow-up remarks to some of the emerging issues proposed by the BSC. Dr. Yulia Carroll, the NCEH/ATSDR Acting Associate Director for Science, reported that CDC's noise-induced hearing loss (NIHL) activities were presented during the November 2017 BSC meeting. During the June 2018 meeting, CDC provided an update and its point-by-point response to the BSC's guidance. For the benefit of the BSC members who did not attend these meetings, she summarized CDC's key efforts over the past two years on its NIHL activities.

CDC conducted a systematic literature review and a meta-analysis on safe noise levels and the health effects associated with noise exposure. The research showed an increase in the risk for cardiovascular events related to noise exposure. CDC will release its NIHL report in early 2019 and also will present an update to the BSC during one of the meetings in 2019.

Ms. Josephine Malilay, Chief of the NCEH Asthma and Community Health Branch (ACHB), reported that ACHB's activities cover a broad range of EH topics, such as heat, wildfires, cold, and pollen. ACHB also funds 18 programs to implement the Building Resilience Against Climate Effects (BRACE) framework. ACHB's website (https://www.cdc.gov/asthma/community-health) provides extensive information on its activities, partnerships, publications, and resources for health professionals and schools.

Drs. Perry and Antonia Calafat, Chief of the DLS Organic Analytical Toxicology Branch, presented a brief update on an emerging laboratory issue that has been a key topic of discussion at previous BSC meetings. The BSC previously provided input to DLS regarding the critical importance of focusing on emerging pesticides and developing sound biomarkers for specific chemicals, such as neonicotinoids and glyphosate. These pesticides are systemic in the environment and are widely used in the United States and other countries.

DLS recently published new methods for the detection of six neonicotinoid parent compounds and metabolites. The paper was published in *Analytical and Bioanalytical Chemistry* and is available for review online. DLS also will release the National Health and Nutrition Examination Survey (NHANES) data at the end of December 2018 that served as the source for its biomonitoring methods and analyses.

Dr. Perry emphasized that DLS's exceptional analytical chemical expertise will play an important role over time in evaluating the health effects from these pesticides. To continue to make significant contributions to public health protection, she encouraged DLS to partner with its NCEH colleagues to implement tracking, monitoring, and surveillance of pesticide exposures.

Dr. Perry informed the new members that during the November 2017 meeting, the BSC went on record with its strong recommendation to NCEH/ATSDR to add research on climate issues and weather-related events to its current list of priorities. She noted that the BSC also is free to reiterate its previous request for an update on the Climate and Health Program. Based on its charter, she explained that the BSC can vote on and submit formal recommendations on the Climate and Health Program to the HHS Secretary, CDC Director, and NCEH/ATSDR Director.

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 OD and individual programs to present their 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. NCEH/ATSDR's updates and responses to the BSC's guidance from the June 2018 meeting are summarized below.

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

Dr. Pavuk described the progress that ATSDR has made on its PFAS health-related activities since the June 2018 BSC meeting. A *Federal Register* notice was published with a 60-day public comment period on the PFAS proof of concept. All comments that were submitted have been addressed. Institutional Review Board (IRB) approval was received on the PFAS proof of concept. Contracts were competed and awarded in August and September 2018. A meeting with the contractors was held to review the work plan and discuss staff training, data security, and other important protocols. After the 30-day HHS review process is completed, the Office of Management and Budget (OMB) review and approval process will be initiated in the spring or summer of 2019 for data collection for the PFAS multi-site health study.

The draft protocol for the PFAS multi-site health study currently is being revised based on comments that were submitted during internal and external peer reviews. Similar to the PFAS proof of concept, the multi-site health study will undergo the same 60-day public comment period as well as the IRB, HHS, and OMB review and approval processes. However, the PFAS multi-

site health study will be supported by CoAgs rather than contracts. A Notice of Funding Opportunity (NOFO) will be released for applicants to submit proposals.

ATSDR's responses to the BSC's guidance on the PFAS proof of concept and the PFAS multi-site health study are outlined below.

PRESENTATION: ATSDR'S PROOF OF CONCEPT STUDY/PFAS MULTI-SITE HEALTH STUDY	
BSC Guidance	**ATSDR Response**
Explore prenatal exposures *in utero*.	The PFAS multi-site health study has a cross-sectional design and will evaluate children 4-17 years of age. The study will not include a birth cohort and will not specifically address pregnant women and fetuses. However, detailed information will be collected from mothers on potential *in utero* exposures. New questions will be added to the study to collect information on menstruation cycles and blood loss.
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).	The data collection questionnaire cannot be expanded to address infertility because this issue is extremely complex and time-consuming. Because the questionnaire already is designed to gather multiple data endpoints in various categories, the inclusion of new infertility questions will be overly burdensome to the study participants. However, the set of questions on women's reproductive history will include simple infertility questions, such as "How many months have you been trying to conceive?"
Minimize the burden of the core NEPSY-II® tests by only administering the attention and executive function subtests.	ATSDR does not expect the full set of the core NEPSY-II® tests to require a significant amount of additional time for children in the study to complete. However, ATSDR currently is obtaining professional input from the contractor that will administer the core NEPSY-II® tests.
Include cancer malignancies as an additional health outcome.	Cancer is included in the study protocol, but is not part of the main hypothesis. The sample size of 6,000 adults and 2,000 children is not sufficient to address individual cancers, but broad questions will be asked, such as individual and family histories of cancer. Medical records will be collected to verify all cancers reported by the study participants.

Dr. Breysse added that NCEH/ATSDR is developing a broader PFAS health assessment strategy due to the limitations of the cross-sectional study design. Discussions are underway to explore potential study designs and methods to address other data endpoints in more detail, such as cancer history, developmental outcomes, and *in utero* exposures. NCEH/ATSDR will then shift its focus to identifying resources for the PFAS health assessment and initiating discussions with various audiences, including communities, Congressional staff, and federal partners.

LT Brad Goodwin, PhD
Scientist Officer
ATSDR Division of Community Health Investigations

Dr. Goodwin described the progress that ATSDR has made on its Citizen Science Project since the June 2018 BSC meeting. The three particulate matter (PM) monitors that were proposed for the project were selected and currently are being evaluated. The monitors were used to collect preliminary data for a period of two weeks during an ongoing exposure investigation at a site in Washington State. The results were compared to those from ATSDR's standard instrumentation. Data from the low-cost sensors are available at this time, but the final validated dataset for the standard methods is pending.

College-level computer science students were recruited to assist ATSDR in developing data analysis tools that will be used to automate the data processing and visualization features of the lost-cost sensors. ATSDR's project was accepted for presentation at the March 2019 National Citizen Science Association conference. ATSDR will use this event to leverage networking opportunities and obtain lessons learned from other groups with experience in implementing a citizen science approach.

ATSDR's responses to the BSC's guidance on the Citizen Science Project are outlined below.

PRESENTATION: USE OF CITIZEN SCIENCE FOR ASSESSMENT OF HEALTH RISKS	
BSC Guidance	**ATSDR Response**
Review key lessons learned from historical efforts and conduct a more extensive literature review.	Efforts are underway to engage as many communities as possible in the Citizen Science Project. Discussions were initiated with federal partners at EPA and NIEHS. The March 2019 National Citizen Science Association conference will be used as an opportunity to identify additional partners and continue to build the knowledge base on the citizen science approach.
Explore whether NIEHS's key findings or experiences in addressing specific issues in its funded community-based participatory research (CBPR) projects can be applied to the Citizen Science Project.	ATSDR's community engagement specialists currently are synthesizing data from other studies, including NIEHS's CBPR projects. These data collection efforts will inform the development of a fact sheet to pilot the Citizen Science Project. The fact sheet will provide an overview of citizen science, the uses of this approach in the past, and the role of this approach in public health.
Use the 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.	ATSDR did not fully understand this recommendation. Based on Dr. Goodwin's interpretation of the BSC's guidance, however, he confirmed that the Citizen Science Project will be piloted at non-controversial sites to ensure the focus is placed on the development of solid procedures rather than other issues. "Non-controversial" sites will include those in which PM already is a contaminant of concern and ATSDR's site-specific activities are underway. Other criteria to select non-controversial pilot sites will include those with no active litigation, no community dissent or hostility toward federal and state agencies, and relatively sound working relationships at the local level. After the pilot has been completed and the Citizen Science Project is fully implemented, its potential role as a tool for arbitration or mediation can be explored at that time.

PRESENTATION: USE OF CITIZEN SCIENCE FOR ASSESSMENT OF HEALTH RISKS	
BSC Guidance	**ATSDR Response**
Design and incorporate a workforce development component into the Citizen Science Project that will serve as a long-term, sustainable asset to communities.	Workforce development will be an informal rather than a formal component of the Citizen Science Project. Most notably, training, tools, and other resources will be available to provide community members with sustainable skills and capabilities to effectively deploy the low-cost sensors and accurately interpret data.
Inform communities that data collected by citizen scientists for EPA's multi-year CBPR project are available on the EPA.gov website.	Communication materials that will be developed for the Citizen Science Project will provide communities with multiple resources, such as available data and links to relevant websites.
Design a transparent process to manage community expectations at the outset.	ATSDR's community engagement specialists will design a risk communication process to ensure that communities have realistic expectations of the Citizen Science Project, particularly the abilities and limitations of data collected from the low-cost sensors.
Develop effective strategies well in advance of piloting the Low-Cost Sensor Project to address potential problems with the citizen science approach.	The data collection efforts and evaluation of new technologies are being conducted well in advance of piloting the Low-Cost Sensor Project. Based on preliminary performance results, the low-cost sensors are moderately over-predicting PM 2.5 concentrations compared to reference methods. ATSDR currently is considering whether to correct this minor flaw or simply inform communities that the low-cost sensors generate conservative estimates of exposure.

Sharunda Buchanan, PhD, MS
Director, NCEH/ATSDR Office of Priority Projects and Innovation
Centers for Disease Control and Prevention

Dr. Buchanan presented NCEH/ATSDR's responses to the BSC's guidance on its tribal activities.

PRESENTATION: NCEH/ATSDR ACTIVITIES WITH TRIBES AND TRIBAL PROGRAMS	
BSC Guidance	**NCEH/ATSDR Response**
Formal recommendation: Convene the 2020 Tribal Environmental Health Summit; ensure that the summit results in actual change and does not merely serve as another federally sponsored event. Collaborate with and leverage the resources of federal partners, particularly EPA and the National Institutes of Health (NIH), to hold the 2020 Tribal	The National Indian Health Board (NIHB) is a non-profit organization that represents tribal governments and provides a variety of services to tribal groups across the country. NIHB was awarded funding from CDC to launch regional listening sessions and will use key outcomes from these events to inform planning efforts for the 2020 Tribal EH Summit. NCEH/ATSDR formed an internal planning group that has initiated discussions on the needs and concerns of Indian Country to include in the 2020 Tribal EH Summit. However, the NCEH/ATSDR planning group will be expanded to a larger workgroup to engage EPA,

PRESENTATION: NCEH/ATSDR ACTIVITIES WITH TRIBES AND TRIBAL PROGRAMS	
BSC Guidance	**NCEH/ATSDR Response**
EH Summit that is national in scope.	NIH, other parts of CDC with tribal activities, and the ATSDR Regional Offices in the planning efforts for the 2020 Tribal EH Summit. EPA already has expressed an interest in providing funding and support for this event.

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

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

- The possibility of incorporating data from the Citizen Science Project into the NCEH National Environmental Public Health Tracking Network.
- NCEH/ATSDR's plans to coordinate its efforts with the CDC/ATSDR Tribal Advisory Committee during the planning phase of the 2020 Tribal EH Summit.

BSC GUIDANCE

- ATSDR's rationale for selecting non-controversial sites to pilot the Citizen Science Project is appreciated and completely understandable from the professional perspective of designing a study. However, the public likely will negatively view and interpret this approach as ATSDR's intentional effort to avoid sites with the most complex exposures and longstanding community concerns. ATSDR should attempt to strike an appropriate balance for the pilot by selecting "X" percent of controversial sites (smaller number) and "X" percent of non-controversial sites (larger number).
- NIEHS regularly posts podcasts on its website on a broad range of EH topics. ATSDR should leverage its existing partnership with NIEHS to post a new podcast on the Citizen Science Project (https://www.niehs.nih.gov/news/podcasts/index.cfm).
- NCEH/ATSDR is commended for including NIHB as a key partner at the outset of the planning efforts for the 2020 Tribal EH Summit. Most notably, NIHB brings to bear a strong focus on clinical practice. However, the BSC reiterated its previous guidance and also suggested other potential tribal partners for NCEH/ATSDR to consider for the planning activities.
    - Federally funded tribal groups should be engaged to provide their perspectives and represent the missions of their respective sponsoring agencies: the ATSDR-funded Tribal Public and Environmental Health Think Tank; the EPA-funded National Tribal Toxics Council, National Tribal Air Association, and National Tribal Water Council; and the NIH-funded Tribal Advisory Committee.
    - The National Congress of American Indians (NCAI) should be engaged from a "tribal endorsement/tribal credibility" perspective because high-level and respected tribal leaders account for the vast majority of its membership. NCAI was founded in 1944 and is the oldest and largest non-profit organization that represents tribal governments and communities.
    - The Oregon State University (OSU) Superfund Research Program should be engaged due to its close collaborations with tribes to conduct various EH research projects in Indian Country.
    - The OSU Center for Health Sciences should be engaged due to its partnership with the Cherokee Nation to open the nation's first college of medicine on tribal

land in 2020. The role of this new academic institution in strengthening tribal workforce development likely will be a key discussion topic during the summit.

