







## 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 November 15-16, 2017 at the CDC Chamblee Campus in Atlanta, Georgia.

### MEETING OVERVIEW

The Designated Federal Official (DFO) conducted the meeting in accordance with all rules and regulations of the Federal Advisory Committee Act (FACA). 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 November 15-16, 2017 BSC meeting.

### NCEH/ATSDR DIRECTOR'S UPDATE

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

- CDC's fiscal year (FY) 2018 budget, including solutions by the NCEH/ATSDR Office of the Director (OD) to address the possibility of severe decreases in funding or the elimination of certain programs or activities.
- CDC's activation of its Emergency Operations Center and other activities in the response and recovery efforts for the 2017 hurricane season.
- NCEH/ATSDR's current activities to support its four environmental health (EH) priorities: (1) lead, (2) safe water, (3) efforts to enhance ATSDR's infrastructure and capacity to better respond to hazardous waste problems in the nation, and (4) the retention of the high-quality NCEH laboratory as a worldwide resource.
- The NCEH/ATSDR reorganization, including the new NCEH Division of Environmental Health Science and Practice; the new NCEH/ATSDR Office of Environmental Health Emergency Management; the establishment of a new ATSDR OD; and the appointment of a new ATSDR Deputy.

### CDC'S NOISE-INDUCED HEARING LOSS (NIHL) ACTIVITIES

The NCEH/ATSDR Office of Science presented an overview of CDC's activities to address NIHL.

- Development of a strategic plan, with three key objectives, to increase awareness of and prevent NIHL in homes and communities by providing data and education.
- Collection of data from multiple sources to document the public health, economic, and societal burden of NIHL.
- A collaborative effort with partners to fund a report by the National Academies of Sciences, Engineering, and Medicine in 2016, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, that directs four recommendations to CDC.
- Publications, communications products, and media articles to widely publicize NIHL.
- Analyses of audiometric data to estimate the level of hearing loss associated with exposure to loud noise among adults.
- Sponsorship of a Public Health Grand Rounds in June 2017, *It's Loud Out There: Hearing Health Across the Lifespan*.
- A partnership with the World Health Organization to address NIHL at a global level.
- A systematic review of the literature to determine an association between occupational or non-occupational noise exposure and health effects:
- Development and dissemination of new NIHL guidelines in 2018.

#### **BIOMONITORING METHODS FOR CONTEMPORARY PESTICIDES**

The NCEH Division of Laboratory Sciences (DLS) described its efforts to develop new biomonitoring methods for neonicotinoids and glyphosate, including strategies to overcome analytical challenges. DLS plans to publish the biomonitoring methods and analyses of National Health and Nutrition Examination Survey samples in peer-reviewed journals as soon as possible after the CDC National Center for Health Statistics publicly releases the data.

#### **PREVIOUS BSC GUIDANCE**

The DFO presented ATSDR's response to the guidance that the BSC provided during the January 2017 meeting on two key presentations: (1) activities related to unconventional oil/gas extraction and hydraulic fracturing (i.e., "fracking") and (2) the Federal Research Action Plan on recycled tire crumb rubber.

The BSC Chair made a commitment to solicit volunteers from the BSC to serve on a new cross-center workgroup to provide guidance to CDC on vector management and pesticides. The new workgroup will be represented by the BSCs for both the CDC Office of Infectious Diseases and NCEH/ATSDR.

#### **CDC'S RESPONSE TO THE 2017 HURRICANE SEASON**

The NCEH/ATSDR Office of Environmental Health Emergency Management described CDC's hurricane response and recovery activities in Florida (Hurricane Irma), Texas (Hurricane Harvey), and Puerto Rico and the U.S. Virgin Islands (Hurricanes Irma and Maria). In the aftermath of the hurricanes, NCEH/ATSDR is conducting environmental assessments to address mold, carbon monoxide poisoning, and other EH problems in the affected areas.

#### **UPDATE ON NCEH/ATSDR'S LEAD ACTIVITIES**

NCEH presented three updates on its current lead activities. The presentations covered the following topics.

- CDC's cross-cutting lead programs and initiatives.
- New Congressional appropriations to CDC in fiscal year (FY) 2017 to rebuild the NCEH Lead Program and address the lead-contaminated water crisis in Flint, Michigan.

- NCEH's collaboration with the U.S. Food and Drug Administration to issue a recall warning and health advisory to advise the public of problems with using Magellan Diagnostics' LeadCare® Testing Systems for testing blood lead levels (BLLs).
- The next steps in CDC's formal approval and adoption of the BSC recommendation to lower the current blood lead reference value from 5 to 3.5 µg/dL.
- NCEH's leadership role on the Lead Subcommittee of the President's Task Force on Environmental Health Risks and Safety Risks to Children.
- New funding that was awarded by CDC and four other HHS agencies to five grant recipients to launch new initiatives in Flint in response to the lead-contaminated water crisis, such as the establishment of the new "Lead Exposure Registry of Flint Residents-Michigan."
- Legislative requirements that will guide the establishment of the new Lead Exposure and Prevention Advisory Committee.

### **FEDERAL PARTNERSHIP EFFORTS**

The NCEH/ATSDR Director presented multiple examples of NCEH/ATSDR's federal partnerships efforts. In response to the Director's request for input, the BSC proposed a number of new or existing federal partnerships that NCEH/ATSDR should aggressively pursue or strengthen. Most notably, the BSC advised NCEH/ATSDR to establish new partnerships with regulatory agencies and enhance collaborations to increase its focus on environmental impacts in occupational settings and infectious diseases in the environment.

### **NATIONAL AMYOTROPHIC LATERAL SCLEROSIS (ALS) REGISTRY**

ATSDR covered several topics in its update on the National ALS Registry and described the key features of this platform: the methodology and algorithm to collect data from multiple sources; the web portal registration system to recruit and enroll ALS patients; efforts to widely publicize the registry to the scientific and research communities; and the establishment of the new National ALS Biorepository for persons with ALS to donate biospecimens. ATSDR highlighted its major accomplishments in 2016-2017 for both the registry and biorepository.

### **NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING NETWORK**

NCEH presented an update on the Tracking Network. NCEH reviewed the progress of the Tracking Network since its establishment in 2002; the priorities and major features of the Tracking Network that are available to users; and plans to include new data, tools, and initiatives to improve the Tracking Network in the future. NCEH showed examples in which Tracking Network data were used to drive public health actions and influence policy at state and local levels.

### **BSC *EX-OFFICIO* UPDATES**

- The National Institute for Occupational Safety and Health (NIOSH) described the implementation of its new programmatic approach to improve the National Occupational Research Agenda (NORA) by eliminating silos; increasing the focus on obtaining input from partners and stakeholders; and strengthening internal/external collaborations in conducting both intramural and extramural NIOSH activities. NIOSH formed non-FACA councils to provide guidance on 10 NORA industrial sector programs and seven NORA health-based cross-sector programs. The councils will create an occupational research agenda, in collaboration with a broad range of partners, that is specific to their individual NORA programs.

- The U.S. Environmental Protection Agency (EPA) summarized its comprehensive portfolio of activities to address health effects related to wildfire smoke, including the release of an updated guide for public health officials; the launch of the new “Smoke Sense Project;” and the announcement of the new “Wildland Fire Sensor Challenge” to promote innovation in the development of sensor technology. EPA’s other priority activities include the dissemination of web-based information, tools, and other resources to assist health care providers in protecting the health of their patients by reducing air pollution exposure. EPA also is a proud supporter of the Million Hearts® initiative that was designed to prevent a million heart attacks and strokes over the next five years.
- The U.S. Department of Energy (DOE) reviewed its long history of allocating funds and providing support to its federal partners at CDC. To address offsite, non-occupational environmental exposures, NCEH and ATSDR conduct dose reconstruction studies and public health assessments (PHAs) of communities near DOE sites. To address onsite, occupational environmental exposures, NIOSH conducts mortality studies of DOE workers. DOE currently is providing funds to ATSDR to conduct a PHA of the West Lake community in St. Louis, Missouri. Radioactive waste materials from uranium processing operations of the Mallinckrodt Chemical Company were illegally dumped in the community. The DOE Comprehensive Epidemiologic Data Resource (CEDR) currently maintains de-identified mortality data that have been collected over the past 40 years. Scientists, postgraduate students, and other researchers can submit an application to DOE to obtain access to and utilize CEDR data.
- The National Institute of Environmental Health Sciences, National Toxicology Program (NTP) presented a comprehensive list of its technical reports and literature-based evaluations that were or are scheduled to be completed (from July 2017 to the spring of 2018). NTP provided an update on the publication of its perfluorooctanoic acid/perfluorooctane sulfonate technical reports. NTP described the three components of its tire crumb rubber studies (e.g., chemical characterization, *in vitro* characterization, and *in vivo* feasibility testing).

#### **CURRENT BSC GUIDANCE**

In general, the BSC provided extensive input over the course of the meeting in response to updates and presentations by NCEH/ATSDR OD and the individual programs. The discussion sessions that follow each presentation in the Meeting Minutes fully capture the BSC’s comments and suggestions. In particular, the BSC provided guidance and proposed agenda topics for future meetings to ensure that NCEH/ATSDR maintains a strong focus on several priority issues.

- The BSC was aware of the uncertain future of and lack of political will for the NCEH Climate and Health Program. Most notably, the BSC expressed concern regarding the proposal in the FY2018 budget to eliminate this initiative. The BSC reiterated its overwhelming consensus to protect, preserve, maintain, and support the essential activities of the Climate and Health Program. To reassert and reaffirm the critical importance of this effort, the BSC requested an update on the Climate and Health Program at all future meetings. The BSC also went on record to strongly urge NCEH/ATSDR to add research on climate issues and weather-related events to its current list of priorities
- The BSC found the focus on water as the sole source of lead contamination in Flint to be problematic. The BSC advised NCEH/ATSDR to focus on more significant exposures from lead-based paint in old housing stock in Flint by using its new Congressional

appropriations for lead and leveraging the strong economic and political will for lead at this time. The BSC noted that lead-based paint is still the single largest contributor to children's BLLs in the United States.

- The BSC expressed concern regarding the \$9 million reduction that has been proposed for the Tracking Network line-item in the FY2018 budget. The BSC requested an update on the Tracking Network, including its FY2018 funding level, at the first meeting in 2018.

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



**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  
November 15-16, 2017  
Atlanta, Georgia**

**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 November 15-16, 2017 in Building 107 of the CDC Chamblee Campus in Atlanta, Georgia.

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

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

**November 15, 2017 Opening Session: Welcome, Introductions, and  
Agenda Review for Conflict of interest Topics**

**William Cibulas, Jr., PhD, MS**  
Deputy Associate Director for Science, NCEH/ATSDR  
BSC Designated Federal Official (DFO)















infrastructure will be better aligned with its core mission to “protect communities from harmful health effects related to exposure to natural and manmade hazardous substances.”

Dr. Cibulas reported that in addition to the PFAS activities Dr. Breyse highlighted in his update, another federal effort also is underway at the highest level of government. A Chemical Toxicity Assessment Workgroup was formed under the White House Committee on the Environment, Natural Resources, and Sustainability/Toxics and Risk Subcommittee to promote coordination and communications among federal agencies regarding their PFAS activities.

### **BSC DISCUSSION: NCEH/ATSDR DIRECTOR’S UPDATES**

The BSC discussed the following topics during the question/answer session with Dr. Breyse.

- Ongoing efforts to support the grant recipients, staff, and activities of the NCEH Climate and Health Program.
- Occupational components of the PFAS activities that might stimulate joint research or other collaborative efforts between ATSDR and the National Institute of Occupational Safety and Health (NIOSH), such as PFAS exposure to firefighters through aqueous firefighting foam.
- The possibility of ATSDR expanding the use of the PEATT for PFAS biomonitoring and exposure assessment in communities to also include exposures in occupational settings.
- The extent to which the toxic effects of PFOA and PFAS chemicals are additive, independent, or co-exist in individuals and the environment.
- The number of laboratories in the United States that are appropriately equipped to perform PFAS biomonitoring.
- NCEH/ATSDR’s role in the new Federal Lead Strategy that is being developed by the Lead Subcommittee of the President’s Task Force on Environmental Health Risks and Safety Risks to Children and will be released for public comment in late 2018.
- ATSDR’s ongoing involvement in hydraulic fracturing (i.e., “fracking”) activities at sites, such as the ban on fracking in the western part of Maryland in May 2017.
- CDC’s reorganization at the agency level that might affect NCEH/ATSDR’s reorganization at the center level, such as a mandatory requirement for enhanced collaboration, coordination, and communication across CDC centers, institutes, and offices as part of the “Reimagine HHS” initiative.

### **BSC GUIDANCE**

- The NCEH Climate and Health Program potentially could be eliminated in the FY2018 budget, but CDC is the only federal agency that is addressing climate and health issues at this time. The BSC already is on record with its overwhelming consensus to protect, preserve, maintain, and support the essential activities of the Climate and Health Program. To reassert and reaffirm the critical importance of this initiative, an update by the Climate and Health Program should be placed on all BSC meeting agendas, beginning with the first meeting in 2018.
- DLS should disseminate messaging on an ongoing basis to promote and widely publicize its role and capabilities as the “premier” model for other laboratories and the “gold standard” in environmental biomonitoring of PFAS and other chemicals.
- NCEH/ATSDR should place more emphasis on tribal communities in its site-specific activities. Most notably, NCEH/ATSDR’s current priorities and other focus areas (e.g., lead, safe water, climate and health, and PFAS/PFOA) have a direct and profound impact

on Native populations. Efforts to conduct epidemiologic and other types of studies in Native communities have been difficult to date due to cultural issues and relatively small sample sizes. However, exposures to environmental contaminants in surface water and other media disproportionately affect Native populations, particularly tribes in the Northeast and Northwest that still practice subsistence lifestyles in terms of catching fish and utilizing plants for food, cultural activities, and religious ceremonies.

