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
May 18-19, 2011
Atlanta, Georgia

Record of the Proceedings

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List of Participants

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Mr. Daniel Kass
Dr. Michelle Kegler
Dr. Michael Kleinman
Dr. Shannon Marquez
Hon. Gerard Scannell
Dr. Marie Swanson
Dr. Andrea Kidd Taylor
[via conference call]
Dr. Sacoby Wilson

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(U.S. Department of Energy)
Dr. Kristina Thayer (National Toxicology Program, National Institute of Environmental Health Sciences)
Dr. Hal Zenick
(U.S. Environmental Protection Agency)

Designated Federal Official
Dr. Vikas ("Vik") Kapil, Chief Medical Officer, Associate Director for Science, NCEH/ATSDR

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Cassandra Smith
Anne Sowell
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Jana Telfer

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Clement Welsh
John Wheeler
Pamela Wigington
Lynn Wilder
David Williamson
Rachel Worley

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Vincent Cogliano (U.S. Environmental Protection Agency)
Danielle Hunt (Epidemiology International)
Elizabeth Matovinovic (Griffith University)
Michael Samuhel (Social and Scientific Systems, Inc.)

ATTACHMENT 2

Glossary of Acronyms

ALS	Amyotrophic Lateral Sclerosis
APHA	American Public Health Association
APRHB	Air Pollution and Respiratory Health Branch
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
BLLs	Blood Lead Levels
BMD	Benchmark Dose
BMDL	Benchmark Dose Lower Bound
BMR	Benchmark Response
BRFSS	Behavioral Risk Factor Surveillance System
BSC	Board of Scientific Counselors
CBPR	Community-Based Participatory Research
CCP	Climate Change Program
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CPSC	Consumer Products Safety Commission
CRSCI	Climate Ready States and Cities Initiative
DGMQ	Division of Global Migration and Quarantine
DHAC	Division of Health Assessment and Consultation
DHS	Division of Health Studies
DHS	Department of Homeland Security
DLS	Division of Laboratory Sciences
DOE	Department of Energy
DRO	Division of Regional Operations
DTEM	Division of Toxicology and Environmental Medicine
EEHS	Division of Emergency and Environmental Health Services
EHHE	Division of Environmental Hazards and Health Effects
EHS-Net	Environmental Health Specialists Network
EHTB	Environmental Health Tracking Branch
EI	Exposure Investigation
EOC	Emergency Operations Center
EP	Emergency Preparedness
EPA	U.S. Environmental Protection Agency
EPH	Environmental Public Health
GAO	U.S. Government Accountability Office
GIS	Geographic Information Systems
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCDI	Healthy Community Design Initiative
HGVs	Health Guidance Values
HHS	Department of Health and Human Services
HIAs	Health Impact Assessments
HISA	Highly Influential Scientific Assessment
HUD	U.S. Department of Housing and Urban Development
IARC	International Agency for Research on Cancer

IRIS	Integrated Risk Information System
ISI	Influential Scientific Information
IT	Information Technology
JIC	Joint Information Center
KI	Potassium Iodide
LOAEL	Lowest Observed Adverse Effect Level
MMWR	*Morbidity and Mortality Weekly Report*
MRL	Minimum Risk Level
NACCHO	National Association of County and City Health Officials
NAHAs	Nerve Agent Hemoglobin Adducts
NCEH/ATSDR	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NHANES	National Health and Nutrition Examination Survey
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NPL	National Priorities List
NRC	Nuclear Regulatory Commission
NTP	National Toxicology Program
OD	Office of the Director
OHAT	Office of Health Assessment and Translation
PAHs	Polycyclic Aromatic Hydrocarbons
PBDEs	Polybrominated Diphenyl Ethers
PEHSUs	Pediatric Environmental Health Specialty Units
PHA	Public Health Assessment
POD	Point of Departure
PPACA	Patient Protection and Affordable Care Act
PUFAs	Polyunsaturated Fatty Acids
PwC	PricewaterhouseCoopers
SARA	Superfund Amendments and Reauthorization Act
SCHIP	State Children's Health Insurance Program
USGS	U.S. Geological Survey
VOCs	Volatile Organic Chemicals
VSP	Vessel Sanitation Program
WHO	World Health Organization

EXECUTIVE SUMMARY

The 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 May 18-19, 2011 in Atlanta, Georgia.

During the opening session, the BSC Chair welcomed the new BSC members who were in attendance. The participants applauded three outgoing BSC members whose terms would expire in June 2011 for their outstanding service to NCEH/ATSDR and contributions to the broader environmental health community.

In accordance with Federal Advisory Committee Act regulations, the BSC Chair confirmed the presence of a quorum on both days of the meeting, asked the voting members to be mindful of real or perceived conflicts of interest, and called for public comment at all times noted on the agenda published for the May 18-19, 2011 BSC meeting.

The NCEH/ATSDR Director presented a comprehensive report that covered the following areas:

- recent activities conducted by NCEH/ATSDR at the level of the Office of the Director (OD);
- highlights of recent activities conducted by NCEH and ATSDR programs;
- the NCEH and ATSDR FY2011 and FY2012 budgets;
- findings and recommendations from two assessments that were designed to (1) evaluate scientific policies and practices guiding ATSDR's site activities and (2) evaluate ATSDR's organizational structure in terms of its function, structure and programs; and
- the new Request-Track System to provide high-level knowledge to NCEH/ATSDR OD in real time for all work requests and projects to facilitate informed input by OD.

A panel of NCEH Division of Environmental Hazards and Health Effects (EHHE) leadership presented comprehensive responses to the peer review of three EHHE programs that the BSC conducted in October 2010. The Acting Chief of the Environmental Health Tracking Branch, the Chief of the Air Pollution and Respiratory Health Branch, and the Associate Director of the Climate Change Program gave point-by-point responses to each of the BSC's peer review recommendations.