NCEH/ATSDR OD and program staff made several remarks in follow-up to the BSC's input. Dr. Goodwin clarified that ATSDR will select "non-controversial" sites for the pilot because the focus must be placed on refining the overall citizen science approach, such as identifying and correcting technical issues with the low-cost sensors and training community members.

ATSDR will launch the one- to two-year pilot at two of its sites with ongoing air quality investigations of PM. However, all types of sites with important EH concerns will be included when the Citizen Science Project is fully implemented. The overarching goal of the tools, training materials, and other resources will be to empower communities to collect samples and interpret air quality data at their sites without the involvement or federal or state agencies.

Dr. Breysse explained that the 2020 Tribal EH Summit will serve as a starting point in establishing closer collaborations with tribal programs, identifying gaps and needs in workforce development and other important tribal issues, and targeting resources to these efforts. He emphasized that the summit also will serve as only one component of NCEH/ATSDR's broader focus on EH inequities and environmental justice.

Drs. Buchanan and Breysse responded to the BSC's question regarding the agenda for the 2020 Tribal EH Summit. The planning workgroup has not yet developed a process to identify, prioritize, and select agenda topics. However, the planning workgroup will initiate this effort by gathering information from a broad range of sources, including input provided to NIHB via the regional listening sessions; input provided by NCEH/ATSDR's internal and external partners, including tribal organizations; and lessons learned from ATSDR's small-scale tribal summit in Washington State in 2018.

Update on the ATSDR ToxProfiles™

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

Dr. Cibulas presented an update on the ATSDR ToxProfiles™. The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) is the legislation that mandates ATSDR to develop the ToxProfiles™. The Superfund Amendments and Reauthorization Act of 1986 made three important changes to the CERCLA legislation. First, a Substance Priority List will be prepared, in order of priority, of the most commonly found hazardous substances. Second, the ATSDR Administrator will prepare toxicological profiles of available toxicological information and epidemiologic evaluations. Third, toxicologic testing will be performed to identify adverse health effects in humans.

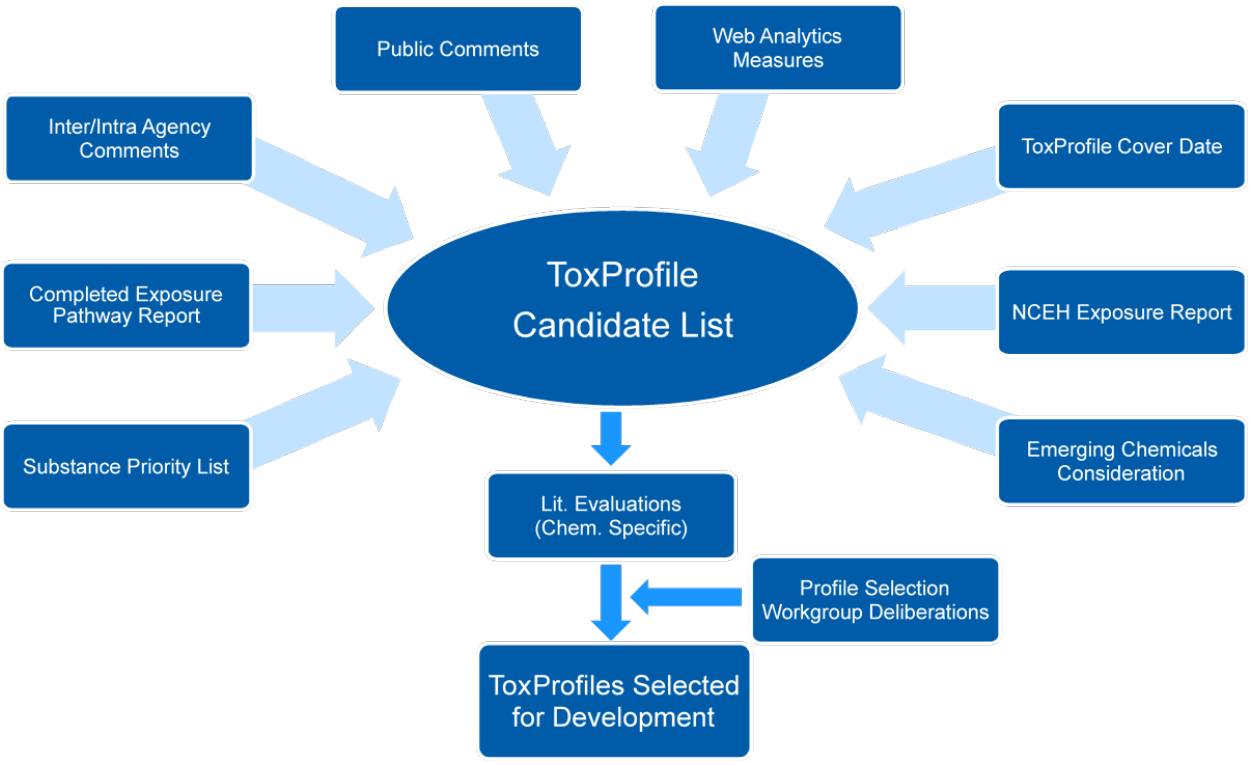
ATSDR applies a rigorous algorithm to identify, rank, and annually evaluate the 275 most hazardous substances based on their toxicity, frequency of occurrence at National Priorities List sites, and potential for human exposure. Arsenic, lead, and mercury have been the top three contaminants on the Substance Priority List for over 30 years. The purpose of the ToxProfile™ is three-fold: (1) succinctly characterize toxicological and adverse health effects information; (2) identify levels of exposure that present a significant risk to human health (i.e., minimal risk levels

[MRLs]); and identify research areas needed to fill data gaps. The ToxProfiles™ undergo rigorous intra-/ interagency peer review processes and are made available for public comment.

ATSDR established MRLs to estimate the amount of a chemical an individual can eat, drink, or breathe each day without a detectable risk to health. MRLs are developed for non-cancer health effects; are not intended to define clean-up or action levels; and serve as a screening tool to help public health professionals target their efforts. The MRL is calculated by using the point of departure as the numerator and the uncertainty factor multiplied by the modifying factor as the denominator.

The point of departure reflects "no observed adverse effect level" (NOAEL), the "lowest observed adverse effect level" (LOAEL), or the lower limit of a benchmark dose. The uncertainty factor is the value applied to account for any uncertainties related to intra-human variability, interspecies extrapolation, and NOAEL-to-LOAEL extrapolations. The modifying factor of less than 0 is applied to account for inadequacies in the database that are not covered by uncertainty factors.

Dr. Cibulas presented the following graph to illustrate the rigorous process and specific criteria that ATSDR applies to identify candidates for new ToxProfiles™ or select existing ToxProfiles™ to be updated.



ATSDR also uses a comprehensive decision tree to evaluate toxicological studies and human epidemiology studies in the literature to inform the development and/or update of the ToxProfiles™. ATSDR's decisions are based on the quality of the study; exposure criteria; and the ability of the study to address data needs, provide new information, and support new MRL derivations.

ATSDR has drastically redesigned the content and organization of the ToxProfiles™ over time. Based on surveys to and interviews with stakeholders, the content of site assessment documents was analyzed. To support this effort, the ToxProfiles™ were characterized based on their usage by health assessors, clinicians, and other government users. Information needs were identified and input was solicited to make improvements. To enhance readability, for example, redundant information was removed; more graphics and visual summaries were added; synthesis of the data was increased; and study narratives were decreased. ToxProfile™ users also suggested more frequent updates.

The public health statement was separated from the ToxProfile™. Chapter 1 was extensively revised with three major changes for this section to serve as a more effective Executive Summary. First, only a brief discussion is provided on the MRLs. Second, based on input from health assessors, a "thermometer" figure is included to illustrate doses at which the literature indicates the occurrence of acute, intermediate, and chronic effects. Third, new tables and figures are included to feature the most sensitive endpoints.

The "Levels of Significant Exposure" table is presented in color-coded rows. Appendix A is included to facilitate easier and more frequent updates. The "Health Effects" chapter is organized by individual endpoints rather than by route of exposure. The discussion within each endpoint covers exposure routes and duration-specific data. Epidemiology study tables were added to facilitate rapid updates to the ToxProfiles™. For example, a row can be easily added to the table for each new study.

Specific chapters were combined, while other content was entirely removed, such as methods for reducing exposure and analytical methods that were infrequently used. The "Systematic Review Appendix" was created to illustrate the risk of bias and the scoring of the quality of each study for the systematic review of the ToxProfiles™. A similar process is used for the non-systematic review of the ToxProfiles™.

Based on input from health assessors, more clearly defined MRL worksheets were added to facilitate easier copying/pasting of this information in health assessment documents and/or fact sheets. A summary statement with the "Rationale for Not Deriving an MRL" was included to improve transparency and readability. ATSDR solicited follow-up input after the ToxProfiles™ were redesigned to validate the redesign elements and identify additional needs of the users. The feedback has been positive overall.

ATSDR's recent and overall accomplishments include releasing 27 ToxProfiles™ in FY2017-FY2018; completing 183 ToxProfiles™ in total; calculating a total of 449 MRLs; and performing targeted updates in FY2018 for 45 percent of older ToxProfiles™ that were developed more than 15 years ago. ATSDR also has significantly increased the impact and reach of the ToxProfiles™ to diverse audiences. From a policy perspective, the ToxProfiles™ informed one or more exposure-related policies in 88 percent of states (2004-2017); 124 state policy actions or MRLs (2015-2017); and 22 federal policy actions or MRLs (2015-2017).

From a public health perspective, most recommendations made at hazardous waste sites (e.g., 71-100 percent) in 2011-2018 were based on MRLs or NOAELs/LOAELs from the ToxProfiles™. These results are based on public health assessments and health consultation documents published by ATSDR and state governments. From an academic/scientific perspective, the number of citations of ToxProfile™ data in peer-reviewed health and environmental studies

ranged from 1,940 in 2013 to 1,310 in 2018. These results are based on a Google Scholar search of literature citations.

ATSDR is focusing on 46 ToxProfiles™ with a high level of public interest at this time.

30 Ongoing ToxProfiles™

- PFAS
- Glyphosate
- Lead
- Ethylene oxide
- Trichloroethylene
- Perchloroethylene (i.e., tetrachloroethene)

16 New ToxProfiles™

- Inorganic mercury
- Beryllium
- Chlorodibenzofurans

Additional details on two new substances are summarized as follows. ATSDR calculated MRLs for four PFAS ToxProfiles™ and closed the third public comment period for these draft documents in August 2018. Differences between ATSDR's MRLs for the four PFAS chemicals and EPA's long-term health advisories for the same PFAS chemicals caused controversy. Most notably, the public comment period generated approximately 800 comments from 60 different sources. ATSDR is making strong efforts to finalize and publish the PFAS ToxProfiles™ as quickly as possible. However, ATSDR anticipates that these documents will need to be updated on an annual basis to reflect emerging research and data.

The glyphosate ToxProfile™ is another highly anticipated document due to the ongoing debate in the public health and scientific communities regarding the carcinogenicity of this chemical. ATSDR expects to release the public comment version of the glyphosate ToxProfile™ in early 2019. The ToxProfile™ website is (https://www.atsdr.cdc.gov/toxprofiledocs/index.html).

Overall, ATSDR is obtaining input on an ongoing basis to validate the redesigned ToxProfiles™. Most notably, five usability questions are now included in the charge to all peer reviewers and the *Federal Register* notice announcing the public comment period. Dr. Cibulas concluded his update by asking the BSC to consider and provide input on the same questions.

1. "Does the chapter organization make it easier for you to find the information you need? For example, are you satisfied with the organization of the health effects chapter by organ system rather than exposure route?"
2. "Are the new tables and figures clear and useful? Do they make the Toxicological Profile easier to read?"
3. "If you have previously used any Toxicological Profile(s) for your work, which parts or content are the most useful to you and what do you use it for?"
4. "Does the profile contain all of the information you need? If no, please elaborate on what additional information would be helpful."
5. "Is there information you would like to see in the profile that is not currently included? If yes, please elaborate on the additional information you would like to see in the profile."

BSC DISCUSSION: ATSDR TOXPROFILES™

Dr. Cibulas and other DTHHS staff provided additional details on the following topics in response to specific questions by the BSC members.

- The extent to which immune effects are discussed in the new glysophate ToxProfile™.
- ATSDR's process or plans to systematically apply the redesigned, modernized format to older ToxProfiles™.

BSC GUIDANCE

Individual BSC members confirmed their long-term use of the ToxProfiles™. The members found these outstanding products to be extremely valuable and extraordinarily useful in their respective professions. The BSC's overall position was that the ToxProfiles™ serve as the best synthesis of toxicology information in the world. In response to Dr. Cibulas's request, the BSC provided input on the five usability questions.

Question 1

- The organization of the "Health Effects" chapter by organ system is a sound approach and is a much better design than the previous ToxProfile™ format.

Question 2

- The redesigned ToxProfile™ format has greatly enhanced the overall usability of these products in the field.

Question 3

- The BSC members have used the ToxProfiles™ for research purposes; day-to-day EH practices in occupational and environmental medicine clinics; teaching tools in academic settings; and an evidence base to support EPA's regulatory authority.