- Tribes and tribal organizations typically do not have the same level of resources and capacity to compete for NOFOs that also are open to state and local health departments. Moreover, the amount of funding in the NCEH/ATSDR budget that is dedicated to or set aside for tribes and tribal organizations has been limited to date, particularly for data collection, research, and operational issues. NCEH/ATSDR should encourage NIOSH and its other internal CDC partners to establish specific line-items for tribal activities in their respective budgets.

## CDC's Noise-Induced Hearing Loss Activities

### **John Eichwald, MA**

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

Mr. Eichwald presented an overview of CDC's activities to address noise-induced hearing loss (NIHL). CDC has a nearly 50-year history of targeting NIHL programs to various populations, including activities by NIOSH through the Occupational Safety and Health Act of 1970 (for workers); the CDC National Center on Birth Defects and Developmental Disabilities (NCBDDD) through the Children's Health Act of 2000 (for infants and children); and NCEH through the "2016 Hearing Loss at Home and Community" initiative (for teens and adults).

NCEH/ATSDR, NIOSH, NCBDDD, and two operating units serve on an intra-agency workgroup to provide guidance, oversight, and support of CDC's NIHL activities. CDC's request for \$10 million to increase the scope of its NIHL activities was not approved in the FY2017 budget and was not been included in the FY2018 budget. As a result, CDC used its current funding to develop a strategic plan for the future direction of its NIHL activities.

The vision of CDC's strategic plan is to increase awareness of and prevent NIHL in homes and communities by providing data and education. The three objectives to achieve the strategic plan goal are highlighted as follows. To build strong evidence, data will be identified, gathered, and analyzed to support evidence-based decisions. To strengthen internal capacity, evidence and educational resources will be developed to support CDC's partners and other stakeholders. To enhance partnerships, innovative collaborations will be established and facilitated to advance NIHL awareness and prevention. CDC's current NIHL partners include federal agencies (e.g., DoD, FDA, and VA), nonprofit organizations, and professional associations that have a mission to address hearing health care issues.

Data have been collected from multiple sources to document the public health, economic, and societal burden of NIHL. According to the CDC National Health Interview Survey, hearing loss is the third most commonly reported condition in the United States and is nearly the equivalent of the combined prevalence of diabetes and cancer. The health effects of exposure to loud noise include hearing loss, tinnitus, cardiovascular and psychological impacts, and sleep disturbance.



The Occupational Safety and Health Administration (OSHA) reported that in 2017, businesses paid \$1.5 million in penalties and \$242 million in workers' compensation due to hearing-related exposures. Based on 2003 data, costs for the diagnosis and treatment of NIHL in persons over 65 years of age were estimated at \$8 billion. However, this estimate is projected to dramatically increase to \$85 billion by 2030 because one out of five persons in the United States is expected to be in the age group of 65 years and older at that time.

CDC estimates a potential cost-savings of \$50 billion by preventing 20 percent of NIHL. CDC has identified a number of simple and inexpensive activities for individuals to prevent hearing loss: increase the distance from the source of loud noise, shorten the time of exposure to loud noise, decrease the volume of personal listening devices, wear hearing protection, and consult with health care providers (HCPs). Most notably, patients should use their regular medical and wellness visits to ask HCPs about hearing and noise exposures. HCPs should examine the hearing of their patients and make referrals to hearing evaluation and treatment if needed.

The release of different recommendations by various agencies and organizations has led to confusion, a lack of consensus, and an unclear definition of a "safe noise exposure level." The 1974 EPA guidelines recommend 24 hours at 70 dB for community and environmental noise exposures. The 1972 and 1998 NIOSH criteria documents recommend 8 hours at 85 dB for occupational noise exposure, but this level is for a 40-year period. Both the EPA and NIOSH guidelines protect 96 percent of the population. The 1983 OSHA occupational noise exposure standard recommends 8 hours at 90 dB. The 1999 World Health Organization (WHO) guidelines recommend 24 hours at 70 dB for community noise. The American Conference of Governmental Industrial Hygienists recommend 8 hours at 85 dB.

The National Academies of Sciences, Engineering, and Medicine published a report in 2016, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, that was co-funded by CDC, other federal agencies, and the Hearing Loss Association of America. Of the 12 recommendations in the report that were targeted to federal agencies and other stakeholders in the hearing health community, four were specifically directed to CDC.

- Improve population-based information on hearing loss and hearing health care.
- Promote hearing health care in wellness and medical visits.
- Evaluate and implement innovative models of hearing health care.
- Improve publicly available information on hearing health.

The National Academies report is available for review at:

[www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults](http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults).

CDC engaged internal and external senior officials and staff at the federal level to coauthor an article that was published in the February 7, 2017 edition of the *Morbidity and Mortality Weekly Report (MMWR)*, "Vital Signs: Noise-Induced Hearing Loss Among Adults – United States, 2011-2012." The article was accompanied by a media release, fact sheet, website content, town hall webinar, and multiple social media tools. Most of these products were provided in both English and Spanish. Mr. Eichwald presented a series of slides to illustrate the communications products from the "Vital Signs: Too Loud! For Too Long" Campaign ([www.cdc.gov/vitalsigns/hearingloss](http://www.cdc.gov/vitalsigns/hearingloss)).

CDC was extremely pleased that the Vital Signs campaign was covered by over 75 media outlets, including the major television networks. CDC also published hearing damage articles in magazines that were specifically targeted to teens and young adults, such as the "Now Hear

This!" article in *Seventeen* in July 2017 and the "Loud and Unclear" article in *Cosmopolitan* in August 2017. Moreover, *The New York Times* published an op-ed in October 2017 that referenced CDC's data from the Vital Signs campaign.

CDC used the Healthy People 2020 algorithm to analyze audiometric data from mobile examination centers and estimate the level of hearing loss associated with exposure to loud noise among adults. Of 3,583 audiograms included in the analysis, unilateral notches (i.e., one ear) accounted for 18.2 percent and bilateral notches (i.e., both ears) accounted for 6.2 percent of audiometric notches. Hearing losses were consistently greater in men than in women in four categories: unilateral notches with and without work exposure and bilateral notches with and without work exposure. The analysis showed that hearing damage associated with exposure to loud noise in the U.S. population affects 40 million persons in the workplace and 21 million persons outside of the workplace.

CDC reviewed data from both unilateral and bilateral audiometric notches to demonstrate that hearing damage accumulates over time.

- Age 20–29 years = 19 percent
- Age 30–39 years = 25 percent
- Age 40–49 years = 29 percent
- Age 50–59 years = 27 percent
- Age 60–69 years = 21 percent

CDC administered surveys that showed unrecognized hearing loss occurs frequently. Most notably, individuals typically do not recognize that noise is the cause of their auditory damage. For example, an audiometric notch was detected in one of every four individuals who self-reported their hearing as "excellent" or "good." Moreover, 70 percent of adults who were exposed to loud noise in the past 12 months reported never or seldom wearing hearing protection.

CDC sponsored a Public Health Grand Rounds in June 2017, *It's Loud Out There: Hearing Health Across the Lifespan*. The Grand Rounds featured four presentations from experts in the field: "Hearing Loss: Poorly Recognized but Often Preventable" (Mr. John Eichwald, CDC); "Child and Adolescent Hearing Health" (Dr. Deanna Meinke, University of Northern Colorado); "Hearing Health Among Adults" (Dr. William Murphy, NIOSH); and "Hearing Health Across the Lifespan" (Dr. Shelly Chadha, WHO). The Grand Rounds presentations are archived and available for review at [www.cdc.gov/cdcgrandrounds/archives/2017/june2017.html](http://www.cdc.gov/cdcgrandrounds/archives/2017/june2017.html).

CDC is partnering with WHO to address NIHL at a global level. The World Health Assembly (WHA) (i.e., the decision-making body for WHO) unanimously passed a resolution in May 2017 that called for the Secretariat to produce a "World Hearing Report" and for countries to address hearing loss worldwide. CDC met with WHO and other global partners in July 2017 to promulgate the WHA resolution. This meeting resulted in WHO declaring March 3 as "World Hearing Day" to focus on NIHL, childhood hearing loss, and the economic impact of hearing loss.

CDC is conducting a systematic review of the literature to determine an association between occupational or non-occupational noise exposure and the following health effects:

- Hearing loss
- Ischemic heart disease

- Hypertension
- Psychiatric disorders
- Injuries and falls
- Sleep disturbance
- Low birth weight and/or prematurity
- Endocrine disruption
- Cognitive impairment

CDC's next steps to advance its NIHL activities are described as follows. CDC will complete its systematic review of the literature in December 2017 and produce recommendations on the correlation between occupational/non-occupational noise exposure and health effects in 2018. CDC will develop guidelines to address exposure to noise/loud sound in homes and communities. CDC will develop guidelines regarding adult hearing screening, but another organization likely will be asked to lead this effort. CDC will publish a new study on hearing loss in adolescents at some point in 2018.

Mr. Eichwald concluded his presentation by asking the BSC to provide input in response to two questions on CDC's NIHL activities. First, is CDC's strategic plan and future directions appropriate? Second, what will be the BSC's role in reviewing and providing feedback on the draft content of CDC's new guidelines? Additional information can be obtained from the NCEH Loud Noise Can Cause Hearing Loss website at ([www.cdc.gov/nceh/hearing\\_loss](http://www.cdc.gov/nceh/hearing_loss)).

#### **BSC DISCUSSION: CDC'S NOISE-INDUCED HEARING LOSS ACTIVITIES**

The BSC discussed the following topics during the question/answer session with Mr. Eichwald.

- CDC's partnership with the U.S. Department of Transportation to reduce loud noise in the built environment and child care centers or schools that are sited near highways.
- CDC's plans to conduct research on central auditory processing.

#### **BSC GUIDANCE**

- CDC should gather and publicize data from the National Health and Nutrition Examination Survey (NHANES) that demonstrate key trends in hearing decrements over time. CDC should use its existing media relationships to raise public awareness of NIHL, particularly since the dramatic increase in the continuous use of ear buds is contributing to deteriorated hearing among individuals in younger age groups.
- NIOSH's important role and partnership in CDC's NIHL activities should be strengthened. For example, NIOSH conducted an excellent ototoxicity study that showed a synergistic effect from the combination of toluene, styrene, and noise in occupational settings. Moreover, NIOSH launched the "Buy Quiet" prevention initiative that aims to achieve three key objectives:
  - Encourage companies to purchase or rent quieter machinery and tools to reduce noise exposure among workers.
  - Provide information on equipment noise levels to facilitate the purchase of quieter products and improve workplace safety.
  - Encourage manufacturers to design quieter equipment by creating a demand for these products.

CDC should replicate the Buy Quiet initiative for non-occupational settings to encourage manufacturers to design quieter lawnmowers, machinery, and other equipment that are used in the home.

- CDC is commended for providing leadership at the federal level to address NIHL, but several actions should be taken at this time in preparation of releasing the new noise exposure guidelines in 2018. CDC should identify and obtain commitments from key partners that can play an instrumental role in ensuring the implementation of the new guidelines in the field. CDC should define concrete public health goals and outcomes for the new guidelines. For example, collaborations should be formed with children's health initiatives to promote hearing health care and target hearing loss prevention interventions to young children.
- CDC formed an intra-agency workgroup to conduct its NIHL activities, but this group should be expanded to include external federal partners. For example, the EPA National Exposure Resource Laboratory also has a strong interest in NIHL, particularly roadway noise. Dr. Wayne Cascio, the BSC *ex-officio* member for EPA, offered to provide Mr. Eichwald with a point of contact for the EPA laboratory.

Dr. Breyse commended the intra-agency workgroup for conducting a broad range of NIHL activities in a short period of time with no direct financial support. He confirmed that efforts already have been initiated to address one of the BSC's suggestions. Most notably, CDC currently is focusing on NIHL as an important public health/EH problem by collecting data to document that hearing acuity in young children has worsened over time and likely will lead to an epidemic as these children age.

## Update on Biomonitoring Methods for Contemporary Pesticides

### **Antonia Calafat, PhD**

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

Dr. Calafat presented an update on DLS's ongoing efforts to develop biomonitoring methods for new classes of pesticides. DLS adheres to certain requirements to produce high-quality laboratory data. In terms of the general requirements, biomonitoring methods must be sensitive, specific and selective, accurate, and precise. In terms of the specific requirements, biomonitoring methods must have the following characteristics: ability to use a minimum volume of the sample to reduce solvent use and waste; capacity to measure multiple analytes with high-throughput to increase efficiency; a rugged design to improve reproducibility; a quality assurance/quality control component to ensure accountability; and a highly automated design to ensure cost-effectiveness.

DLS developed a new biomonitoring method to incorporate the measurement of neonicotinoids into the existing panel to measure DEET, an insect repellent, and some of its metabolites. However, several analytical challenges needed to be addressed at the outset. Most notably, native and isotopically-labeled standards were lacking. DLS developed custom-made synthesis for some compounds to overcome this problem, but <sup>13</sup>C-labeled standard materials were unable to be obtained.

DLS's initial attempts to add neonicotinoids to the existing DEET online method were unsuccessful due to inadequate separation and resolution as well as the failure of atmospheric pressure chemical ionization. The wide spectrum of chemical properties among the biomarkers presented extraction and separation challenges. However, the identification of alternative strategies minimized interferences and maximized sensitivity. DLS's experiments resulted in the

development of a new neonicotinoids method that only uses 0.2 mL of urine and includes two DEET biomarkers.