A Senior Scientist in the NCEH/ATSDR Office of Science presented a comprehensive overview of NCEH/ATSDR's modified and new clearance, external peer review and priority-setting policies to assure quality in science.

The NCEH/ATSDR Associate Director for Program Development presented an update on progress to date and next steps to advance the National Conversation on Public Health and Chemical Exposures. The Director of the NCEH Division of Laboratory Sciences made several remarks in response to the BSC's suggestions on the biomonitoring recommendations in the National Conversation Action Agenda.

The Director of the ATSDR Division of Toxicology and Environmental Medicine proposed an approach to modify ATSDR's existing process to evaluate the quality of studies to include in ToxProfiles. Data sources that ATSDR reviewed and considered in modifying its existing study

quality assessment process were highlighted in the overview. ATSDR requested the BSC's input on three questions: (1) Is ATSDR's proposed approach defensible? (2) Does ATSDR's proposed approach have "built-in" biases? (3) Is the BSC aware of alternative approaches that are available to assess the quality of studies?

The BSC Federal Expert Member for the National Institute of Environmental Health Sciences (NIEHS) presented an overview of ongoing efforts to improve its existing study quality assessment process for better transparency, consistency and clarity. NIEHS is currently collaborating with ATSDR on a Study Quality Workgroup and the development of a data extraction model. However, the long-term goal is to harmonize study quality assessment methods across all HHS agencies up to the point of hazard identification.

To assist in achieving this goal, NIEHS will sponsor three events with representation by CDC, other federal agencies and experts in the field: (1) a workshop to evaluate experimental animal data and human observational studies using a variety of approaches; (2) a public meeting in the fall of 2011 to compare approaches for study quality assessment; and (3) a meeting in the spring of 2012 to apply the recommended approach to a collection of animal, human and mechanistic studies for a weight of evidence/level of concern case study.

The NCEH/ATSDR Director proposed an experimental approach to evaluate mixtures at sites and include these data in ATSDR's ToxProfiles. The presentation included the mathematical equation of the methodology; results of an experiment using the methodology in 23 completed ToxProfiles; and an example of applying the methodology to a mixture of cadmium, uranium and barium salts.

The NCEH/ATSDR Chief Medical Officer and Associate Director for Science described NCEH/ ATSDR's leadership role in CDC's response to an earthquake, tsunami and radiation release in Japan that occurred on March 11, 2011. NCEH/ATSDR partnered with numerous federal, state and territorial agencies and professional organizations to provide expertise in several important areas: radiation health, food safety, border protection, worker exposures, risk assessment and communication, public health messaging, emergency response, surveillance and monitoring, laboratory assessment capacity with radionuclide screening, and countermeasures.

NCEH/ATSDR is currently developing CDC's after-incident report of its response to the tragedy in Japan. The report will be submitted to the HHS Secretary in June 2011 and will highlight important public health issues, communication strategies and lessons learned from the Japan response to improve domestic preparedness. The HHS Secretary will use CDC's report as a foundation to closely collaborate with other federal agencies in creating and implementing a U.S. government preparedness plan.

The Chief of the CDC Healthy Homes/Lead Poisoning Prevention Branch joined the meeting to present an overview of CDC's healthy homes portfolio. During the presentation, the BSC received answers to its questions on (1) CDC's interagency collaborations with the U.S. Environmental Protection Agency and the U.S. Department of Housing and Urban Development on healthy homes issues; (2) the focus on healthy school environments and weatherization issues in CDC's individual healthy homes portfolio or its joint efforts with other agencies; and (3) implications of the FY2012 budget cut on CDC's future healthy homes projects and research.

During its open discussion, the BSC provided commentary on the need to increase public participation at future meetings, the length of future meetings (e.g., 1.5 versus 2 full days), and future agenda items.

NCEH/ATSDR leadership and program staff thanked the BSC for providing extensive input and suggestions to NCEH/ATSDR on all of the overviews and presentations over the course of the meeting. NCEH/ATSDR emphasized that the BSC's expertise would continue to be valuable in strengthening CDC's portfolio of environmental public health activities, projects and research.

The BSC acknowledged that NCEH/ATSDR would call for its formal vote and solicit its approval during a future meeting to proceed on two agenda items: (1) ATSDR's proposed approach to assess the quality of studies to include in ToxProfiles and (2) ATSDR's proposed approach to evaluate mixtures at sites and include these data in ToxProfiles.

The BSC Chair announced that the next meeting would be held in either the last two weeks in October 2011 or the first week in November 2011. The Office of Science staff would poll the BSC members, Designated Federal Official and NCEH/ATSDR Director by e-mail to determine their availability and confirm the date.

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BOARD OF SCIENTIFIC COUNSELORS
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Minutes of the Meeting

The 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 May 18-19, 2011 in Building 106 of the CDC Chamblee Campus in Atlanta, Georgia.

