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 October 16-17, 2012 Atlanta, Georgia

**Record of the Proceedings** 

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## **ATTACHMENT 1**

## List of Participants

#### **BSC Members**

Dr. Tina Bahadori Dr. Darryl Barnett Dr. Julia Gohlke Dr. Rebecca Head Mr. Daniel Kass Dr. Ewa King Dr. Michael Kleinman Dr. Kenneth Ramos

#### **BSC Federal Expert Members**

Dr. Abee Boyles (Alternate) National Toxicology Program, National Institute of Environmental Health Sciences

Dr. John Decker National Institute for Occupational Safety and Health

Dr. Bonnie Richter U.S. Department of Energy

Dr. Hal Zenick U.S. Environmental Protection Agency

#### **Designated Federal Official**

Dr. Paula Burgess Deputy Associate Director for Science, NCEH/ATSDR

Dr. Vikas ("Vik") Kapil Chief Medical Officer & Associate Director for Science, NCEH/ATSDR (Alternate)

#### **CDC/NCEH/ATSDR Representatives**

Dr. Christopher Portier (NCEH/ATSDR Director) Dr. Thomas Sinks (NCEH/ATSDR Deputy Director) Henry Abadin Doris Ash Anne Boyer Mary Jean Brown William Brown

Sharunda Buchanan Sue Casteel Sascha Chaney William Cibulas Burt Cooper Stephanie Davis Tim Dignam Stephanie Doan Gerard Dublin Peter Edwards Barbara Ellis Obaid Faroon Julie Fishman Tina Forrester David Fowler Maribel Gallegos Barbara Gray Olivia Harris Michael Hatcher James Holler Kevin Horton Lindsey Horton Yulia lossifova Katherine Isbell Diane Jackson Jeff Jarrett Robert Jones Chinaro Kennedy Lauren Lewis Shirley Little Sandra Malcom Josephine Malilay Ted Meinhardt Sarah Merkle Susan Moore Mary Mortensen Amy Mowbray Moiz Mumtaz Ed Murray Whitney Neal Youlanda Outin Radha Pennotti James Pirkle Judith Qualters Rob Robinson

Michael Sage Franco Scinicariello Regina Seider Dolly Sinha Steve Skowronski Cassandra Smith Jamille Taylor Denise Tevis Claudia Vousden Nikki Walker John Wheeler Lynn Wilder Sharon Williams-Fleetwood Alan Yarbrough

### Members of the Public

Joel de Jesus Mirepoix

Caroline Grossman Magellan Diagnostics/Mirepoix

Maury Nation Vanderbilt University

## **ATTACHMENT 2**

# **Glossary of Acronyms**

ACC	American Chemistry Council
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ALS	Anyotrophic Lateral Sclerosis
APHA	American Public Health Association
BLLs	Blood Lead Levels
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CoAgs	Cooperative Agreements
CPSC	Consumer Product Safety Commission
DCHI	Division of Community Health Investigations
DFO	Designated Federal Official
DHAC	Division of Health Assessment and Consultation
DLS	Division of Laboratory Sciences
DOE	U.S. Department of Energy
DRO	Division of Regional Operations
DTHHS	Division of Toxicology and Human Health Sciences
EEOICP	Energy Employees Occupational Illness Compensation Program
EH/EPH	Environmental Health/Environmental Public Health
EHPM	Environmental Health Portfolio Management
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FWP	Former Worker Medical Screening Program
HCDI	Healthy Community Design Initiative
HHLPPB	Healthy Homes/Lead Poisoning Prevention Branch
HHS	U.S. Department of Health and Human Services
HSEES	Hazardous Substances Emergency Events Surveillance System
HUD	U.S. Department of Housing and Urban Development
LOC	Level of Concern
MMWR	Morbidity and Mortality Weekly Report
NCEH/ATSDR	National Center for Environmental Health/
	Agency for Toxic Substances and Disease Registry
NCIPC	National Center for Injury Prevention and Control
NEHC	National Environmental Health Council
NHANES	National Health and Nutrition Examination Survey
NHBs	Non-Hispanic Blacks
NHWs	Non-Hispanic Whites
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
NTSIP	National Toxic Substance Incidents Program
OD	Office of the Director
PAHs	Polycyclic Aromatic Hydrocarbons

PATH	Population Assessment of Tobacco and Health
PFOA	Perfluorooctane Sulfonic Acid
PHAs	Public Health Assessments
REL	Recommended Exposure Limit
RfC	Reference Concentration
SHCRP	Sustainable and Healthy Communities Research Program
SHS	Secondhand Smoke
TCE	Trichloroethylene
VOCs	Volatile Organic Compounds
WHO	World Health Organization
WTC	World Trade Center

## EXECUTIVE SUMMARY

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) on October 16-17, 2012 in Atlanta, Georgia.

In accordance with Federal Advisory Committee Act regulations, the Designated Federal Official verified that the voting members and Federal Expert members constituted a quorum for the BSC to conduct its business on both days of the meeting. The BSC voting members were reminded of their individual responsibility to identify real or perceived conflicts of interest with any of the agenda items and recuse themselves from participating in these matters. None of the BSC voting members disclosed any conflicts of interest for the record.

The Acting Chair called for public comment at all times noted on the agenda published for the October 16-17, 2012 BSC meeting.

The comprehensive NCEH/ATSDR Director's report covered the following topics:

- recent activities by the National Environmental Health Council;
- new features for the National Amyotrophic Lateral Sclerosis Registry;
- sharing of World Trade Center health registry data;
- NCEH/ATSDR's research awards;
- implementation of recommendations by the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP);
- activities by the Healthy Community Design Initiative;
- the epidemiological investigation of unidentified liver disease in Ethiopia caused by pyrrolizidine alkaloids in grains;
- the updated *Fourth National Report on Human Exposure to Environmental Chemicals* and other recent activities by the Division of Laboratory Sciences;
- the new Environmental Health Portfolio Management System;
- outcomes from the fifth year of the Collegiate Leaders in Environmental Health Program;
- the response to the 2012 drought;
- chemical terrorism preparedness activities;
- application of the new trichloroethylene reference value at four sites;
- ATSDR's investigation of 83 emergencies or time-critical responses in 2012;
- ATSDR's updates to and development of ToxProfiles<sup>™</sup>;
- investigation of reported laundry pod exposures among children <5 years of age;
- the ATSDR reorganization; and
- the NCEH/ATSDR strategic planning process.

CDC presented its formal response to four ACCLPP recommendations that are under its control. CDC charged ACCLPP with evaluating new approaches, terminology, and strategies for defining elevated blood lead levels among children. The update also included a status report on both internal and external impacts of terminating extramural funding of the CDC Healthy Homes/Lead Poisoning Prevention Branch.

The NCEH Division of Laboratory Sciences (DLS) presented an update on its laboratory research related to exposure to harmful constituents in tobacco. The update described CDC's

interagency agreement with the Food and Drug Administration for DLS to conduct research and development in support of its regulation of tobacco products. Unique findings from DLS's tobacco studies were highlighted as well.

DLS summarized data from the *Fourth National Report on Human Exposure to Environmental Chemicals.* Findings by age, gender and race/ethnicity were presented for several chemicals outlined in the Fourth Report: lead, total urinary cadmium, serum cotinine, urinary 2,5-dichlorophenol, serum perfluorooctane sulfonic acid, blood trichloromethane (chloroform), urinary mono-isobutyl phthalate, and urinary mono-(carboxyoctyl) phthalate.

NCEH/ATSDR presented an overview of its new Environmental Health Portfolio Management (EHPM) System. EHPM is an automated system for leadership and staff to manage work requests and projects in real time, including ATSDR's site-specific activities and Center-wide requests, projects and activities. EHPM is designed for staff to identify NCEH/ATSDR's priorities; track and monitor the progress of activities with clearly defined timelines; and provide notifications of new work, updates and the need to track certain portfolios. At this time, 14 topics are designated as priorities for data entry into EHPM: hydraulic fracturing, lead, drywall, formaldehyde, cancer clusters, climate change, and 8 sites of interest.

ATSDR described its challenges and progress related to the reorganization of the former Division of Health Assessment and Consultation and Division of Regional Operations into the new Division of Community Health Investigations (DCHI). DCHI currently is devising strategies to overcome challenges in four key areas: timely response leading to action, the best science to arrive at assessments and conclusions, streamlined products, and understandable messages targeted to communities.

CDC presented an update on its recent global environmental health activities for the following issues: indoor air pollution and health, global response to urgent issues, water safety and quality, extreme weather events, environmental disasters, radiation emergencies, global laboratory research, vessel sanitation, and environmental and occupational health issues in India.

NCEH/ATSDR presented a comprehensive overview on public health surveillance following emergency events. The BSC provided extensive advice and recommendations on this issue in response to two questions posed by NCEH/ATSDR: (1) Are the NCEH/ATSDR surveillance systems advancing in appropriate directions? (2) Should the NCEH/ATSDR surveillance systems be expanded as national programs?

Based on the BSC's input, the NCEH/ATSDR Director noted five action items NCEH/ATSDR would address to improve public health surveillance following emergency events.

- 1. **NCEH:** Present an overview of activities by the NCEH/ATSDR Office of Environmental Health Emergencies
- 2. **NCEH:** Administer a survey to determine reasons for the reduction in the number of states that are willing to share surveillance data with CDC
- ATSDR: Perform an analysis to determine the economic impact of the reduction from 19 Hazardous Substances Emergency Events Surveillance System grantees to 7 National Toxic Substance Incidents Program (NTSIP) grantees
- 4. **NCEH:** (1) Explore strategies to engage schools of public health in disaster readiness, response and preparedness nationally; (2) conduct a meta-analysis of existing surveillance data to determine and characterize the number, types and health outcomes

of specific emergencies; and (3) form an expert workgroup to compile case studies of public health surveillance

5. **ATSDR:** Contact the American Chemistry Council to discuss collaborative efforts in funding NTSIP

The BSC Federal Expert members provided updates on recently completed or ongoing EH activities of their respective agencies: National Institute for Occupational Safety and Health, National Toxicology Program, U.S. Department of Energy, and U.S. Environmental Protection Agency.

The Acting Chair moderated an open discussion with the BSC that focused on improving the format of future meetings. Suggestions were made to provide the BSC with materials well in advance of meetings (e.g., focused questions and video clips of presentations) and designate BSC "leaders" or "champions" to guide specific discussion topics during meetings.

# 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 October 16-17, 2012 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 October 16-17, 2012 in Building 106 of the CDC Chamblee Campus in Atlanta, Georgia.

## **Opening Session: October 16, 2012**

#### Paula Burgess, MD, MPH

Deputy Associate Director for Science, NCEH/ATSDR Centers for Disease Control and Prevention BSC Designated Federal Official

Dr. Burgess welcomed the participants to the meeting and opened the floor for introductions to determine the BSC voting members and Federal Expert members who were in attendance. She verified that the members constituted a quorum for the BSC to conduct its business on October 16, 2012 and called the meeting to order at 8:32 a.m. The list of participants is appended to the minutes as <u>Attachment 1</u>.

Dr. Burgess reminded the BSC voting members of their individual responsibility to identify real or perceived conflicts of interest with any of the agenda items for October 16, 2012 and recuse themselves from participating in these matters. None of the BSC voting members disclosed any conflicts of interest, but two members noted that their institutions are current or former recipients of CDC funding:

- Daniel Kass, MSPH: The New York City Department of Health and Mental Hygiene currently receives funding from CDC.
- Ewa King, PhD: The Rhode Island Department of Health previously received funding from the CDC Lead Poisoning Prevention Program.

Dr. Burgess entertained a motion for the BSC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Dr. Darryl Barnett and Mr. Daniel Kass, respectively, for the BSC to approve the previous meeting minutes. The BSC unanimously adopted the Draft May 17-18, 2012 Meeting Minutes with no changes or further discussion.

#### Christopher Portier, PhD

Director, CDC National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry

Dr. Portier also welcomed the participants to the meeting and announced that Dr. Burgess would serve as the BSC Chair in addition to the Designated Federal Official (DFO). Dr. Timothy Ryan, the BSC Chair, was unable to attend the meeting. Dr. Ryan's term ended in June 2012, but a six-month extension was granted in order for HHS to officially appoint the new BSC members.

Dr. Portier emphasized that he looked forward to the BSC's continued advice and guidance on NCEH/ATSDR's environmental health (EH) programs, research and activities.