DLS also faced analytical challenges in its development of a new biomonitoring method for glyphosate. The chemical properties of glyphosate include being small in size, highly polar, and having no chromophore/fluorophore. Glyphosate also has an affinity to glass, low solubility in organic solvents, and the ability to form metal complexes. DLS evaluated several techniques, but those initial attempts to quantify glyphosate failed. DLS proposed one alternate strategy that required the purchase of a new system. However, this strategy required retuning initially due to inadequate sensitivity and dependence on the mass spectrometer. DLS's experiments ultimately resulted in the development of a new glyphosate method that includes six dialkylphosphates (DAPs), aminomethylphosphonic acid, and glyphosate.

DLS's progress to date and next steps with the new biomonitoring methods for pesticides are highlighted as follows. Validation of the methods was completed for the quantification of six biomarkers for four neonicotinoids: imidacloprid, thiacloprid, clothianidin, and acetamiprid. The neonicotinoid measurements were incorporated into NHANES and analyses are underway. Validation of the method for the quantification of glyphosate and six DAPs was initiated.

Analyses will be completed for the 2015-2016 NHANES cycle to provide the first reference dataset for neonicotinoid insecticides. DLS also intends to explore additional neonicotinoid biomarkers. After the validation of the glyphosate method is complete, DLS will request approval from the CDC National Center of Health Statistics (NCHS) to analyze 2013-2014 NHANES samples. The biomonitoring methods and results from analyses of the NHANES samples will be published in peer-reviewed journals as soon as possible after NCHS publicly releases the data.

#### **BSC GUIDANCE: NEW BIOMONITORING METHODS**

The BSC commended DLS for its outstanding progress in developing and validating new biomonitoring methods to measure human exposure to glyphosate and neonicotinoids. However, DLS's role as the gold standard and leading authority in biomonitoring should be maximized to allow laboratories and researchers to more rapidly advance to epidemiologic studies and exposure assessments with one consistent and validated method. For example, DLS's two-step approach of publishing its biomonitoring methods in peer-reviewed journals and disseminating its analyses and other supporting data should be streamlined into one process.

Dr. James Pirkle, Director of DLS, explained that a process has been established to address the BSC's suggestion. DLS will provide a detailed summary of its biomonitoring methods at any time upon request. The 50- to 120-page summaries provide comprehensive guidance and training for laboratories and researchers to implement the DLS biomonitoring method of interest. Moreover, DLS's regular updates of the *National Report on Human Exposure to Environmental Chemicals* include a detailed methods section and links to additional laboratory data.

## **NCEH/ATSDR Program Responses to BSC Guidance**

**William Cibulas, Jr., PhD, MS**

Deputy Associate Director for Science, NCEH/ATSDR  
BSC Designated Federal Official (DFO)

Dr. Cibulas explained that the first part of his overview would focus on ATSDR's responses to the guidance the BSC provided during the January 2017 meeting on two key presentations. However, he also planned to provide the BSC members with ATSDR's responses in writing after the meeting.

Dr. Tina Forrester, of the ATSDR Division of Community Health Investigations, presented an update on ATSDR's activities related to unconventional oil/gas extraction and hydraulic fracturing (i.e., "fracking"). Her response is summarized as follows. ATSDR appreciated the BSC's guidance to improve its engagement in fracking activities. ATSDR has refocused its site-specific activities to address PFAS contamination in drinking water, but the BSC's proposed actions will be taken into account after the fracking activities resume. In the interim, ATSDR has addressed several of the BSC's suggestions since the January 2017 meeting.

- ATSDR analyzed the rich source of data from the Texas Commission on Environmental Quality, including air comparison values and air quality reports. ATSDR will use this valuable data source to plan and conduct further fracking activities.
- ATSDR is using its existing partnerships in the industrial hygiene field to avoid issues in government/industry relationships. ATSDR is collaborating with EPA, NIEHS, and NIOSH to better understand the findings of these agencies that can be used to assist in addressing community exposures. ATSDR is applying NIOSH's findings on occupational exposures to develop air monitoring strategies for site releases in communities. ATSDR has engaged one industry partner to date and will follow-up with additional opportunities in the future.
- ATSDR will ensure that affected communities, public health agencies, and environmental agencies at state and local levels are provided with summary information of its findings in a timely manner. ATSDR is participating in local forums to discuss its fracking activities.
- ATSDR will follow-up with endpoints related to silica and polycyclic aromatic hydrocarbons during its analyses of site-specific data.

Dr. Angela Ragin-Wilson, of the ATSDR Division of Toxicology and Human Health Sciences, presented an overview of the Federal Research Action Plan (FRAP) on recycled tire crumb rubber (TCR) that is used on playing fields and playgrounds. Her response to the BSC's guidance is summarized as follows.

- ATSDR and EPA began analyzing TCR samples after the synthetic turf field activities ended in October 2017. ATSDR, EPA, and the Consumer Product Safety Commission (CPSC) plan to submit a draft of the final report for peer review in early 2018. The agencies will share the final report with and communicate the results to stakeholders, including the Pediatric Environmental Health Specialty Units.
- ATSDR, EPA, and CPSC will develop evidence-based messaging for stakeholders, including parents. ATSDR will review existing fact sheets and frequently asked questions while developing messages that are specific to FRAP activities and outcomes.
- ATSDR will continue to clearly communicate the limitations of current studies and will identify follow-up activities.

Dr. Cibulas provided an update on another agenda item that was presented during the January 2017 BSC meeting. Dr. Scott Deitchman presented a proposal for the BSC to establish a new workgroup to address NCEH/ATSDR's role in CDC's vector management and pesticide recommendations. The BSC expressed a great deal of support for this effort during its discussion.

After the meeting, agreement was reached to expand the workgroup to include representation by the BSCs for both the CDC Office of Infectious Diseases (OID) and NCEH/ATSDR. OID and NCEH/ATSDR senior leadership drafted specific activities for the workgroup to accomplish. In addition to receiving a tremendous level of support from internal OID and NCEH/ATSDR staff, the workgroup also will be permitted to engage external subject-matter experts as needed. To date, only one NCEH/ATSDR BSC member has expressed an interest in serving on the new workgroup, but two members are required to serve. Dr. Cibulas announced that the new workgroup will represent CDC's first cross-center advisory body.

Dr. Perry confirmed that she will revisit this issue before the meeting was adjourned on the following day to solicit one or more BSC members to serve on the new workgroup. BSC members with expertise in the use of chemicals to control insects and vector-borne diseases will be particularly helpful. She emphasized that the workgroup will serve as an opportunity for NCEH/ATSDR to contribute its epidemiologic and toxicologic expertise to CDC's decision-making process on the development of vector management and pesticide guidelines.

## CDC's Response to the 2017 Hurricane Season

### **CAPT Renée Funk, DVM, MPH&TM, MBA, DACVPM**

Associate Director for Emergency Management  
NCEH/ATSDR Office of Environmental Health Emergency Management

Dr. Funk presented an overview of CDC's response to the 2017 hurricane season. CDC began distributing health communications messaging to the public on August 24, 2017 and activated the EOC on August 31, 2014. CDC has completed its response activities, but the recovery phase in the aftermath of hurricanes is still underway in Florida, Texas, Puerto Rico, and the U.S. Virgin Islands (USVI).

CDC acknowledges that warmer ocean temperatures are contributing to the increase in the number of hurricanes and their intensity. The 2017 hurricane season is still ongoing, but 17 named hurricanes already have occurred. The current season also accounted for the first hurricane that reached landfall in the continental United States since Hurricane Katrina in 2005.

CDC's specific activities in hurricane-affected areas are highlighted as follows. In Texas, Hurricane Harvey was accompanied by heavy rainfall and flooding that resulted in several drownings. CDC is addressing severe mold issues related to the hurricane by conducting an Epi Aid investigation on invasive mold infection. CDC also is performing a landscape assessment in healthcare facilities, Head Start programs, and other HHS-funded facilities to identify the impact of the storm and address barriers to recovery services. In Florida, Hurricane Irma caused massive power outages that resulted in carbon monoxide poisoning. CDC is performing a landscape assessment in Florida as well.

In Puerto Rico and USVI, Hurricanes Irma and Maria magnified the existing infrastructure problems on these islands in terms of deploying staff, supplies, and other resources. Most notably, the buildings that housed the health departments in Puerto Rico and USVI were severely damaged or entirely condemned. The 69 CDC staff members who are still actively deployed are conducting environmental assessments of healthcare facilities, shelters, schools, and water systems. A separate laboratory team is transporting specimens to CDC Headquarters in Atlanta for testing.

CDC's other response activities in Puerto Rico and USVI are summarized as follows. CDC is providing support to USPHS staff that is operating federal medical stations (i.e., "tent hospitals") to ensure the availability of vaccines and supplies. Because the Internet and telecommunications capacity are still suboptimal, CDC's health communications efforts primarily have been limited to the dissemination of printed materials. CDC is providing epidemiologic support to the VA hospitals and clinics as well as emergency management support to the health departments. CDC is preparing to transition to the recovery phase in early December 2017. CDC projects that at least five years will be required to rebuild the health departments in Puerto Rico and USVI.

#### **BSC DISCUSSION: CDC'S RESPONSE TO THE 2017 HURRICANE SEASON**

The BSC discussed the following topics during the question/answer session with Dr. Funk.

- Efforts to ensure a coordinated federal response among the Federal Emergency Management Agency, the HHS Office of the Assistant Secretary for Preparedness and Response, CDC, and USPHS.
- NCEH/ATSDR's emergency management and disaster response activities at this time to prepare for the 2018 hurricane season.
- The availability of support to retain the sound mental health of front-line staff and other responders who have witnessed extreme devastation during their involvement in hurricane response and recovery efforts for the past three months.

### **Update by the NCEH Lead Poisoning Prevention Program**

#### **Adrienne Ettinger, ScD, MPH, MS**

Chief, NCEH Healthy Homes and Lead Poisoning Prevention Program  
Centers for Disease Control and Prevention

Dr. Ettinger covered several topics in her update to the BSC on the current activities of the NCEH Lead Program.

#### **CDC'S CROSS-CUTTING LEAD ACTIVITIES**

NCEH and ATSDR are responsible for the majority of CDC's lead activities, but other centers also conduct lead initiatives in their programs.

- Healthy Homes and Lead Poisoning Prevention Program & Childhood Blood Lead Surveillance System (NCEH)
- Biomonitoring and Blood Lead Proficiency Program (NCEH)
- Environmental Public Health Tracking (NCEH)
- Regional Activities (ATSDR)
- ToxProfiles™ (ATSDR)
- Adult Blood Lead Epidemiology and Surveillance (NIOSH)
- National Health and Nutrition Examination Survey (NCHS)
- Refugee Screening Program (National Center for Emerging and Zoonotic Infectious Diseases)

#### **FY2017 LEAD FUNDING**

The Water Infrastructure Improvements for the Nation (WIIN) Act includes the Water Resources Development Act (WRDA) of 2016 that called for enhanced surveillance, the development of the Flint Registry, and the establishment of LEPAC. In accordance with the legislation, NCEH used



Prevention and Public Health Fund dollars to entirely or partially support grant awards to Childhood Lead Poisoning Prevention Programs (CLPPPs) in FY2017.

A Year 3 supplement of \$11 million was awarded to NCEH's 35 existing state and local lead programs. Year 1 funding of \$4 million for a new WRDA NOFO was awarded to 14 new lead programs. A consortium led by MSU will be awarded up to \$14.4 million over a four-year project period to develop the new "Lead Exposure Registry of Flint Residents–Michigan." Dr. Ettinger presented a map to illustrate the CLPPPs that were awarded funds in FY2017. The 49 funded CLPPPs represent 39 states, five counties, four large cities, and the District of Columbia.

#### **NCEH/FDA COLLABORATION**

FDA issued a safety communication that included the following Class I recall warning: "Magellan Diagnostics' LeadCare® Testing Systems should no longer be used with venous blood samples due to the potential for falsely low test results." FDA's safety communication can be reviewed in its entirety at <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm>.

FDA is aggressively investigating the root cause of the problem and recently announced its plans to take legal action against Magellan Diagnostics for failing to report the required warning to FDA in a timely manner. NCEH issued a health advisory with retesting recommendations for sensitive subpopulations, particularly children and pregnant lactating women. NCEH is continuing to partner with FDA to better characterize analytic issues. NCEH's health advisory can be reviewed in its entirety at <https://emergency.cdc.gov/han/han00403.asp>.

#### **ESTABLISHMENT OF A NEW BLRV**

The BSC extensively reviewed data as part of its discussion during the January 2017 meeting on whether NCEH/ATSDR should lower the current childhood BLRV from 5 to 3.5 µg/dL. The BSC noted that similar guidance was set forth in ACCLPP's 2012 report and raised two key points in its discussion. First, the BLRV is equal to the 97.5<sup>th</sup> percentile of distribution for BLLs in children 1-5 years of age in NHANES. Second, analyses of the most recent NHANES data for the 2011-2014 cycle indicate that the 97.5<sup>th</sup> percentile of distribution for BLLs in children 1-5 years of age is 3.5 µg/dL. The BSC unanimously voted to approve the recommendation for NCEH/ATSDR to lower the current childhood BLRV from 5 to 3.5 µg/dL, but one member changed his vote from "approve" to "abstain" after the January 2017 meeting.

The BSC also reached several major conclusions in its discussion. Because no safe BLL exists, efforts should be made to continually strive to prevent any exposure. A shift in the BLRV will allow HCPs to identify more children who are exposed to lead, particularly children in the youngest age groups who are especially sensitive to the effects of lead. This information can be used to target high-risk populations and geographic areas with the greatest need for interventions and also to provide children the recommended services for follow-up of their potential exposure to lead.

NCEH will clearly define the BLRV in its communication materials with several key messages. The BLRV is a policy tool that can be used to identify the largest population of at-risk children who are at the upper end of the blood lead distribution. The BLRV also can be used to target activities for primary, secondary, and tertiary prevention; evaluate effectiveness of prevention efforts; and monitor trends over time. The BLRV is not a health-based toxicity threshold or a clinical reference value that defines an acceptable range of BLLs in children.