Opening Session: May 18, 2011

Dr. Timothy Ryan, Chair of the BSC, confirmed the presence of a quorum and called the meeting to order at 8:32 a.m. on May 18, 2011. He welcomed the participants to the meeting and particularly recognized the new BSC members who were in attendance:

- Daniel Kass, MSPH; Deputy Commissioner, New York City Department of Health and Mental Hygiene, Division of Environmental Health
- Michael Kleinman, PhD; Professor of Occupational and Environmental Medicine, University of California at Irvine, Department of Medicine
- Shannon Marquez, PhD, MEng; Associate Dean for Academic and Faculty Affairs in Mayes College, Chair, Department of Health Policy & Public Health, University of the Sciences in Philadelphia, College of Graduate Studies
- Sacoby Wilson, PhD, MS; Research Assistant Professor, University of South Carolina, Department of Epidemiology and Biostatistics

Dr. Ryan asked the BSC voting members to recuse themselves from participating in discussions or voting on issues scheduled on the May 18-19, 2011 agenda for which they had a real or perceived conflict of interest. Dr. Ryan opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Dr. Christopher Portier, Director of NCEH/ATSDR at CDC, joined Dr. Ryan in welcoming the participants to the BSC meeting. He thanked the BSC members for taking time from their busy

schedules to contribute their valuable expertise to NCEH/ATSDR. He announced that the terms of three BSC members would expire in June 2011:

- Anna Fan, PhD, DABT; Chief, Pesticide & Environmental Toxicology Branch, California EPA Office of Environmental Health Hazard Assessment
- Andrea Kidd Taylor, DrPH, MSPH; Assistant Professor, Morgan State University, School of Community Health and Policy
- Honorable Gerard Scannell

Dr. Portier presented a certificate of appreciation to Mr. Scannell who was in attendance. He confirmed that certificates of appreciation would be mailed to Drs. Fan and Kidd Taylor who were unable to attend the meeting. The participants joined Dr. Portier in applauding the three outgoing BSC members for their outstanding service to NCEH/ATSDR and their contributions to the broader environmental health community.

NCEH/ATSDR Director's Report

Christopher Portier, PhD
Director, NCEH/ATSDR
Centers for Disease Control and Prevention

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

Office of the Director (OD) Update. NCEH/ATSDR provided 15 Congressional briefings from October 2010 to May 2011. The Camp Lejeune, North Carolina site and short-/long-term health effects from contaminated drywall accounted for topics at nine of the briefings. The remaining six briefings focused on the Vieques, Puerto Rico site, uranium contamination, safe drinking water, the Endicott, New York site, the FY2012 ATSDR budget, and asthma, lead poisoning prevention and healthy homes issues. NCEH/ATSDR is currently completing its final review of a new report on the Vieques site. An update on this issue will be placed on the agenda of the next BSC meeting.

NCEH/ATSDR served as the lead incident commander for CDC's response to the Fukushima Nuclear Power Plant incident and the earthquake that caused the tsunami. NCEH/ATSDR assigned >100 staff to various aspects of the response. Public health protective action guidance was provided on potassium iodide, passenger and cargo screening, and air, food and water contamination. Extensive public health communication materials were developed. Consultation was provided to HHS, the White House, Nuclear Regulatory Commission (NRC), State Department, Government of Japan and a number of other groups.

Urine samples were analyzed for radionuclides, including cesium-134, cesium-137 and iodine-131, among Department of Energy (DOE) employees returning from Japan. Unique urine methods for radionuclides of concern were provided to several state public health laboratories. Urine collection instructions and supplies were provided to the offices of all 50 state Conference

of Radiation Control Program Directors in collaboration with Customs and Border Patrol screening of returning U.S. citizens.

The Consumer Products Safety Commission (CPSC) is the lead agency for the federal effort to address contaminated drywall, but NCEH/ATSDR has extensive involvement in this issue. ATSDR provided technical support to CPSC; assisted the U.S. Environmental Protection Agency (EPA) and state health departments with the development of air sampling plans; and helped CPSC, EPA, state health departments and other groups to interpret data.

ATSDR-/EPA-funded Pediatric Environmental Health Specialty Units (PEHSUs) provided clinical guidance. ATSDR began the public health assessment (PHA) process on contaminated drywall by reviewing data on emission rates from drywall and conducting modeling to predict potential short-/long-term health effects from levels of hydrogen sulfide and other gases in homes. NCEH continues to represent CDC on the Federal Drywall Task Force.

NCEH/ATSDR has consistently delivered messages to emphasize that contaminated drywall is a safety hazard and should be remediated. NCEH/ATSDR intends to analyze the potential long-term health effects of contaminated drywall because many property owners cannot afford to remediate this hazard. NCEH/ATSDR released a number of publications over the past few months.

A new Environmental Public Health Partnership Group was established and will report directly to NCEH/ATSDR OD. The overarching goals of this group are to inform and support national environmental public health (EPH) policies; create dialogue between NCEH/ATSDR and its partners; and increase collaboration among stakeholders at the national level.

The specific role of the EPH Partnership Group is to discuss and determine new directions for EPH research with NCEH/ATSDR OD, increase the effectiveness of NCEH/ATSDR's EPH agenda, strengthen the influence of external partners and coalitions on CDC's EPH portfolio, identify potential resources to support new EPH research, and raise awareness of EPH issues throughout the nation. The EPH Partnership Group will compliment and coordinate efforts with the National Conversation on Public Health and Chemical Exposures.

The American Public Health Association is coordinating this effort and contracted RESOLVE to oversee consensus-building activities within organizations. The Planning Committee will conduct several activities during the summer of 2011 to advance the EPH Partnership Group. Key informant interviews will be held to obtain input on EPH issues that are most critical to the United States. An environmental scan will be performed to identify EPH issues that are most relevant to stakeholders. The development of a strategic plan for the EPH Partnership Group will be initiated. Meetings will be convened with the Steering Committee and the full EPH Partnership Group.

ATSDR Program Highlights. The Division of Health Assessment and Consultation (DHAC) investigated chemical exposures at two sites. The purpose of the exposure investigation (EI) at the Corpus Christi, Texas site was to measure current exposures to benzene and related petroleum volatile organic chemicals (VOCs) in residents living near refinery row. Personal air,

blood and urine samples were collected, analyzed and compared to National Health and Nutrition Examination Survey (NHANES) reference values.