## NCEH/ATSDR Director's Report

#### **Christopher Portier, PhD**

Director, CDC National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry

Dr. Portier covered the following topics in his Director's report to the BSC.

**NCEH/ATSDR Office of the Director (OD) Highlights.** NCEH/ATSDR funded the American Public Health Association (APHA) and RESOLVE to convene the National Environmental Health Council (NEHC) with 25 diverse stakeholders that are committed to help NCEH/ATSDR expand and sustain awareness, education, policies and practices related to EH. NEHC held its most recent meeting in September 2012.

NEHC's ongoing activities and recent achievements include facilitating dialogue and interaction among environmental public health (EPH) stakeholders; developing materials that communicate the value of the EPH field; and amplifying key activities and publications of EPH stakeholders and NCEH/ATSDR. NEHC also is developing common communication tools and messages to promote and improve collaboration and uniformity across EPH organizations.

NCEH/ATSDR deployed a clinical research linking mechanism in April 2012 that allows qualified researchers to use the National Amyotrophic Lateral Sclerosis (ALS) Registry to recruit patients for clinical trials and studies. An iPad application also was launched in September 2012 that allows ALS patients to find ALS clinics and support groups in their local areas.

NCEH/ATSDR signed a memorandum of understanding for the New York Department of Health and Mental Hygiene to transmit World Trade Center (WTC) health registry data. This agreement will allow NCEH/ATSDR to support and promote current and future studies of WTC exposures.

NCEH/ATSDR was honored to receive the "American Public Health Association Occupational Safety and Health Research Award" and 5 nominations for the "Charles Shepard Award" for its scientific publications.

NCEH/ATSDR currently is implementing formal recommendations by the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). ACCLPP was charged with examining CDC's level of concern for childhood blood lead levels (BLLs) of 10  $\mu$ g/dL. A comprehensive update on this activity would be presented during the meeting.

The NCEH/ATSDR Healthy Community Design Initiative (HCDI) and the U.S. Department of Transportation are co-funding a \$600,000 project over a three-year period. The purpose of this joint effort is to create a health and transportation tool that will compile existing data sources to inform communities of their strengths and opportunities in enhancing the transportation infrastructure while improving health at the local level. The federal partners will convene a kickoff meeting on October 19, 2012 to refine the parameters of the project.

NCEH/ATSDR established an interagency agreement with the National Parks Service for HCDI to collect data and identify research gaps regarding the health benefits of parks. HCDI will use seed funding to compile a list of all parks throughout the country and pilot a "health and parks checklist" to better understand the role of access to parks in supporting healthy living.

NCEH/ATSDR is continuing its epidemiological investigation of unidentified liver disease in Ethiopia. The investigation showed that toxic pyrrolizidine alkaloids in grains were the cause of this disease. In collaboration with the Ethiopian government, NCEH/ATSDR provided grain farmers with information to protect themselves and their families.

NCEH updated the *Fourth National Report on Human Exposure to Environmental Chemicals* with new and nationally-representative biomonitoring exposure data from the National Health and Nutrition Examination Survey (NHANES). NCEH developed new or updated laboratory methods for 29 markers of tobacco product exposure as well as harmful or potentially harmful constituents. NCEH developed two methods for the Urine Radionuclide Screen to rapidly detect and quantify radioactive phosphorus (P-32) and iridium (Ir-192) in persons contaminated with these radionuclides.

The NCEH/ATSDR Anthrax Toxin Team received both the "CDC Director's Award for Innovation and Efficiency" and the "Excellence in Laboratory Research Award." Dr. Dana Henahan of NCEH received the "Excellence in Environmental Conservation Award" for her accomplishments in environmental conservation and the establishment of an internal recycling program. NCEH/ATSDR is actively using its new Environmental Health Portfolio Management System to improve the tracking and monitoring of EH "hot spots" in communities. Dr. Thomas Frieden, Director of CDC, has been encouraging other National Centers to use this outstanding tool.

For the fifth year of the Collegiate Leaders in Environmental Health Program, NCEH/ATSDR received 450 applications to fill 10-12 positions in 2012. Under this internship program, NCEH/ ATSDR offers rising university juniors and seniors a broad overview of EPH at the federal level to foster interest in this field as a career. Of 66 interns who have completed the program to date, most are pursuing careers or degrees in EH or public health. NCEH/ATSDR also sponsors the Summer Program in Environmental Health and the Graduate Environmental Health Program. To date, 99 students have completed the three internship programs.

NCEH/ATSDR and APHA organized four webinars in response to the 2012 drought: (1) "The Public Health Implications of Drought;" (2) "State and Locals Respond to Drought;" (3) "When Every Drop Counts: Adapting to Drought-What Next?" and (4) "When Every Drop Counts: Initiatives in Indian Country." The webinars were used to alert public health partners to drought-related issues and describe various responses by states, localities and American Indian/Alaska Native communities. Of >1,700 registered participants for the first three webinars, state, local and tribal governments accounted for 36%. NCEH/ATSDR also presented the health implications of the drought to HHS for a departmental response.

NCEH is continuing its involvement in chemical terrorism preparedness. Most notably, the civil war in Syria has caused international concern regarding the security of alleged chemical weapon stockpiles in this country. NCEH/ATSDR conducted a cross-Center review of U.S. preparedness for terrorist use of military chemical weapons and also collaborated with federal partners in this effort. For example, the Food and Drug Administration (FDA) reviewed new medical countermeasures for treatment of persons exposed to chemical weapons, while the Department of Defense and U.S. Environmental Protection Agency (EPA) reviewed protocols after a chemical weapons release and environmental cleanup standards.

ATSDR utilized the new trichloroethylene (TCE) reference value to protect residents from harmful vapors in living spaces at four sites: Navy Yard Mills in Massachusetts, Chicago Heights in Missouri, Cabo Rojo in Puerto Rico, and the ChemFab Facility in Pennsylvania. EPA used ATSDR's recommendations to justify protective actions at these sites, including the installation of vapor mitigation systems in the basements of affected residents.

ATSDR investigated 83 emergencies or time-critical responses in 2012. For example, hydrogen sulfide spontaneously combusted in a facility in Mishawaka, Indiana that caused a cyanide vapor cloud and resulted in evacuation by the local fire department. ATSDR provided onsite assistance and guided the response by EPA and local authorities. During the investigation, ATSDR analyzed data in real time to determine harmful chemicals in the cyanide vapor cloud and provided the fire department with information to safely lift the evacuation order.

ATSDR plans to update the TCE and tetrachloroethylene ToxProfiles<sup>™</sup> in the near future. TCE is a solvent that is used to remove grease from metal parts and is a common ingredient in paint removers and strippers, adhesives, spot removers and rug cleaning fluids. TCE primarily

affects the central nervous system, but also impacts the liver, kidney, heart, lung system and immune system. Tetrachloroethylene is a solvent that is used to dry-clean fabrics, degrease metals, and make other chemicals and consumer products (e.g., water repellents, silicone lubricants, fabric finishers, spot removers, adhesives and wood cleaners). The chemical primarily affects the central nervous system, but also may cause liver and kidney damage.

ATSDR will update the hydrogen sulfide ToxProfile<sup>™</sup> and create a new carbonyl sulfide ToxProfile<sup>™</sup> due to their presence in Chinese drywall. These chemicals cause respiratory and gastrointestinal effects. ATSDR will create a new glutaraldehyde ToxProfile<sup>™</sup>, primarily because of its use as a biocide in hydraulic fracturing fluids that potentially could migrate to pits or dump sites. The health effects of this chemical include throat and lung irritation, asthma and breathing difficulty, contact or allergic dermatitis, nasal irritation, sneezing, wheezing, burning eyes and conjunctivitis.

ATSDR will create a new parathion ToxProfile<sup>™</sup>. The chemical serves as an insecticide, acaricide and cholinesterase inhibitor and is a possible human carcinogen that causes numerous health effects. ATSDR is finalizing the perfluoroalkyls ToxProfile<sup>™</sup> based on public comments that were previously submitted. The chemical is used as oil, grease and water repellants, surface protection products, and a component in fire-fighting foams. Long-term occupational exposure of this chemical is associated with changes in sex hormones and cholesterol. Animal studies have shown that the chemical causes stunted growth and irritation of the nose, eyes and skin.

ATSDR is revising the toxaphene ToxProfile<sup>™</sup> based on public comments that were previously submitted. The chemical was one of the most heavily used pesticides in the 1970s-1980s to control insects on cotton and other crops. The chemical potentially damages the nervous system, liver and kidneys. ATSDR is revising the trichlorobenzenes ToxProfile<sup>™</sup> based on public comments that were previously submitted. This group of chemicals is used as solvents and chemical intermediates to produce other compounds. The chemicals potentially irritate the eyes, skin and throat and also may damage the liver and kidneys.

In May 2012, CDC and the American Association of Poison Control Centers began tracking reported laundry pod exposures primarily among children <5 years of age. From May 17-June 17, 2012, 48% of laundry detergent ingestion was due to laundry pods. The health impacts of exposed children include gastrointestinal, respiratory and central nervous system adverse effects. These findings have led some manufacturers to modify their packaging of laundry pods with childproof locks.

NCEH developed a new and unique mass spectrometry method to decrease the production time of influenza vaccine. The method detects neuraminidase, indicates the ratio of hemagglutinin and neuraminidase to internal influenza proteins, and identifies better performing seed strains.

**ATSDR Reorganization.** The HHS Secretary approved the ATSDR reorganization. The Congressional notification period was completed as well. After CDC signs and issues the *Federal Register* notice in the near future, the ATSDR reorganization will be officially finalized. In addition to 10 new regional assignees, other key features of the ATSDR reorganization

include the combination of the former Division of Health Assessment and Consultation (DHAC) and Division of Regional Operations (DRO) into the new "Division of Community Health Investigations."

A new Eastern Branch, Central Branch and Western Branch will be housed in Atlanta to oversee regional offices and cooperative agreements (CoAgs) within their respective areas. The branches also will include health assessors to provide health assessment expertise for geographic-specific issues. The new "Science Support Branch" will support exposure investigations, dose reconstructions and statistical analyses across the three branches.

The new "Division of Toxicology and Human Health Sciences" (DTHHS) combines the former Division of Health Studies and Division of Toxicology and Environmental Medicine to improve ATSDR's scientific guidance to communities and health providers; unify ATSDR's expertise in these scientific disciplines; and streamline the creation of education materials for diverse stakeholders. DTHHS also will support the new "Science Innovation Program" that will provide opportunities for staff to identify and develop public health solutions to environmental problems.

OD's next steps in the ATSDR reorganization will be to launch a strategic planning process and undertake a comprehensive study and evaluation of ATSDR's existing procedures, approaches and methods (e.g., ToxProfiles<sup>™</sup>, public health assessments (PHAs), exposure investigations and chemical mixtures).

**NCEH/ATSDR Strategic Planning Process.** OD launched a Center-wide strategic planning process because neither NCEH nor ATSDR has a formal strategic plan at this time. The strategic plans will clearly define the EPH vision, missions, roles, goals and priorities for both NCEH and ATSDR to better align their organizations with strategies and goal-setting initiatives.

The five major phases and timeline of the NCEH/ATSDR strategic planning process are outlined as follows. <u>Phase 1</u> was completed in June 2012. The strategic planning process was established and inputs were synthesized. <u>Phase 2</u> was completed in August 2012. NCEH/ ATSDR's desired position and role as an EPH agency in the United States were identified. After engaging and receiving extensive input from both internal and external stakeholders, organizational visions and missions were drafted and shared internally within NCEH/ATSDR.

<u>Phase 3</u> is expected to be completed in November 2012. Goals and strategic areas of focus will be established, options will be developed, and selections will be made for NCEH, ATSDR, and NCEH/ATSDR collectively. <u>Phase 4</u> is expected to be completed in January 2013. Objectives and activities will be developed for ATSDR. <u>Phase 5</u> is expected to be completed in February 2013. Options, objectives and priorities will be selected, developed and designed for NCEH.

The draft NCEH/ATSDR vision is "healthy people in a healthy environment." The draft ATSDR mission is "ATSDR works with communities to protect people from toxic chemical exposure." ATSDR proposes to follow the mission statement with the following language: "ATSDR does this by identifying and investigating chemical exposures, recommending actions to protect human health, conducting research, studying diseased populations, and translating complex science into actions that the public, health professionals and others can use to protect health."