NCEH acknowledges that the new BLRV has certain implications and is likely to present challenges in four major areas.

- *Laboratory proficiency and limits of detection:* Some laboratories do not have the ability to measure extremely low BLLs. Issues have been reported regarding the sensitivity and precision of low BLL measurements. If the new BLRV is implemented, additional research will be required on the proficiency of laboratories to measure low BLLs between 3.5 and 5 µg/dL.
- *Impact of state and local implementation:* CDC's current BLRV of 5 µg/dL has been adopted at various levels by stakeholders, including federal, state, and local partners, HCPs, and the general public. The lower BLRV will allow HCPs and public health agencies to identify additional sources of lead contamination. If the CLPPPs change their case management and follow-up action levels based on the new BLRV, however, state and local health departments will encounter intensified workloads due to the increased number of children who exceed the lower BLRV.
- *Communication and public interpretation:* NCEH will target significant efforts to accurately communicate the meaning of the lower BLRV and clearly describe specific actions that should be taken. NCEH's communication materials will be designed to inform the public that the BLRV is intended to be used as an indicator to identify whether a child has been exposed to lead.
- *Federal agency adoption and coordination:* Efforts by other federal agencies to establish rule-making standards to meet the lower BLRV might be difficult. Time will be needed for CDC's federal partners to revise and align their standards with the new BLRV.

NCEH's completed activities and next steps for CDC to formally adopt the new BLRV are highlighted as follows. NCEH senior management drafted a decision memorandum that was forwarded to Dr. Breyse for approval at the center level. Final approval by Dr. Fitzgerald, the new CDC Director, at the agency level is pending at this time. A communication and implementation plan was drafted that will include the publication of an *MMWR* Policy Note to summarize the results of NHANES analyses and notify state/local health departments of CDC's formal adoption of the new BLRV.

NCEH will use the new BLRV in all of CDC's future recommendations that involve follow-up evaluation of children after BLL testing. NCEH will continue to evaluate the BLRV every four years based on data in the two most recent NHANES cycles. NCEH's overall goal will be to widely promote primary prevention of lead exposure. Dr. Ettinger represents NCEH on CDC's Strategic Planning Committee that was formed to identify programs, projects, and other activities across the agency related to early brain development. NCEH is well positioned to contribute its expertise to this initiative.

#### **FEDERAL LEAD PARTNERS**

The Clinton Administration issued an Executive Order in 1998 to establish the President's Task Force on Environmental Health Risks and Safety Risks to Children. The purpose of this initiative is to provide a high-level platform for federal agencies to jointly plan and recommend strategies to address children's EH and safety issues within the limits of the Administration's budget. The Task Force convened the Lead Subcommittee to facilitate interagency coordination regarding childhood lead exposures and related effects to better understand and prevent disease and disabilities in children from lead. The Lead Subcommittee co-chairs include HHS (Dr. Ettinger), EPA, and the U.S. Department of Housing and Urban Development (HUD).

The Lead Subcommittee has made tremendous progress to achieve its two major objectives to conduct research activities and share information with the public. Most notably, a comprehensive report was published in November 2016, *Key Federal Programs to Reduce Childhood Lead Exposure and Eliminate Associated Health Impacts*. The report is available for review at: <https://ptfceph.niehs.nih.gov/activities/lead-exposures/index.htm>.

The current priority of the Lead Subcommittee is to release the draft “Federal Lead Strategy and Stakeholder Engagement–2018.” The members are contributing their scientific, programmatic, and policy expertise to this effort to inform policymakers about the current gaps in evidence and the action steps that are needed to further reduce lead exposures of children in the United States. The 2018 Federal Lead Strategy will serve as an update to the recommendations in the 2000 strategy that focused on lead paint hazards. The new strategy also will be informed by the Lead Subcommittee’s 2016 report on key federal programs that are available to address childhood lead exposures.

The Lead Subcommittee expects to release a draft of the new Federal Lead Strategy for public comment in late 2018, but the proposed outline is highlighted below.

- *Proposed Vision:* “The United States will become a place where children, especially those in vulnerable communities, live, learn, and play free 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.”
- *Proposed Goals:*
  - Reduce sources of lead in children’s environments
  - Improve monitoring of lead exposure to children, including surveillance of children’s BLLs
  - Improve the follow-up and health outcomes of children who are exposed to lead by making referrals to appropriate services to decrease the impact of lead health effects
  - Improve effective cross-federal communication with communities, policymakers, and families
  - Conduct innovative research to improve scientific knowledge, inform cost-effective decision-making, and strengthen the effectiveness of interventions
- *Next Steps*
  - Determine the status of current federal lead programs (completed in November 2016)
  - Identify opportunities to collaborate across federal programs to reduce lead exposure and improve children’s health (ongoing activity)
  - Conduct outreach campaigns to the general public and industry stakeholders (ongoing activity)

## Lead Exposure Registry of Flint Residents-Michigan

**Stephanie Davis, MSPH**

Project Officer, NCEH Healthy Homes and Lead Poisoning Prevention Program  
Centers for Disease Control and Prevention

Ms. Davis presented an overview of the new Flint Registry. The WIIN Act of 2016 authorized funding for the development of the new Flint Registry. NCEH released a NOFO in May 2017 for a four-year \$14.4 million non-research grant to MSU. In August 2017, MSU received a Year 1 award of \$3.2 million from NCEH to establish the Flint Lead Exposure Registry and will use these funds to lead its extensive consortium of partners. MSU previously received a \$500,000 Flint Registry Planning Grant from the Michigan Department of Health and Human Services.

Ms. Davis presented a slide of the detailed logic model that NCEH designed to guide the development of the Flint Registry. The processes include inputs, activities, and outputs/products. Short-term, intermediate, and long-term outcomes are described as well. The activities that MSU will conduct over the four-year project period in accordance with the NOFO requirements are highlighted below.

MSU will aim to achieve the following long-term program goals. To ensure quality improvement of community services, MSU will create decision tools for agencies and policymakers; build a sustainable referral network to support lead poisoning prevention; and continuously improve service delivery to lead-exposed residents. To develop a robust registry and data repository, MSU will ensure the privacy of registrants; establish a system to inform policy and administrative decisions; make data available to agencies and the general public; and create framework for future research.

MSU will implement several strategies to build state and local capacity in accordance with the NOFO requirements. For outreach and training, MSU will establish community advisory boards to promote the registry; obtain community, provider, and workforce support for the registry; increase media presence, health education, and training; and identify a referral network for registrant services.

MSU will create a rigorous protocol for the Flint Registry by taking the following actions: identify eligible residents who were exposed to lead from the Flint Water System from April 25, 2014 to October 15, 2015; recruit and enroll eligible residents; collect baseline data; make referrals to services as needed; and gather follow-up data to make improvements in outcomes and other areas. MSU will collaborate with and integrate information into the registry from a Referral Network that will provide diagnosis and treatment, therapy, enrichment services, environmental assessments and interventions, and data sharing with the registry. The Referral Network will receive funding from other sources.

NCEH represents CDC on an HHS Coordination Workgroup that will have oversight of awards totaling \$37 million to five grant recipients in Michigan, including MSU, over the next three to five years. The purpose of the workgroup is to avoid duplication in the requirements of the five recipients of HHS awards and to coordinate data collection efforts. Details on the four non-CDC recipients are outlined below.

In March 2016, the Centers for Medicaid & Medicare Services (CMS) expanded eligibility for Medicaid and Children's Health Insurance Program (CHIP) services to include children up to 21 years of age who were exposed to the Flint Water System and pregnant women at 400 percent of the Federal Poverty Level.

In August 2016, CMS established its "Connecting Kids to Coverage Outreach and Enrollment" initiative. The Greater Flint Health Coalition is the CMS recipient and will be awarded \$300,000 through a three-year CoAg. The goal of the CMS-funded initiative is to educate families on

Medicaid and CHIP; identify children who are eligible for services; assist with the application process; support the renewal of applications; and maximize outreach efforts for newly eligible individuals.

The Health Resources and Services Administration (HRSA) is funding the “Addressing and Preventing Lead Exposure through Healthy Start” initiative. The Genesee County Health Department is the HRSA recipient for this activity and will be awarded \$15 million through a five-year CoAg. The goal of this HRSA-funded initiative is to minimize developmental delays among lead-exposed children up to 6 years of age in Flint and connect pregnant women and children to appropriate screening, services, and supports.

HRSA also is funding the “Maternal Child Environmental Health Collaborative Improvement and Innovation Network” (EH CoIIN) that will enable teams of federal, state, and local leaders to address common problems within a specified period of time. The Association of Maternal and Child Health Programs is the HRSA recipient for this activity, along with 11 EH CoIIN team members, and will be awarded \$2.6 million through a three-year CoAg. The goal of this HRSA-funded initiative is to decrease maternal and child morbidity and mortality associated with lead exposure and increase access to systems of coordinated care among infants and children.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is funding the “Flint Resiliency in Communities After Stress and Trauma” (Flint ReCAST) program. The City of Flint is the SAMHSA recipient, along with its extensive consortium of community-based partners, and will be awarded \$5 million through a five-year grant. The goal of the SAMHSA program is two-fold: (1) help the community to provide services and support to youth and their families who are exposed to trauma through natural or manmade disasters or civil disturbances; and (2) promote resilience and equity through programs for violence prevention and youth engagement.

## **Legislative Requirements of the New Lead Exposure and Prevention Advisory Committee**

**James Stephens, PhD**  
Senior Advisor  
NCEH/ATSDR Office of the Director

Dr. Stephens reported that the WIIN Act was signed into law on December 16, 2016 and included the WRDA legislation of 2016. He reviewed the legislative requirements and other language in the WIIN Act to establish LEPAC.

### **LEPAC Membership**

- The HHS Secretary shall establish, within ATSDR, an Advisory Committee in coordination with the Director of CDC and other relevant agencies as determined by the HHS Secretary that consists of federal members and non-federal members, and which shall include:
  - an epidemiologist;
  - a toxicologist;
  - a mental health professional;
  - a pediatrician;
  - an early childhood education expert;
  - a special education expert;
  - a dietician; and

- an environmental health expert.
- The LEPAC membership shall not exceed 15 members and not less than 50 percent of the members shall be federal members.
- The HHS Secretary shall designate a chair from among the federal members appointed to LEPAC.
- The LEPAC members shall serve for a term of not more than three years. The HHS Secretary may reappoint members for consecutive terms.
- LEPAC shall be subject to FACA.

### **LEPAC Responsibilities**

- LEPAC shall, at a minimum:
  - review the federal programs and services available to individuals and communities exposed to lead;
  - review current research on lead poisoning to identify additional research needs;
  - review and identify best practices, or the need for best practices, regarding lead screening and the prevention of lead poisoning;
  - identify effective services, including services relating to health care, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry; and
  - undertake any other review or activities that the HHS Secretary determines to be appropriate.

### **LEPAC Reporting Requirements**

- Annually for five years and thereafter, as determined necessary by the HHS Secretary or as required by Congress, LEPAC shall submit to the HHS Secretary; the Committees on Finance, Health, Education, Labor, and Pensions, and Agriculture, Nutrition, and Forestry of the Senate; and the Committees on Education and the Workforce, Energy and Commerce, and Agriculture of the House of Representatives a report that includes:
  - an evaluation of the effectiveness of the federal programs and services available to individuals and communities exposed to lead;
  - an evaluation of additional lead poisoning research needs;
  - an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead poisoning;
  - input and recommendations for improved access to effective services relating to health care, education, or nutrition for individuals and communities impacted by lead exposure; and
  - any other recommendations for communities affected by lead exposure, as appropriate.

Dr. Stephens reported that NCEH/ATSDR's next steps will be to receive the signed LEPAC charter from the HHS Secretary; publish a *Federal Register* notice to initiate the recruitment process of federal and non-federal members to represent the eight areas of expertise; and submit a formal nomination package to the HHS Secretary for approval. The timeline for the completion of these tasks is uncertain, but approximately eight to 10 months typically are required to establish a new FACA committee after the federal agency receives the signed charter.

Dr. Stephens confirmed that NCEH/ATSDR will circulate the signed LEPAC charter and the *Federal Register* notice to the BSC members for their awareness. To assist NCEH/ATSDR in

recruiting potential candidates to serve as non-federal LEPAC members, the BSC members should respond to the *Federal Register* notice and follow the instructions for submission.

#### **BSC GUIDANCE: LEAD UPDATES**

- NCEH/ATSDR's efforts to effectively, efficiently, and rapidly award federal funds to address the lead-contaminated water crisis in Flint are impressive. NCEH/ATSDR should ensure that this model can be replicated to quickly respond to similar EH problems in other communities in the future.
- NCEH/ATSDR's leadership at the federal level to reduce BLLs across the country and its success in achieving an important milestone in EPH are commendable. The BSC was particularly pleased that the enactment of the WIIN Act and WRDA has resulted in new funding to increase the enthusiasm, rigor, and national attention for the NCEH Lead Program.
- The focus on water as the sole source of lead contamination in Flint is problematic. Most notably, the allocation of new federal funding to address lead-contaminated water will not address more significant exposures from lead-based paint in old housing stock, particularly since over 90 percent of homes in Flint were built before the 1970s. Moreover, lead-based paint is still the single largest contributor to children's BLLs in the United States. In the implementation of their new WIIN- and WRDA-funded activities in Flint, NCEH/ATSDR and its federal partners should be mindful that emphasis on the elimination of lead paint hazards will generate a much higher return on investment in terms of reducing childhood BLLs. NCEH/ATSDR also should leverage the strong economic and political will that exists at this time to strengthen its focus and resources on the elimination of lead paint hazards.
- NCEH/ATSDR and its federal partners should promote and allocate resources to a holistic, comprehensive public health approach to lead. Instead of targeting funds to address a specific source of lead, the federal agencies should focus on building "lead-free" communities. For example, incentives for remediation of deteriorated housing should be offered to renters of pre-1970 properties on a large-scale, community-wide basis.
- CDC convened an expert panel in 2015 that published a report, *Educational Interventions for Children Affected by Lead*. NCEH/ATSDR should use the authors of this report as a source to identify potential non-federal candidates to serve on LEPAC.
- The LPPS will be retired when LEPAC is formally approved to operate as a standalone FACA committee. The BSC thanked Dr. Strickland and the LPPS members for their outstanding expertise and valuable contributions to provide sound guidance on complex lead issues.