Extremely high levels of VOCs detected at the site by Texas A&M University were of considerable concern to the community. However, the DHAC EI found that exposures to benzene and other VOCs among refinery row residents were not higher than those of the general U.S. population.

DHAC acknowledged two key limitations of the Corpus Christi EI. The conclusions were limited to the narrow period of time when the EI was conducted. The small sample of ~100 participants may not be representative of the remainder of the community. DHAC held a town hall meeting to communicate the findings of the Corpus Christi EI to the community and released the results to the broader public in January 2011. DHAC is continuing to investigate health disparities between the Corpus Christi site and other parts of Texas.

DHAC conducted a health investigation of the Saufley C&D Landfill in Escambia County, Florida. The investigation included environmental and personal sampling for hydrogen sulfide gas and environmental sampling for particulate matter. DHAC collaborated with NCEH, EPA and the Florida Department of Health to provide an EIS officer, technical assistance and training for the health investigation. A community respiratory health survey was administered at the site.

DHAC was able to fully fund 28 supporting state programs with grants totaling ~$10.2 million to assist in the evaluation of sites. DHAC is extremely proud of the activities conducted by ~100 state environmental health professionals in the field.

DHAC directly collaborated with communities on several activities. At the Mossville, Louisiana site, DHAC facilitated the development of a joint interagency/community “Access to Healthcare Steering Committee” in partnership with the Health Resources and Services Administration. The purpose of this initiative is to provide guidance to the Mossville community in establishing a Federally Qualified Health Center at the site to decrease health disparities associated with environmental exposures.

NCEH/ATSDR jointly developed and provided training to community health representatives of the Navajo Nation to build capacity in delivering health study results within their communities. Training materials were created to improve the ability of NCEH/ATSDR staff and cooperative agreement partners to collaborate with tribal governments. DHAC distributed geographic information systems (GIS) data on Superfund and environmental justice sites to characterize healthcare access issues across the nation.

The Division of Health Studies (DHS) launched the National Amyotrophic Lateral Sclerosis (ALS) Registry in October 2010 as a secure web portal to facilitate self-registration of all ALS patients, particularly those not enrolled in a national administrative database. The major objectives of the ALS Registry are to (1) estimate the number of new ALS cases identified each year; (2) estimate the number of persons who have ALS at a specific point in time; and (3) better understand persons who develop ALS and specific factors that affect the disease.

Of 3,520 individuals who enrolled in the ALS Registry as of May 12, 2011, 2,877 (or 81.8%) were ALS patients. To date, >7,800 risk factor surveys have been completed and returned to ATSDR and >16,000 patients were identified in 2001-2005 administrative databases.

DHS is launching new studies and services. Beginning in early June 2011, DHS will mail questionnaires on contaminated water from chemicals for the Camp Lejeune, North Carolina Health Survey and Morbidity Study. The health survey is expected to cover ~250,000 persons. Health effects of Camp Lejeune residents will be compared to those of Marines at Camp Pendleton, California. Chemicals in the water supply will be modeled on a month-by-month basis during the study period to determine dose-responses.

ATSDR received $23 million from the Patient Protection and Affordable Care Act (PPACA) to address health effects at any site declared as an EPH emergency by the Administrator of EPA with agreement from the Director of CDC. Of these dollars, DHS was awarded a four-year $10 million grant to screen for pulmonary health effects related to asbestos and asbestos-like materials from long-term mining at the Libby, Montana site. Residents found with pulmonary health effects will be referred to Medicaid services for follow-up, treatment and care. DHS estimates that 10,000 persons are eligible for screening to determine their Medicare eligibility.

The Division of Regional Operations (DRO), EPA and a number of other partners launched an urban land reuse event in April 2011 to provide safe access to quality food. The Philadelphia Soil Kitchen is a new, unique and temporary art and educational installation that served as the location for the event. EPA provided free testing of soil samples from local areas for lead and arsenic. Other attractions included free soup and outreach on sustainability to 1,400 visitors to the Philadelphia Soil Kitchen over the six-day period. Due to the success and popularity of this event, DRO and its partners are exploring the possibility of sponsoring similar Soil Kitchens in the future.

The Division of Toxicology and Environmental Medicine (DTEM) released an updated and peer-reviewed ToxProfile on uranium for public comment. The updated ToxProfile reflects the latest scientific literature on chemical and radiological effects from uranium exposure. DTEM made a presentation to a special panel on “Strengthening Environmental Justice and Decision-Making.” DTEM assisted the special panel in establishing a foundation to incorporate psychosocial data into environmental policy.

DTEM is continuing its efforts to enhance and strengthen professional education. A new interactive and multimedia continuing education module was designed as an e-learning course to encourage use of the new ALS Registry. To date, 89 health professionals have obtained continuing education from the ALS e-learning course and 15,733 online page views have been recorded.

NCEH Program Highlights. The Division of Emergency and Environmental Health Services (EEHS) released a number of major publications to support public health. *Safety and Health in Manufactured Structures* identifies and summarizes safety and health issues in manufactured structures. *A Healthy Home for Everyone: The Guide for Families and Individuals* provides information about the linkage between housing and health.

Healthy Homes Manual: Smoke-Free Policies in Multiunit Housing is targeted to state and local Healthy Homes Programs that are taking actions to reduce exposure to secondhand smoke in multi-unit housing. The U.S. Department of Housing and Urban Development (HUD) is currently exploring the feasibility of developing and enforcing a rule to prohibit smoking inside of multi-unit public housing buildings. EEHS is partnering with other parts of CDC and HUD to identify the societal benefits of the new policy and determine its cost-effectiveness in terms of saving lives and impacting health.