The draft NCEH mission is "NCEH protects people from environmental exposures that threaten health." NCEH proposes to follow the mission statement with the following language: "NCEH does this by advancing knowledge of environmental influences on health through monitoring, research, guidance, and service and by providing information needed to support healthy decision-making."

On September 21, 2012, NCEH/ATSDR branch and program staff held a retreat to identify and discuss the most important outcomes of the strategic plan, synthesize directional statements, and identify needs in key capacity to meet the draft vision, missions and goals. On September 24, 2012, "strategic thinkers" within NCEH/ATSDR Divisions held a retreat to review, discuss and evaluate direction and capacity needs and recommend strategic areas of focus.

On October 26, 2012, an internal steering committee of NCEH/ATSDR senior leadership will hold a retreat to review the strategic areas of focus, analyze gaps, formally adopt the draft vision and mission statements, and finalize goals and strategic areas of focus. Both Center-wide and agency-specific goals and objectives for the next 5-10 years will be incorporated into the strategic plan from November 2012 to February 2013.

During the two retreats in September 2012, NCEH/ATSDR staff discussed a variety of important outcomes for NCEH/ATSDR over the next five years based on a number of key inputs (e.g., external assessments, interviews and stakeholder recommendations). The initial discussions and review of these materials resulted in staff ranking nine areas of focus in the following order of priority.

<u>Priority 1</u> is research. Environmental factors and exposures linked to health effects should be identified and characterized. Exposures with the greatest need for response or prevention should be prioritized. <u>Priority 2</u> is surveillance and information. A knowledge base should be developed to inform decision-making. Public health actions should be guided to reduce the disease burden related to environmental exposures.

<u>Priority 3</u> is communication. Targeted and timely information on reducing harmful exposures should be provided. Decision-making should be guided for individuals and groups. <u>Priority 4</u> is environmental emergencies. Capacity and capability should be sustained and strengthened for the United States to prepare and respond to emergencies, including protection, prevention and mitigation response and recovery as well as post-emergency response research to improve emergency response capacity over time.

<u>Priority 5</u> is state, territorial, local and tribal support. A national approach should be developed to maximize state, territorial, local and tribal capacity. EPH issues that are most important to states, territories, tribes and localities should be identified and addressed. <u>Priority 6</u> is communities. Health should be promoted, enhanced and sustained when communities are built, redeveloped or remediated. The best available science and research-based practices should be brought to bear in communities.

<u>Priority 7</u> is emerging environmental concerns. Harmful exposures should be anticipated, detected and prevented as early as possible. <u>Priority 8</u> is visibility. NCEH/ATSDR should

leverage its scientific expertise and demonstrate its role as a worldwide leader in EPH. <u>Priority</u> <u>9</u> is global EH. A global EH strategy should be developed for CDC that clearly prioritizes needs and identifies resources.

Dr. Portier concluded his Director's report by asking the BSC to provide feedback on the nine priority areas of focus for the strategic plan that were recommended during the staff retreats. He particularly asked the BSC to identify the top three priorities as well as gaps in the proposed list. Dr. Portier clarified that although the strategic focus areas were prioritized by internal staff only, the strategic plan would be broadly disseminated for external comment before being finalized.

Dr. Burgess moderated the BSC's discussion with Dr. Portier on the NCEH/ATSDR Director's report. The discussion topics included:

- potential new laboratory methods in the future for inhalable influenza vaccine (e.g., FluMist<sup>®</sup>);
- ATSDR's process to develop and update ToxProfiles<sup>™</sup> (e.g., review of the toxicological literature, selection of studies by an expert workgroup to determine potential short-term, intermediate and long-term health effects of chemicals, and development of minimum risk levels);
- ATSDR's ongoing collaboration with the National Institute of Environmental Health Sciences (NIEHS) and discussions with the EPA Integrated Risk Information System regarding the creation of joint contracts to conduct systematic reviews, generate costsavings, and minimize duplication of efforts in developing and updating ToxProfiles<sup>™</sup>;
- ATSDR's formal nomination process for developing and updating ToxProfiles<sup>™</sup> that would be proposed to the BSC during the next meeting;
- ATSDR's ongoing efforts to use the Cochrane evaluation system to grade ToxProfiles<sup>™</sup> and other toxicological evidence;
- NCEH/ATSDR's role as an EPH agency in influencing the policies of other agencies (e.g., EPA's regulation of pesticides and the Consumer Product Safety Commission's (CPSC) regulation of consumer products);
- ATSDR's mechanisms to track the effectiveness, impact and use of ToxProfiles<sup>™</sup> in the field (e.g., website hits, dissemination of CD-ROMs and publications);
- OD's timeline to fill positions for new Division Directors after the ATSDR reorganization is officially finalized;
- NCEH/ATSDR's rationale for soliciting internal input only on prioritizing focus areas for the strategic plan;
- NCEH/ATSDR's rationale for placing a stronger emphasis on "protecting health and saving lives" in the strategic plan rather than "preventing disease;"
- next steps in the strategic planning process (e.g., specific objectives, activities, workflow and support to address the nine priority areas);
- inclusion of an educational component in the strategic focus areas;
- alignment of the NCEH/ATSDR strategic plan with the CDC strategic plan; and
- opportunities for external investigators to use NCEH/ATSDR data for research purposes.

The BSC was pleased that Dr. Portier planned to propose a new nomination process for ToxProfiles<sup>TM</sup> during the next meeting. Some members were particularly interested in using ToxProfiles<sup>TM</sup> to track incidental low-dose exposures in addition to acute exposures to chemicals.

The BSC also made a number of comments and suggestions on the NCEH/ATSDR strategic planning process.

- NCEH/ATSDR should solicit external expertise on the nine priority areas for the strategic plan at this time to identify potential synergies and opportunities in EH. For example, NCEH/ATSDR should convene a one-day meeting with internal leadership and outside stakeholders to obtain critical feedback during the development process rather than passive input after the draft strategic plan is completed and submitted for public comment.
- NCEH/ATSDR should explore the possibility of consolidating the nine priority areas into broad categories and subtopics for the strategic plan (e.g., "practice," "research" and "on-the-ground support").
- Efforts should be made to incorporate some of the explanatory language into the NCEH and ATSDR mission statements to clearly articulate differences between the two organizations. The current versions of the mission statements are extremely similar and do not highlight the unique roles of NCEH and ATSDR.
- The NCEH mission statement should be revised to highlight and promote healthy environmental components and place less emphasis on negative aspects of the environment.
- NCEH/ATSDR should prioritize the strategic areas of focus based on their potential to leverage resources in other areas (e.g., clinical, medical or academic research). For example, NCEH's surveillance data have the ability to drive response actions by other agencies (e.g., EPA, HHS, Department of Homeland Security or Medicare reform).
- ATSDR should more widely promote the "registry" component of its mandate in the strategic plan to increase visibility, utilization and dissemination of registry data.
- NCEH/ATSDR should replicate the model by the National Institute for Occupational Safety and Health (NIOSH) in overcoming budgetary constraints to improve and advance the high priority area of surveillance. Most notably, NIOSH has incorporated data fields into electronic medical records that are applicable to and relevant for occupational health.
- NCEH/ATSDR's strategic plan should place more emphasis on consultation with state budget directors to obtain input from the field on effective approaches in building, supporting and sustaining state EPH programs.
- NCEH/ATSDR should engage the Department of Defense as an EPH partner due to its increasing role and presence in ATSDR's site-specific activities.

In response to Dr. Portier's specific request, several BSC members were challenged by ranking the top three priorities for the strategic plan without knowledge of NCEH/ATSDR's current resources, strengths and weaknesses. However, other BSC members proposed priorities for NCEH/ATSDR to consider in its ongoing efforts to revise the strategic plan.

- Communities, environmental emergencies, and surveillance/information should serve as the top three priorities for the NCEH/ATSDR strategic plan. NCEH/ATSDR's expertise in the communities, particularly during emergencies, is one of the nation's most valuable resources in EPH.
- NCEH/ATSDR should ensure that its unique assets and areas of expertise are prioritized in the strategic plan:
  - Exposure characterization of individual chemicals and mixtures
  - Advancements in biomonitoring and NHANES, including the use of emerging biomarkers and blood spot research
  - Development of a public health-driven framework for health tracking
  - Use of the Public Health Network to improve prevention and intervention at state, regional and global levels

Dr. Portier closed the discussion by confirming that strong efforts would be made to convene a retreat over the next two months. He explained that if logistical arrangements could be made, the BSC members and other external stakeholders would be invited to the retreat to critically evaluate and review a newer version of the draft NCEH/ATSDR strategic plan.

## Update on CDC's Healthy Homes/Lead Poisoning Prevention Activities

#### Mary Jean Brown, ScD, RN

Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program Centers for Disease Control and Prevention

Dr. Brown covered two major topics in her update to the BSC on CDC's healthy homes/lead poisoning prevention activities.

**CDC's Response to the ACCLPP Recommendations.** In late 2010, ACCLPP formed a workgroup to address CDC's charge to evaluate new approaches, terminology, and strategies for defining elevated BLLs among children. In January 2012, ACCLPP voted to formally adopt 13 recommendations proposed by the workgroup. The recommendations were designed to focus the nation's efforts on primary prevention as the most essential strategy to eliminate childhood lead poisoning through targeted interventions for individual children and communities with BLLs at or above the reference value for lead of 5  $\mu$ g/dL.

In May 2012, CDC responded to the ACCLPP recommendations based on one of three options. To <u>concur</u>, CDC would agree to implement the recommendation based on available funding, staff and control. To <u>concur in principle</u>, CDC would agree that the recommendation should be implemented, but funding, staff or control was not available. When feasible, however, CDC would request funding or other necessary resources and implement the recommendation if the request was approved. To <u>not concur</u>, CDC would disagree with the recommendation and provide its rationale for disagreement. CDC either "concurred" or "concurred in principle" with all 13 of ACCLPP's recommendations.

After meeting with key staff at EPA and the U.S. Department of Housing and Urban Development (HUD) in August 2012, CDC and its federal partners presented the ACCLPP recommendations and a status report on implementation, challenges and future directions to the Presidential Task on Children's Environmental Health in September 2012.

During the November 2012 ACCLPP meeting, the three agencies also would present status reports and implementation plans along with other federal partners: CPSC, FDA, NIOSH, NIEHS, U.S. Department of State, and Centers for Medicare and Medicaid Services. The federal partners, particularly the regulatory agencies, would describe their major challenges in implementing the ACCLPP recommendations.

For the BSC meeting, Dr. Brown presented status reports and implementation plans for the four recommendations that are within CDC's control.

**Recommendation 1:** Based on the scientific evidence, ACCLPP recommends that (a) the term "level of concern" be eliminated from all future agency policies, guidance documents and other CDC publications, and (b) current recommendations based on the "level of concern" be updated according to the recommendations contained in the report.

CDC concurred with recommendation 1 and outlined its specific means to address or implement this guidance. The CDC Healthy Homes/Lead Poisoning Prevention Branch (HHLPPB) has discontinued its use of the term "level of concern" (LOC). All current and future CDC publications will replace LOC with the reference value and the date NHANES used to calculate the reference value.

CDC will issue the following standard language for clinical settings: "A level at or above the reference value for blood lead that is established as the 97.5 percentile for the distribution of BLLs of U.S. children 1-5 years of age (5  $\mu$ g/dL in 2012) is unusual/atypical. BLLs at or above the reference value indicate a child is exposed to lead above that experienced by most children in the same age group. Further assessment of the child and his/her environment is warranted."

CDC will issue the following standard language for publications: "The reference value for U.S. children 1-5 years of age is the 97.5 percentile of the population blood lead distribution (5 µg/dL in 2012)." CDC will issue the following standard language for a population or community: "On a community basis, any distribution of BLLs significantly higher than that of the U.S. childhood population 1-5 years of age indicates the community has lead sources in the environment that put children living there at higher risk for unusual/atypical BLLs than the general U.S. childhood population."

HHLPPB will make the standard language available to operating divisions across CDC and also will use the formal cross-clearance and review process to ensure that authors in other National Centers adopt this language prior to the release of documents. Materials on the website (www.cdc.gov/nceh/lead) will use terminology that existed at the time of their publication.