Dr. Breyse provided several follow-up remarks to some of the BSC's comments and suggestions. In terms of funding allocations, CDC's new Congressional appropriations for lead are instrumental in rebuilding the NCEH Lead Program. However, these resources are still much lower than the fully funded lead budget of \$35 million prior to FY2012. Most notably, NCEH's current grant awards to state and local lead programs are now approximately 33-50 percent of the previous funding levels.

Despite the ongoing budget constraints, Dr. Breyse was proud to announce that the NCEH Lead Program is increasing its role in performing assessments and investigations of hazardous waste sites with associated lead issues. NCEH's primary functions in this effort will be to analyze lead surveillance data and characterize exposures to lead across communities.

In terms of lead contamination sources in Flint other than water, Dr. Breyse announced that The Pew Charitable Trusts issued a report in August 2017, *10 Policies to Prevent and Respond to Childhood Lead Exposure*. The report assessed the risks experienced by communities; offered solutions to key federal, state, and local agencies, and estimated the cost-savings of various interventions.

The eradication of lead paint hazards from older homes of children in low-income families and compliance with EPA's rule that requires contractors to implement lead-safe renovation, repair, and painting practices were two of the major solutions featured in the Pew report. Dr. Breyse confirmed that NCEH/ATSDR hopes to use the powerful Pew report as leverage to expand its lead activities and advance toward making Flint and other affected cities "lead-free."

Dr. Breyse concluded his follow-up remarks by reminding the BSC of an important and fundamental issue that has been a longstanding concern of communities throughout the country, including tribal communities. Individuals view safe and clean water as their basic human right. Moreover, the American public expects and demands federal, state, and local governments to provide clean water and enforce standards to ensure the safety of water. For example, previous surveys have shown that communities prioritize safe and clean water over lead in deteriorated homes, lead in soil, mold, and high crime rates.

Dr. Breyse appreciated the BSC's guidance for NCEH/ATSDR to increase its focus on more significant exposures from lead-based paint in old housing stock. During its discussion, for example, the BSC referenced data that show 90 percent of homes in Flint were built before the 1970s. However, the Flint residents have no interest in this or any other EH issue until the lead-contaminated water problem is fully resolved. Overall, he emphasized that federal, state, and local governments have an obligation to respect and seriously address the perspectives, expectations, and concerns of communities regarding safe and clean water.

### Public Comment Period: LPPS Members

The LPPS members joined the BSC meeting via teleconference to provide their comments on the lead updates.

#### **Dr. Patrick Parsons**

New York State Department of Health

Dr. Parsons pointed out that the activities by the NCEH Lead Program reflect a remarkable public health success in terms of reducing children's BLLs. DLS's achievements in measuring low BLLs with tremendous precision and accuracy have greatly contributed to this success. However, DLS's high-level capacity, expertise, and resources are not representative of most laboratories in the United States, including those with the ability to use inductively coupled plasma mass spectrometry. Most notably, laboratories that use the LeadCare® instrument are unable to distinguish between BLLs at 3.5 and 5 µg/dL.

Dr. Parsons's position was that the implementation of the lower BLRV for public health actions is not particularly prudent at this time due to existing flaws in laboratory proficiency. He advised CDC to consider delaying its formal adoption of the new BLRV at 3.5 µg/dL until more data can be gathered on the quality of blood lead testing results. For example, a BLL result of 3.5 µg/dL can be due to background contamination, particularly with fingerstick testing.



Dr. Parsons encouraged NCEH to develop and disseminate recommendations and technical guidance to laboratories, HCPs, and other public health professionals regarding the limitations of the current methods for BLL testing. He noted the critical need to address the practical consequences of measuring blood lead at lower levels to ensure that high-quality data continue to be produced.

**Dr. Michael Kosnett**

University of Colorado School of Medicine & Colorado School of Public Health

Dr. Kosnett reminded the BSC of the six formal recommendations that the LPPS presented during the January 2017 meeting. He thanked Dr. Breyse for his thoughtful responses during the meeting, but he asked NCEH to develop and present a formal plan of action to the BSC. He was particularly interested in NCEH's plans to address three of the recommendations.

- *Recommendation 4:* CDC should provide guidance and support the scientific rationale for OSHA to revise its outdated occupational lead standards.
- *Recommendation 5:* CDC should develop a standardized template for the clinical interpretation of blood lead results for use by clinical laboratories nationwide on their test reports. Dr. Kosnett asked CDC to consider forming an internal workgroup or task force to support this effort.
- *Recommendation 6:* CDC should communicate to the HHS Secretary regarding the need for CMS to implement recommendations to tighten guidelines for blood lead proficiency testing criteria to  $\pm 2$   $\mu\text{g/dL}$ ,  $\pm 10$  percent under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Dr. Kosnett noted that the current CLIA requirements for blood lead proficiency testing are outdated and should be revised for consistency with the new BLRV of 3.5  $\mu\text{g/dL}$ .

**Dr. Jennifer Lowry**

Children's Mercy Hospital

Dr. Lowry was aware that the purpose of the lower BLRV of 3.5  $\mu\text{g/dL}$  is to identify more children with elevated BLLs. The most recent NHANES data indicate that the 97.5<sup>th</sup> percentile of distribution for BLLs in children 1-5 years of age is 3.5  $\mu\text{g/dL}$ , but this approach will not result in an increased number of children. Instead, the population of children will be the same.

Dr. Lowry clarified that a large number of HCPs have no understanding of the difference between a blood lead "action level" and "reference level." As a result, thoughtful consideration and a significant amount of planning should be devoted to provider education before CDC announces its formal adoption of the lower BLRV of 3.5  $\mu\text{g/dL}$ . Most notably, CDC did not disseminate sufficient guidance and education to the provider community when the previous "level of concern" of 10  $\mu\text{g/dL}$  was lowered to the current BLRV of 5  $\mu\text{g/dL}$ .

Dr. Lowry acknowledged that CDC's implementation of the current BLRV of 5  $\mu\text{g/dL}$  began in May 2012, but pediatricians still have limited knowledge of actions to take for their patients with BLLs at 5  $\mu\text{g/dL}$ . Provider education also will be critical to explain the potential need to increase the BLRV in the future. Increased screening likely will result in a larger population of children with elevated BLLs.

Dr. Breyse responded to the comments by Dr. Parsons. The BLRV is not intended to distinguish between BLLs at 3.5 and 5 µg/dL or serve as a regulatory limit. CDC has no authority to require states and local jurisdictions to adopt the lower BLRV. Instead, the lower BLRV is a policy tool that will expand the population of at-risk children who should receive primary, secondary, and tertiary prevention interventions to further reduce and eliminate lead exposure. If BLLs do not continuously decrease when NHANES data are reviewed every four years, NCEH/ATSDR OD will reevaluate the current strategy of establishing a BLRV.

Dr. Breyse noted that Dr. Parsons raised concerns regarding the precision and accuracy of measuring BLLs at  $\geq 3.5$  µg/dL. The same problems exist for BLL measurements at  $\geq 5$  µg/dL, but the BLRV at this level was successfully implemented. He agreed with Dr. Parsons's suggestion to carefully consider the type of guidance that will be disseminated to laboratories and HCPs. He announced that NCEH will partner with the Association of Public Health Laboratories (APHL) to develop guidance for the lower BLRV. APHL's primary role will be to create clear, straightforward messages regarding the uncertainties and limitations of laboratory measurements at lower BLLs.

Dr. Breyse also agreed with Dr. Parsons's comments regarding the imperfection of current analytical methods. However, his position was that these uncertainties do not serve as sufficient justification or provide a convincing argument to maintain the current BLRV at 5 µg/dL. He emphasized that similar issues were likely raised during the decision-making process for CDC to lower the previous "level of concern" of 10 µg/dL to the current BLRV of 5 µg/dL.

In response to Dr. Kosnett's comments, Dr. Ettinger confirmed that the NCEH Lead Program will present a formal response to the BSC on the LPPS's six recommendations. In response to Dr. Lowry's comments, she would provide her with CDC's surveillance data and the most recent NHANES data that were used to define the lower BLRV of 3.5 µg/dL.

## Federal Partnership Efforts

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

Dr. Breyse reported that as part of the "Reimagine HHS" Initiative, the current Administration is challenging federal agencies to reconsider and re-envision their traditional approaches to conducting business. At the agency level, CDC is taking steps to achieve this goal by enhancing its collaborations with HHS agencies and other federal partners to eliminate silos. At the center level, examples of NCEH/ATSDR's federal partnerships efforts are highlighted below.

- The four federal partners that serve as BSC *ex-officio* members (e.g., EPA, NIEHS, NIOSH, and the U.S. Department of Energy [DOE]) provide an opportunity for NCEH/ATSDR to maintain close communications with these agencies and explore opportunities for interagency collaboration on EH issues. For example, Dr. Breyse regularly meets with EPA to determine potential areas of overlap and synergy in their EH activities.
- NCEH represents HHS as the co-chair of the Lead Subcommittee of the President's Task Force on Environmental Health Risks and Safety Risks to Children. To support this effort, Dr. Breyse frequently consults with the EPA and HUD co-chairs.
- ATSDR, EPA, and NIEHS formed a Federal Interagency Coordinating Committee on PFAS in March 2017. The FDA, VA, and several other federal agencies also serve on the

committee. The committee's efforts are aligned with the November 2017 publication, "Proposal for Coordinated Health Research in PFAS-Contaminated Communities in the United States."

- DLS is contributing its laboratory expertise to support the FDA's ongoing activities to regulate nicotine in cigarettes. The development of nicotine-free cigarettes would be one of the most significant public health successes in recent history. DLS will present the strategic plan for this effort to the FDA Commissioner. DLS's partnership with the FDA also includes its leadership on new laboratory research to develop biomonitoring methods for marijuana exposure.
- NCEH closely collaborated with the FDA to issue a recall warning and other materials to inform the public of problems with BLL measurements with Magellan Diagnostics' LeadCare® Testing Systems.
- NCEH/ATSDR has ongoing partnerships with DoD and VA on issues other than PFAS, such as addressing hazardous waste problems at DoD sites across the country.
- ATSDR and EPA characterized exposures to TCR to provide samples to NIOSH to determine the bioavailability of this substance. ATSDR, EPA, and NIOSH will be listed as coauthors of a new TCR exposure characterization report that will be released in 2018.

Dr. Breysse requested the BSC's input on new or existing federal partnerships that NCEH/ATSDR should aggressively pursue or strengthen. For example, NCEH/ATSDR is aware of the need to engage partners to increase the focus on climate and health at the federal level. However, no actions will be taken on this initiative until a decision is made on whether the NCEH Climate and Health Program will be eliminated in the FY2018 budget. He asked other federal staff to describe additional federal partnership efforts for the BSC to consider in its discussion.

Dr. Ettinger reported that NCEH recently submitted documentation to the Office of Management and Budget to combine its Childhood Blood Lead Surveillance System (e.g., surveillance of non-occupational BLLs in children 0-16 years of age) with the NIOSH Adult Blood Lead Epidemiology and Surveillance System (e.g., surveillance of occupational BLLs in persons 16 years of age and older). The integrated NCEH/NIOSH surveillance system will eliminate duplication in collecting BLL data on the same population of individuals who are 16 years of age, particularly girls in this age group who are of reproductive age or are pregnant.

Dr. Cascio reported that wildfire smoke causes tremendous health impacts to the general public and significant occupational exposures to firefighters. As a result, multiple federal agencies formed the Wildfire Research Council to identify gaps in knowledge, review existing data, and describe research needs related to wildfire smoke for both occupational and non-occupational purposes. The council plans to broadly share its findings for use both within and outside of the government.

Dr. Ruth Lunn, the BSC *ex-officio* member for NIEHS, reported that NIEHS has established interagency agreements with NIOSH to conduct exposure assessments in occupational settings, such as exposure to manganese in asphalt among welders. She raised the possibility of NIEHS expanding the NIOSH occupational exposure assessments to address environmental exposures to the general public.

#### **BSC GUIDANCE: FEDERAL PARTNERSHIP EFFORTS**

- DLS's partnership with the FDA on the regulation of nicotine in cigarettes should be expanded to include e-cigarettes.