EEHS is advancing restaurant food safety through its Environmental Health Specialists Network (EHS-Net). EHS-Net published a 2011 study in the *Journal of Food Protection* that identified factors associated with workers who continue to work while ill with vomiting or diarrhea. The study found that the implementation of policies to encourage workers to inform managers of their gastrointestinal illnesses could reduce the number of workers who work while ill.

EEHS conducted several activities to promote healthy community design. A pilot program was launched to train 175 health professionals in Oregon on conducting, interpreting and utilizing health impact assessments (HIAs) to inform decision-making processes. The pilot program resulted in three local HIAs and one state-level HIA that influenced changes in state legislation.

EEHS issued the second edition of the *Walking and Biking Benchmark Report*. The report reflects a compilation and analysis of data on bicycling and walking in all 50 states and the 50 most populated U.S. cities. EEHS partnered with EPA to implement components of the National Environmental Policy Act to promote health through improved design of land-use projects.

EEHS led CDC's investigation of acute lead poisoning from ore processing activities among children in Zamfara State, Nigeria. CDC Headquarters staff administered a house-to-house survey and collected and analyzed blood and soil samples to fully characterize villages known to have lead contamination. This initiative is designed to ensure that CDC's past and current activities are effective in addressing childhood lead poisoning in Zamfara State.

EEHS published the *Vessel Sanitation Program 2011 Construction Guidelines*. The document provides consistent construction and design guidance to protect the health of the crew and passengers. EEHS held five public meetings in 2008-2010 with the cruise industry to obtain input on the 2011 guidelines. EEHS published the *Vessel Sanitation Program 2011 Operations Manual*. The document provides guidance on program operations and inspections. EEHS held four public meetings in 2009-2010 with the cruise industry to obtain input on the 2011 guidelines.

EEHS recently administered a survey that showed its guidance documents have played a critical role in the dramatic improvement of vessel safety over the last two years and the significant increase in inspection scores of cruise ships over the past 21 years. EEHS will complete ~255 cruise ship inspections in FY2011 and has trained ~330 cruise ship supervisory staff to date.

The Division of Environmental Hazards and Health Effects (EHHE) recently held a press briefing to announce the May 3, 2011 release of *Asthma Vital Signs* in conjunction with World Asthma Day. The document is published in the *Morbidity and Mortality Weekly Report* (*MMWR*) and

also is available online at www.cdc.gov/vitalsigns. The document reported that 24.6 million persons in the United States have asthma. In 2007, asthma accounted for 3,447 deaths and a total annual cost of $56 billion, including medical costs and lost work time for asthma-related events of workers or their children.

The document further reported that the current prevalence of asthma is higher among children than adults, boys than girls, women then men, African Americans than whites, and persons with incomes below the federal poverty level. CDC data showed that the prevalence of asthma trended upward in 2001-2009 among all demographic groups. However, African Americans accounted for higher attack rates, hospitalizations and deaths from asthma compared to whites.

The document described the significant burden, disparities and costs of asthma. The asthma prevalence increased from 7.3% in 2001 to 8.2% in 2009. Of 24.6 million persons in the United States with asthma, 5 million are below poverty line. Of all children with asthma in the United States, African American children account for 16% of the burden compared to 8% of white children. Of the $56 billion total annual cost for asthma, Medicaid pays $8 billion per year for children only.

CDC is the only agency that builds state and local capacity to address the U.S. asthma burden. CDC's policies support state asthma coalitions. CDC collaborates with state partners to promote and implement a variety of effective and cost-effective interventions to reduce asthma costs and decrease the incidence of asthma in the United States. The majority of these interventions are targeted to patients who routinely report to emergency departments for asthma treatment and care. CDC's surveillance systems are designed to document the burden of asthma across the United States. CDC rigorously evaluates its asthma activities to disseminate best practices.

The Division of Laboratory Studies (DLS) developed a cook-stove intervention to reduce exposure to polycyclic aromatic hydrocarbons (PAHs) in Peru. DLS published a study that showed >50% of the global population uses coal and biomass fuels for cooking and energy. Indoor air pollution from solid fuels is among the top ten causes of morbidity and mortality worldwide. Based on measurements of excreted urinary metabolites pre-/post-installation, the study concluded that the installation of improved stoves with chimneys in the homes of Peruvian women reduced exposures to PAHs and other harmful air pollutants by 17%-41%.

DLS conducted a study that suggested young children, particularly those 4-6 years of age, may receive higher exposures to polybrominated diphenyl ethers (PBDEs) compared to adults. PBDEs are flame retardants that are present in numerous products and are emitted into the environment over a long period of time. The study found that serum levels of PBDEs increased with age from newborns to children 4-6 years of age and then decreased with increasing age. The study reported substantial mother-to-child transmission of PBDEs.

DLS recently developed methods to increase the efficiency of its laboratories. Nerve agent hemoglobin adducts (NAHAs) are excellent for detecting exposure to bioterrorism agents. However, NAHAs present a challenge in measuring exposures to individuals and large populations in real time and providing public health officials with accurate information to inform their decision-making during emergencies. DLS improved its automation procedures for NAHAs

and increased the sample analysis throughput from 10 to 200 per analysis per day for rapid responses.

DLS developed a novel analytical method with urinary phytoestrogens to conduct a complete analysis and measure the impact of dietary estrogen-mimicking compounds in human populations. The novel method has much better analytical sensitivity and sample throughput and also has the ability to measure compounds in smaller amounts. Moreover, the method will provide a basis for further epidemiological studies and sampling to inform the development of future editions of the CDC *National Report on Human Exposure to Environmental Chemicals*.

DLS developed a technique to measure individual plasma polyunsaturated fatty acids (PUFAs) in the U.S. population. The goal of DLS's method is three-fold: (1) determine if Food and Drug Administration labeling helped to reduce PUFAs in the blood of persons in the United States; (2) determine if the New York City intervention to reduce PUFAs had an impact; and (3) determine if additional research is needed in this area. PUFAs are associated with cardiovascular and other diseases.