The 1975-1991 CDC Lead Statement contains the following footnote: "These documents are being kept on this website for historical purposes and are no longer in print." The footnote also

will be added to the 2005 CDC Lead Statement along with additional language: "These documents refer to various blood lead thresholds and levels of concern for adverse health outcomes in children. This terminology is no longer current and readers should refer to the 2012 ACCLPP recommendations that are available at:

http://www.cdc.gov/nceh/lead/ACCLPP/CDC\_Response\_Lead\_Exposure\_Recs.pdf."

A similar statement was applied to the CDC 2002 paper, *Managing Elevated Blood Lead Levels Among Children*: "This document refers to a blood lead level of 10 µg/dL as the CDC level of concern for adverse health outcomes in children. This terminology is no longer current and readers should refer to the ACCLPP 2012 recommendations. However, the 2012 document does not recommend changes to guidelines for the evaluation and treatment of children requiring chelation (those with BLLs  $\geq$  45 µg/dL) published here."

CDC's response to recommendation 1 included a comment that the statement would be placed on <u>www.cdc.gov/nceh/lead</u> no later than March 1, 2012. A joint publication summarizing the ACCLPP recommendations and CDC's response would be submitted to the *Morbidity and Mortality Weekly Report (MMWR)* and *Pediatrics* no later than May 2012. Although the statement was placed in the *MMWR* on May 25, 2012, NCEH subsequently decided that a joint publication would not necessary because the documents are available on the website.

CDC participated in a webinar for EPA and ATSDR regional staff, Pediatric Environmental Health Specialty Units, and other groups in Region 7 to discuss the ACCLPP recommendations, CDC's response and implications for implementation. The August 2012 webinar was held for state and local health departments and childhood lead poisoning prevention programs, while a second webinar will be convened in the fall of 2012 for a diverse group of national stakeholders

Based on these actions, CDC's position is that recommendation 1 is being addressed. Statements will be applied to historical documents by the end of 2012. A section of the CDC website (<u>www.cdc.gov/nceh/lead</u>) will be dedicated to the 2012 ACCLPP recommendations and CDC's response to allow for easier retrieval and reference.

**Recommendation 8:** CDC should encourage local, state and other federal agencies to: (a) facilitate data-sharing between health and housing agencies; (b) develop and enforce preventive lead-safe housing standards for rental and owner-occupied housing; (c) identify financing for lead hazard remediation; and (d) provide families with information needed to protect their children from lead hazards in the home.

CDC concurred with part (d) of recommendation 8 and outlined its specific means to address or implement this guidance. CDC utilized a wide variety of networks and media outlets to develop and distribute materials to help families identify and control or eliminate lead hazards in their homes. Many of these materials are available at <a href="http://www.cdc.gov/nceh/lead">www.cdc.gov/nceh/lead</a> in both English and Spanish.

CDC recognized that the development of new materials was beyond its current capacity due to severe resource constraints, but a multi-agency website (<u>www.healthyhomes.hud.gov</u>) currently is under construction with representation by CDC, HUD, EPA and the U.S. Department of

Agriculture. The website will include several pages related to making homes lead-safe and also will provide new information on lead-safe renovations. The federal partners expect to launch the new website in the fall of 2012. Based on these actions, CDC's position is that part (d) of recommendation 8 is being addressed.

**Recommendation 10:** CDC should (a) emphasize the importance of environmental assessments to identify and mitigate lead hazards before children demonstrate BLLs above the reference value and (b) adopt prevention strategies to reduce environmental exposures from lead in soil, dust, paint and water before children are exposed.

CDC concurred with part (a) of recommendation 10 and outlined its specific means to address or implement this guidance. For over 20 years CDC, has and will continue to emphasize the importance of environmental assessments and mitigation of lead hazards before children are exposed (e.g., before their BLLs are above the reference value) in CDC policies, CoAgs, interagency agreements and publications.

NCEH/ATSDR established a workgroup to consider the best strategies for implementing primary prevention at Superfund cleanup sites and determining the appropriate screening value for lead in soil. ATSDR's existing policy is that soil with lead concentrations below the screening value is considered to be of minimal risk.

ATSDR may consider various approaches to address contaminated sites, such as "lead-safe" measures that control soil lead hazards. ATSDR also may consider "lead-free" measures that require complete replacement of lead-contaminated soil based on lead concentrations and the risk for exposure to vulnerable populations (e.g., children and pregnant women). Based on these actions, CDC's position is that part (a) of recommendation 10 is being addressed.

**Recommendation 13:** Additional research priorities should include efforts to improve the use of data from screening programs, develop next generation point-of-care lead analyzers, and improve the understanding of epigenetic mechanisms of lead action

CDC concurred with recommendation 13 and outlined its specific means to address or implement this guidance. CDC is continuing to partner with NIEHS, academic partners and laboratory instrument manufacturers to encourage research in these important areas. Based on its ongoing interactions with NIEHS and other groups to foster collaboration in developing a research agenda, CDC's position is that recommendation 13 is being addressed.

CDC is aware that ACCLPP's major recommendation to shift from the existing "level of concern" to a "reference value" for childhood BLLs will have implications in several areas other than federal policy (e.g., nutrition, early childhood education, and laboratory proficiency testing criteria). As a result, ACCLPP and CDC extensively discussed and conducted an exhaustive literature review of these proposed changes with both internal and external stakeholders.

For NCEH, ACCLPP and CDC provided data from a recent review of laboratory performance within individual events. The current laboratory proficiency testing criteria for BLLs allow for  $\pm 4 \mu g/dL$  or  $\pm 10\%$  (whichever is greater), but several options have been proposed:  $\pm 3 \mu g/dL$  or  $\pm$ 

10% (whichever is greater);  $\pm 2 \mu g/dL$  or  $\pm 10\%$  (whichever is greater); or  $\pm 1 \mu g/dL$  or  $\pm 10\%$  (whichever is greater). The review showed that 90% of clinical laboratories could improve their proficiency testing of BLLs to  $\pm 3 \mu g/dL$  or  $\pm 10\%$ . Blood lead proficiency testing experts and environmental lead proficiency testing experts have been invited to attend the next EPA/HUD Lead Paint Task Force meeting on October 18, 2012 to discuss this issue in greater detail.

For ATSDR, ACCLPP and CDC developed and provided several key messages for health assessors to include in their reports: (1) "No safe level of lead in blood has been identified." (2) "Some effects from lead in children are irreversible." (3) "CDC will eliminate and replace the old action level with a reference value." (4) "Caution should be taken in not referring to 400 ppm of lead in soil as the ATSDR cleanup value." (5) "Primary prevention is a key strategy for health messaging." Although very few lead sites currently are on hold at ATSDR, health assessors are continuing to discuss individual sites with management and also are devising the best strategies to reflect the reference value in primary prevention of Superfund sites.

**Status of the CDC Healthy Homes/Lead Poisoning Prevention Branch (HHLPPB).** CDC funding of state and local lead poisoning prevention programs ended on September 1, 2012 and resulted in a cut of ~\$19.8 million to 35 state and local health departments. CDC funding supported ~170 HHLPP jobs at state and local levels, including epidemiology, surveillance, clerical, education, program management, case management, data entry, and information technology functions. Based on a review of 27 of the 35 funded states on September 12, 2012, CDC provided no-cost extensions of 3-9 months to 24 states.

Programs are implementing multiple strategies to respond to the severe funding shortfalls (e.g., combining activities with other internal programs and providing limited services; seeking reimbursement from Medicaid and other funding sources; concentrating on very limited lead poisoning prevention activities; and relying on foundations and other outside partners for program components).

CDC's review also showed that 13 programs have reported a loss of jobs to 44 staff. Most programs achieved reductions by contract cancellations or attrition. Staff loss was reported in all program areas, but epidemiology and data entry functions were most severely impacted. If possible, 5 programs will continue to report data to CDC after their no-cost extensions end.

CDC identified a number of developing and anticipated external impacts due to the elimination of HHLPPB funding. The concept of statewide comprehensive programs will be lost. The merger of program management functions with other programs will result in a dilution of effort. Education and outreach programs will be drastically reduced. Healthcare provider education and consultation will be discontinued.

Surveillance capacity will be reduced due to the loss of epidemiology staff. Case management capacity will be reduced due to longer wait times for environmental inspections and less ability to make follow-up contact with families. Program effectiveness will be reduced due to the elimination of program evaluations. State funding to local programs for inspections, home visits and health education will be eliminated. State programs that fully depended on CDC funding will be eliminated.

Elimination of HHLPPB funding also has resulted in internal impacts, including a reduction in the workforce from 28 staff to 4 scientists and 2 public health advisors. The remaining 6 staff will provide lead poisoning prevention expertise and analysis required by FY2012 Congressional appropriations language. These activities include continued support for ACCLPP, surveillance, and limited epidemiological responses to lead issues in the field.

The following internal activities have been entirely eliminated from the HHLPPB portfolio:

- support for public health professionals to participate in lead poisoning prevention training through the Healthy Homes Training Center and Network;
- participation in conferences, meetings or expert consultation to state and local decisionmakers;
- implementation of health education campaigns;
- analyses and presentations of national and state data;
- program evaluations; and
- management of CoAgs.

Dr. Burgess moderated the BSC's discussion with Dr. Brown on her update on CDC's healthy homes/lead poisoning prevention activities. The discussion topics included:

- communication strategies for CDC to raise the reference value for childhood BLLs if needed in the future; and
- difficulties in reconciling the reference value with laboratory proficiency testing criteria.

The BSC made several comments and suggestions for CDC to consider regarding its response to the ACCLPP recommendations and public health messaging of the reference value for childhood BLLs.

- For CDC's response to ACCLPP recommendation 1, the BSC voiced concerns that the
  periodic reevaluation of the reference value based on different NHANES datasets could
  result in a situation whereby increased lead exposures could lead to upward adjustments
  of the reference value and hence reduce potential protection to children. Moreover, a
  "moving scale" might increase the difficulty in assessing whether the change in support
  of lead monitoring programs would lead to reduced remediation efforts and increased
  exposure risks for children.
- CDC included the following language in its response to ACCLPP recommendaton 1: "On a community basis, any distribution of BLLs **significantly** higher than that of the U.S. childhood population 1-5 years of age indicates the community has lead sources in the environment that put children living there at higher risk for unusual/atypical BLLs than the general U.S. childhood population." The BSC noted that the word "significantly" is subject to interpretation. The same language should be used in both community and clinical settings. Alternatively, the following language should be used for the sake of simplicity: "Any distribution of BLLs >5 µg/dL would indicate a child's exposure to lead above that experienced by most children in the same age group."

- CDC should ensure that its messaging clearly distinguishes between the public health implications of the reference value and clinical decision-making in terms of actions clinicians should take. To minimize confusion, clinicians should be given a list of recommended clinical actions for childhood BLLs.
- CDC should address confusion that will arise between the clinical and laboratory aspects of the reference value. The shift from the LOC to a reference value is a new concept for clinicians, but state programs no longer have funding to communicate this change and provide support to clinicians in interpreting laboratory reports.
- CDC should explore the possibility of conducting a retrospective review of NHANES data to develop and compare a fixed reference value on a basis year. This approach might minimize confusion with reviewing and potentially changing the reference value every four years.
- CDC should ensure that its public health messaging on the reference value for childhood BLLs covers social equity and vulnerable populations.

Dr. Portier emphasized that despite the devastation to the nation in terminating extramural funding of HHLPPB, Dr. Brown and her staff were to be commended on their outstanding efforts in preserving the most important programmatic functions.

## Update by the Division of Laboratory Sciences (DLS)

## James Pirkle, MD, PhD

Director, NCEH Division of Laboratory Sciences Centers for Disease Control and Prevention

Dr. Pirkle covered two major topics in his update to the BSC on DLS's recent activities.

**Laboratory Research on Exposure to Harmful Constituents in Tobacco.** CDC and FDA entered into an interagency agreement for DLS to conduct research and development in support of FDA's regulation of tobacco products. The agreement covers several projects in six major categories:

- 1. Analysis of design features, ingredients or harmful/potentially harmful constituents in tobacco and tobacco smoke from products of specific concern to FDA
- 2. Analysis of cigarette butts for harmful/potentially harmful delivery of constituents to smokers of tobacco products
- 3. Analysis of biomarkers for persons using specific tobacco products
- 4. Rapid development of methods for analysis of harmful/potentially harmful constituents in tobacco and tobacco smoke
- 5. Transfer of methods to FDA analytical laboratories for ongoing product evaluation in support of FDA compliance actions
- 6. Consultation on tobacco product technical areas related to FDA regulations

In the National Cigarette Study, DLS is analyzing addictive and toxic chemicals in the 50 topselling cigarette brands in the United States. For each cigarette, >120 different measurements will be taken from mainstream smoke, tobacco and product design. DLS also is expanding the measurement of tobacco biomarkers from 33% to 100% of smokers in NHANES. These measurements include polycyclic aromatic hydrocarbons (PAHs), metals and volatile organic compounds (VOCs).