Questions 4 and 5

- Based on ATSDR's decision tree, only "good quality" studies are evaluated to include in the ToxProfiles™. However, some "lower quality" studies contain sound data that might be important and relevant to a specific ToxProfile™. ATSDR should consider this caveat during the systematic review process.
- ATSDR should explore the possibility of adopting other forms of systematic review, including risk of bias. ATSDR also should produce evidence to show that its existing methods are "tried and true" and generate a fair assessment of a good quality study. Moreover, ATSDR should publish its systematic review process for the ToxProfiles™ in the peer-reviewed literature.
- ATSDR should take a "one-health" approach in the ToxProfiles™ by synthesizing the environmental state content and animal toxicity data for a particular toxin. This new section should clearly describe health effects that might occur if a toxin migrates into water or contaminates land.
- ATSDR should develop new ToxProfiles™ on microcystins and brevetoxins. These emerging toxins have a high potential of contaminating the water supply.
- ATSDR is commended for its achievements in increasing the reach and impact of the ToxProfiles™ to diverse audiences, including the policy, public health, academic/scientific, and research sectors. However, more emphasis should be placed on outreach to clinicians and other providers as an additional audience for the ToxProfiles™. To better address the EH needs and concerns of their patients, for example, pediatricians would

greatly benefit from more toxicological information on hazardous substances in the ToxProfiles™ in relation to children's health. To support this effort, ATSDR should consider adopting EPA's methodology. Most notably, EPA conducts modeling by using pediatric-specific data to calculate exposure values. Toxicity data are then extrapolated from adults to children.

- ATSDR published the methyl mercaptan ToxProfile™ in 1992 with outdated studies from the 1970s, but this substance is present in the current gas supply. Most notably, limited evidence has shown that mercaptan directly contributed to the gas explosion in Merrimack Valley, Massachusetts in September 2018. Methyl mercaptan reflects a significant gap due to the clear discrepancy between an existing ToxProfile™ and the absence of data to support health concerns from this exposure. ATSDR should review the recent literature and conduct research to update the methyl mercaptan ToxProfile™.

Based on the discussion, Dr. Perry noted that the BSC's guidance on the five ToxProfile™ usability questions was overwhelmingly positive. Similar to her BSC colleagues, she also applauded ATSDR's recent accomplishments, particularly the tremendous efforts to modernize and update the ToxProfiles™ and the increased reach and impact of these products on diverse audiences. However, she pointed out that the overall ToxProfile™ program faces imminent or future threats. Over the past six years, for example, the highest number of citations of ToxProfile™ data in the peer-reviewed literature was in 2013 (1,940); the lowest number of citations was in 2015 (1,203); and the current number of citations in 2018 (1,310) reflected another decrease from the previous year.

Dr. Perry identified several factors that potentially could be contributing to this downward trend, such as the reliance on data from other credible sources; publications of fewer studies on the hazardous substances evaluated in the ToxProfiles™; or the decreasing role of the ToxProfiles™ as a stalwart source of information. She requested the BSC's input on effective strategies to further increase the reach of the ToxProfiles™. The BSC made two additional comments in this regard.

- ATSDR should perform testing to determine the feasibility of using cell phones, tablets, and other mobile devices as new methods to disseminate the ToxProfiles™ to a new generation of users. The lengthy ToxProfiles™ are still best reviewed on desktop/laptop computers, but these technologies do not meet the needs of current users who rely on their mobile devices to obtain information.
- ATSDR should recruit summer interns, graduate students, or fellows to produce brief 30-second videos as marketing tools for the ToxProfiles™. For example, the videos could feature end-users from diverse sectors describing their personal experiences in applying the ToxProfiles™ to their daily work. The availability of the videos on the ATSDR website and CDC's social media sites (e.g., Facebook, Twitter, and YouTube) might help to reach new audiences, such as local elected officials and city planners.

Dr. Cibulas and Mr. Henry Abadin, of DTHHS, thanked the BSC for its thoughtful and helpful input to assist ATSDR in its ongoing efforts to refine the ToxProfiles™ and further increase the reach of these products. ATSDR would present its detailed responses to the BSC's guidance during the next meeting, but they made several follow-up remarks in the interim.

- The ToxProfiles™ are not necessarily intended for clinical use, but ATSDR is making efforts at this time to include more content to address the specific needs of providers.

- ATSDR will consider an approach to better address and more prominently feature children's EH risks in the ToxProfiles™.
- ATSDR regularly reviews the literature to identify emerging and/or priority EH issues that potentially should be addressed in the ToxProfiles™.
- ATSDR adopted the NTP Office of Health Assessment and Translation's (OHAT) systematic review process for the development of the ToxProfiles™. ATSDR also is exploring the possibility of adopting new systematic review tools that are being utilized by the EPA National Center for Environmental Assessment, such as artificial intelligence and the Health Assessment Workspace Collaborative. These new tools might improve and streamline ATSDR's existing tried and true methods for the ToxProfiles™.
- ATSDR currently is exploring options to disseminate ToxProfile™ data in a compatible format for hand-held devices. Most notably, ATSDR's recent review of its website metrics showed that multiple users now use their mobile devices to access ToxFaqs™ (i.e., hazardous substance fact sheets).
- The BSC is free to provide comments to ATSDR and submit nominations of ToxProfiles™ based on data needs and adverse health effects in humans, such as the suggestion to update the 1992 methyl mercaptan ToxProfile™. The BSC can use the public comment periods for the ToxProfiles™ that are published in the *Federal Register* and/or request to be added to ATSDR's electronic listserve for its "Dear Colleague" letters. If sufficient data are not available for a nominated toxic substance, however, the issue could still be addressed in an ATSDR product other than a ToxProfile™.

Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts

Sharunda Buchanan, PhD, MS
Director, NCEH/ATSDR Office of Priority Projects and Innovation
Centers for Disease Control and Prevention

Dr. Buchanan presented an overview of the draft Federal Lead Action Plan (FLAP), including the proposed vision and mission statements, goals, key priorities, timeline, and overall process for this initiative. The President's Task Force on Environmental Health Risks and Safety Risks to Children was established in 1997 by Executive Order 13045. The key function of the Task Force was to submit recommendations and federal strategies to President Clinton on children's EH and safety risks within the limits of the Administration's budget. EPA and HHS were designated as the co-chairs of the 17-member Task Force of federal departments and agencies.

The Executive Order called for the Task Force to achieve three key objectives. First, priority issues of EH and safety risks to children that could be best addressed by federal interagency efforts would be identified. Second, interagency actions to protect and promote children's EH and safety would be recommended and implemented. Third, communications would be established with federal, state, and local decision-makers to protect children from EH and safety risks. The Task Force formed a Lead Subcommittee and designated HHS/CDC, EPA, and the U.S. Department of Housing and Urban Development as the co-chairs.

The Task Force issued a publication in February 2000, *Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards*. The report primarily focused on expanding efforts to correct lead paint hazards, particularly in low-income housing. The report also included

recommendations to eliminate childhood lead poisoning in the United States as a major public health problem by 2010. Lead paint hazards continue to serve as the primary source of children's lead exposure, but emphasis must be placed on other sources due to the severity of lead problems in Flint, Michigan and other communities.

The Task Force issued another publication in November 2016, *Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts*, to focus on current and planned federal activities to reduce childhood lead exposure. The report identified over 58 federal programs and efforts and served as the foundation for the development of the current FLAP.

The Task Force initiated the process to develop the FLAP in the winter of 2016-2017 by soliciting public input through various sources, including presentations at public meetings, an online survey, and a *Federal Register* notice to announce a public comment period. These sources generated over 700 public comments in four broad categories: changes to legislation, outreach suggestions, proposed federal actions, and funding.

The principals of the Task Force convened a meeting in February 2018 to reach consensus on the FLAP. The meeting led to several key outcomes. The principals confirmed that addressing childhood lead exposure is a priority for all federal departments and agencies represented on the Task Force. Agreement was reached on the FLAP goals and an aggressive deadline was established to complete the FLAP activities, including interdepartmental clearance. The Task Force has achieved several key milestones since the principals' meeting.

- Spring 2018:
    - The federal partners committed to conducting specific actions.
    - The Task Force co-chairs submitted drafts of the FLAP for the interagency and OMB reviews.
- Summer 2018: The Task Force members reviewed the latest draft of the FLAP.
- October 2018: The Task Force Steering Committee and Lead Subcommittee members held a meeting to respond to comments from the interagency and leadership reviews.
- November 2018:
    - The Task Force co-chairs and Lead Subcommittee members revised the pre-clearance draft of the FLAP.
    - The Task Force Steering Committee held a meeting to discuss comments submitted by leadership and the agencies.
    - The Task Force co-chairs and Lead Subcommittee began production on the final draft of the FLAP and initiated coordination with Public Affairs and Communication Offices.
- December 20, 2018: The Task Force will publish the FLAP.

Dr. Buchanan highlighted the major sections of the FLAP, but she emphasized that this content cannot be cited or quoted before the release date on December 20, 2018.

- Proposed vision: "The United States will become a place where children, especially those in vulnerable communities, live, learn, and play protected from the harmful effects of lead exposure."
- Proposed mission: "Improve the health of children in the United States by eliminating harm from lead exposure through federal collaboration."
- Goals and key priorities:

FEDERAL LEAD ACTION PLAN	
Goal	**Key Priority**
Goal 1: Reduce children's exposure to lead sources	Reduce children's exposure to: ➢ Lead-based paint ➢ Lead service lines ➢ Contaminated drinking water ➢ Contaminated soil
Goal 2: Identify children in high-risk communities and improve their health outcomes	Improve the identification of children who are exposed to lead and assure linkage to follow-up services through patient-centered medical homes in a coordinated system of care.
Goal 3: Communicate more effectively with stakeholders	Consolidate and streamline federal messages to
Goal 4: Support critical research areas	Prioritize and address critical research needs, including lead research and data needs identified by states and tribes, to inform policies and gaps in knowledge.

BSC GUIDANCE: FEDERAL LEAD ACTION PLAN

The BSC looked forward to periodic updates on the FLAP after the release of the document on December 20, 2018. In the interim, Dr. Payne-Sturges provided several comments for the Task Force to consider in its ongoing efforts to finalize the draft. She questioned the rationale for the continued narrow focus on the old lead model (e.g., children as an indicator) at the federal level. She emphasized that a shift to a broader focus (e.g., elimination of lead sources in the environment) will be particularly important to federally funded lead programs.

Dr. Payne-Sturges proposed three key changes to the FLAP in this regard. First, the language in Goal 1, "Reduce children's exposure to lead sources," should be modified and expanded as follows: "Reduce lead hazards in the environment." Second, the FLAP should include a clear explanation on the importance of the federal government shifting to a broader focus of eliminating lead sources in the environment. Third, the FLAP should include a compelling statement to emphasize the major financial investments that will be needed to remove the reservoir of lead from the environment.

Dr. Buchanan made several remarks in response to Dr. Payne-Sturges's comments. Financial investments to achieve the FLAP goals and priorities are not mentioned because no new federal funding has been allocated to support this initiative. In addition to describing the ongoing and new lead activities of the federal agencies, however, the Task Force also acknowledged that private foundations and other non-governmental organizations (NGOs) will need to play a critical role in the national effort to eliminate lead sources from the environment.

The brief overview of the draft FLAP to the BSC was limited to the four goals and their key priorities regarding children's exposures to lead sources, effective communications, and critical research needs. However, the full document includes broader guidance by the federal agencies on eliminating lead sources from the environment. Moreover, NCEH/ATSDR, as the operational arm of HHS's membership on the Task Force, has made a commitment to conduct ongoing

surveillance and evaluation to measure the effectiveness of its efforts and activities in achieving the FLAP goals and priorities over time.

In response to a specific question by Dr. Brown, Dr. Buchanan explained that ATSDR, EPA, and the U.S. Department of Education have described their specific activities in the FLAP to address school-based lead exposures to children.

Overview of Cannabis and Public Health

CAPT Althea Grant-Lenzy, PhD
Senior Advisor for Science for the Deputy Director for Non-Infectious Diseases
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Dr. Grant-Lenzy presented an overview of CDC's public health role in addressing cannabis. She explained that her interchangeable use of the terms "marijuana" and "cannabis" would refer to dried leaves, flowering tops, other products, and drugs derived from cannabis plants. The 2017 National Survey on Drug Use and Health reported that marijuana is the most commonly used illicit drug and accounts for more than 26 million users annually in the United States. Marijuana use is highest and increasing among adults 18-25 years of age. Most surveillance data show that marijuana use among children 12-17 years of age has remained unchanged or decreased over recent years.

CDC is concerned about the health and safety risks associated with the use of marijuana, such as respiratory and cardiac illnesses; dependence; mental health-related problems; impaired driving; and adverse effects on the developing adolescent brain related to negative or impaired social, cognitive, educational, and emotional development. In addition to these adverse health effects, the cannabis plant also has chemicals that might help symptoms for some health problems.

That cannabis plant contains over 500 national components with over 100 cannabinoids. The tetrahydrocannabinol (THC) component is largely responsible for the psychoactive effects or the "high" associated with marijuana use. The cannabidiol (CBD) component has some medicinal effects, but does not cause psychoactive effects. The balance between THC and CBD is believed to be important due to their interaction.

States increasingly are legalizing the use of cannabis plants as medicine for certain conditions. However, limited evidence has been produced to date to demonstrate the effectiveness of cannabis for most of the conditions that are included on lists of approved indications across states. The evidence supports the potential role of THC in increasing appetite and reducing nausea associated with chemotherapy in patients with cancer; reducing chronic pain in adults for some conditions; and reducing spasms reported by patients with multiple sclerosis. The U.S. Food and Drug Administration (FDA) recently approved the first drug that contains purified CBD directly derived from the cannabis plant to treat seizures associated with two rare and severe forms of epilepsy: Lennox-Gastaut syndrome and Dravet syndrome.

Marijuana is illegal under federal law, but some state and local laws allow the use of this product or the use of some of its constituents for medical and/or recreational purposes. Most notably, recreational use by adults 21 years of age and older has been legalized in 10 states and the

District of Columbia. Comprehensive medical marijuana programs have been implemented in 23 states. The use of medical recommendations for low-THC products is allowed in 14 states. The use of marijuana is not legally approved for any purpose in three states. Up-to-date information on state medical marijuana laws is available at (http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx).