- During the December 2015 BSC meeting, the NCEH Healthy Community Design Initiative (HCDI) presented its innovative ecological analysis to identify an association between parking prices and walking or bicycling to work. The HCDI was the only federal program that solely focused on the built environment and its impact on public health, but the budget line-item for this initiative was eliminated. NCEH/ATSDR should initiate discussions with its federal partners to explore the possibility of reestablishing the HCDI.
- NCEH/ATSDR should identify and obtain commitments from key federal partners that can play an instrumental role in ensuring the implementation of two sets of guidelines in the field: (1) NCEH's new NIHL guidelines and (2) ATSDR's guidelines on siting early child care and education programs to reduce children's risk of being exposed to dangerous chemicals. Most notably, coordination between EPA's siting guidelines for children in grades K-12 and ATSDR's guidelines on siting early child care and education programs would be an excellent interagency partnership.
- NCEH/ATSDR should improve its communications with the NIEHS National Toxicology Program (NTP) to explore collaborative efforts and synergies on overlapping EH activities that are smaller in scope or not publicized. For example, NTP's expertise in toxicological testing, comprehensive literature reviews, and data extraction could be useful in DLS's development of new biomonitoring methods for contemporary pesticides. NCEH/ATSDR and NTP should regularly convene meetings to identify potential cost-savings in EH activities that are common between the two agencies.
- NCEH/ATSDR has a strong and longstanding partnership with NIOSH, but its relationship with OSHA has been limited to date. NCEH/ATSDR should collaborate with OSHA on an ongoing basis to develop integrated models and address overlapping areas between occupational and non-occupational environmental exposures. For example, NCEH/ATSDR should use its new NIHL activities and biomonitoring methods for contemporary pesticides as a foundation to establish a partnership with OSHA. This relationship will be particularly important because similar to EPA, OSHA also has rule-making authority.
- NCEH/ATSDR should increase its focus on infectious diseases in the environment. NCEH/ATSDR's partners in the response and recovery efforts for the 2017 hurricane season would provide a tremendous opportunity to make progress in this area.
- A new report will be published in the near future on emissions from 18 compressor stations that are associated with natural gas pipelines in New York. The new report will document that the compressor stations are emitting 20 carcinogens per day with known respiratory and cardiac health effects. NCEH/ATSDR and its federal partners should engage in a collaborative effort to assist local jurisdictions in making public health decisions on this issue.
- The BSC returned to Dr. Breyse's comments regarding the uncertain future of and lack of political will for the NCEH Climate and Health Program, but the members reiterated their role as a group of external advisors. As a result, the BSC went on record to strongly urge NCEH/ATSDR to add research on climate issues and weather-related events to its current list of priorities. The BSC proposed two opportunities for collaboration in this regard.
  - NCEH should initiate discussions with CMS to explore the possibility of conducting a new study on the impact of extreme weather events on health care utilization, waterborne diseases, and other effects in Medicare/Medicaid beneficiaries.
  - NCEH/ATSDR should review two recently published reports. First, the National Climate Assessment report reflects an outstanding model of cross-agency leadership. This consortium gathered a massive amount of evidence on the impacts of climate on public health. Second, *The Lancet* Commission on Pollution

and Health report addresses this issue in the context of the global burden of disease.

Dr. Breyse thanked the BSC members for their thoughtful perspectives, helpful guidance, and critical input. He made several comments in response to some of the suggestions that the BSC proposed during the discussion.

- NCEH/ATSDR contributes its EPH expertise and provides other support whenever possible to the built environment activities that are conducted by the CDC National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). However, NCEH/ATSDR has no plans or resources at this time to reestablish the HCDCI.
- Dr. Breyse will reach out to ATSDR staff that has oversight of the CSPECE initiative. He agreed with the BSC that EPA should serve as a major federal partner in ATSDR's activities related to the siting of early child care and education programs.
- NCEH/ATSDR and NIEHS recently convened a meeting to identify and discuss their shared EPH goals. Dr. Breyse was particularly interested in developing an interagency process for NCEH/ATSDR, EPA, and NIEHS to combine their resources to conduct literature reviews. For example, the three federal partners traditionally have devoted their efforts to performing independent literature reviews on the same EH topics. With a new collaborative effort, however, one agency would be assigned to conduct a literature review on a specific EH topic and share the findings with the other two agencies.
- ATSDR has conducted limited investigations on compressor stations associated with natural gas pipelines in its fracking activities in Pennsylvania. Dr. Breyse confirmed that he looked forward to reviewing the new report on this issue by the New York State researchers.

## Public Comment Period

### **Dr. Michael Kosnett**

University of Colorado School of Medicine & Colorado School of Public Health

Dr. Kosnett returned to the BSC's earlier comments regarding NCEH/ATSDR's impressive efforts to rapidly award federal funds to address the lead-contaminated water crisis in Flint. He advised NCEH/ATSDR to take action on the BSC's suggestion to ensure that the Flint model can be replicated to quickly respond to similar EH problems in other communities in the future. Although 7 percent of children in Flint had BLLs greater than 5 µg/dL at the height of the lead crisis in 2014, the incidence of BLLs was double (or 14.2 percent) among children in Cleveland, Ohio at the same time.

Dr. Kosnett noted that the WIIN Act will not require the newly established LEPAC to limit its advice and guidance on lead to water (as the only source of exposure) or children (as the only affected population). He hoped that LEPAC will be charged with addressing a broad range of lead issues in various populations. For example, lead has a demonstrated risk of increased cardiovascular disease in adults, particularly from occupational exposures.

With no further discussion or business brought before the BSC, Dr. Perry recessed the meeting at 3:52 p.m. on November 15, 2017.

## November 16, 2017 Opening Session: Welcome-BSC Meeting Reconvenes

### **William Cibulas, Jr., PhD, MS**

Deputy Associate Director for Science, NCEH/ATSDR  
BSC Designated Federal Official (DFO)

Dr. Cibulas opened the floor for introductions and confirmed that the 15 voting members and *ex-officio* members in attendance constituted a quorum for the BSC to conduct its business on November 16, 2017. He reconvened the proceedings at 8:33 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 November 16, 2017 published agenda.

## Update on the National Amyotrophic Lateral Sclerosis (ALS) Registry

### **Kevin Horton, DrPH, MSPH**

Chief, Environmental Health Surveillance Branch  
ATSDR Division of Toxicology and Human Health Sciences

Dr. Horton presented an update on ATSDR's National ALS Registry. ALS (i.e., Lou Gehrig's disease) is a progressive and fatal neurological disease that is caused by the degeneration of motor neurons. Of all ALS patients, approximately 80 percent die within two to five years of symptom onset; 90-95 percent are sporadic cases; and 5-10 percent are familial cases. The causes of sporadic ALS cases are unknown. Potential ALS risk factors include exposure to heavy metals, volatile organic compounds, (VOCs) and pesticides, occupational exposures, head trauma, smoking, and alcohol consumption. No cure has been developed for ALS.

In response to the enactment of new legislation in October 2008 that directed CDC to create a population-based ALS registry for the United States, ATSDR launched the National ALS Registry in October 2010. The registry was designed to address the lack of reliable incidence and prevalence estimates for ALS in specific geographic areas and the entire nation. The legislative language outlined the three key functions of the registry: (1) describe the incidence and prevalence of ALS; (2) describe the demographics of ALS patients; and (3) examine risk factors for ALS. Because ALS is a non-notifiable condition that is not required to be reported to CDC, ATSDR incorporated a novel approach into the registry to track cases.

ATSDR designed the methodology of the National ALS Registry with two parts. In part 1, ATSDR collects information from large national databases, such as the Medicare, Medicaid, and VA databases, to identify ALS patients. ATSDR identifies ALS patients by applying an algorithm to these large datasets. The algorithm includes the ALS-specific ICD code, the frequency of neurology visits, and prescription data.

In part 2, ATSDR identifies ALS patients through a web portal registration system. Patients answer a series of validation questions (e.g., “Has a neurologist ever diagnosed you with ALS?”). Depending upon the responses, ATSDR enrolls individuals who are validated as actual patients into the National ALS Registry. ATSDR merges data from both parts of the methodology to eliminate duplicate registrants.

At the completion of the registration process, the actual ALS patients are asked to complete 17 online risk factor surveys. As of November 6, 2017, a total of 70,563 surveys have been completed. These surveys include:

- Demographics
- Occupational history
- Military history
- Smoking and alcohol history
- Physical history
- Family history of neurological diseases
- Disease progression (based on the ALS Functional Rating Scale)
- Clinical data (e.g., devices used and onset of bodily signs/symptoms)
- Open-ended etiological questions
- Lifetime residential history
- Lifetime occupational history
- Residential pesticide use
- Hobbies with toxicant exposures
- Caffeine consumption
- Reproductive history (of women)
- Health insurance status
- Head and neck injuries

ATSDR reviews the risk factor survey data to identify patterns, trends, and other issues that are common among ALS patients. ATSDR also reviews published studies and unpublished data to determine the national burden of ALS and the demographics of ALS patients. ATSDR’s findings are largely consistent with historical data from long-established European ALS registries and small-scale U.S. epidemiological studies.

Based on the identification of 15,908 cases from January to December 2013, the U.S. prevalence rate of ALS is 5.0 cases per 100,000 population. Based on the identification of 3,819 incident cases from January 2009 to December 2011, the U.S. incidence rate of ALS is 1.5 cases per 100,000 population. Based on the identification of 24,328 decedent cases from January 2011 to December 2014, the U.S. mortality rate of ALS is 1.7 cases per 100,000 population.

Persons with ALS are more likely to be white, male, non-Hispanic, and 50-79 years of age. The median age for an ALS diagnosis is 64 years. Males develop ALS more frequently than females at a ratio of 1.7 males to 1 female. Of all ALS patients, approximately 4 percent have a family member with ALS. Significant racial and ethnic differences have been reported in the incidence of ALS:

- 1.79 cases per 100,000 population (Whites) versus 0.80 cases per 100,000 population (Blacks)

- 1.79 cases per 100,000 population (Whites) versus 0.79 cases per 100,000 population (Asians)
- 1.65 cases per 100,000 population (non-Hispanics) versus 0.57 cases per 100,000 population (Hispanics)

The National ALS Registry performs several important functions in addition to counting the number of cases. The registry performs the difficult function of recruiting patients for research. Of all persons with ALS who are enrolled in the registry, approximately 95 percent have an interest in participating in research. The registry links persons with ALS to scientists who are involved in recruitment efforts, such as clinical trials and epidemiologic studies. At this time, 32 domestic and international institutions have used the registry for recruitment purposes.

The registry supports extramural research to increase knowledge of the etiology and risk factors of ALS. ATSDR has funded 13 research studies to date and a new R01 grant award is pending. The information collected from extramural research helps ATSDR to prioritize topics for risk factor surveys in the future. However, ATSDR's extramural grant awards are subject to the availability of funds.

The registry performs the critical function of collecting biospecimens. ATSDR piloted a biorepository from 2011-2015 to determine its feasibility and conduct logistical testing. ATSDR launched the National ALS Biorepository in January 2017 to collect specimens to help external researchers with etiologic research as well as to develop new therapies and diagnostic markers. Persons with ALS must enroll in the registry to donate biospecimens to the biorepository.

As part of the biorepository, ATSDR has secured contracts with phlebotomists to facilitate the collection of blood, urine, and saliva biospecimens from living ALS patients in their homes. ATSDR has established a goal to collect 250 blood and urine biospecimens and 50 saliva biospecimens in FY2018 from living ALS patients. ATSDR also has established a goal to collect 10 biospecimens in FY2017 from deceased ALS patients, including bone, brain, spinal cord, cerebrospinal fluid, and muscle specimens. The in-home specimens from 585 participants and the post-mortem specimens from 26 deceased patients were collected from diverse geographic areas, including rural communities. To date, over 40,000 specimens are available to researchers.

The National ALS Biorepository significantly differs from other biorepositories by linking extensive risk factor survey data with the biospecimens; providing a nationally representative sample rather than a referral center-specific sample; using in-home phlebotomists to ensure that the biospecimen collection process is user-friendly to persons with ALS; gathering specimens specifically for the biorepository rather than using leftover study samples; and maintaining pre-/postmortem samples in one central biorepository. The overarching goal of the biorepository is to serve as the largest collection of pristine ALS samples for research on genetics, biomarkers, and disease progression.

ATSDR is collaborating with multiple partners to widely publicize and promote the availability of the National ALS Biorepository to the scientific and research communities. ATSDR created an online platform for researchers to request biospecimens, epidemiologic data, and/or risk factor data for various purposes, such as the recruitment of patients for ALS studies and clinical trials.

To utilize the online platform, applicants must upload a standardized form; describe the goals, objectives, and protocol of the study; specify whether data, biospecimen, or recruitment materials are being requested; and provide supporting documentation (e.g., Institutional Review Board



approval, funding details, and curriculum vita and other information on the principal investigators). An internal/external evaluation committee reviews all applications that are submitted. To date, the evaluation committee has approved five applications.

ATSDR made several notable accomplishments in 2016-2017 with both the National ALS Registry and Biorepository. A Global Unique Identifier was created in 2017 to follow each individual ALS patient across studies without releasing their private information. The registry and biorepository were featured in approximately 17 peer-reviewed publications and presented at approximately 20 ALS conferences and patient forums. ATSDR hosted CDC's Public Health Grand Rounds on ALS with a panel that included a neurologist, researchers, and an ALS patient. The audience included over 200,000 Facebook live viewers.

Overall, the National ALS Registry is the first and only population-based ALS registry that has been developed for the United States. ATSDR is fulfilling its Congressional mandate to collect data on the incidence, prevalence, demographics, and risk factors of ALS. ATSDR expanded the use of the registry to include a rigorous research component that is designed to support extramural research; recruit patients for clinical trials and epidemiologic studies; collect biospecimens for research; and disseminate data and biospecimens to researchers.

The National ALS Registry potentially can serve as a model for other non-notifiable conditions, such as mesothelioma. ATSDR will continue to refine the repository with its extensive group of partners, including other federal agencies, researchers, non-profit organizations, industry, HCPs, and ALS patient advocacy and support groups.

#### **BSC DISCUSSION: NATIONAL ALS REGISTRY**

The BSC discussed the following topics during the question/answer session with Dr. Horton.

- ATSDR's collaborations with internal CDC partners to use the registry data for chronic diseases.
- ATSDR's plans to collect fecal samples to increase its microbiome activities.
- ATSDR's methods to publicize the online platform for the National ALS Biorepository.
- The clinical criteria that ATSDR uses to validate an ALS case for inclusion in the registry.
- The decision-making and vetting processes that ATSDR's internal/external evaluation committee uses to determine whether an application for the biorepository should be approved.
- ATSDR's overall process and data sources that are used to update the registry with the deaths of ALS patients.