DLS used 2003-2004 NHANES data from adults to create a high throughput isotope-dilution gas chromatography-mass spectroscopy method that allowed individual quantification of 10 PUFAs and the percent of total fatty acids. The DLS method was used to analyze the relationship between PUFA concentrations in plasma and health effects in humans for the first time. DLS is now applying the PUFA method to compare the 2003-2004 data to more recent NHANES data. The DLS method is an exciting technique that will play a critical role in advancing new areas in medical science and interventions to better understand the role of PUFAs.

FY2011 and FY2012 Budgets. The FY2011 budget reflects challenges in the current economic climate that will require CDC to change its operations to be more efficient and effective. At the agency level, CDC's budget of ~$6 billion was substantially reduced by $740 million in FY2011. At the National Center level, decreased funding levels in NCEH's budget will result in significant changes for CDC's EPH programs.

In comparing NCEH's FY2010 and FY2011 budgets, funding for environmental health activities decreased by ~$5 million, while funding for the Environmental Health Laboratory remained flat. Funding for the Asthma and Healthy Homes/Lead Programs collectively was ~$70 million in FY2010. The President's FY2012 budget requests funding of ~$35 million for NCEH's Healthy Homes and Community Environment Programs.

The overall decrease of ~$46 million between NCEH's FY2010 and FY2011 budgets included reductions of ~$36 million for environmental health activities, ~$5.5 million for the Healthy Homes/Lead Program, ~$3.5 million for the Asthma Program, and $791,000 for the Environmental Health Laboratory. The substantial reduction of ~$36 million for environmental health activities was due to the shift of $35 million for the EPH Tracking Program to the PPACA Prevention and Public Health Fund.

NCEH leadership is currently addressing problems associated with combining the Asthma and Healthy Homes/Lead Programs, while maintaining the cost-effectiveness, cost-savings and efficiency of the individual programs in the newly combined structure. The National Asthma

Control Program has generated a significant return on CDC's investment in asthma prevention and control despite the 12.3% increase in the incidence of asthma in the United States.

In 2008, the Asthma Program prevented 1.7 million asthma attacks, 1,470 asthma-related deaths, and 245,000 hospitalizations that resulted in healthcare cost-savings of $3.7 billion. Economic data show that for every $1 spent, asthma interventions can save up to $35 in healthcare costs and workdays lost.

The Healthy Homes/Lead Poisoning Prevention Program has generated a significant return on CDC's investment in eliminating childhood lead poisoning and addressing other home-related hazards. The economic benefit of preventing lead exposure over the past 10 years is estimated to be $18.6 billion.

NHANES data show that the percentage of children 1-5 years of age with blood lead levels (BLLs) ≥10 µg/dL sharply declined from 88.2% in 1980 to 0.9% in 2008. Significant reductions in risks for elevated BLLs by race and socioeconomic status also were reported. The CDC Healthy Homes/Lead Program contributed to the increase of comprehensive lead poisoning prevention laws from five states in 1990 from to 23 states in 2010.

Similar to the NCEH Asthma and Healthy Homes/Lead Programs, ATSDR also has generated a significant return on the federal investment in preventing and identifying chemical exposures. Over the past two years, ATSDR investigated 116 sites that posed health hazards in the United States.

In addition to the 116 site investigations, ATSDR ensured safe water for 44,948 at-risk persons at 24 sites; reduced or mitigated air emissions for 325,172 at-risk persons at 45 states; prevented or mitigated exposures to contaminated soils for 716,258 at-risk persons at 50 sites; and provided emergency assistance for 54 acute chemical releases across the country.

CDC developed an agency-wide strategy to address challenges related to the decreased FY2012 budget. The goals of this strategy are to maximize health impact, address emerging threats and opportunities, maximize efficiencies, make difficult choices that will affect state partners and current public health activities, and remain attuned to the overall context. The overarching objectives of CDC's FY2012 strategy are to obtain the most health value for the health dollar and maximize the return on investment for each program.

The NCEH budget decreased from $181 million in FY2010 to ~$170 million in FY2011. The NCEH funding level will further decrease to ~$138 million in FY2012 if Congress approves the President's budget request. The ATSDR budget of ~$76 million has remained relatively flat from FY2010 to FY2012. The budgets of other CDC National Centers decreased from FY2010 to FY2012, but a few organizational units had increased funding levels over the same period of time due to a shift to the PPACA Prevention Fund.

Organizational Assessments. NCEH/ATSDR funded two assessments to evaluate ATSDR's organizational structure. Assessment 1 was conducted by Dr. Susan Klitzman, Professor, City University of New York Graduate Center. The assessment focused on scientific policies and practices that guide ATSDR's site activities.

Dr. Klitzman held interviews with ATSDR senior science leadership, BSC members, National Conversation leaders and other influential partners. She also reviewed relevant documents, including ATSDR's policies, procedures, protocols and completed scientific documents (e.g., EIs, PHAs, public health consultations and health studies).

Dr. Klitzman made several observations that were characteristic of ATSDR's site activities. Some activities were found to be reactive due to ATSDR's agenda being driven by external players rather than the best EPH priorities, practices and policies. Some activities were found to be "high stakes" or "high profile" that resulted in competing agendas of stakeholders, media and political interest or strong public scrutiny.

ATSDR's ability to collect data was found to be sharply limited due to its practice of relying on data from other groups and constructing theoretical risk assessments to estimate exposures and health effects. Dr. Portier has prioritized exposure assessments and set aside dollars in the FY2011 and FY2012 budgets for this site activity. Moreover, ATSDR's strong partnerships with EPA and state programs in conducting exposure assessments will be maintained.