The 2016 ElSohly, *et al.* study described changes in the potency of cannabis from 1995-2014. The study defined "potency" as a percentage of THC in illicit cannabis plants. The study reported a consistent increase in the potency of cannabis from approximately 4 percent in 1995 to approximately 12 percent in 2014. Over the same two decades, the CBD content decreased, on average, from approximately 0.28 percent in 2001 to less than 0.15 percent in 2014. This trend resulted in a change in the ratio of THC to CBD from 14 times in 1995 to approximately 80 times in 2014.

Smoking is still the primary delivery method for marijuana, but the product increasingly is being consumed through other methods due to more widespread policy changes in some states that have legalized medical and recreational uses of marijuana. The various methods to consume marijuana are listed below, but each method is associated with different health effects and harms based on its THC potency.

- Combustible products (joints, pipes, bongs, bowls, and blunts)
- Vaporizers (e-cigarette-like devices)
- Edibles (brownies, cookies, and candies)
- Drinks (elixirs, syrups, and hot chocolate)
- Dabbing (concentrates and waxes)
- Other emerging products (gas masks, oral pill formulations, topical preparations, and suppositories)

CDC has identified several areas of public health concern due to the much higher population of marijuana consumers in the United States; the absence of data on new and emerging delivery methods to use marijuana; and the unprecedented potency levels of marijuana. In terms of chronic diseases, the public health concerns include limited understanding of the long-term health effects of cannabis, particularly in terms of cancer, respiratory disease, and cardiovascular disease. CDC recognizes the need for additional surveillance and research to increase current knowledge on the long-term effects of marijuana use on chronic diseases.

In terms of vulnerable populations, the public health concerns include data that show an increase in marijuana use among pregnant and breastfeeding women. However, published studies in the literature clearly demonstrate that marijuana crosses the placental barrier and is present in breast milk. The American College of Obstetricians and Gynecologists and other medical professional associations have issued strong position statements against the use of marijuana by pregnant and breastfeeding women. In terms of youth, the public health concerns include prevention efforts to decrease access in this population because marijuana can harm the developing brain, impact educational attainment, and impair performance. In terms of injury prevention, the public health concerns include severely impaired driving, workplace accidents, or other acute injuries from marijuana use.

In terms of product safety and environmental health, the public health concerns include the use of pesticides, pathogens, and chemicals in the production of cannabis that can decrease the safety of products, reduce workplace safety, adversely impact the environment, and result in

biological effects from exposure to secondhand marijuana smoke. In terms of mental health, substance abuse, and dependence, the public health concerns include adverse mental health consequences and the potential development of substance use disorders due to the increasing potency and prevalence of marijuana use.

Dr. Grant-Lenzy concluded her overview by emphasizing that CDC has no official mandate or funding to address public health concerns related to marijuana use. However, she described the activities that CDC is conducting in three major areas to support states in their initiatives on the public health outcomes of marijuana use.

1. CDC is collecting and disseminating data to states to strengthen their understanding of trends in marijuana use. CDC began expanding its existing public health surveillance systems in 2016 (e.g., Behavioral Risk Factor Surveillance System, Youth Risk Behavior Surveillance System, Pregnancy Mortality Surveillance System, and NHANES) to support this effort. CDC established several key objectives for its expanded surveillance systems: integrate new modules and questions to collect more useful, higher quality data on marijuana use; enhance monitoring of trends in this area; and more effectively assess health effects related to marijuana use. CDC's ongoing efforts to build the marijuana surveillance infrastructure at the national level are designed to support the epidemiologic response and analytic capacity of public health partners at the state level; provide technical assistance (TA) to these programs; and gather and distribute relevant data on the use of marijuana in various populations for broader dissemination to local policymakers. However, CDC acknowledges that national, state, and local marijuana surveillance and data collection efforts will not capture exposure from homegrown cannabis plants.

2. CDC is sharing accurate information with the public from evidence-based sources and experts. CDC partnered with multiple federal and state agencies to commission a new report by the National Academies of Sciences, Engineering, and Medicine (NAS). The NAS report summarized the best available science on marijuana and its impact on health, including the potential therapeutic benefits and adverse health consequences of this product on 21 health conditions. The key findings of the NAS report were expected and consistent with the existing literature. For example, the major conclusion was the critical need for additional research on the public health effects of marijuana use. The strongest evidence of harm from marijuana was found to be the risk of schizophrenia in people with an underlying family history of this mental illness and the potential for brain and cognitive effects (e.g., learning, attention, and memory deficits) in both adults and adolescents. However, two surprising results of the NAS report were the risk of preterm birth from marijuana use among pregnant women and the potential for marijuana use to advance to dependence on other substances. As a companion document, the CDC Foundation translated the key findings from the 500-page NAS report into an online communication toolkit for states to share with their communities, healthcare providers, and other local partners.

3. CDC is translating complex science into simplified messaging and guidance documents for the public. CDC collaborated with a diverse group of partners (e.g., states, unions, and industry) to address occupational health and safety hazards and ensure the protection of workers in the legalized marijuana growing, processing, and retail industry. NIOSH led this effort for CDC by conducting onsite health hazard evaluations and producing reports of the key findings. CDC also formed the "Multi-State Marijuana and Public Health

Learning Collaborative" to convene public health leaders in states that have legalized retail and recreational marijuana use. The overarching goals of the collaborative are for the state partners to exchange experiences and lessons learned; synchronize and share relevant resources; and identify best practices to protect public health at the local level.

BSC DISCUSSION: CANNABIS AND PUBLIC HEALTH

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

- CDC's approaches to overcome barriers to underreporting and inaccurate reporting of marijuana use by key respondents to its national surveys (e.g., adolescents and pregnant women) since the product is still illegal under federal law.
- CDC's ongoing laboratory studies that are highlighting the similarities and differences between health effects from exposure to secondhand smoke from tobacco cigarettes versus marijuana.
- CDC's ongoing plans to partner with Canada on research, surveillance, and data collection efforts, including changes in social norms, since this country has legalized marijuana at the national level as of October 16, 2018.

BSC GUIDANCE

- CDC should add new questions to its national surveys to determine the frequency by which mixtures of marijuana products and other drugs, particularly fentanyl, are being used. For example, serious health consequences are occurring among users who are expecting to consume marijuana only, but are required to be intubated or undergo other medical procedures due to their unintentional use of other drugs.
- CDC should target more of its current research efforts to systematically track and monitor health outcomes from new marijuana delivery methods. Most notably, Massachusetts has reported two outbreaks of Legionella pneumonia from marijuana use through unsanitary, reused bongs.
- CDC should provide states with more data to support their policy debates on the critical importance of maintaining smoke-free laws. For example, longstanding state and local non-smoking policies are continuing to be eroded because an increasing number of states are legalizing the use of marijuana for recreational and/or medicinal purposes. The scientific rigor of CDC's data will greatly assist states and localities in presenting strong evidence-based arguments to policymakers on the adverse effects of secondhand marijuana smoke exposure.
- CDC should promote DLS's recent accomplishments and provide strong leadership to support the development of a new marijuana research agenda at the federal level. For example, new funding of $9 million was allocated to DLS to improve laboratory methods to measure exposure to fentanyl and fentanyl-like compounds. Moreover, DLS has conducted groundbreaking tobacco studies in the laboratory, including "gold-standard" research on exposure to secondhand smoke and health effects from e-cigarettes. DLS's leadership role in CDC's new marijuana research agenda should be to prioritize the development of methods to simultaneously identify interactions across several different analytes and provide FDA with analytical capacity in this area. DLS also should explore the possibility of serving as a resource laboratory to FDA to evaluate the presence of these analytes in food products.

Dr. James Pirkle, Director of DLS, and Dr. Benjamin Blount, Chief of the DLS Tobacco and Volatiles Branch, made several remarks in follow-up to the BSC's guidance that was directed to DLS. DLS recently published a paper in *Pediatrics* on exposure to secondhand marijuana smoke among children who live with a caregiver who actively smokes this product. The paper reported measurable marijuana metabolites at a fairly high prevalence in the urine of this population of children.

The paper also described DLS's development of an analytical method that can measure two different types of cannabonoids in human urine. Most notably, DLS's new analytical method has capacity in two key areas: (1) accurately distinguish between exposures to different types of recreational or medicinal cannabis products and (2) quantify levels of exposure biomarkers that broadly range from active marijuana users to people with exposure to secondhand marijuana smoke.

DLS already has applied its urinary cannabonoid method to a few small studies to assist in interpreting biomarkers of exposure. However, DLS is extremely interested in leveraging long-term funding to achieve its vision of characterizing secondhand marijuana smoke exposure to the same degree, breadth, and magnitude as secondhand tobacco smoke exposure. This new initiative will generate regulatory interventions to decrease exposure to secondhand marijuana smoke and stimulate new efforts to document the efficacy of these interventions.

DLS currently is collaborating with the FDA Center for Tobacco Products on various laboratory projects, but these activities exclusively focus on tobacco, particularly ongoing efforts to estimate population-level harm based on biomarkers that are associated with the use of tobacco products. However, multiple questions on marijuana use are directed to the Population Assessment of Tobacco and Health cohort. Due to the federal requirement for these funds to support tobacco research only, DLS will apply its analytical tools to better address marijuana use. Moreover, DLS welcomes the opportunity to contribute its analytical expertise, but an evaluation of marijuana analytes in food products likely will be conducted outside of DLS.

Overview of the CDC and NCEH/ATSDR Open Data and Privacy Protection Policies

Hao Tian, PhD, CIPP/G
Scientific Data Manager, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Tian presented an overview of the CDC and NCEH/ATSDR open data and privacy protection policies. The CDC/ATSDR Open Data Policy (ODP) on Public Health Research and Non-Research Data Management and Access became effective on January 26, 2016. The ODP applies to all new public health data collection proposed after this date. The overarching goal of the ODP is to ensure public access to federally funded public health data in accordance with three key federal policies: "Increasing Access to the Results of Federally Funded Scientific Research;" "Open Data Policy: Managing Information as an Asset;" and "Making Open and Machine Readable the New Default for Government Information."

The ODP defines "public health data" as digitally recorded factual material that is commonly accepted in the scientific community as the basis for public health findings, conclusions, and implementation. The broad definition includes data collected, generated, or funded by CDC/

ATSDR as well as data reported to CDC/ATSDR to become part of its information system. Examples of non-public health data include research plans, financial/administrative data, internal reports, grantee progress reports, development of laboratory methods, and laboratory quality assurance protocols.

The ODP covers data in research/non-research projects, intramural/extramural programs, data collection systems, emergency projects, and publications. The ODP requires data to be made publicly available at the time of the publication of a manuscript or by 30 months after the end of data collection (whichever event is first). Moreover, ongoing data collection systems are required to comply with the ODP before January 25, 2019 or when data systems undergo substantial revision (whichever event is first).

The ODP identifies three data access levels. The "public release" level is for de-identified data only. Data at this level are NCEH/ATSDR's default selection and include a full individual-level dataset, aggregate data only, and data by ad-hoc request. The "restricted release" level is for restricted data sharing via data use agreements and restricted data access via the CDC Research Data Center. The "no release" level is for data that CDC is not allowed or responsible to share. With the exception of the full individual-level dataset, justification is required for the selection of all other data access levels.

The ODP calls for all CDC centers to develop implementation plans for their open data policies. The Office of Science is leading this effort for NCEH/ATSDR and has established processes to ensure all of the following activities comply with the ODP: (1) all scientific projects that collect and generate public health data; (2) all new and existing information technology systems; and (3) manuscripts published in peer-reviewed journals or the *Morbidity and Mortality Weekly Report* (*MMWR*).

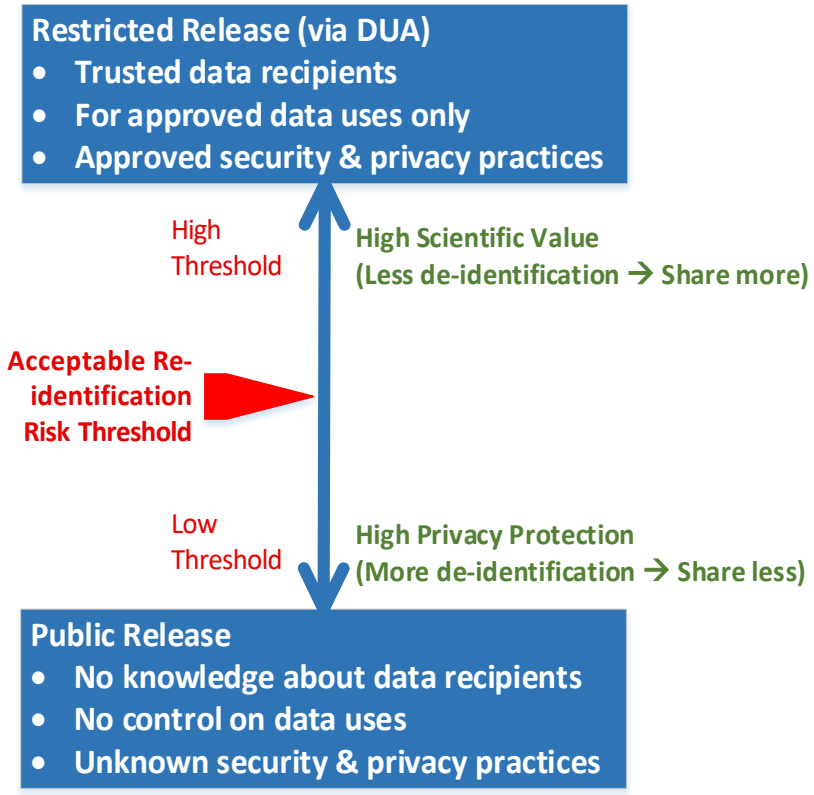
Of 165 NCEH/ATSDR manuscripts that were cleared for publication in peer-reviewed journals and the *MMWR* from January-October 2018, data in 24 manuscripts are or will be available to the public; 29 manuscripts used data collected prior to the effective date (January 26, 2016) of the ODP; 22 manuscripts contained only non-public health data; data in 65 manuscripts are not owned by NCEH/ATSDR; and 25 manuscripts had no datasets.