FDA is funding the "Population Assessment of Tobacco and Health" (PATH) Study to assess the impact of its regulatory authority over tobacco products on the health of Americans and inform product standards and tobacco risk communication. PATH will serve as the largest national longitudinal cohort study ever conducted in the United States with a cohort of >40,000 persons, including users of tobacco products and persons  $\geq$ 12 years of age at risk for tobacco use.

The PATH Study will be piloted in December 2012 and the first cycle of samples will be submitted in September 2013. Restricted data will be available in January 2016. The nationally representative cohort will be followed for >20 years. The young age sample will be annually refreshed. The multi-stage sample design of 71,800 addresses will include 37,870 adults and young adults, 26,052 current tobacco users, and 11,818 current tobacco non-users. Blood, urine and discarded cigarette butts will be collected.

The PATH Study will focus on and over-sample several important subgroups: youth, young adults 18-24 years of age, menthol smokers, dual users of cigarettes and smokeless tobacco products, daily smokers, persons who quit smoking within the past 2 years, racial/ethnic minority groups, and users of new products or modified "risk reduced" harm products.

DLS's role in the PATH Study will be to provide technical assistance and guidance during the planning stages and analyze blood, urine and cigarette butts in directed studies of exposure and health effects in subgroups of the cohort. The National Cigarette Study and PATH Study have resulted in allocations to CDC totaling \$25 million per year over the past 14 months.

DLS plans to publish a large data set of at least 20 different compounds in the future. To support this publication, DLS has been compiling unique findings from its studies that show an association between exposure to tobacco smoke and exposure to toxic chemicals causing cancer, heart disease and lung disease. Key findings from these studies are summarized below.

Exposure to secondhand smoke (SHS) is correlated with increased tobacco-specific carcinogen levels in urine of non-smokers over time. Smoking tobacco increases exposure to carcinogenic butadiene, acrolein, benzene and crotonaldehyde. Exposure to tobacco smoke is correlated with urine levels of carcinogenic acrylonitrile in smokers and non-smokers. Urine cyanide biomarker levels are correlated with exposure to tobacco smoke in smokers and non-smokers.

Compared to non-smokers, smokers have a 41-fold higher exposure to carcinogenic acrylonitrile, a 2.4-fold higher exposure to carcinogenic acrylamide, a 3.8-fold higher exposure to the respiratory toxicant acrolein, a 2.3-fold higher exposure to carcinogenic propylene oxide,

a 2.9-fold higher exposure to carcinogenic ethylene oxide, a 2-fold higher exposure to toxic xylenes, a 4.6-fold higher exposure to carcinogenic crotonaldehyde, a 3.9-fold higher exposure to carcinogenic dimethylformamide, a 2.1-fold higher exposure to carcinogenic styrene, a 5.6-fold higher exposure to carcinogenic 1,3-butadiene, and an 8.1-fold higher exposure to carcinogenic benzene.

DLS is analyzing the designs of cigarette filters to measure their charcoal content. For these analyses, mainstream tobacco smoke is being measured to determine the levels of acrolein, acetaldehyde, benzene and nicotine. DLS also is addressing FDA's concerns regarding advertisements of "new and improved" Skoal smokeless tobacco products. DLS's analyses showed that the new and improved products have 6- to 7-fold higher levels of free-base nicotine and are tremendously more addictive.

**Fourth National Report on Human Exposure to Environmental Chemicals.** In September 2012, DLS revised the Fourth Report with updated tables for 119 chemicals and tables for 34 new chemicals. Dr. Pirkle summarized key data in the updated Fourth Report, but he also informed the BSC that the entire document is available at:

www.cdc.gov/exposurerePort/pdf/FourthReport\_UpdatedTables\_Sep2012.pdf.

For lead, the mean BLL in persons of all ages decreased from 1.6  $\mu$ g/dL in the 1999-2000 NHANES to 1.2  $\mu$ g/dL in the 2009-2010 NHANES. Similar downward trends of BLLs were observed over the same time period in specific age groups: 1-5 years, 6-11 years and 12-19 years. However, the decrease in BLLs for the age group of  $\geq$ 20 years was not as prominent. By gender, the downward trend in BLLs was higher in males than in females. By race/ethnicity, BLLs have remained relatively stable in Mexican Americans, non-Hispanic blacks (NHBs) and non-Hispanic whites (NHWs).

For total urinary cadmium, levels have remained relatively stable from the 1999-2000 NHANES to the 2009-2010 NHANES in both the U.S. population and the age group of  $\geq$ 20 years, including the 95<sup>th</sup> percentile. For serum cotinine in non-smokers of all ages, levels have decreased from the 2001-2002 NHANES to the 2009-2010 NHANES. Reductions in SHS exposure among children in the age groups of 3-11 years and 12-19 years have markedly decreased their serum cotinine levels by 50% over the past 10 years. However, the decrease in serum cotinine levels in adults  $\geq$ 20 years of age has not been as dramatic.

By gender, the reduction in serum cotinine levels was higher in males than in females. However, males had higher SHS exposures than females at baseline. By race/ethnicity, a steady downward trend was observed in Mexican Americans. Although reductions also were observed in NHBs and NHWs, baseline serum cotinine levels were much higher in these racial/ ethnic groups. However, DLS is aware of the limitations of questionnaires, particularly for "socially non-desirable" issues. For example, DLS studies of self-reported data versus laboratory measurements showed that 70% of pregnant women in Missouri were untruthful in characterizing themselves as non-smokers on questionnaires.

For serum perfluorooctane sulfonic acid (PFOA), levels have dramatically decreased from  $\sim$ 30  $\mu$ g/L in the 1999-2000 NHANES to  $\sim$ 10  $\mu$ g/L in the 2009-2010 NHANES due to the removal of

this chemical from Scotch 3M products. For urinary 2,5-dichlorophenol, levels have decreased from the 2003-2004 NHANES to the 2009-2010 NHANES due to a reduction in industrial production of this chemical. By race/ethnicity, however, the levels are much lower in NHWs than in NHBs and Mexican Americans.

For blood trichloromethane (chloroform) that is used in disinfection byproducts, the change in levels from ~17 pg/mL in the 2001-2002 NHANES to ~10 pg/mL in the 2005-2006 NHANES is statistically significant. For urinary mono-isobutyl phthalate, creatinine levels have dramatically increased from ~2.5  $\mu$ g/g in the 2001-2002 NHANES to ~8  $\mu$ g/L in the 2009-2010 NHANES. By race/ethnicity, the levels are much higher in NHBs and Mexican Americans than in NHWs.

For urinary mono-(carboxyoctyl) phthalate, creatinine levels have dramatically increased from ~5  $\mu$ g/g in the 2005-2006 NHANES to ~13.5  $\mu$ g/L in the 2009-2010 NHANES. By age, the levels are much higher in the age group of 6-11 years than in the age groups of 12-19 years and  $\geq$ 20 years.

Dr. Burgess moderated the BSC's discussion with Dr. Pirkle on DLS's recent activities. The discussion topics included:

- the timeline for DLS to include new laboratory data into ATSDR's ToxProfiles<sup>™</sup> and publish these findings for application in the field;
- the potential for DLS to perform repeat measurements of chemical exposures on the same day for specific segments of the population;
- DLS's definition and comparison of "smokers" versus "non-smokers" and differences between measuring chemical exposures in these two groups;
- DLS's review of NHANES data to collect demographic data beyond age, gender and race/ethnicity (e.g., occupational exposures and chemical interactions);
- the decrease in the DLS influenza vaccine budget to \$0 in September 2013; and
- DLS's analyses of biomarkers of effect (e.g., DNA adducts) in addition to biomarkers of exposure.

The BSC was impressed by the sound science of DLS's laboratory methods and commended DLS on its success in applying its unique expertise to leverage funds outside of CDC.

Dr. Vikas Kapil is the NCEH/ATSDR Chief Medical Officer, Associate Director for Science and the alternate DFO for the BSC. He confirmed that during the May 2013 BSC meeting, another tour of the NCEH laboratories would be scheduled on the agenda for the benefit of the new members.

#### Overview of the NCEH/ATSDR Environmental Health Portfolio Management System

#### Sascha Chaney, BA

Chief of Staff, CDC National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry

Ms. Chaney presented an overview of the NCEH/ATSDR Environmental Health Portfolio Management (EHPM) System. NCEH and ATSDR are the two National Centers with responsibility for CDC's broad portfolio of international, national and local EH projects and activities. In addition to these responsibilities, NCEH/ATSDR also manages ad-hoc requests at international, federal, state, local, tribal and private levels, including requests from the White House, Congress, HHS/CDC leadership, communities, private citizens and the media.

Of 1,334 documents that NCEH/ATSDR staff submitted to the clearance process over the past year, 457 were from NCEH epidemiology or surveillance programs, 343 were from NCEH laboratory sciences programs, 424 were from ATSDR, and 110 were from NCEH/ATSDR OD. In addition to these internal documents, ATSDR state partners also released 458 PHAs and public health consultations over the past year.

In response to recommendations in the Government Accounting Office report and the external assessment by Price Waterhouse Coopers, NCEH/ATSDR developed EHPM as an automated system to manage work requests and projects in real time, including ATSDR's site-specific activities and Center-wide requests, projects and activities. EHPM is designed for staff to identify NCEH/ATSDR's priorities; track and monitor the progress of activities with clearly defined timelines; and provide notifications of new work, updates and the need to track certain portfolios.

Other notable features of EHPM include a touch screen for iPad users and innovative functions for staff to easily conduct searches and share knowledge in an open and transparent manner. EHPM generates both canned and ad-hoc reports and also provides data for management decision-making and communication of accomplishments. OD staff is responsible for quality assurance/quality control to address duplicate requests submitted into EHPM. Moreover, criteria have been established for requests, projects or activities in 14 areas that should be entered into EHPM as emerging or high profile EH issues and topics of interest at ATSDR sites.

At this time, the 14 priority topics include hydraulic fracturing, lead, drywall, formaldehyde, cancer clusters, climate change and 8 sites of interest: Puerto Rico, Camp Lejuene, Libby, Mossville, Midlothian, Corpus Christi, Fukushima and the World Trade Center. Daily e-mail notifications are distributed to OD and senior staff on any information that is entered into EHPM on these 14 priority topics, but NCEH/ATSDR users also may flag or prioritize any entry for review by OD. The ATSDR site triage process, forecast items, document release process and Documentum are all linked to EHPM.

Of 2,283 requests, priorities and activities that have been entered into EHPM since April 2012, 211 are OD items of interest, 252 are high priority items, 2 are urgent ATSDR sites, 20 are

priority 1 ATSDR sites, and 17 are externally referred requests. NCEH/ATSDR also is currently tracking 31 "Category A" documents and 13 "Category B" documents.

NCEH/ATSDR is using EHPM for tracking and decision-making through daily electronic notifications to senior staff; private and public portfolios for staff to review, discuss and take action on specific events; the weekly "Must See" report, event calendar, and canned, ad-hoc and open/closed reports; status reports on the clearance and release of documents; issues, updates and success stories; and a linkages to forecasting and Documentum.

Ms. Chaney concluded her overview by presenting slides of outputs from EHPM, including daily notifications on HHS's request for information on the CDC Lead Program and restaurant inspection standards, the October 10, 2012 "Must See" Report, and the three-month planning calendar. She offered to present a live demonstration of EHPM during a future meeting.

Dr. Burgess moderated the BSC's discussion with Ms. Chaney on EHPM. The discussion topics included:

- the process to close records in EHPM;
- OD's establishment of performance standards for staff to enter data into EHPM;
- unexpected benefits of EHPM (e.g., flagging activities or documents that are duplicated or have gaps, communicating the value of NCEH/ATSDR's activities in a clear and understandable manner, and improving the response time for data requests);
- plans for NCEH/ATSDR to utilize EHPM more for forecasting and measuring priorities and making data-based decisions;
- the amount of staff time devoted to EHPM data entry; and
- OD's future plans to survey and interview staff to obtain their perspectives on EHPM and propose strategies to improve the system.