Dr. Klitzman identified a number of challenges with ATSDR's scientific practices. The historical challenges include political and legal controversies about ATSDR's role and relationships with other agencies, unrealistic mandates and expectations from external stakeholders, criticisms about PHAs, reliance on existing data, and limited ability to collect new data.

The current challenges include ATSDR's flat budget over the past 15 years and confusion about policies and procedures due to the transition to new leadership. The 2009 BSC peer review of ATSDR found an inconsistent quality of peer reviews, deficiencies in the tracking system, and a lack of metrics to determine effectiveness. The 2010 U.S. Government Accountability Office (GAO) review of ATSDR found a lack of managerial oversight and inconsistent peer review policies.

Dr. Klitzman concluded that ATSDR scientists are held to the highest scientific and ethical standards, have a wealth of scientific expertise, and are nationally recognized well-published experts. ATSDR's challenges were not found to be a matter of scientific integrity. Dr. Klitzman identified a "misalignment between scientific knowledge and methods, the agency's mission and resources, and external stakeholders' expectations."

Dr. Klitzman's key recommendations are summarized as follows. ATSDR should establish both agency-wide and site-specific priority setting and planning processes. NCEH/ATSDR OD should increase its management and oversight of projects. Communications should be improved by clarifying the internal role of ATSDR scientists and staff, implementing systems to better support information exchange, increasing engagement of external stakeholders, and strengthening site assessments. Best practices should be compiled and broadly disseminated. Training should be offered to improve the peer review and clearance processes. A rigorous evaluation with strong scientific metrics should be conducted after the recommendations have been implemented.

Assessment 2 was conducted by PricewaterhouseCoopers (PwC) to evaluate and document ATSDR's organizational structure in terms of its function, structure and programs. PwC offered several organizational design options, developed a framework for managing results, and made recommendations about possible areas for improvement in ATSDR.

PwC reported its initial findings to NCEH/ATSDR OD in February 2011. ATSDR's strengths and core competencies include its unique community focus, toxicological products, scientific and technical skills, emergency response capability, and strong passion for environmental health. ATSDR's major challenges include various interpretations of its Congressional mandate, less external advocacy and support than other public health agencies, confusion about strategic objectives, and a lack of clear accountability for ownership of projects, performance and results.

PwC made observations on ATSDR's organizational structure in several areas. The absence of a formal strategic plan has created difficulty in balancing functions and allowed for confusion about ATSDR's future direction. Confusion about ATSDR's core services had created difficulty in articulating the worth of the agency. Persistent residual effects of past changes has resulted in an "antibody to change" among staff.

ATSDR's current structure is not optimal to support its mission and has created difficulty in meeting mandated obligations. The lack of consistency in oversight and input has resulted in less effective decision-making. Limited understanding of ATSDR's role among external partners has led to missed opportunities for external advocacy.

The uneven nature of agency morale has fostered mistrust between leaders and staff. The perception of limited career opportunities has resulted in the potential for increased attrition. The lack of clarity in operating processes has created inefficiencies. The decentralized information structure has hindered capacity to effectively manage staff at every level. Fragmented data systems at division and branch levels have created redundancy and fostered a lack of coordination.

PwC's key recommendations are summarized as follows. ATSDR should engage in a formal strategic planning process to develop a strategic plan with a clear definition of its core strategy, vision, objectives and targets for the next five years. ATSDR should select a detailed organizational design that is linked to the strategic plan, has the capacity to clearly align its efforts and mission, and has the ability to drive productivity.

A human capital plan should be documented that illustrates current leadership and staff, training needs, retention of workforce and succession planning. Coaching and mentoring of staff should be increased. The selection of staff to conduct projects should be balanced. Operational processes should be changed to migrate from informal methods driven by experience. Procedures and support should be documented with job aids, templates and other tools. Core data management tools and systems should be identified to improve reporting. A "dashboard" system should be developed to facilitate management awareness of activities. Core tools should be simplified to eliminate redundancy.

Request-Track System. NCEH/ATSDR developed the new Request-Track system based on the findings and recommendations of the external Klitzman, PwC and GAO reviews. The

purpose of Request-Track is to provide high-level knowledge to NCEH/ATSDR OD in real time for all work requests and projects to facilitate informed input by OD. The objectives of the new system are to monitor and track all NCEH/ATSDR site activities and projects and ensure that OD and other leadership have knowledge and input into these initiatives.

NCEH/ATSDR will launch Request-Track on June 15, 2011. All NCEH/ATSDR employees will have access to enter projects into the system. Request-Track will provide acknowledgement of the project to the requesting program within 24 hours. ATSDR, NCEH and NCEH/ATSDR OD projects that meet one of the following conditions can be entered into Request-Track: at least 40 hours of work by one or more persons, a cost of "$X," site-related travel required, report by a national media outlet, request by Congress or state legislator, submission of a formal petition through the Superfund process, request for an environmental health Epi-Aid, approved NCEH Laboratory project, or ToxProfile information.

Request-Track will allow NCEH/ATSDR to conduct portfolio management and track all projects; facilitate a process to triage and prioritize incoming activities and projects; ensure entries are clear and appropriately coordinated; validate the establishment and achievement of timelines; and coordinate communications with stakeholders. NCEH/ATSDR is currently developing Request-Track processes to offer training to staff, obtain user feedback, modify the system over time as needed, add electronic notifications and automated functions, establish tracking milestones and develop reports.

Since the Klitzman, PwC and GAO reviews, NCEH/ATSDR has modified its internal peer review process, developed a new prioritization scheme for site activities, and refined its external peer review process. A detailed presentation was scheduled on the agenda to inform the BSC of NCEH/ATSDR's revised and new policies related to clearance, external peer review and priority setting. Dr. Portier concluded his Director's report by inviting the BSC to follow NCEH/ATSDR's activities on Twitter at CDC_DrCPortier.