The critical importance of upholding individual and institutional privacy and confidentiality is highly recognized in open data activities. As a result, the public release of data is for de-identified datasets only and restricted data sharing is required when sharing personally identifiable information (PII) or limited datasets. Restricted data sharing must be for approved or consented purposes.

OMB released an official definition of PII in 2007 as "information which can be used to distinguish or trace an individual's identity, such as name, SSN, biometric records, etc., alone OR when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc." OMB later reinforced that the identification of PII must be evaluated on case-by-case basis.

Multiple challenges exist in de-identification: (1) The HIPAA Safe Harbor method has weak coverage of indirect PII and does not consider specific characteristics of each particular dataset. (2) Due to the temporary rather than permanent state of de-identified data, non-PII might become PII over time. (3) The loss of the scientific value in a dataset caused by de-identification might significantly decrease the usefulness of individual-level de-identified data.

Overall, efforts must be made to strike an appropriate balance between protecting privacy and maximizing the scientific value of data when sharing information. CDC/ATSDR's position is that public health and scientific investments are best served when data are properly shared with others. However, the rights of individuals and their data must be fully protected and respected. Dr. Tian concluded his overview by presenting a graph to illustrate the different acceptable risk levels in de-identified datasets.



BSC GUIDANCE: CDC/ATSDR OPEN DATA AND PRIVACY PROTECTION POLICIES

Dr. Bernstein acknowledged that federal agencies have been directed to select a full individual-level dataset as the default for data in the "public release" category. However, he advised NCEH/ATSDR to explore the possibility of including a new policy in the default that will allow for a screening protocol or a protective barrier prior to the public release of any data. For example, people might publicly disclose information that could be compromising to their privacy in the future, particularly in the genomics field.

Public Comment Period

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

Update on the PFAS Community of Practice

Christopher Reh, PhD, MS
Associate Director
Agency for Toxic Substances and Disease Registry

Dr. Reh presented an update on the PFAS initiatives, including a brief overview of PFAS; new funding to ATSDR to conduct PFAS research; ATSDR's planned and future PFAS studies; and ATSDR's new PFAS CoP design. PFAS chemicals were introduced in products in the 1950s. Due to their extremely strong carbon fluorine bond, PFAS chemicals are used in non-stick cookware, stain- and water-repellent carpet and clothing treatments, food packaging, dental floss and applications, paper and cardboard packaging, and AFFF.

The sources of PFAS include waste from manufacturing facilities, AFFF runoff, and PFAS-containing sludge used as soil amendments. The PFAS exposure pathways include drinking water from private residential wells and municipal systems; air and dust; fish, dairy products, produce, and meat (including game); consumer products (e.g., food containers, wrapping, clothing, and cookware); and gestational and lactational exposures. PFAS has a long biologic half-life due to its ability to rapidly bind with serum protein and its reabsorption in the kidney. Because PFAS was not designed to break down, the chemicals are environmentally persistent.

PFAS is a unique set of chemicals that affect nearly all human organ systems, including the kidney, liver, thyroid, and immune systems. Moreover, PFAS has an impact on multiple groups, including pediatric and adult populations, women during childbirth, and children (due to reduced vaccine efficacy). Recent studies indicate that more than 60 million people in the United States have been exposed to PFAS. Data also have been produced that show a correlation between cancer outcomes and PFAS.

ATSDR received new funding of $20 million in FY2018 from the National Defense Authorization Act (NDAA) to conduct PFAS studies and expects to receive an additional $20 million in FY2019. Congress has prioritized PFAS-related research and directed ATSDR to use the NDAA funds to better understand the health outcomes from these chemicals. In response to this directive, ATSDR will conduct various activities in the following four categories.

October 2018-October 2021: Exposure Assessments

- A NOFO will be released in January 2019 to select eight communities with contaminated water that are associated with DoD facilities. The contract for the exposure assessments and data collection at these sites was awarded in September 2018. An in-person contractor meeting for this effort was held at CDC in October 2018.

October 2018-October 2021: Community Engagement and Communications

- A process will be created to ensure effective community engagement/communications to diverse audiences regarding PFAS-related health effects as data are collected from the eight exposure assessment sites. This activity will include engaging communities in the study recruitment process; translating complex science into clear, simplified messages to the public; and developing provider-specific guidance (e.g., family medicine physicians, pediatricians, and internists). The contract for community engagement/communications was awarded in September 2018. An in-person contractor meeting was held at CDC in October 2018.

October 2018-October 2021: PFAS Proof of Concept Study

- The Proof of Concept Study at Pease International Tradeport in Portsmouth, New Hampshire will be piloted with a cross-sectional design to focus on PFAS exposures and health outcomes. The contract for the pilot study was awarded in September 2018. An in-person contractor meeting was held at CDC in October 2018.

October 2019-October 2023: PFAS Multi-Site Health Study

- The national multi-site health study will be designed to evaluate PFAS exposures and health outcomes. The NOFO and protocol for this effort are currently being developed.

ATSDR is engaging its internal and external partners to consider other PFAS initiatives in addition to the NDAA-funded studies. A contract was awarded in FY2018 for various activities to enhance the overall PFAS science and strengthen the community engagement efforts, including the development of a new PFAS research agenda as well as ecological analyses of PFAS-related birth outcomes and adult/pediatric cancers. Water modeling will be performed to support the exposure assessments at the eight selected sites. An analysis of community resilience and stress will be conducted at sites with PFAS-contaminated water.

ATSDR designed the PFAS Exposure Assessment Technical Tools (PEATT) to help health departments conduct statistically-based PFAS biomonitoring activities in communities in which drinking water is the primary source of PFAS exposure. The statistically-based sampling design allows states to generalize their findings to the affected community. NCEH/ATSDR awarded funding to the Association of State and Territorial Health Officials to implement the PEATT at two sites and solicit feedback. The Pennsylvania Department of Health and the New York State Department of Health will present the findings from their PEATT studies at an in-person meeting on December 19, 2018 in Fort Washington, Pennsylvania.

ATSDR will evaluate available data related to dietary exposure to PFAS in food and food products, including fish, milk, deer, food packaging materials, and locally grown produce. ATSDR will reach out to FDA and other federal partners to identify the next steps in addressing concerns regarding PFAS exposure from food. ATSDR is conducting a systematic review to better understand the relationship between lactational exposures to PFAS and health effects. Limited animal and human data have been produced on this topic, but the current guidance calls for nursing mothers to continue breastfeeding. Moreover, the preliminary findings of ATSDR's systematic review did not provide evidence to change the existing guidance. ATSDR will develop a multi-year PFAS strategy to compile immunologic studies, pediatric cancer research, and other relevant data.

ATSDR identified multiple factors that demonstrated the need for a PFAS CoP. National attention has increased on PFAS as an emerging class of contaminants and the potential health effects of these compounds. Stronger collaboration, information sharing, and strategic planning are needed across ATSDR's current and future PFAS initiatives. The implementation of consistent standards, procedures, processes, and effective and efficient resource allocation is needed when addressing PFAS-related projects and challenges. Consistent communications, policies, data management protocols, and other cross-cutting support functions need to be launched for PFAS initiatives.

ATSDR designed the new PFAS CoP with an overarching objective to facilitate collaboration, coordination, knowledge sharing, and problem-solving among public health professionals. ATSDR established five key goals to achieve this objective: (1) deliver a meaningful contribution of health effects science on PFAS; (2) share data, study results, and best practices across PFAS initiatives; (3) identify solutions to issues that are identified as "community priorities;" (4)

collaborate with internal and external public health partners; and (5) connect the network of PFAS investigations across the country with the broader public health community.

ATSDR identified eight existing and new NCEH/ATSDR products that will be linked to all PFAS initiatives in the new CoP:

- NDAA Exposure Assessments
- NDAA Community Engagement
- NDAA Pease Proof of Concept Study
- NDAA Multi-Site Health Study
- ATSDR ToxProfiles™
- ATSDR PEATT
- NCEH Health Consultations
- MRLs and Environmental Media Evaluation Guides

Dr. Reh concluded his update by presenting an organizational chart to illustrate the PFAS CoP staffing structure, including the ATSDR leads for the cross-cutting functional roles and the ATSDR technical officers for ongoing PFAS-related activities.

BSC DISCUSSION: PFAS COMMUNITY OF PRACTICE

Dr. Reh and other ATSDR staff provided additional details on the following topics in response to specific questions by the BSC members.

- ATSDR's strategies to collaborate with and engage external partners in the PFAS CoP, including academia, health departments, and communities.
- The extent to which public health laboratories have the ability to measure and conduct high-quality analyses of PFAS chemicals at the local level.
- The extent to which ATSDR will target prevention efforts to communities in its PFAS health-related initiatives.

BSC GUIDANCE

- ATSDR is commended for including community engagement/communications as an independent activity in its PFAS health-related research. However, the BSC made several suggestions for ATSDR to consider to ensure collaboration and outreach on a broader scale.
    - The NOFO for the PFAS multi-site health study should include language to strongly encourage collaboration, such as a requirement for health departments to describe their plans to partner with an academic institution.
    - NOFO applicants for the PFAS multi-site health study should be encouraged to consult with or reach out to national coalitions and advocacy organizations that have existing relationships with communities affected by PFAS, such as Safer States, the Cancer Free Economy Network, and the National PFAS Contamination Coalition.
    - CDC's Facebook and Twitter pages should be used to periodically post webinars on the ongoing PFAS activities to ensure that up-to-date information is provided to affected communities and the general public.
- ATSDR should consult with international organizations that also are conducting PFAS-related research to ensure that lessons learned and best practices are not limited to the United States.
- ATSDR informed the BSC that the data collection questionnaire for the PFAS health studies cannot be expanded to address infertility and reproductive issues because these topics are extremely complex and time-consuming. However, ATSDR should reconsider

the BSC's previous guidance to include simple, standard questions, such as "How many months have you been trying to conceive?" If these types of questions cannot be included in the survey, ATSDR should use other mechanisms to provide guidance on evaluating PFAS-related reproductive effects, such as measuring hormones and sperm or describing the length of time of infertility/efforts to conceive.

The ATSDR leads and technical officers thanked the BSC for their creative suggestions on the community engagement/communications component of its PFAS initiatives. They confirmed that ATSDR is leveraging its existing partners and forming new relationships to engage a wide range of sectors in its new PFAS CoP, including academia, communities, national organizations, and health departments. As the PFAS initiatives are further developed, they emphasized that the ongoing updates to the BSC would include more specific details on these partnerships. Most notably, Dr. Breysse was particularly interested in continuing to obtain the BSC's guidance on community engagement/communication strategies that would be more effective and innovative than the traditional "Community Advisory Board" approach.

Dr. Breysse noted that the BSC reemphasized its previous guidance to ATSDR to address infertility and reproductive issues in the PFAS health-related studies. He proposed a potential option in this regard. NIEHS has made substantial investments in collecting and retaining longitudinal data and archiving biological samples from several studies that followed birth cohorts from *in utero* to 20-29 years of age. ATSDR has initiated discussions with NIEHS to explore the possibility of leveraging resources that will support the use of longitudinal data and biological samples from these birth cohort studies to analyze infertility and reproductive issues related to PFAS.

With no further discussion or business brought before the BSC, Dr. Perry recessed the meeting at 4:00 p.m. on December 12, 2018.

December 13, 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 18 voting members and *ex-officio* members in attendance constituted a quorum for the BSC to conduct its business on December 13, 2018. He reconvened the proceedings at 8:34 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 December 13, 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 day 2 of the BSC meeting. She briefly reviewed the December 13, 2018 agenda items and opened the floor for the first presentation.

Overview of the CDC Cancer Cluster Investigation Guidelines

Tegan Boehmer, PhD, MPH
Acting Chief, NCEH Health Studies Section
Centers for Disease Control and Prevention

Stephanie Foster, MPH, MA
Lead, Geospatial Epidemiology and Applied Research Unit
Agency for Toxic Substances and Disease Registry

Dr. Boehmer and Ms. Foster presented an overview of the CDC Cancer Cluster Investigation Guidelines, including the background and history of these investigations and CDC's approach to update the current guidelines. Communities submit approximately 1,000 cancer cluster concern inquiries to state/local health departments (SHDs/LHDs) annually. The key challenges in SHDs/LHDs responding to these inquiries are summarized below.

The SHD/LHD must effectively communicate with the community at the outset of the investigation. The SHD/LHD must establish realistic expectations for its response to the investigation. The ability of the SHD/LHD to respond to and meet the expectations of the public typically is delayed or inhibited by epidemiological or methodological challenges, such as the geographic resolution or timeliness of data.

Of all cancer cluster concern inquiries submitted by communities to SHD/LHDs, only a few results in the identification of a statistically-based cancer cluster. Of the small number of suspected cancer clusters that warrant follow-up investigations, only a few actually identify an associated environmental contaminant or cause. Because the findings of cancer cluster investigations typically are inconclusive, the overall process is frustrating to community members who believe SHD/LHDs have minimized their concerns. SHD/LHDs also are frustrated because cancer cluster investigations require extensive resources, including labor, state and local funding, and expertise.