The BSC commended NCEH/ATSDR on developing EHPM as a thoughtful and well-designed system.

## **Overview of the ATSDR Division of Community Health Investigations**

## Tina Forrester, PhD

Acting Director, Division of Community Health Investigations Agency for Toxic Substances and Disease Registry

Dr. Forrester presented an overview of the challenges and progress associated with the reorganization of DRO and DHAC into the new ATSDR Division of Community Health Investigations (DCHI). DCHI's overall mission will be to protect and improve the health of communities with four key objectives: timely response leading to action, the best science to arrive at assessments and conclusions, streamlined products, and understandable messages targeted to communities.

Dr. Forrester described major challenges in each of the four objectives. For "timely response to action," DCHI will be challenged in prioritizing activities and requests. Decisions about work plans and timeframes for site activities will be made by a large team, including the Branch Chief, regional field staff, CoAg project officers and team leads. The timeframe for completing site activities must meet the needs of the customer's request.

For "use of the best science," DCHI will be challenged in conducting site activities in light of changing standards. Most notably, EPA's continued use of 400 ppm as the cleanup value at sites is inconsistent with CDC's adoption of ACCLPP's recommendation to shift to a reference value of 5  $\mu$ g/dL for childhood BLLs. As a result, ATSDR will conduct a pilot study at the AMC Smelter in Region 8 to test a comprehensive approach to reduce lead exposure with multiple components (e.g., EPA's actions to mitigate exposure, education to communities on best practices to reduce exposure, surveillance, and collaboration with state and local entities).

DCHI also will be challenged in delivering public health messages on EPA's new inhalation reference concentration (RfC) level for TCE of 2  $\mu$ g/m<sup>3</sup> based on cardiac malformation in the fetus and liver. Some state action levels for TCE are not aligned with EPA's new RfC. ATSDR has applied EPA's new TCE value to work at four sites: Navy Yard Mills in Massachusetts, Chicago Heights in St. Louis, ChemFab in Pennsylvania, and Cabo Rojo in Puerto Rico.

DCHI acknowledges the need to update existing guidance documents to conduct PHAs with a more scientifically-based and timely approach. The documents should be modified with more recent data in several areas (e.g., input parameters, exposure assumptions, comparison values, exposure scenarios and mixture evaluations). DCHI is aware of the need to utilize consistent toxicological approaches to contaminants across sites (e.g., PAHs, PFOA and hydraulic fracturing constituents).

For "streamlined products," DCHI will be challenged in conducting site activities without modern technology, particularly computational tools and applications that can more rapidly calculate risk. Moreover, standard language and templates are needed for multiple sites with the same issues (e.g., lead and vapor intrusion). A consistent process is needed to review documents and ensure the same scientific conclusions are included in similar documents.

For "understandable messages to communities," DCHI will be challenged in meeting the new mandate to utilize plain language in outreach efforts. DCHI also will need to develop new approaches to deliver audience-specific messages and continue to engage communities with less resources. DCHI has considered several potential approaches to address this issue, such as the replication of community participatory engagement models; prioritization of sites that need the most engagement and education; implementation of broad campaigns rather than site-specific health education; and engagement with communities on public health issues other than chemical exposures.

DCHI will take a number of actions to overcome these challenges after the reorganization is officially finalized. Technical assistance will be more readily available because DCHI will be responsible for all site-specific activities. DCHI staff will be closer to their respective

communities. NCEH/ATSDR OD already has approved the addition of 10 new staff to ATSDR regional offices and plans to fill 10 additional positions in the future.

The Branch Chief, Regional Director, state CoAg project officer, team lead and state representative will serve on a team to make decisions and prioritize site-specific work plans and requests based on several factors (e.g., urgent public health need and staff availability). The team approach is expected to eliminate inconsistencies between site activities internally within DCHI and externally in the field. Timeframes for requests will be clearly understood by staff. EHPM will be used to track the timeliness of responses to requests.

DCHI will review assessment approaches across similar sites to assure the consistency of toxicological evaluations, conclusions and recommendations. DCHI's initial review will include similar sites with issues related to TCE, lead, dioxin, PAHs and hydraulic fracturing constituents. Efforts are underway to link the DHAC and DRO strategic planning processes, align reports and consolidate performance management standards for staff.

Dr. Burgess moderated the BSC's discussion with Dr. Forrester on the challenges and progress related to the DCHI reorganization. The discussion topics included:

- DCHI's plans to consider and include recommendations by the Chemical Exposure Workgroup on community engagement; and
- DCHI's potential leadership role in improving communication between federal agencies and communities by compiling a list of best practices.

Drs. Tina Bahadori and Rebecca Head are BSC members. They offered to provide Dr. Forrester with contact information for the National Association of County and City Health Officials and other groups that have experience in community-based participatory research and the development of community-driven tools, particularly those for exposure characterizations. These resources might assist DCHI in its efforts to overcome challenges in delivering understandable messages to communities.

The BSC members also made another suggestion for DCHI to consider during the reorganization. The National Research Council released a new report in September 2012, *Exposure Science in the 21<sup>st</sup> Century: A Vision and Strategy*, with several recommendations on high-throughput, technology-driven tools. DCHI should review and use the report as a resource in its efforts to develop computational tools and applications that can more rapidly calculate risk. The report is available on the National Academies website at no charge.

## Public Comment Session

Dr. Burgess opened the floor for public comments; no participants responded.

## Update on CDC's Global Environmental Health Activities

Vikas ("Vik") Kapil, DO, MPH, FACPOEM Chief Medical Officer and Associate Director for Science, NCEH/ATSDR Centers for Disease Control and Prevention Alternate BSC Designated Federal Official

Dr. Kapil presented an update on some of CDC's global EH activities. The CDC Center for Global Health is responsible for coordinating and conducting global health activities in ~65 countries worldwide. CDC conducts these activities with Ministries of Health, the World Health Organization (WHO), healthcare organizations, academic institutions and other partners with an in-country presence.

For "indoor air pollution and health," CDC and its domestic and global partners are continuing to conduct a significant multi-agency effort in Africa, Latin America, Central America and Asia. These activities have shown that the use of wood, coal, and animal and agricultural wastes in stoves and as biomass fuels for heating and cooking are tremendous sources of exposure for women and children worldwide. These toxic components have been linked to significant health outcomes (e.g., childhood pneumonia, adverse reproductive outcomes, cardiovascular disease, chronic lung disease and lung cancer).

WHO's recent publication reported that exposure to toxic chemicals from stoves and biomass fuels can be attributed to ~1.9 million deaths annually worldwide. CDC and its partners are developing a multidisciplinary approach to address health effects associated with indoor air pollution. CDC is focusing on the acceptability, selection and feasibility of using stoves in Guatemala, Kenya and India. CDC also is collaborating with academic partners to provide training and conduct research on stove exposures, including health outcome studies.

For "global response," CDC recently investigated a number of urgent issues (e.g., aflatoxin exposure in Kenya, toxic pyrrolizidine alkaloid exposure in Ethiopia, pesticide exposure in Bangladesh, childhood BLLs in Indonesia, and a severe childhood lead poisoning outbreak in Zamfara State, Nigeria due to gold ore processing). CDC and its partners also are providing technical consultation and expertise to develop public health prevention programs in Vietnam in response to Agent Orange exposures.

For "water safety and quality," CDC and its partners have trained ~250 water technicians in Haiti to improve water safety and quality and also have monitored the sustainability of water, sanitation and hygiene interventions over the past 10 years. For "extreme weather events," CDC awarded a CoAg to Health Canada. For "environmental disasters," CDC has an agreement with the Canadian government to provide training, expertise and support.

For "radiation emergencies," CDC played an instrumental role in WHO's recent consultation to compile lessons learned from the nuclear disaster at the Fukushima Nuclear Power Plant that occurred in March 2011. For "global laboratory research," CDC is continuing to provide

technical consultation and expertise to several countries (e.g., establishment of a biomonitoring program in England).

For "vessel sanitation," CDC is continuing to provide expert consultation to ship builders, designers and cruise ship lines in several countries, including Italy and Germany. For "environmental and occupational health," CDC is in the process of renewing its formal agreement with the government of India to address a broad range of issues, (e.g., chemical, radiation, arsenic and groundwater exposures, indoor and ambient air pollution, and injury prevention and control). CDC has engaged a diverse group of domestic and global partners, private companies and foundations to serve on an interagency workgroup to conduct activities in India.

Overall, CDC develops creative mechanisms and leverages resources from both public and private partners to conduct global EH activities because specific line-items are not allocated to fund this work. Dr. Kapil confirmed that based on the BSC's interest, a more comprehensive presentation on CDC's global EH initiatives could be scheduled on a future agenda.

Dr. Burgess moderated the BSC's discussion with Drs. Kapil and Portier on CDC's global EH activities. The discussion topics included:

- resources and collaboration on global EH activities between NCEH/ATSDR and the CDC Center for Global Health; and
- factors involved in selecting and prioritizing NCEH/ATSDR's involvement in global EH issues due to limited funding (e.g., staff availability, expertise and public health burden).

With no further discussion or business brought before the BSC, Dr. Burgess recessed the meeting at 4:01 p.m. on October 16, 2012.

## **Opening Session: October 17, 2012**

Dr. Burgess welcomed the participants to day 2 of the meeting and opened the floor for introductions to determine the BSC voting members and Federal Expert members who were in attendance. She verified that the members constituted a quorum for the BSC to conduct its business on October 17, 2012 and called the meeting to order at 8:31 a.m.

Dr. Kapil asked the participants to join him in welcoming Dr. Maury Nation, of Vanderbilt University, to the BSC meeting. Dr. Nation is a member of the BSC for the CDC National Center for Injury Prevention and Control (NCIPC) and would observe the proceedings to increase interaction and collaboration between the NCEH/ATSDR and NCIPC BSCs.

## **Overview of Public Health Surveillance Following Emergency Events**

#### Kevin Horton, DrPH, MSPH, CPH

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

#### Lauren Lewis, MD

Chief, Health Studies Branch NCEH Division of Environmental Hazards and Health Effects

Drs. Horton and Lewis presented an overview of public health surveillance activities following emergency events.

**ATSDR.** Public health surveillance extends far beyond the collection of data. Most notably, surveillance also must include the analysis, interpretation, planning, implementation, evaluation, dissemination and use of data to achieve a beneficial public health impact, particularly prevention and control.

Surveillance serves as the cornerstone of public health by identifying a problem, its cause and an appropriate intervention. The intervention is broadly implemented to achieve a meaningful impact. Public health surveillance has multiple purposes (e.g., estimating the magnitude of the problem, defining a problem, generating hypotheses and facilitating planning).

ATSDR currently is conducting surveillance for acute toxic substance incidents in 8 states. As an example, Dr. Horton presented a video of a release from a chlorine tank that occurred in a scrap yard in California in 2010. ATSDR also captures routine HazMat events in its surveillance system.

Because federal agencies historically tracked chemical spills for regulatory and cleanup purposes only, data were lacking on the public health consequences of HazMat events. As a result, ATSDR launched the Hazardous Substances Emergency Events Surveillance System (HSEES) in 1993 and funded up to 19 state health departments in five-year competitive cycles.

ATSDR designed HSEES to reduce morbidity and mortality from HazMat events by determining injured populations (e.g., responders and workers), characterizing specific types of injuries, and identifying reasons for these injuries. From 1993-2009, HSEES grantees investigated >100,000 HazMat events.

On January 1, 2010, ATSDR replaced HSEES with the National Toxic Substance Incidents Program (NTSIP) and funded 7 state health departments in a three-year competitive cycle with awards ranging from \$150,000 to \$200,000. ATSDR collected a great deal of external input during the transition to ensure that NTSIP would be more useful to stakeholders. To date, NTSIP grantees have investigated >9,000 toxic substance incidents.

The key features of NTSIP include updated surveillance definitions and new components. Most notably, NTSIP defines a "toxic substance incident" as any uncontrolled or illegal release of a toxic substance into the environment that reasonably could cause harm. Although the definition includes chemical, biological and radiological substances, ~98% of all events captured in NTSIP are chemical-related. In order for ATSDR to quantify the percentage of events with victims, HazMat spills are not limited to those that result in an injury, evacuation or other public health consequence.