#### **BSC GUIDANCE**

- The question on "occupational history" in the ALS risk factor survey should be expanded to collect more detailed information on specific types of metal exposures.
- The registry should have the capacity to provide data on changes in ALS diagnosis practices or patterns to identify differences in the rates of disease over time.
- Information on the "lifetime residential history" that is provided for the ALS risk factor survey should be coded with a geographic information system to identify common issues. For example, past residential areas of ALS patients could be overlaid with data on specific EH issues.
- The registry should maintain information on the typical amount of time between the patient's initial signs/symptoms and first neurological diagnosis versus the definitive ALS

diagnosis. This information could help to improve the efficacy of the new ALS drugs by administering medication as early in the course of disease as possible. This information also could heighten awareness of ALS among primary care physicians and trigger a much earlier referral to a neurologist.

- The demographics of participants in the National ALS Registry should be compared to the subset of participants who donate biospecimens to the National ALS Biorepository. This approach would help to address potential bias in the datasets because persons with ALS are more likely to be white males 50-79 years of age. However, this population does not include disadvantaged groups that are uninsured or have no access to neurologists and ALS services.
- Data should be maintained on the non-ALS patients who are not entered into the registry because this population can serve as a control group.
- Planning activities should be initiated to ensure coordination and linkages between the National ALS Registry and the Camp Lejeune registry of VOCs in drinking water. To support this effort, specific information should be collected on the occupational history of military personnel during the time of exposure at Camp Lejeune.

## National Environmental Public Health Tracking Network

### **Alex Charleston, MPH**

Acting Deputy Branch Chief, Environmental Public Health Tracking Network  
Centers for Disease Control and Prevention

Mr. Charleston presented an update on the Tracking Network that NCEH established in 2002 in response to the Pew Commission report, *America's Environmental Health Gap*. The report identified gaps in critical knowledge that were found to hinder efforts to reduce or eliminate diseases with the potential of being prevented by managing environmental factors. The report highlighted three major data gaps: limited data that are gathered for non-infectious diseases; the collection of environmental hazard data for regulatory rather than public health purposes; and insufficient data on human exposure to environmental hazards.

The Pew Commission concluded that the three data gaps do not allow important questions to be answered regarding the contribution of environmental hazards to adverse outcomes. As a result, the report recommended the establishment of a "Nationwide Health Tracking Network for Diseases and Exposures."

NCEH designed the Tracking Network with a vision of "healthy informed communities" and a mission to "translate environmental and public health data into meaningful information leading to increased knowledge and actions that result in healthy communities." NCEH fulfills this mission by providing information from a nationwide network of integrated health and environmental data that drives public health actions to improve the health of communities. The key functions of the Tracking Network include the ongoing collection, analysis, dissemination, and evaluation of data.

NCEH's current grant recipients of the Tracking Network include 25 states and one city. NCEH and ASTHO have jointly supported 41 Tracking Fellowships since 2008. NCEH's other partners in the Tracking Network include other public health and environmental agencies at federal, state, and local levels as well as national organizations. To date, Tracking Network data have been used to inform over 400 public health actions.

Mr. Charleston presented a series of slides to illustrate the major features of the online Tracking Network portal ([www.cdc.gov/ephtracking](http://www.cdc.gov/ephtracking)), including the new Data Explorer tool; the “Info by Location” tool that provides data by county and zip code; links to each state and local tracking program; downloadable datasets; and an application program interface. He also presented a graphic to illustrate the infrastructure of the Tracking Network portal, including its data and users.

The Tracking Network currently maintains 419 EH measures, 59 GB of data, 1.1 billion rows of data, and 1.6 million unique maps. NCEH identifies content areas to include in the Tracking Network based on several key factors, such as the availability and applicability of existing data. Of the 20 current content areas, 12 contain nationally consistent data and standardized measures that can be compared across the nation over time.

The Tracking Network was designed to drive public health actions with the capabilities that are listed below. All of these functions aim to inform, improve, and evaluate programs, interventions, and policies to address EH issues.

- Detect and monitor trends
- Identify populations at risk
- Identify exposure to hazards
- Examine the relationship between hazards and disease
- Assess potential disease clusters or exposures
- Track progress
- Enhance surveillance
- Improve access to quality data

Mr. Charleston presented a series of examples to showcase grant recipients that have used Tracking Network data to inform state and local policies. California and Georgia translated findings from heat-health risk assessments for the United States to develop heat alerts for specific communities. New York City’s efforts to target sources of air pollution led to the enactment of a new local law in 2011 to phaseout the use of low-grade heating oil, by 2030, that releases harmful particulate matter pollutants into the air. Based on Tracking Network projections, the full implementation of this public health law will prevent approximately 200 deaths annually.

NCEH’s priorities for the Tracking Network from 2002-2015 focused on the establishment of a strong foundation and capacity building; implementation of the national infrastructure, including the workforce, state programs, and collaborations on data linkages; and expansion efforts (e.g., new grant recipients, data, and functionalities). Beginning in 2016, NCEH shifted its priorities for the Tracking Network to increase public health impact and value to stakeholders through innovation and new or enhanced capabilities.

The new data, tools, and initiatives that NCEH has planned for the Tracking Network include developing an online tool to identify populations at risk of wildfire smoke hazards in real-time; collecting relevant data to address exposures to PFCs in community drinking water and their potential health impacts; advancing innovation through electronic health records and Meaningful Use performance measures; and increasing the use of geographic resolution technology to provide community-level data to users.

In response to the BSC’s request for information, Mr. Charleston provided details on the Tracking Network’s “Enviro Health App Challenge.” NCEH announced the launch of this new initiative in

April 2017 to promote innovative uses of Tracking Network data to explore the connections between the environment and health. The top three winners will receive prize awards in the amounts of \$20,000 (first place), \$7,000 (second place), and \$3,000 (third place).

### **BSC DISCUSSION: TRACKING NETWORK**

The BSC discussed the following topics during the question/answer session with Mr. Charleston.

- Potential actions to take at this time to prevent the significant \$9 million reduction that has been proposed for the Tracking Network in the FY2018 budget, such as widely publicizing the benefits of the data, public health actions, and policy changes.
- Strategies to improve the data dissemination component of the Tracking Network by collecting more up-to-date data from states in a timelier manner and rapidly releasing these data to the public.

### **BSC GUIDANCE**

- Efforts should be made to ensure that users at the graduate/postgraduate level can access and utilize Tracking Network data.
- The 20 content areas for the Tracking Network should be separated by populations, routes of exposure, and outcomes to promote hypothesis-driven research.
- The Tracking Network grant recipients should be expanded to include at least one tribal nation to collect EH data on tribal communities. Native populations comprise only 2 percent of the U.S. population, but the U.S. government has a documented trust responsibility to address the health needs of tribes. Moreover, tribal communities are extremely vulnerable to EH issues. For example, approximately 90-100 percent of the 20 content areas in the Tracking Network have direct, measurable, and profound impacts on Native populations.
- The “heart disease” content area in the Tracking Network should be expanded to include hypertension and stroke and also should be divided into three subcategories: ischemic heart disease, heart failure, and arrhythmia.
- A new activity for the Tracking Network will include the development of an online tool to identify populations that are at risk for wildfire smoke hazards in real-time. However, this tool should be designed to also measure health-related quality of life issues, such as the stress of community residents who lose their homes and personal belongings due to wildfires.
- Texas and Puerto Rico are not Tracking Network grant recipients. As a result, Tracking Network data collected from Florida should be shared to address similar mold and carbon monoxide issues that were caused by hurricanes in Texas and Puerto Rico.
- State and local regulations should be reviewed and evaluated to identify the role of the Tracking Network in decreasing EH exposures or reducing health outcomes. New York City’s enactment of a new local law to phase out the use of low-grade heating oil by 2030 should be highlighted as a successful public health model in this effort.
- National ALS Registry data should be incorporated into the Tracking Network portal to provide an additional rich source of data on environmental risk factors and exposures.

Dr. Breyse acknowledged the BSC’s concern regarding the \$9 million reduction that has been proposed for the Tracking Network line-item. However, he reminded the BSC that he and senior management officials are exploring potential solutions to address significant decreases in the NCEH/ATSDR FY2018 budget. Tracking Network data have been successfully used to drive

public health actions and influence policy at state and local levels, but efforts are underway to expand the use of this platform to support projects that are national in scope.

Dr. Breyse emphasized that the Tracking Network is uniquely positioned to focus on all communities in the country with high levels of PFAS in their source water, link tracking data to users of these water systems, and identify PFAS-associated health outcomes. This new national approach will be helpful in showcasing the ability of the Tracking Network to improve the health of communities on a much broader scale.

## Updates by the BSC *Ex-Officio* Members

### **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 NIOSH launched the National Occupational Research Agenda (NORA) in 1996 and began implementing a new portfolio of NORA programs in 2007. The new NORA programmatic approach cuts across all NIOSH divisions to eliminate silos; increases the focus on obtaining input from partners and stakeholders; and strengthens internal/external collaborations in conducting both intramural and extramural NIOSH activities.

NIOSH formed non-FACA councils to provide guidance on 10 NORA industrial sector programs and seven NORA health-based cross-sector programs. The councils will create an occupational research agenda that is specific to their individual NORA programs. The councils will engage a broad group of partners to obtain input from diverse sources, including other CDC centers, academia, labor and employer groups, professional organizations, and external stakeholders. For example, CDC/NCCDPHP serves on the council that is developing an agenda for the NORA Cancer Reproductive Health and Cardiovascular Disease Program.

NIOSH will publish the draft occupational research agendas in the *Federal Register* for public comment. Because extensive external input will inform the development and revision of the agendas, NIOSH will use these documents as a foundation to launch, guide, and prioritize new occupational safety and health research for the nation.

### **Wayne Cascio, MD, FACC**

Acting Director, National Health and Environmental Effects Research Laboratory

Office of Research and Development

U.S. Environmental Protection Agency

Dr. Cascio reported that EPA collaborated with CDC and other key partners to revise *Wildfire Smoke: A Guide for Public Health Officials*. The 2017 guide will be released before the next wildfire season in the late summer or early fall of 2018. The 2017 guide has undergone significant revisions and will include an updated format, an explanation on smoke versus urban particles, new data related to the ozone, and three new sections (e.g., a particulate matter web course and information on sensors and ash cleanup).

EPA will release the 2017 Wildfire Smoke Guide in conjunction with standalone fact sheets on multiple topics: children, older adults, pets/livestock, pre-season preparedness, respirator use,

exposure reduction, ash clean-up, and “Know When to Evacuate.” Dr. Cascio presented a slide to illustrate examples of three of the new fact sheets.

EPA recently launched its new “Smoke Sense Project.” This initiative aims to measure the effect of wildfire smoke exposure on health and productivity and develop health risk communication strategies to improve public health outcomes. The project includes a mobile phone application that is designed to (1) collect input from users regarding the impact of smoke events on their health and daily activities and (2) provide information on smoke exposure and recommended health risk messages.

Dr. Cascio presented a slide to illustrate the different types of data that the Smoke Sense Project can generate for users. The project has been tremendously successful to date. Of nearly 5,000 iPhone and Android cell phone subscribers who have accessed the Smoke Sense mobile phone application, 90 percent are regular users. Data that have been collected from over 50,000 individual responses to the project regarding the impact of wildfire smoke are now being analyzed. This project reflects one of EPA’s ongoing efforts to translate its environmental research into information that is relevant to public health, social sciences, and the general public.

EPA announced its launch of the “Wildland Fire Sensor Challenge” in March 2017 to stimulate the development of low-cost, high-quality, lightweight, and accurate sensor technology that can be easily deployed and used by first responders and public health agencies during wildland fires. This project reflects a collaborative effort between EPA internal and regional offices, multiple federal partners, and non-governmental organizations. EPA’s next steps will be to complete the nine-month development phase; test and judge the applications in 2018 that were submitted by companies and individuals; and design complimentary projects with EPA regional offices and other interested groups to field test the sensors in wildland fire scenarios.

EPA disseminated web-based information, tools, and other resources in both English and Spanish to assist HCPs in protecting the health of their patients by reducing air pollution exposure. The website includes information to HCPs that explains the cardiac and respiratory health effects associated with outdoor air pollution exposure as well as educational materials for HCPs to provide to their patients ([https://www.airnow.gov/index.cfm?action=health\\_providers.index](https://www.airnow.gov/index.cfm?action=health_providers.index)).

EPA launched an online course, “Particle Pollution and Your Patients’ Health,” with two major goals: (1) describe the biological mechanisms that are responsible for cardiovascular and respiratory health effects associated with particle pollution exposure and (2) provide educational tools to help patients understand the impact of particle pollution exposure on their health as well as to use the Air Quality Index to protect their health. The online course offers continuing education credits from CDC for physicians, nurses, and health educators. The course is available at ([K W W S V Z Z Z H S D J R Y S P F R X U V H](https://www.airnow.gov/index.cfm?action=health_providers.index)).

EPA is a proud supporter of and a strong partner with CDC and CMS on the Million Hearts® initiative that was designed to prevent a million heart attacks and strokes over the next five years. EPA also contributes to the fight against heart attacks and strokes as well as the Healthy Heart program that was adopted by the Surgeon General’s National Prevention Council to improve health in older individuals. This initiative is now linked to EPA’s materials on particle pollution and health and is available at (<http://millionhearts.hhs.gov/aboutmh/partners/epa.html>).

EPA is continuing its efforts to improve linkages between the public health and health care communities to better understand air pollution and its health effects. Most notably, the National

Ambient Air Quality Standards serve a public health benefit by promoting primary and secondary prevention for heart disease through EPA's 24-hour and annual standards for particulate matter. EPA is attempting to apply three categories in the prevention framework (e.g., total population and community-wide prevention, innovative clinical prevention, and traditional clinical prevention); use randomized clinical trial data to drive decision-making; and offer tools to public health officials, HCPs, and patients at high-risk for heart disease to assist in lowering exposures to air pollution.