NCEH/ATSDR's role in CDC's cancer cluster investigations is two-fold: (1) develop guidance for SHDs/LHDs with a specific focus on potential cancer clusters in residential and community settings and (2) provide TA to SHD/LHDs. NCEH/ATSDR fulfills its role by verifying that state/local approaches adhere to current guidelines; reviewing documents (e.g., survey instruments, analysis plans, and reports); and reviewing communication strategies. ATSDR has an additional role to collaborate with states to review environmental data and cancer incidence data; respond to TA requests submitted by grant recipients; and respond to petitions submitted by communities.

The timeline of the CDC Cancer Cluster Investigation Guidelines is highlighted below.

- 1990: Publication of *Guidelines for Investigating Clusters of Health Events* (including non-infectious diseases, injuries, birth defects, and cancer)
- 2011: Introduction of the Strengthening Protections for Children and Communities from Disease Clusters Act
- 2013: Publication of *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists*
- 2016: Passing of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (i.e., Trevor's Law)
- 2019: Congressional Appropriation of $1 million to CDC to develop guidelines for investigation of potential cancer clusters as outlined in Section 399V-6(c) of Trevor's Law

The 2013 CDC/Council of State and Territorial Epidemiologists (CSTE) Guidelines, *Investigating Suspected Cancer Clusters and Responding to Community Concerns*, were developed in coordination with the release of the CDC National Public Health Information Coalition Cancer Cluster Communications Toolkit (https://www.cdc.gov/nceh/clusters/default.htm). The goal of the 2013 guidelines was to provide necessary decision support to public health agencies. This support was intended to promote sound public health perspectives and approaches, facilitate transparency, and build community trust. The scope of the 2013 guidelines was limited to situations in which an SHD/LHD responded to an inquiry regarding a suspected cancer cluster in a residential or community setting.

The 2013 guidelines defined a cancer cluster as "a greater than expected number of cancer cases that occurs within a group of people in a geographic area over a defined period of time." Based on this definition, the guidelines were designed with a systematic, four-step approach that served as a tool for evaluating and managing reported potential cancer clusters.

Step 1: Initial contact and response

- Information is gathered from the inquirer. The health agency determines whether the concern warrants further follow-up. Step 1 includes extensive guidance to communicate with the public.

Step 2: Assessment

- A determination is made on whether the observed number of cancer cases have a statistically significant elevation compared to the expected number of cancer cases.

Step 3: Feasibility Assessment

- The health agency evaluates the biological plausibility and feasibility of performing an epidemiologic study to identify an association between the cancer type and a specific environmental contaminant of concern.

Step 4. Formal epidemiologic investigation

- A full epidemiologic investigation is conducted to examine exposures and health outcomes.

Trevor's Law amended the Public Health Service Act by adding Section 399V-6, "Designation and Investigation of Potential Cancer Clusters," which outlines four key activities in Sections 399V-6(b) through 399V-6(e):

1. Develop criteria for the designation of potential cancer clusters.

2. Develop, publish, and periodically update guidelines for investigation of potential cancer clusters. To support this activity, new funding of $1 million was appropriated to CDC in FY2019.

3. Provide consultation and coordination in investigating potential cancer clusters.

4. Conduct other duties, such as providing TA to state/local health departments, maintaining staff expertise, consulting with community members, and disseminating reports.

Within section 399V-6(c), Trevor's Law also outlines specific criteria for developing guidelines for investigation of potential cancer clusters. Most notably, cancer cluster investigations should be based on criteria for the designation of potential cancer clusters. The best available science should be used and reliance should be placed on the weight of scientific evidence. Standardized methods of reviewing and categorizing data should be provided, including those from health surveillance systems and reports of potential cancer clusters. Guidance should be provided on using appropriate epidemiological and other approaches for investigations.

The rationale for updating the current guidelines is based on the need to explore new concepts and methods in science and technology. Since the publication of the 2013 CDC/CSTE guidelines, for example, advances have been made in cancer genomics. New statistical methods, software, and tools have been developed to improve spatial and temporal analyses of cancer cases. New methods have been designed to better understand exposure pathways in the evaluation of potential cancer clusters. Moreover, the existing communication strategies and tools will be revised to further engage communities in the process of sharing results from the cancer cluster investigations and identifying next steps. The four-step approach that initially was introduced in the 1990 guidelines as a tool for evaluating and managing reported potential cancer clusters also will be revisited.

NCEH/ATSDR recently formed an internal steering committee with colleagues from NIOSH and the CDC National Center for Chronic Disease Prevention and Health Promotion to thoroughly review the policies and procedures involved in the CDC guideline development process. The seven-member internal steering committee reflects broad expertise in the fields of cancer, communications, epidemiology, geospatial science, and policy development. However, the steering committee also is interested in engaging external subject-matter experts (SMEs) to obtain input in the areas of statistics/spatial statistics, epidemiology, toxicology, oncology, and community engagement. To achieve this goal, the internal steering committee is proposing the establishment of a new "BSC Cancer Cluster Guideline Workgroup."

The internal steering committee will gather input from the following sources to update the CDC Cancer Cluster Guidelines: the published and "grey" literature; the general public and community members; SHDs/LHDs; individual SMEs; and the BSC NCEH/ATSDR based on input from the newly proposed Cancer Cluster Guideline Workgroup of the BSC NCEH/ATSDR. Additional details on the primary functions of these sources are summarized below.

The systematic review of the published literature will be performed to collect data on methods and statistical approaches to investigate potential cancer clusters. Efforts will be made to engage public health partners in other countries to obtain lessons learned, best practices, and experiences on a global scale. A *Federal Register* notice will be released with a request for the public to submit comments on the current CDC Cancer Cluster Guidelines, including their effectiveness, gaps, and areas of improvement. CSTE will be engaged to gather input from SHDs/LHDs.

The establishment of a new BSC Cancer Cluster Guideline Workgroup is being proposed to inform the development of the new guidelines. The workgroup will be charged with completing three major tasks over a one-year period: (1) providing expert input on methods for identifying and investigating potential cancer clusters; (2) providing expert input on addressing exposure pathways; and (3) providing expert input on approaches for community engagement and education. The workgroup's deliverable will be to develop a report summarizing the expert input obtained from the workgroup members and ad-hoc consultants.

The membership of the new BSC Cancer Cluster Guideline Workgroup must include at least two NCEH/ATSDR BSC members to serve as the chair and a member. The non-BSC workgroup members will represent federal agencies, academia, and NGOs, such as the American Cancer Society, CSTE, National Association of City and County Health Officials, National Environmental Health Association, and North American Association of Central Cancer Registries.

NCEH/ATSDR established a two-year timeline from FY2019-FY2021 to complete the update of the CDC Cancer Cluster Guidelines. NCEH/ATSDR identified six major milestones over the course of the two-year timeline to achieve this goal: initiate the project, solicit input, analyze feedback, draft the updated guidelines, launch the external review process, and release the updated guidelines.

Ms. Foster concluded the overview by requesting the BSC's input on CDC's proposed approach to update the Cancer Cluster Guidelines; the proposed charge and deliverable for the new BSC Cancer Cluster Guideline Workgroup; and the proposed list of stakeholders and SMEs.

BSC GUIDANCE: CANCER CLUSTER INVESTIGATION GUIDELINES

- The BSC proposed several groups to serve on the new Cancer Cluster Guideline Workgroup:
    - National Cancer Institute (NCI). NCI also should serve on NCEH/ATSDR's internal steering committee.
    - Tribal Epidemiology Centers
    - Cancer epidemiologists
    - Pediatric oncologist. This SME also should serve as an external peer reviewer of the updated guidelines.
    - Community leaders/members
    - SME in cancer mechanistic research
- The updated Cancer Cluster Guidelines should emphasize the need to collect better data on residential history, particularly to address children's cancers from exposures *in utero* and in early childhood. These data would be extremely helpful because the information is not captured on death certificates or in surveillance systems.
- NCEH/ATSDR should consider using the National Environmental Public Health Tracking Network as a mechanism to obtain direct access to cancer registry data, encourage

collaboration at the national level, and serve the needs of the public by disseminating better information on a timelier basis.

The BSC agreed by consensus to establish a new Cancer Cluster Guideline Workgroup.

Workgroup Membership

- Ms. Suzanne Condon
- Mr. Ralph McCullers
- Dr. Marilyn Underwood
- Ms. Nsedu Witherspoon
- Pediatric oncologist (to be identified by Dr. Bernstein)

Next Steps

- The workgroup chair will be designated at a later time.
- The BSC members will email Dr. Perry (mperry@gwu.edu), with a copy to Dr. Cibulas (wic1@cdc.gov), to recommend cancer epidemiologists to serve on the workgroup.
- The workgroup will regularly present updates to the BSC to highlight their ongoing activities and solicit input.

Update on the Pediatric Environmental Health Specialty Unit Program

Michael Hatcher, DrPH
Chief, Environmental Medicine Branch
ATSDR/DTHHS

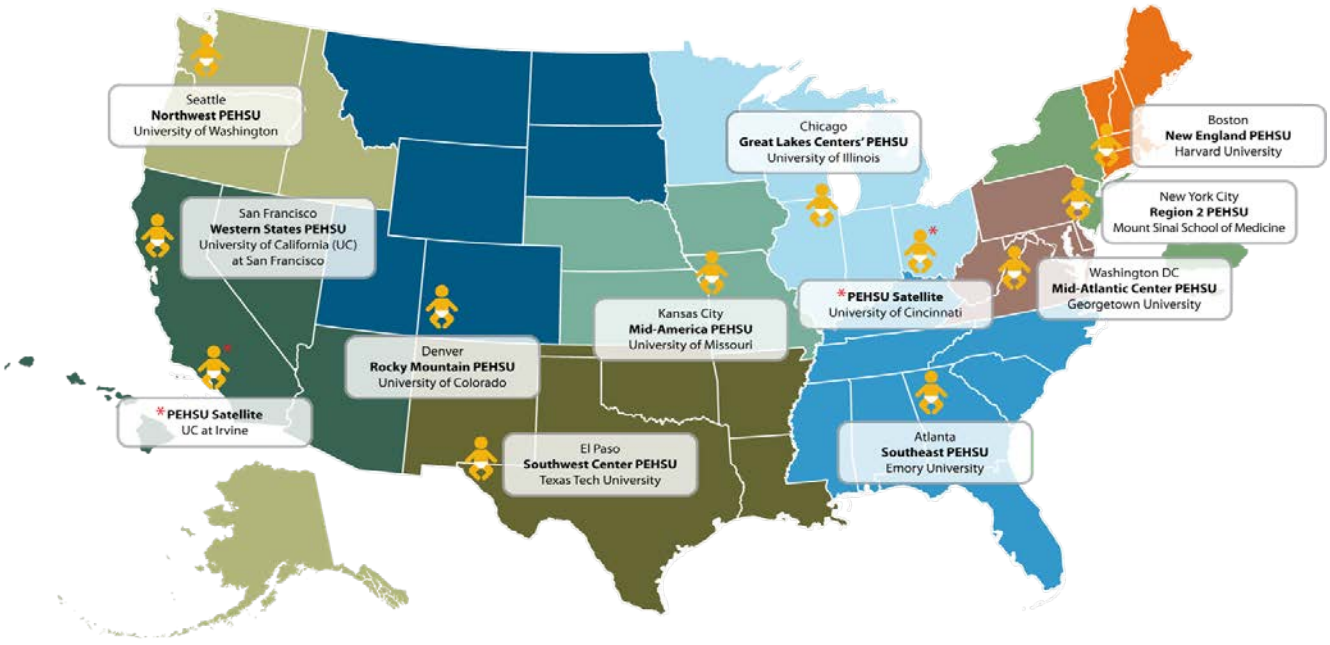
Dr. Hatcher presented an update on the Pediatric Environmental Health Specialty Unit (PEHSU) Program (https://www.pehsu.net). ATSDR (60 percent) and EPA (40 percent) have jointly funded the PEHSUs through an interagency agreement since the program was established in 1998. The American Academy of Pediatrics and the American College of Medical Toxicology are the current grant recipients of the PEHSU CoAg. The PEHSUs serve as a national network of clinical EH specialists who provide medical advice on exposures to hazardous substances in the environment. The primary focus of the PEHSUs is exposures that have the potential to impact reproductive and child health outcomes.

The PEHSUs are an available resource with the capacity to respond to questions by, collaborate with, and serve clinicians, public health professionals, government officials and policymakers, school and childcare leaders, and parents and communities. ATSDR and EPA established the PEHSUs to address undiagnosed causes of illnesses associated with toxic contamination of homes where children and others became ill after two reported events. In the first incident, an industrial plant that produced mercury vapors in New Jersey was converted to residences where children became ill. In the second incident, multiple states reported pesticide poisoning in 6,000 properties that resulted in several thousand emergency department visits. These two events demonstrated that children are more susceptible to environmental contaminants than adults.

Dr. Hatcher presented a series of photographs to illustrate the factors that cause children to be more vulnerable to environmental hazards. Most notably, children undergo periods of rapid fetal and childhood development. The ratio to the size of children and their intake of air, food, and fluids is larger than the ratio to an adult per kilogram of body weight. Children's behaviors, such as hand-to-mouth interaction and indoor/outdoor play on floors and the ground, increase their

exposure risk. Moreover, children have a longer life expectancy for potential health impacts to occur.

Dr. Hatcher presented the following map to illustrate the locations of the PEHSUs, primarily in academic medical centers, in each of the 10 federal regions.