ATSDR designed NTSIP with three components. The "state component" includes 7 state health departments that are funded by ATSDR to collect surveillance data, make follow-up contact, and use Geographic Information Systems to map locations in communities where hazardous chemicals are spilled, stored, or shipped based on their proximity to vulnerable populations (e.g., children in schools and elderly persons in nursing homes). NTSIP grantees also conduct outreach to educate companies on preventing future chemical spills and using less harmful chemicals with inherently safer technologies.

The "national component" includes ATSDR's efforts to conduct surveillance of toxic substance incidents in the 43 non-funded states. Because implementation of NTSIP is not feasible in all 50 states due to budget constraints, ATSDR makes projections of the public health consequences of hazardous chemical spills based on databases maintained by other agencies (e.g., Department of Transportation and U.S. Coast Guard). The "field-based component" includes onsite epidemiologic assistance that ATSDR provides to any requesting state or local health department.

In addition to morbidity and mortality data from hazardous chemical spills, NTSIP also collects information on other important issues (e.g., evacuation and shelter-in-place procedures, personal protective equipment requirements, decontamination in the field, state-based prevention outreach activities, situational awareness, and emergency preparedness). The design of NTSIP as an intuitive, web-based program with drop-down menus helps to minimize errors in data entry.

The first three-year funding cycle ended on September 30, 2012, but ATSDR received no new dollars for continued support of NTSIP. As a result, ATSDR collaborated with the CDC Public Health Assistance Program to train 10 college graduates to serve as state coordinators in 8 states over the next two years. To sustain NTSIP over time, ATSDR is exploring other funding opportunities with the Department of Homeland Security and existing CoAgs in CDC and other parts of ATSDR.

Despite the termination of the NTSIP CoAg, ATSDR is proud of its accomplishments. Most notably, NTSIP data have played an important role in driving policy, training workers, improving public health response, and changing legislation in several states (e.g., mercury in schools). Grantees also use NTSIP data to distribute important alerts throughout their states.

**NCEH.** NCEH is facing a major challenge in fulfilling its role as the lead National Center with responsibility for CDC's epidemiologic response during natural disasters and extreme weather events. Most notably, NCEH relies on states to provide situational awareness data during a

disaster, but states increasingly are not collecting or sharing surveillance data with CDC. This trend is particularly problematic because the White House, HHS and the media depend on CDC for accurate and up-to-date morbidity and mortality information during a natural disaster or extreme weather event.

NCEH is aware of the critical need to promote data sharing among states and improve surveillance data collected by states. Although natural disasters result in the most significant public health impact compared to other national emergencies, CDC receives no funding to respond to natural disasters. Moreover, states are not required to collect and report morbidity and mortality data related to natural disasters.

NCEH needs surveillance data in the four major phases of a disaster: (1) acute response phase, (2) community recovery phase through resource allocation, (3) improvement phase through a stronger infrastructure for future responses, and (4) preparation phase through targeted interventions and additional planning for the next disaster.

The cycle of surveillance data during a disaster includes data collection by clinical entities at the local level, submission of these data to the state public health infrastructure for decision-making, and potential sharing of data with federal agencies. NCEH's support, technical assistance and relationships with states play a critical role in states sharing their data with CDC and other federal agencies.

To assist states in making decisions and taking action during and immediately following a disaster, NCEH provides a broad range of support in collecting epidemiologic and public health surveillance data. NCEH's support to states includes capacity building, web-based forms, standardized surveillance tools, training, deployment of staff to the field, and distribution of national surveillance data from the American Red Cross and National Poison Data System. These resources help states in situational awareness, outbreak identification, rapid needs assessment for resource allocation to communities, program evaluation, and analysis, dissemination and evaluation of data to inform and improve future responses.

NCEH has contributed its public health surveillance expertise to a number of significant natural disasters and extreme weather events. During the Deepwater Horizon oil spill in 2010, for example, NCEH organized the collection of clinical surveillance data to determine the mental health needs and other adverse health impacts to communities in affected Gulf States. During the Alabama tornado outbreak in 2011, NCEH conducted unique research by utilizing a variety of surveillance sources to better understand the circumstances of tornado-related deaths.

During the 2012 heat wave, NCEH collaborated with several states in their efforts to implement interventions and allocate resources to provide relief from the heat to local communities. NCEH plans to publish surveillance data from ~5 states that were heavily impacted by the heat wave and experienced power outages. NCEH provided its entire cadre of public health surveillance products and tools to help American Samoa conduct morbidity and mortality surveillance, assess infrastructure needs, and sustain a syndromic surveillance system over time.

NCEH is aware of several challenges that need to be addressed, particularly state capacity in collecting surveillance data and limited incentives for states to share surveillance data with CDC. NCEH is continuing to explore potential strategies and discuss other available data sources to overcome these challenges (e.g., existing state-based syndromic surveillance systems and capacity building to implement active surveillance in states during an event).

Drs. Horton and Lewis concluded their overview by asking the BSC to provide feedback in response to two questions. One, are the NCEH and ATSDR surveillance systems advancing in appropriate directions? Two, should the NCEH and ATSDR surveillance systems be expanded as national programs?

Dr. Burgess moderated the BSC's discussion with Drs. Horton and Lewis on public health surveillance systems following emergencies. The discussion topics included:

- the need for uniform definitions and measurements for states to track morbidity and mortality from heat-related events in a standardized manner;
- NCEH's plans to conduct a meta-analysis of its existing surveillance data to determine and categorize the number, types and health outcomes of specific emergencies (e.g., chemical, radiological or weather-related event);
- ATSDR's evaluation criteria to select states for funding during the NTSIP competitive application process (e.g., the need, value and importance of a chemical surveillance system in the state; state capacity and resources to support NTSIP in light of competing priorities; and state representation of the geography, demographics and industry of the entire U.S. population);
- reasons for the significant decrease in states sharing public health surveillance data with CDC (e.g., severe cuts in state funding and staff, limited authority of state health departments in responding to emergencies, and the absence of environmental epidemiologists in many states):
- NCEH's existing partnerships and proactive approaches at this time to maintain a strong, accurate and reliable national public health surveillance system despite the increasing trend of limited surveillance data from states;
- ATSDR's plans to more extensively engage with new and existing partners (e.g., local, state and federal agencies as well as industry) in the collection of surveillance data;
- the ability of local agencies to directly enter data into NCEH/ATSDR surveillance systems to provide alerts of emerging events; and
- the critical need for NCEH/ATSDR to demonstrate the value and success of its public health surveillance systems at high levels of government (e.g., Congress and HHS).

Dr. Josephine Malilay is the Associate Director for Science for the NCEH Division of Environmental Hazards and Health Effects. In response to the BSC's comment regarding a meta-analysis of NCEH's responses to disasters, she reported that CDC published a 2011 *MMWR* article describing all responses to EH-related emergencies over the 1961-2010 time period, including natural and technological disasters. The paper is available at: www.cdc.gov/mmwr/preview/mmwrhtml/su6004a14.htm.

In response to the two questions posed by Drs. Horton and Lewis, the BSC members made several suggestions for NCEH/ATSDR to consider in enhancing public health surveillance for emergency events.

- NCEH should compile, formally evaluate and disseminate lessons learned or best practices from other states as an incentive for states to share emergency-related surveillance data with CDC, such as the most successful and cost-effective interventions during the 2012 heat wave.
- NCEH should make efforts to pilot the Alabama model in other states due to its success in both academic and data collection aspects. For example, a field officer in the Alabama Department of Public Health has taken proactive steps to build capacity, conduct training, and use schools of public health to actively engage and deploy students to the field for disaster readiness, response and preparedness.
- ATSDR should perform an analysis of its public health surveillance data to determine the economic impact of the reduction from 19 HSEES grantees to 7 NTSIP grantees. The analysis should cover healthcare costs from injuries or deaths related to toxic substance incidents in states that never received HSEES or NTSIP funding. ATSDR could use these data to demonstrate the economic impact and value of NTSIP.
- NCEH/ATSDR should establish strong relationships with and collect surveillance data from police departments, emergency management agencies and other groups that play an important role in emergency events at state and local levels. NCEH/ATSDR should increase its outreach and communication to inform state and local entities outside of health departments about the availability of CDC's public health surveillance systems for emergency events.
- NCEH/ATSDR should continue to conduct surveillance of emergency events at a smaller level than on a national scale. For example, state and local surveillance data are extremely useful in identifying doses and health effects to specific communities after an event and alerting responders to specific risks during an event (e.g., the destruction of methamphetamine laboratories). State and local surveillance systems also could be replicated to develop a uniform and systematic process to report case study data from exposure assessments of emergency events. NCEH/ATSDR could use low-cost methods (e.g., webinars and print materials) to provide education and training in this area.
- NCEH/ATSDR should launch marketing campaigns to increase funding, support and the customer base for public health surveillance following emergency events.
  - ATSDR should approach CHEMTREC® to discuss continued funding of NTSIP. The American Chemistry Council (ACC) funds the program with an annual budget of \$1-\$2 million. CHEMTREC® was founded in 1971 as the public service arm of ACC to assist emergency responders in collecting data from HazMat events. ACC has used CHEMTREC® to build and sustain strong relationships with state agencies over the past 40 years.
  - NCEH should form an expert workgroup to compile and highlight case studies of its public health surveillance system to develop a new customer base. The workgroup should be charged with demonstrating the broad application of NCEH surveillance data and the ability of the system to perform meta-analyses.

Dr. Portier thanked the BSC for its rich and insightful discussion on improving public health surveillance following emergency events. He noted several actions NCEH/ATSDR would take in response to the BSC's comments and suggestions.

- 1. The NCEH/ATSDR Office of Environmental Health Emergencies is responsible for coordinating the CDC response to EH emergencies. An overview of activities by this office would be placed on the next BSC agenda.
- 2. NCEH would administer a survey to determine reasons for the reduction in the number of states that are willing to share surveillance data with CDC. NCEH would use the survey responses to develop effective strategies to better engage states in collecting and sharing surveillance data with CDC.
- ATSDR would review and use its surveillance data as the foundation to perform an analysis to determine the economic impact of the reduction from 19 HSEES grantees to 7 NTSIP grantees. Dr. Portier would use the economic impact analysis to justify restoring NTSIP to its previous funding level.
- 4. NCEH would explore potential strategies to take action on three of the BSC's suggestions: (1) replicate the Alabama model nationally to engage schools of public health in disaster readiness, response and preparedness; (2) conduct a meta-analysis of existing surveillance data to determine and characterize the number, types and health outcomes of specific emergencies (e.g., chemical, radiological or weather-related event); and (3) form an expert workgroup to compile case studies of its public health surveillance system.
- 5. ATSDR would contact ACC to discuss collaborative efforts in funding NTSIP. OD has estimated that a minimum investment of \$10-\$15 million would be needed for ATSDR to expand NTSIP nationally.

## Public Comment Session

Dr. Burgess opened the floor for public comments; no participants responded.

## Updates by the BSC Federal Expert Members

Dr. Burgess opened the floor for the BSC Federal Expert members to provide updates on recently completed or ongoing EPH activities in their respective agencies. The updates are summarized below.

## John Decker, RPh, CIH Senior Scientist, Office of the Director

NIOSH/Centers for Disease Control and Prevention

Dr. Decker reported that NIOSH's FY2012 resources include ~1,200 staff and a budget of ~\$300 million. The NIOSH budget has remained flat since FY2008, but funding has increased

for the treatment of WTC responders and survivors and the Energy Employees Occupational Illness Compensation Program (EEOICP).

NIOSH recently awarded multiple WTC Health Program Research Cooperative Agreements. Several types of cancers were added to the list of WTC-related health conditions as well. NIOSH and the Occupational Safety and Health Administration issued a hazard alert on worker exposure to silica during hydraulic fracturing. NIOSH's planned and potential hydraulic fracturing research projects in the future will include an exposure characterization of diesel particulates, VOCs, metals and physical hazards, animal studies on mixed exposures, worker rosters and health hazard evaluations.

NIOSH and its federal partners published the *National Response Team Technical Assistance Document: Emergency Responder Health Monitoring and Surveillance* in January 2012 with guidance in three major areas. The "pre-event" recommendation is to ensure that only qualified, trained and properly equipped personnel are selected for deployment. The "during event" recommendation is to ensure that all personnel receive sufficient onsite training, monitoring and risk assessment. The "post-event" recommendation is to ensure that responders receive long-term tracking of health where appropriate and recommended.