**Bonnie Richter, PhD, MPH**

Senior Epidemiologist, Office of Environment, Health, Safety and Security  
U.S. Department of Energy

Dr. Richter reported that the mission of DOE is to serve as a steward of the U.S. nuclear weapons stockpile. DOE has a long history of allocating funds and providing support to its federal partners at CDC. To address offsite, non-occupational environmental exposures, for example, NCEH and ATSDR conduct dose reconstruction studies and public health assessments of communities near DOE sites. To address onsite, occupational environmental exposures, NIOSH conducts mortality studies of DOE workers.

DOE established the Comprehensive Epidemiologic Data Resource (CEDR). CEDR currently maintains de-identified mortality data that have been collected over the past 40 years from published studies in the peer-reviewed literature. Scientists, researchers, and postgraduate students can submit an application to DOE to obtain access to and utilize CEDR data.

DOE's ongoing activities include its funding and support to ATSDR to conduct a public health assessment of the West Lake community in St. Louis, Missouri. Radioactive waste materials from uranium processing operations of the Mallinckrodt Chemical Company were illegally dumped in the community. ATSDR is closely collaborating with community residents to identify their health concerns.

**Ruth Lunn, DrPH, MS**

Director, Office of the Report on Carcinogens  
National Institute of Environmental Health Sciences

Dr. Lunn reported that NTP, including the Office of Health Assessment and Translation, released several reports in July-October 2017 and is scheduled to issue multiple technical reports and literature-based evaluations from November 2017-spring 2018. NTP's recently completed and upcoming reports are listed below.

- Peer Review of the Draft Report on Carcinogens (RoC) Monograph on Haloacetic Acids
- NTP Research Report on Biological Activity of Bisphenol A Structural Analogues and Functional Alternatives
- 4<sup>th</sup> International Symposium on Systematic Review and Meta-Analysis of Laboratory Animal Studies
- Draft NTP Interagency Center for the Evaluation of Alternative Toxicological Methods Strategic Roadmap: New Approaches to Evaluate the Safety of Chemicals and Medical Products
- NTP Approach to Genomic Dose-Response Modeling
- Draft RoC Monograph on Antimony Trioxide
- Draft NTP Monograph on Occupational Exposure to Cancer Chemotherapy Agents

- Draft NTP Monograph on Long-Term Neurotoxicity of Acute Sarin
- Draft Technical Report on Cell Phone Radiofrequency Radiation
- CLARITY- Bisphenol A Core Study Research Report
- Draft NTP Monograph on Long-Term Neurotoxicity of Acute Sarin
- Draft RoC Monograph on *Helicobacter pylori*
- Draft NTP Monograph on Developmental Neurotoxicity of Fluoride
- Draft RoC Monograph on Shiftwork and Light at Night
- Draft NTP Monograph on Gestational Hypertension with Traffic-Related Air Pollution

NTP obtained materials from two manufacturers in California to be tested in its TCR studies. The three components of the studies include a chemical characterization that is near completion, an *in vitro* characterization, and *in vivo* feasibility testing. The incubation with TCR particles and conditioned media showed a decrease in lung cell viability. NTP's ongoing activities and next steps in its TCR research include bioaccessibility studies; analyses of additional endpoints, cell types, and conditioned media; and dermal and inhalation feasibility testing. NTP expects to publish the findings of its TCR studies in the spring of 2018.

NTP will convene a peer review meeting in late 2018 on its Draft Technical Report on PFOA. The NTP Laboratory has completed studies on the developmental and systematic effects of PFOA. The NTP Monograph on Immunotoxicity and PFOA/PFOS has been published as well. The NTP website (<https://ntp.niehs.nih.gov>) includes a tab for individuals to subscribe to receive email alerts of upcoming publications and other key events.

Dr. Breyse noted a great deal of overlap between the ATSDR and NTP studies on TCR, particularly in terms of NTP's chemical characterization and bioaccessibility studies. Moreover, ATSDR has collected TCR samples from multiple manufacturers and synthetic turf playing fields across the country. As a result, ATSDR could submit additional materials to NTP for testing in its *in vitro* characterization. He confirmed that the points of contact on the ATSDR/EPA/CPSC interagency workgroup will reach out to NTP to ensure alignment and coordination between the TCR studies of the federal partners.

**Public Comment Period**

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

**BSC Discussion of Future Agenda Topics**

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

Presenter	Agenda Topic
NCEH/ATSDR OD	Status report on the NCEH Climate and Health Program [standing agenda item].
NCEH	Update on the National Environmental Public Health Tracking Network.



Presenter	Agenda Topic
To Be Determined <sup>1</sup>	Update on NCEH/ATSDR's tribal programs, funding, and activities.
Dr. Adrienne Ettinger	Overview of NCEH's role on the new CDC Strategic Planning Committee that was formed to identify programs, projects, and other activities across the agency related to early brain development.
Dr. Adrienne Ettinger	Overview of the Federal Lead Strategy that is being developed by the Lead Subcommittee of the President's Task Force on Environmental Health Risks and Safety Risks to Children [second BSC meeting in 2018].
<u>Panel Presentation:</u> ATSDR, NIOSH (Dr. Douglas Trout), and State Regulators <sup>2</sup>	Update on fracking activities from occupational, non-occupational, and policy perspectives. <ul style="list-style-type: none"> <li>➤ The update should particularly focus on the specific procedures involved in unconventional oil and gas extraction; the significant economic impact of fracking; the potential relationship between fracking and emissions from compressor stations associated with natural gas pipelines; and lessons learned and experiences that have been applied to improve fracking activities.</li> </ul>
NCEH/ATSDR	Overview of recovery efforts to address mold and other EH impacts that occurred in Texas, Florida, and Puerto Rico as a result of the 2017 hurricanes to improve preparedness for natural disasters in the future.

Drs. Breyse and Perry provided clarification on several agenda topics proposed by the BSC that NCEH/ATSDR likely will be unable to address.

- The BSC requested an overview of the national opioid crisis. The BSC noted that the former HHS Secretary identified this issue as one of the three top priorities for the department. With the exception of DLS's role in the detection of chemicals, NCEH/ATSDR has no direct involvement in this effort. The National Center for Injury Prevention and Control has leadership of CDC's opioid prevention and control activities.
- The BSC requested an overview of linkages between environmental impacts and known cancers. This issue is under the purview of CDC/NCCDPHP.
- The BSC requested an overview of the potential health risks to children in schools due to exposure to Wi-Fi radiofrequency radiation. NCEH/ATSDR has not received a direct request or funding to conduct activities in this area.
- The BSC requested a presentation for Magellan Diagnostics to describe the actions that will be taken to correct problems with its LeadCare® Testing Systems, particularly since CDC is positioned to formally adopt the BSC's recommendation for a lower BLRV of 3.5 µg/dL. The BSC is chartered to provide advice and guidance to the HHS Secretary, CDC

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<sup>1</sup>If a speaker from the CDC Office for State, Tribal, Local, and Territorial Support cannot be secured, NCEH/ATSDR will present the update.

<sup>2</sup>Dr. Michael Honeycutt, of the Texas Commission on Environmental Quality, and state regulators from Colorado and Pennsylvania should be invited to serve on the fracking panel.

Director, and NCEH/ATSDR Director. Recommendations to Magellan Diagnostics would be outside the scope of the BSC's charter.

- The BSC requested an overview on gun violence. NCEH/ATSDR has not received a direct request or funding to conduct activities in this area.

## Closing Session and Adjournment

Dr. Perry thanked the BSC members for their rich discussions, critical input, and tremendously robust participation over the course of the meeting. She also thanked NCEH/ATSDR for its ongoing leadership, expertise, and dedication to improving the environmental conditions for the nation. The participants joined Dr. Perry in applauding the outstanding accomplishments of NCEH/ATSDR over the past year.

The participants also joined Dr. Cibulas in applauding Ms. Shirley Little, Ms. Amanda Malasky, and other NCEH/ATSDR OD staff for their continued commitment to planning and organizing the BSC meetings and overseeing the logistical arrangements for the members.

The next BSC meeting will be held in June 2018. NCEH/ATSDR 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. Cibulas adjourned the meeting at 11:08 a.m. on November 16, 2017.

### **CHAIR'S CERTIFICATION**

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

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Date

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



## Attachment 1: Participants' Directory

### BSC Members Present

Dr. Melissa Perry, Chair  
Dr. Kenneth Aldous  
Dr. Aaron ("Ari") Bernstein  
Dr. Darryl Brown  
Dr. Deborah Cory-Slechta  
Dr. Kim Dietrich  
Dr. Roberta Grant  
Dr. Sharron LaFollette  
Joyce Martin, Esq.  
Mr. Ralph McCullers  
Dr. John Meeker  
Dr. Devon Payne-Sturges  
Dr. Matthew Strickland  
Dr. Phillip Williams  
Ms. Nsedu Witherspoon

### BSC Member Absent

Ms. Suzanne Condon

### BSC Ex-Officio Members Present

Dr. Wayne Cascio  
U.S. Environmental Protection Agency

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

Dr. Bonnie Richter  
U.S. Department of Energy

Dr. Douglas Trout  
National Institute for Occupational Safety and Health

### LPPS Members in Attendance

Ms. Elizabeth Colon  
Dr. Michael Kosnett

Dr. Jennifer Lowry  
Dr. Mark Maddaloni  
Dr. Patrick Parsons

### Designated Federal Official

Dr. William Cibulas, Jr.  
Deputy Associate Director for Science,  
NCEH/ATSDR

### NCEH/ATSDR Director

Dr. Patrick Breyse

### CDC/NCEH/ATSDR Representatives

Ileana Arias  
Jennifer Austin  
Lina Balluz  
Tiffany Bazzelle  
Sharunda Buchanan  
Antonia Calafat  
Kathleen Caldwell  
Yulia Carroll  
Alex Charleston  
Stella Chuke  
Kimball Credle  
Stephanie Davis  
John Decker  
Edward Dieser  
Shirley Ding  
Kristin Dortch  
Kathryn Egan  
John Eichwald  
Alisha Etheredge  
Adrienne Ettinger  
Tina Forrester  
Renée Funk  
Paul Garbe  
Cherie Gray

Olivia Harris  
Tom Hicks  
James Holler  
Kevin Horton  
Jeff Jarrett  
Laurie Johnson  
Robert Jones  
Mateusz Karwowski  
Peter Kowalski  
Monica Leonard  
Shirley Little  
Amanda Malasky  
Josephine Malilay  
Paul Mehta  
Edward Murray  
Moiz Mumtaz  
Oleg Muravov  
James Nowicki  
Maria Ospina  
James Pirkle  
Angela Ragin-Wilson  
Von Roebuck  
Helen Rogers  
Hope Roobol

Perri Ruckart  
Jay Sapp  
Christian Scheel  
Franco Scinicariello  
James Stephens  
Duane Stone  
Jerry Thomas  
Hao Tian  
Eva Trinh  
Padmaja Vempaty  
Clement Welsh  
LaToria Whitehead  
Pamela Wigington  
Lynn Wilder  
Tiffany Winston

### **Federal Partners**

Ami Gadhia  
National Institutes of Health

Suril Mehta  
National Toxicology Program



## Attachment 2: Glossary of Acronyms

Acronym	Definition
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ALS	Amyotrophic Lateral Sclerosis
APHL	Association of Public Health Laboratories
APPLETREE	ATSDR Program to Promote Localized Efforts to Reduce Environmental Exposure
ASTHO	Association of State and Territorial Health Officials
BLLs	Blood Lead Levels
BLRV	Blood Lead Reference Value
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CEDR	Comprehensive Epidemiologic Data Resource
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CLPPPs	Childhood Lead Poisoning Prevention Programs
CMS	Centers for Medicaid & Medicare Services
CoAg	Cooperative Agreement
CPSC	Consumer Product Safety Commission
CSPECE	Choose Safe Places for Early Care and Education
DAPs	Diammonium Phosphates
DFO	Designated Federal Officer
DLS	Division of Laboratory Sciences
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
EH CoIIN	Environmental Health Collaborative Improvement and Innovation Network
EH; EPH	Environmental Health; Environmental Public Health
EOC	Emergency Operations Center
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
Flint ReCAST	Flint Resiliency in Communities After Stress and Trauma

Acronym	Definition
FRAP	Federal Research Action Plan
FY	Fiscal Year
HCDI	Healthy Community Design Initiative
HCPs	Healthcare Providers
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development
LEPAC	Lead Exposure and Prevention Advisory Committee
LPPS	Lead Poisoning Prevention Subcommittee
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MSU	Michigan State University
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEH/ATSDR	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NCHS	National Center of Health Statistics
NHANES	National Health and Nutrition Examination Survey
NIEHS	National Institute of Environmental Health Sciences
NIHL	Noise-Induced Hearing Loss
NIOSH	National Institute of Occupational Safety and Health
NOFO	Notice of Funding Opportunity
NORA	National Occupational Research Agenda
NTP	National Toxicology Program
OD	Office of the Director
OEHEM	Office of Environmental Health Emergency Management
OID	Office of Infectious Diseases
OSHA	Occupational Safety and Health Administration
PEATT	PFAS Exposure Assessment Technical Tool
PFAS	Per-/Polyfluoroalkyl Substances
PFCs	Perfluorinated Compounds
PFOA	Perfluorooctanoic Acid
RoC	Report on Carcinogens
SAMHSA	Substance Abuse and Mental Health Services Administration
TCR	Tire Crumb Rubber
USPHS	U.S. Public Health Service
USVI	U.S. Virgin Islands
VA	U.S. Department of Veterans Affairs
VOCs	Volatile Organic Compounds
WHA	World Health Assembly
WHO	World Health Organization

Acronym	Definition
WIIN Act	Water Infrastructure Improvements for the Nation Act
WRDA	Water Resources Development Act