The PEHSUs offer clinical expertise in various disciplines, including pediatrics, obstetrics, family medicine, medical toxicology, occupational medicine, pediatric neurodevelopment, nursing, and maternal/fetal specialists. The key functions of the PEHSUs are listed below:

- Provide specific clinical information on environmental toxins
- Facilitate early response to public health issues
- Engage in public education and outreach activities
- Participate in clinical assessments and referrals as needed
- Partner with SHDs/LHDs and regional poison control centers
- Provide education and training opportunities to health care providers
- Provide advice to residents and community leaders, including risk communication

Dr. Hatcher highlighted two PEHSU case examples. In case 1, a Somalian refugee family of eight children and two adults had severe lead exposure. Elevated blood lead levels higher than 60 µg/dL were reported in two of the children. The PEHSU provided care to the children and collaborated with the LHD to determine the source of the lead exposure. The LHD identified a cooking utensil as the source on the third home visit. In case 2, a family of four people was exposed to methyl bromide and investigated by the U.S. Virgin Islands Department of Health, ATSDR, and EPA. The family became ill from improper use of methyl bromide used in an apartment below their vacation rental property. The PEHSU was consulted to develop educational materials and training.

Dr. Hatcher presented a chart to illustrate the top 10 agents and health concerns for PEHSU consultations based on a total of 4,088 consultations.

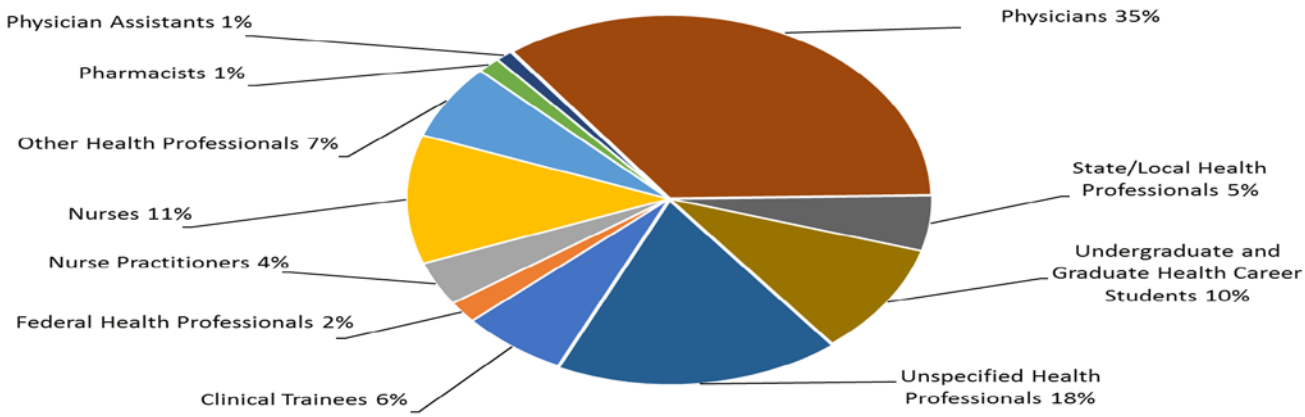
- Lead (41.1 percent)
- Fungus/Mold (4.9 percent)
- Asthma (4.6 percent)
- Gases/Fumes (1.9 percent)
- Drugs/Vaping/ Marijuana (3.6 percent)
- Pesticides (3.3 percent)
- PFAS (2.3 percent)
- Carbon Monoxide (1.7 percent)
- Cleaning Products (1.4 percent)
- Mercury (1.3 percent)

The "Other" category (34.1 percent) includes all other environmental concerns and substances that have fewer than 50 consultation records and represents all other substances the PEHSUs have addressed in their consultation activities in the four-year period.

Dr. Hatcher presented a table to illustrate changes in the top five exposure concerns based on the number of inquiries for PEHSU consultations from FY2007-FY2014.

Substance of Concern	Change in Inquiries Over Time
Increase in lead poisoning concerns based on 2,576 total inquiries	304 in 2007 548 in 2014
Decrease in fungus/mold concerns based on 762 total inquiries	96 in 2007 62 in 2014
Increase in phthalates/bisphenol A concerns based on 399 total inquiries	11 in 2007 77 in 2014
Decrease in pesticide concerns based on 389 total inquiries	95 in 2007 52 in 2014
Decrease in mercury concerns based on 367 total inquiries	66 in 2007 32 in 2014

Of 119,647 people the PEHSUs educated from FY2015-FY2018, health professionals accounted for 75.7 percent and community members accounted for 24.3 percent. Dr. Hatcher presented a chart to illustrate the types of health professionals that received education by the PEHSUs over this time period.



In the current CoAg, the PEHSUs have increased their social media presence, particularly with YouTube videos. The top six videos collectively accounted for approximately 1.1 million views in both English and Spanish. The total number of views of the individual videos in both English and Spanish is set forth in the table below.

Video Title	Total Number of Views (English and Spanish)
The Story About Lead	397,264
The Mysterious Case of Lead	475,212
Save The Family from Pesticides	33,480
Protecting Children from Pesticides	136,161
Killing Bugs Can Be Dangerous	90,317
Love in the Time of Toxicants	745

Bright Futures is a national health promotion and prevention initiative that is led by the American Academy of Pediatrics and supported by the Health Resources and Services Administration, Maternal and Child Health Bureau (MCHB). Bright Futures identifies and provides guidance on all clinical preventive services for children, including screening and well child visits. The initiative has achieved a major impact at the systems level.

The *Bright Futures Guidelines, First Edition* was published in 1994. However, the PEHSUs played a key role in expanding the Fourth Edition of the guidelines to include a major focus on EH. The feedback and public comments submitted by the PEHSUs led to the inclusion of the following EH topics.

- Air quality
- Chemical spills
- Lead
- Mercury
- Mold
- Pest control
- Pesticides (in home settings and food/diet)
- Radon
- Sun protection (radiation)
- Tobacco (including e-cigarettes and vaping)
- Weather events caused by climate change and wildfires

An example of the new EH guidance in the Fourth Edition of the guidelines is highlighted below and calls for providers to deliver this information at the child's one-month visit.

Risk: Pesticides

- "Pesticides are often used in a variety of products for the control of pests both in the indoor and outdoor environments. They may affect children's health in a variety of ways. Thousands of cases of pesticide poisonings are reported to poison control centers every year."

Sample Question

- "Do you use pesticides inside or outside the home?"

Anticipatory Guidance

- "Avoid using pesticides. Instead, choose the least toxic methods for pest control, commonly referred to as integrated pest management. These include repairing all cracks in your house to prevent pests from getting in and making sure that your food is securely sealed. If needed, use baits, traps, or gels instead of fogging, bombing, or spraying. Store and dispose of these items safely."

Additional impact and achievements of the PEHSUs are highlighted as follows. The PEHSUs have served as a model for addressing children's EH needs globally, including in Canada, Spain, Uruguay, Argentina, and Mexico. Strong interest has been expressed in leveraging funding, resources, and support to replicate the outstanding New York State Centers of Excellence in Children's Environmental Health in other states. The PEHSUs have trained 25 pediatric EH fellows to date to strengthen workforce development in this field. The PEHSUs also have played a critical role in stimulating a pediatric subspecialty in EH.

Overall, the PEHSUs are valued due to their credible clinical guidance; liaison role among EPH, health care, and communities; and high-level skills in effectively communicating environmental risk. Dr. Hatcher concluded his update by requesting the BSC's input on opportunities to enhance the PEHSU Program and build stronger partnerships.

BSC DISCUSSION: PEHSU PROGRAM

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

- The extent to which the PEHSUs focus on underserved communities (e.g., communities of color, communities in close proximity to hazardous waste sites, communities with limited resources, and communities with minimal access to information and protection).
- Collaborative efforts, coordination of resources, and synergies between the PEHSUs and CDC's lead prevention programs.

BSC GUIDANCE

The BSC members described their personal experiences with the PEHSUs and acknowledged the tremendous impact of the program in providing EH protection to children. In response to Dr. Hatcher's request for input, the BSC made several suggestions to raise the prominence of the PEHSU Program to a higher level.

- ATSDR should place much stronger emphasis on widely marketing the PEHSU Program. Most notably, the PEHSUs were established 20 years ago in 1998, but the program is still an untapped, virtually unknown resource to communities with the greatest need for these services. Similar to the PEHSU/Bright Futures partnership, additional opportunities should be identified to collaborate with existing programs that are dedicated to protecting families and supporting healthy children. The PEHSUs also should strengthen their relationships with and become much more integrated in MCHB's outreach efforts and other activities. Ideally, information on the PEHSU in the specific region should be distributed during each home visit by a nurse or community health worker and included in hospital discharge materials for mothers and their newborns. Refrigerator magnets designed by poison control centers should be tailored to create PEHSU magnets.
- ATSDR should consult with EH professional associations to launch innovative and effective marketing campaigns for the PEHSU Program. For example, the Society of

Toxicology has an ongoing recruitment effort to increase its membership with more physicians. ATSDR should leverage this opportunity to publicize the PEHSUs.

- ATSDR should leverage its existing relationship with NIEHS to utilize its network of Environmental Health Sciences Core Centers as a marketing tool for the PEHSUs. All of these centers as well as the NIEHS Superfund Research Program have outstanding community outreach components.
- ATSDR conducts formal evaluations to determine the impact of the PEHSU Program, but the evaluation findings should be made publicly available. For example, the EPA Children's Health Protection Advisory Committee was charged with evaluating the NIEHS/EPA Children's Environmental Health and Disease Prevention Research Centers. The report of the committee's findings was disseminated to the public and played a critical role in maintaining funding for the NIEHS/EPA research centers. In replicating this model, the BSC would conduct a systematic evaluation of the PEHSU Program and develop a report. ATSDR's external stakeholders would then use the evaluation report to encourage the establishment of new PEHSUs in areas of the country that have the greatest need for these services.
    - Other BSC members supported the excellent suggestion to conduct a systematic evaluation of the PEHSU Program and make the report publicly available, but additional comments were made for ATSDR to consider in this regard. For example, a paper was published in 2016 to document the cost of pediatric services in academic medical settings. The study found that approximately $22 million was spent on the PEHSU Program over a 15-year period (or approximately $1 million annually). The major return on this investment was the ability of the PEHSUs to reach 700,000 people, including 300,000 health professionals. Moreover, a centralized system houses rigorous, detailed data on each PEHSU interaction and follow-up activity. These data are readily available and could be compiled in an evaluation report.
    - The systematic evaluation of the PEHSU Program should be comprehensive and thorough, but ATSDR staff should not be overly burdened by collecting PEHSU data.

In response to the BSC's suggestion for a systematic evaluation of the PEHSU Program, Dr. Breysse pointed out that this effort is underway at ATSDR. After ATSDR presents the findings of the PEHSU evaluation at the next meeting, he noted that the BSC will be better positioned to identify its next steps.

Public Comment Period

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

Updates by the BSC *Ex-Officio* Members

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

Dr. Lunn reported that NTP, including OHAT, recently published or will soon complete several reports and monographs. All of the publications are available at (https://ntp.niehs.nih.gov).

Topic	Status
RECENT PUBLICATIONS	
Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity (CLARITY-BPA) Core Study: Report and grantees' data	Published in September 2018
RoC Monograph on *Helicobacter pylori* (Chronic infection)	Published in October 2018
RoC Monograph on Antimony Trioxide	Published in October 2018
NTP Technical Reports on Radio Frequency Radiation Used by Cell Phones	Published in November 2018
RECENT PEER REVIEW MEETINGS	
Draft RoC Monograph on Shift Work at Night and Light at Night	Peer review completed: October 5, 2018
UPCOMING PEER REVIEW MEETINGS	
Draft NTP Monograph on Long-Term Neurotoxicity of Acute Exposure to Sarin (OHAT)	Available for public comment, peer review meeting scheduled for early 2019

NTP launched its strategic realignment process with a focus on three key areas. First, the NTP vision and mission statements will be refined. Second, the translation toxicology pipeline will be enhanced by improving data mining capacity, quantitative structure-activity relationship models, bioactivity screening, *in vitro*/*in vivo* studies, products to inform public health decisions, and the overall NTP portfolio. Third, health effect innovation initiatives will be implemented, including "Carcinogenicity Testing for the 21st Century," developmental neurotoxicity modeling, and cardiovascular hazard assessment in environmental toxicology.

NTP developed more rapid screening tools for its new Developmental Neurotoxicity Data (DNT) Resource. The tools are designed to analyze, compare, and visualize multiple DNT assays in an interactive web application and are available at (https://sandbox.ntp.niehs.nih.gov/neurotox).

NIEHS awarded 43 grants via various funding mechanisms, including investigator-led research; Small Business Innovation Research grants; and NIEHS-funded centers for Superfund, children, and breast cancer activities. NIEHS awarded funding to its Superfund PFAS research sites: Michigan State, University of California, Berkeley, University of Rhode Island, and the Northeast Waste Management Officials Association. NIEHS and ATSDR are coordinating efforts to ensure alignment of their PFAS research initiatives at the federal level.

NIEHS is continuing to focus on its birth cohort studies, including the "Health Outcomes and Measures of the Environment" (HOME) study; "Markers of Autism Risk in Babies-Learning Early Signs" (MARBLES) study; and the Faroe Islands Birth Cohort.

OHAT is conducting a literature-based assessment of immune effects to determine vaccine responses across six PFAS compounds. NTP and EPA are partnering on the "Responsive Evaluation and Assessment of Chemical Toxicity" (REACT) study. The study design includes screening of 110 PFAS compounds, mining of the literature, computational analyses, and *in vitro*/*in vivo* toxicological testing. NTP recently released two-year cancer bioassay data related to perfluorooctanoic acid. The peer review meeting for this study will be convened in 2019.