NIOSH is conducting activities to ensure that green rating systems address occupational safety and health and explicitly include tasks by construction and maintenance workers in life cycle planning. NIOSH also will assist WHO and the International Labour Organization in developing strategies to include worker health in international agreements.

NIOSH will revise its carcinogen and recommended exposure limit (REL) policy in the following areas: the chemical carcinogen classification policy, evidence base for determining if substances are carcinogens, target risk levels for carcinogen RELs, policy for assessing analytical methods and engineering feasibility, application of an "action level" for medical monitoring, and policy for development of RELs for mixed exposures. NIOSH will release the draft policy in late 2012 or early 2013 for public comments.

NIOSH will soon release two bulletins on nanotechnology: *Approaches to Safe Nanotechnology* and *Progress Toward Safe Nanotechnology in the Workplace*. The documents will include an REL for carbon nanotubes and nanofibers as well as medical monitoring recommendations for workers. NIOSH published the 2012 list of antineoplastic and other hazardous drugs in healthcare settings.

The NIOSH Infectious Disease Research Program is conducting several research projects to measure influenza virus in healthcare facilities, including a study to determine the amount of influenza virus patients expel when coughing. NIOSH developed an aerosol sampler to capture aerosol droplets that are produced by patients. Polymerase chain reaction is used to analyze aerosol samples in healthcare facilities. The NIOSH study, "Quantity and Size Distribution of Cough-Generated Aerosol Particles Produced by Influenza Patients During and After Illness," was published the *Journal of Occupational and Environmental Hygiene* in April 2012.

#### Bonnie Richter, PhD, MPH

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

Dr. Richter reported that the U.S. Department of Energy (DOE) has maintained the Former Worker Medical Screening Program (FWP) since 1996. The mission of FWP is to identify and notify former workers at risk for occupational disease in locations close to their residence, including all former federal, contractor and subcontractor workers from all DOE sites. DOE uses FWP to offer medical screening leading to treatment. As of September 2011, >68,000 initial screening examinations and >17,500 re-screening examinations were performed. Re-screening is offered to former workers every three years for ongoing monitoring of conditions with longer latency periods.

DOE awards CoAgs to third-party providers to ensure objective evaluation of the health of former workers; provide information and assistance about medical follow-up and compensation; and use findings to strengthen safety and health protection for current and future workers. Each FWP team focuses on and targets activities to a distinct subset of the former worker population.

DOE obtains rosters of former employees and their current addresses; advertises FWP through several mechanisms (e.g., union and DOE newsletters, television announcements, newspaper notices, public meetings and individual mailings); and provides medical screening to eligible persons with a standardized protocol. Screening is customized according to the individual's work history and likely exposures. Persons with suspicious findings are referred for medical testing and EEOICP at the Department of Labor if applicable.

The medical screening component of FWP includes an extensive medical and occupational exposure history and a physical examination (e.g., spirometry, urinalysis, chest X-ray with a B-reader, blood chemistry, audiometry and exposure-based tests). Low-dose, helical computed tomography scans were added to FWP in 2000 for workers at high risk for occupational lung cancer.

DOE awarded CoAgs to Oak Ridge Associated Universities and the Center for Construction Research and Training to conduct FWP nationally. DOE also awarded five CoAgs to institutions to conduct FWP regionally: Drexel University School of Public Health, Bloomberg School of Public Health at Johns Hopkins University, Queens College of the City University of New York, United Steelworkers, and University of Iowa College of Public Health.

FWP has made several notable accomplishments. Health conditions have been detected at early stages and led to successful treatment of workers. Non-occupational health conditions of workers have been identified (e.g., high blood pressure, diabetes and elevated cholesterol levels). Medical results from screening have supported EEOICP or worker compensation claims filed by workers. Useful information has been provided to guide health and safety programs of current DOE workers. FWP data have been published in 26 peer-reviewed scientific papers from 2001-2012. Additional information on FWP is available at: www.hss.energy.gov/HealthSafety/FWSP/formerworkermed.

#### Abee Boyles, PhD

Health Scientist, NTP Office of Health Assessment and Translation National Institute of Environmental Health Sciences

Dr. Boyles presented the NIEHS update on behalf of Dr. Kristina Thayer who was unable to attend the meeting. In June 2012, NIEHS released a pre-publication copy of the final "National Toxicology Program (NTP) Monograph on the Health Effects of Low-Level Lead" on its website. In August 2012, NIEHS convened a workgroup to discuss the draft "NTP Approach for Reaching Conclusions for Literature-Based Evidence Assessments."

In October 2012, NIEHS convened a diverse peer review panel of oncologists, obstetricians, pediatricians and other experts to make recommendations on the draft "NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use During Pregnancy."

The purpose of the draft NTP monograph is to summarize the effects of gestational exposure to cancer chemotherapy on pregnancy outcomes in the peer-reviewed literature and serve as a tool for physicians and their patients in clinical decision-making. Data show that ~17-100/ 100,000 women are diagnosed with cancer during pregnancy. The current medical paradigm is to avoid treatment during the first trimester, but animal toxicology studies show that treatment in the second or third trimester does not appear to increase the risk of major congenital malformations observed at birth.

The peer review panel concluded that evidence in the draft monograph supported NTP's interpretation of data in five key areas: frequency of congenital malformations by trimester, risk of spontaneous fetal death, pregnancy complication associations, effects on newborn weight and health, and effects on offspring growth and development. NIEHS will release the final monograph in 2013.

NIEHS is continuing its efforts to implement a systematic review of literature-based evidence assessments for EH. In the spring of 2012, NIEHS held a series of webinars with experts in clinical epidemiology to learn aspects of the systematic review process. Web-based tools were developed to facilitate systematic review and evidence assessment.

An interagency meeting was held in June 2012 for NIEHS to share software-based information management tools for extraction, display and data assessment and also to discuss plans for the use of tools in evidence assessments. The NTP approach to systematic review was developed based on recommendations by the Navigation Guide Workgroup and the adoption of existing clinical epidemiology guidelines for EH.

The draft NTP approach for reaching conclusions for literature-based evidence assessments covers seven steps, including preparing the topic, integrating the evidence, and developing hazard identification conclusions. A workgroup of the NTP BSC provided advice and feedback on the draft approach in August 2012. NIEHS will share the draft approach with its federal partners and Executive Committee in November 2012.

After the systematic review and decision-making approach is presented to the full NTP BSC for formal approval in December 2012, NIEHS will finalize the approach. During the Society of Toxicology meeting in March 2013, NIEHS will convene the "Implementing Systematic Review at NTP" session. The session will be repeated and broadcast as a webinar at a later date. NIEHS will continue to participate in an interagency workgroup with EPA, FDA and NIOSH on methods to ensure consistency across federal agencies in the language, messages and other aspects of systematic review.

## Hal Zenick, PhD

Director, National Health and Environmental Effects Research Laboratory U.S. Environmental Protection Agency

Dr. Zenick reported that EPA released a series of influential guidance documents on sustainability, exposure science, and science for environmental protection. EPA's research on sustainability focuses on environmental, societal and economic considerations as well as sustainable decision-making and problem-solving.

Sustainability and interdisciplinary research are prominent features in six EPA programs. The major responsibilities and focus areas of these programs are described below.

- *Air, Climate and Energy Research Program* (climate change, air quality, prevention and reduction of air emissions, and assessments of the impact of air pollution and climate change on ecological and human health factors)
- Safe and Sustainable Water Resources Research Program (protection of coastal and inland waters and assurance of drinking water quality and availability)
- Chemical Safety for Sustainability Research Program (chemical risks in terms of health in the environment, green chemistry issues, and application of new science, informatics and technology to better prioritize and screen chemicals and assess risk)
- Human Health Risk Assessment Program (development of risk assessment documents)
- Homeland Security Research Program (security and protection of water systems from natural and intended attacks and remediation)
- Sustainable and Healthy Communities Research Program (SHCRP) (site cleanup, provision of tools to communities to facilitate decision-making, and research on the interface between ecological services and impacts on human health and well-being)

EPA is soliciting expertise from multiple disciplines (e.g., economics, socioeconomics, social science and behavioral science) to support SHCRP research, activities and new tools for communities. For example, the "National Atlas for Sustainability" will be used to map the location of ecological resources and services and apply these findings to impacted populations.

The "Environmental Quality Index" and "Human Well-Being Index" will be used to identify and prioritize exposures in communities. The "Community-Focused Exposure and Risk Screening Tool" will be used to gather and provide communities with exposure data from a variety of sources and train communities in applying these approaches to address local needs.

EPA is developing a research program on hydraulic fracturing in response to a Congressional directive. During all five phases of program development, EPA will extensively engage stakeholders through public meetings and other mechanisms for the public to submit information on hydraulic fracturing. EPA is expected to present its report to Congress by the end of 2014.

## Open BSC Discussion

The BSC commended Dr. Portier for his leadership in organizing NCEH/ATSDR's activities to be more transparent and available to external stakeholders and the public. The BSC used the remainder of the open discussion to make comments and suggestions for NCEH/ATSDR to consider in improving the format of future meetings.

- NCEH/ATSDR should continue the "open" meeting format that was initiated during the previous meeting. For the current meeting, for example, less formal presentations and longer discussion periods allowed NCEH/ATSDR to easily add two new updates to the agenda that were of interest to BSC members (e.g., the DCHI reorganization and global EH activities).
- NCEH/ATSDR should consider the possibility of developing future agendas based on major themes or topics. For example, the BSC's in-depth guidance on the topic of public health surveillance following emergency events resulted in Dr. Portier assigning concrete action items to NCEH/ATSDR in this area. Moreover, the questions posed by Drs. Horton and Lewis allowed the BSC to focus its comments and suggestions on specific guidance needed by NCEH/ATSDR.
- NCEH/ATSDR should make efforts to provide the BSC with video clips of each presentation along with focused questions in advance of meetings. The distribution of materials during meetings only allows the BSC to respond to NCEH/ATSDR's request for guidance in real time. Pre-meeting video clips would allow individual BSC members to repeatedly review presentations if needed, compile detailed questions and comments in advance, and provide more substantive guidance on NCEH/ATSDR's major initiatives, emerging EPH issues for the nation, or new directions and exciting collaborative opportunities for NCEH/ATSDR. Alternatively, BSC members could be designated as "leaders" or "champions" for a specific topic. With this approach, NCEH/ATSDR presenters and BSC leaders/champions could collectively review video clips before the meeting and identify key discussion points that should be emphasized during the meeting.
- NCEH/ATSDR should provide the BSC with e-mail notifications of upcoming EPH events. Depending on their interest, the members could either attend the events or request presentations on these topics during BSC meetings.

Dr. Portier made several remarks in response to the discussion on the format of BSC meetings. The BSC asked for advance presentations and focused questions during a previous meeting, but NCEH/ATSDR was unable to accommodate this request for the current meeting. As a result, Dr. Portier would engage OD senior management in a critical discussion on strategies to

provide the BSC with presentations and focused questions in advance of meetings. He was particularly interested in and would explore the suggestion to distribute video clips of presentations to the BSC in advance of meetings.

Dr. Portier explained that he would attempt to resolve issues related to pre-meeting materials because an NCEH/ATSDR program review would be scheduled for the next BSC meeting. Because program reviews require extensive time and effort, he was aware that the BSC would need video clips of presentations, focused questions and other materials well in advance in order to complete this task during the 1.5-day meeting.

Dr. Portier reiterated that the draft NCEH/ATSDR strategic plan would be distributed to the BSC for review and comment before the document was released for public comment and finalized.

## **Closing Session**

Dr. Portier thanked the BSC for continuing to provide NCEH/ATSDR with valuable and helpful suggestions to improve CDC's EPH portfolio for the nation.

The participants joined Dr. Kapil in applauding Ms. Sandra Malcom (NCEH/ATSDR BSC Executive Coordinator) and Ms. Shirley Little for their outstanding efforts in overseeing the logistics, making travel arrangements and performing the necessary administrative functions for the BSC meeting.

With no further discussion or business brought before the BSC, Dr. Burgess adjourned the meeting at 11:31 a.m. on October 17, 2012.

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

Date

Paula Burgess, MD, MPH Acting Chair, Board of Scientific Counselors