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

Dr. Zhou reported 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). DOE supports both domestic and international radiation health studies. The RERF is an epidemiological study of Japanese atomic bomb survivors that is implemented under a binational agreement between the United States and Japan. The RERF is the longest running international radiation health effects research program.

The USTUR includes studies on the biokinetics and internal dosimetry of actinides, such as uranium, plutonium, and americium. Former U.S. nuclear workers volunteer their bodies for USTUR scientific research. The USTUR is the longest running domestic radiation health effects research program.

The DOE Office of Domestic and International Health Studies awarded a grant to Washington State University, College of Pharmacy and Pharmaceutical Sciences to manage the USTUR from April 1, 2017-March 31, 2022 with a budget of $5.5 million. The purpose of the USTUR is three-fold:

- Follow occupationally-exposed individuals by examining their biokinetics (e.g., deposition, translocation, retention, and excretion) and tissue dosimetry of uranium and transuranium elements, such as plutonium, americium.
- Obtain, analyze, and preserve samples from people who had documented intakes of uranium and transuranium elements and make these materials available for future research.
- Apply USTUR data to refine dose assessment methods in support of reliable epidemiological studies, radiation risk assessments, and regulatory standards for the radiological protection of workers and the general public.

Of 359 voluntary tissue donors who are posthumous USTUR registrants, 46 are whole-body donors and 313 are partial-body donors. The registrants are former nuclear workers from DOE worksites with documented internal and/or external radiation exposure. The USTUR is a unique data resource that maintains information on the registrant's work history, exposure and medical records, bioassays, and results of autopsy tissue radiochemical analyses. DOE has established a strict protocol for researchers to request and obtain USTUR tissue materials. The process requires researchers to provide a brief summary of the proposed sample usage; sign a confidentiality statement; and provide a copy of IRB approval for the protection of human subjects.

Dr. Zhou concluded his update by presenting a series of slides to illustrate USTUR's contributions to the scientific community: (1) published reports since 1998 for the National Council on Radiation Protection and Measurements; (2) published reports since 1989 for the International Commission on Radiological Protection; (3) more than 240 publications in peer-reviewed journals; and (4) publications of special issues since 1985 in *Health Physics*.

Ronald Hines, PhD, MS
Associate Director for Health
National Health and Environmental Effects Research Laboratory
U.S. Environmental Protection Agency

Dr. Hines reported that the EPA Office of Research and Development (ORD) created its 2019-2022 Strategic Research Action Plans with a focus on approximately 52 different research areas. ORD closely collaborated with states, EPA regional offices, and regulatory offices to inform the development of the Action Plans. EPA leadership currently is reviewing the Action Plans, but the implementation phase has been initiated.

Of the two translational research projects included in the Action Plans, one is focusing on the development of a comprehensive approach to reduce nitrogen loading, meet the total maximum daily load, and achieve water quality goals in bays and watersheds in Cape Cod, Massachusetts. ORD is collaborating with a diverse group of stakeholders to identify data, knowledge, resources, and regulatory constraints associated with the project and also to formulate plans to address these problems. Similar to EPA's other site-specific activities, ORD is building partnerships to foster innovative approaches to reduce nitrogen loading and create models, tools, and strategies that be replicated in other watersheds across the country.

EPA is conducting several PFAS-related projects and is partnering with NTP on some of these efforts. ORD created a library of approximately 500 PFAS compounds that can be made available to external researchers. EPA currently is evaluating 150 different PFAS compounds based on two key criteria: (1) PFAS compounds characterized as a "high priority" based on concerns raised by EPA regional/program offices and states and (2) the structure of individual PFAS compounds that led to designing a screening protocol. EPA's strategy to select the 150 PFAS compounds recently was approved for publication as a commentary in *Environmental Health Perspectives*. EPA views this effort as an opportunity to implement a high-throughput approach for the screening tool.

EPA will conduct total genomic expression profiling on all 150 PFAS compounds and also will perform high-throughput screening to evaluate potential immune responses, biological receptor interactions, developmental and acute neurotoxicity, and multiple toxicokinetic endpoints. EPA is exploring the possibility of adding a series of thyroid disruption assays to this project. EPA will release its PFAS Management Plan, including the ORD Research Strategy, in January 2019. EPA expects to release a broader dataset on these efforts in the fall of 2019. Based on the findings, EPA will design targeted *in vivo* studies.

Ms. Witherspoon asked EPA to address specific issues in its next update to the BSC. First, EPA and NIEHS co-fund the Children's Environmental Health and Disease Prevention Research Centers. During a meeting in October 2018, however, EPA leadership announced that no funding was included in its FY2019 budget to continue to support these centers. Second, the EPA Office of Children's Health Protection has been operating with virtually no leadership for nearly three months.

Third, efforts have been launched that potentially could threaten the current provisions of the Clean Water Act. A public comment period currently is open on possible changes to the provisions. Most notably, the proposed changes would modify the definition of "waterways" in the United States by limiting the types of waterways that fall under federal protection, including tributaries and adjacent wetlands. The BSC members, as individual citizens, should submit their comments to ensure that the existing Clean Water Act standards are strengthened and upheld.

Douglas Trout, MD
Associate Director for Science
Division of Surveillance, Hazard Evaluations and Field Studies
National Institute for Occupational Safety and Health

Dr. Trout reported that the Firefighter Cancer Registry Act of 2018 was passed in July 2018. The legislation requires CDC to develop and maintain a voluntary registry of firefighters and specify the number and types of fires that each firefighter attends. The registry data will be used to enhance knowledge and understanding of the prevalence and incidence of cancer among firefighters. NIOSH is leading this effort for CDC.

Dr. Trout announced that he represents NIOSH on NCEH/ATSDR's internal steering committee to update the CDC Cancer Cluster Guidelines.

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. Christopher Reh Dr. Erik Svendsen	Updates by new NCEH/ATSDR Leadership: ➢ Overview of ATSDR's new brand, strategic approach, and future direction ➢ Overview of the new NCEH Division of Environmental Health Science and Practice
Dr. James Pirkle Dr. Antonia Calafat	Update by DLS: ➢ Development of improved laboratory methods to measure exposure to fentanyl and fentanyl-like compounds ➢ Development of the glyphosate biomarker
Dr. Michael Hatcher	Overview of ATSDR's evaluation of the PEHSU Program
BSC Membership	Updates by the BSC Workgroups: ➢ Report by Dr. Perry on the Cross-Center VBD Workgroup ➢ Report by the chair of the new BSC Cancer Cluster Guidelines Workgroup
ATSDR	Update on the PFAS health-related research initiatives: ➢ Exposure assessments at the eight selected sites ➢ Pilot health effects study at Pease International Tradeport
Dr. Patrick Breysse	NCEH/ATSDR Director's Report: ➢ Response to the BSC's guidance on emerging issues for NCEH/ATSDR, particularly "blue light" pollution ➢ The current status of the appropriations process and its impact on NCEH and ATSDR programs
NCEH	Update on the CDC Vessel Sanitation Program
NCEH	Overview of activities to address indoor mold contamination and disseminate this information to state/local health departments

Presenter	Agenda Topic
NCEH	Update by the Climate and Health Program, particularly NCEH's lessons learned in responding to the increased frequency of wildfires and natural disasters
NCEH/ATSDR OD	Efforts to evaluate and measure the impact of NCEH and ATSDR programs
NCEH	Update on the Flint, Michigan Lead Exposure Registry
ATSDR	Overview of NCEH/ATSDR's activities to address psychological, social, and economic impacts from toxic events as well as efforts and programs to build community resilience ➢ Dr. Breysse proposed including this topic in ATSDR's update on the PFAS health-related activities.
ATSDR	Update on the disease registries maintained by ATSDR

Closing Session and Adjournment

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 participants joined Dr. Perry in thanking the NCEH/ATSDR leadership and staff for their continued commitment and dedication to protect the American public from environmental hazards.

The next BSC meeting will be held in approximately June 2019. 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 11:11 a.m. on December 13, 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. Kenneth Aldous
Dr. Aaron ("Ari") Bernstein
Dr. Darryl Brown
Ms. Suzanne Condon
Dr. Roberta Grant
Dr. Daniel Hryhorczuk
Joyce Martin, Esq.
Mr. Ralph McCullers
Dr. John Meeker
Dr. Devon Payne-Sturges
Dr. Joan Rose
Dr. Marilyn Underwood
Ms. Nsedu Witherspoon

BSC Member Absent

Dr. Paloma Beamer

BSC *Ex-Officio* Members Present

Dr. Ronald Hines
U.S. Environmental Protection Agency
(Alternate for Dr. Wayne Cascio)

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

Dr. Douglas Trout
National Institute for Occupational Safety and Health

Dr. Joey Zhou
U.S. Department of Energy

BSC *Ex-Officio* Member Absent

Dr. Wayne Cascio
U.S. Environmental Protection Agency

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

Henry Abadin
Lorraine Backer
Cathy Bailey
Lina Balluz
John Barr
Rae Benedict
Mark Biagioni
Benjamin Blount
Tegan Boehmer
Sharunda Buchanan
Paula Burgess
Antonia Calafat
Yulia Carroll
Ginger Chew
Selene Chou
Andrea Comquist
Cheryl Cornwell
Janine Cory
Carla Cuthbert
Kenneth Davis
Stephanie Davis
John Decker
Andy Dent
Shirley Ding

Kristin Dortch
Myron Douglas
Katie Egan
Alisha Etheredge
Stephanie Foster
Brad Goodwin
Shannon Graham
Theresa Grant
Althea Grant-Lenzy
Olivia Harris
Michael Hatcher
Elizabeth Heiman
James Holler
Keisha Houston
Susan Ingber
Jeff Jarrett
Laurie Johnson
Robert Jones
Rhonda Kaetzel
Matt Karwowski
Chinaro Kennedy
Peter Kowalski
Joe Laco
Trent LeCoultre
Shirley Little
Amanda Malasky
Josephine Malilay
Eva McLanahan
Maria Mirabelli
Susan Moore
Amy Mowbray
Moiz Mumtaz
Linde Parcels
Alan Parham
Ruth Perou
Christine Pfeiffer
James Pirkle
Xiaoting Qin
Angela Ragin-Wilson
Christopher Reh
Von Roebuck
Nickolette Roney
Perri Ruckart
Raquel Sabogal
John Sarisky
Mary Schmitz
Franco Scinicariello
Vivi Siegel
Rieza Soelaeman
Felicia Suit
Erik Svendsen
Leigh Swaim
Hao Tian
Jana Telfer
Jerry Thomas
Padmaja Vempaty
Richard Wang
Lynn Wilder
Alan Yarbrough

Attachment 2: Glossary of Acronyms

Acronym	Definition
ACHB	Asthma and Community Health Branch
AFFF	Aqueous Firefighting Foam
BRACE	Building Resilience Against Climate Effects
BSC	Board of Scientific Counselors
CBD	Cannabidiol
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CLARITY-BPA	Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity
CoAg	Cooperative Agreement
COEs	Centers of Excellence
CoP	Community of Practice
CSTE	Council of State and Territorial Epidemiologists
DFO	Designated Federal Officer
DLS	Division of Laboratory Sciences
DMP	Data Management Plan
DNT	Developmental Neurotoxicity Data
DOE	U.S. Department of Energy
DTHHS	Division of Toxicology and Human Health Sciences
EH; EPH	Environmental Health; Environmental Public Health
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FLAP	Federal Lead Action Plan
FRAP	Federal Research Action Plan
FY	Fiscal Year
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HOME	Health Outcomes and Measures of the Environment
IRB	Institutional Review Board
LHDs	Local Health Departments

Acronym	Definition
LOAEL	Lowest Observed Adverse Effect Level
MARBLES	Markers of Autism Risk in Babies-Learning Early Signs
MCHB	Maternal and Child Health Bureau
MMWR	*Morbidity and Mortality Weekly Report*
MRLs	Minimum Risk Levels
NAS	National Academies of Sciences, Engineering, and Medicine
NCAI	National Congress of American Indians
NCEH/ATSDR	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NCI	National Cancer Institute
NDAA	National Defense Authorization Act
NGOs	Non-Governmental Organizations
NHANES	National Health and Nutrition Examination Survey
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIHB	National Indian Health Board
NIHL	Noise-Induced Hearing Loss
NIOSH	National Institute of Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NOFO	Notice of Funding Opportunity
NOFO	Notice of Funding Opportunity
NTP	National Toxicology Program
OD	Office of the Director
ODP	Open Data Policy
OHAT	Office of Health Assessment and Translation
OID	Office of Infectious Diseases
OMB	Office of Management and Budget
ORD	Office of Research and Development
OSU	Oregon State University
PEATT	PFAS Exposure Assessment Technical Tool
PEHSU	Pediatric Environmental Health Specialty Unit
PFAS	Per-/Polyfluoroalkyl Substances
PII	Personally Identifiable Information
PM	Particulate Matter
REACT	Rapid Evaluation and Assessment of Chemical Toxicity
RERF	Radiation Effects Research Foundation
RoC	Report on Carcinogens
SHDs	State Health Departments
SMEs	Subject-Matter Experts
SWPs	Safe Water Programs

Acronym	Definition
TA	Technical Assistance
TB	Tuberculosis
TCR	Tire Crumb Rubber
THC	Tetrahydrocannabinol
USTUR	U.S. Transuranium and Uranium Registries
VBD	Vector-Borne Diseases
VOCs	Volatile Organic Compounds
VSP	Vessel Sanitation Program