Dr. Portier and Division leadership and staff provided additional details on CDC's EPH portfolio in response to the BSC's specific questions. The BSC's question and answer session with NCEH/ATSDR covered the following topics.

- NCEH's efforts to promote healthy community design at state and local levels through "complete streets" and other components of HIAs.
- NCEH's focus and future direction in new urbanism and environmental justice for healthy and sustainable communities.
- Widespread adoption and implementation of NCEH's Vessel Sanitation guidelines by the cruise ship industry.
- CDC's efforts to urge Medicaid to reimburse modest home interventions for asthma trigger controls as a component of clinical management.
- The need for NCEH/ATSDR to increase its focus on safe drinking water and unregulated drinking water systems, particularly to compliment the efforts of the NCEH Climate Change Program in this area.
- Coordination and harmonization of water quality initiatives between and among CDC, EPA and the U.S. Geological Survey (USGS).

- Communication and outreach strategies to widely publicize CDC's EPH portfolio to the general public.
- Potential risks associated with shifting funding for the NCEH EPH Tracking Network and other CDC programs to the Prevention Fund due to possible budget cuts of this funding source in the future.
- Broad promotion of effective interagency collaborations between NCEH/ATSDR and its federal partners on EPH issues.
- Evaluation of the efficacy of NCEH/ATSDR's new Request-Track system in the context of the added burden on staff.
- Improved education and communication to communities on ATSDR's role during site activities and potential health risks from environmental exposures.

The BSC thanked NCEH/ATSDR for clarifying a host of issues during the question and answer session, but some members had remaining concerns. For issue 1, the BSC members noted a potential disconnect between placement of the Asthma Program in NCEH and efforts to attract and sustain funding for the program. The BSC members raised this issue because the environment plays an important role in asthma triggers, but is not the primary focus of asthma interventions (e.g., medical management, identification of medical homes for persons with asthma, case management, and patient education to manage symptoms).

The BSC members acknowledged that Asthma Prevention and Control Programs at state and local levels typically interact with the medical community rather than the environmental health community to make a strong case on policies to influence outcomes. Solid evidence is reported in the literature that shows medical interventions are much more effective for asthma than environmental health interventions. The BSC members questioned CDC's rationale for placing the Asthma Program in NCEH rather than in the National Center for Chronic Disease Prevention and Health Promotion.

For issue 2, the BSC was pleased that NCEH is currently piloting seven projects to assess needs and gather existing data on unregulated drinking water systems. However, the BSC members noted that ~30% of the U.S. population still live in rural areas and do not have access to publicly regulated sewer and water infrastructure. The BSC members advised NCEH to focus on unregulated wells in rural areas in its seven pilot projects.

For issue 3, the BSC members appreciated and understood the need for NCEH/ATSDR to develop and implement the new Request-Track system to improve management and oversight of projects and to enhance coordination and communication of activities. However, the BSC members believed that the system could be burdensome and time-consuming from a staff perspective. The BSC members advised NCEH/ATSDR to collect data to guide a rigorous evaluation of Request-Track. The assessment should be designed to determine whether the system was worth the investment of staff time and effort and if the system impeded or interfered with important timelines.

During the discussion session, the BSC congratulated NCEH on its success in reducing the national burden of asthma through prevention and early treatment. The BSC was extremely impressed by the direct impact of the NCEH Asthma Program on decreasing asthma morbidity and mortality across the country in a cost-effective and efficient manner.

The BSC commended ATSDR in making strong efforts to address and resolve its historical and current challenges. The BSC was aware that unlike other public health agencies, ATSDR is in a difficult, unique and complex position of balancing its Congressional mandate to address the EPH needs of communities and stakeholders against political controversies, media scrutiny and public perceptions.

In direct response to Dr. Portier's Director's report, the BSC members made specific suggestions for NCEH/ATSDR to consider in its ongoing efforts to enhance and strengthen CDC's EPH portfolio.

- NCEH should distribute a completed HIA to the BSC for review. The BSC has a strong interest in healthy and sustainable communities and would welcome the opportunity to discuss and provide comments on an HIA during a future meeting.
- NCEH should ensure that social equity planning principles are incorporated into its healthy community design initiatives to place emphasis on access and improve knowledge of underlying built environment disparities in HIAs. Social equity planning principles would play an important role in ensuring that new or non-traditional populations receive the benefits of new development, urban revitalization and smart growth efforts.
- NCEH/ATSDR should place more emphasis on publicizing and presenting the scientific and public health significance of its activities in peer-reviewed journals and various media outlets targeted to the public. Effective outreach and communications strategies would increase public awareness and support of CDC's EPH portfolio.
- NCEH/ATSDR should collaborate with its federal partners to create a framework for agencies to have a solid interest, stake and investment in the programs of other agencies. Due to substantial budget cuts across the federal government, strong interagency partnerships are a critical need at this time to sustain vital programs.
- NCEH should link its newly combined Asthma and Healthy Homes/Lead Programs to activities conducted by HUD and the Department of Education to strengthen interagency collaboration, mobilize efforts with agencies that have overlapping missions and goals, and increase capacity to leverage resources at the federal level.
- ATSDR should develop a community outreach/education program to clearly define its role during site activities and address challenging sociopolitical issues in communities at the outset. ATSDR's interaction with multiple agencies historically has fostered mistrust in communities. This issue should be placed on a future agenda for the BSC's detailed discussion and guidance.

PROGRAM RESPONSE TO THE BSC PEER REVIEW OF THE NCEH DIVISION OF ENVIRONMENTAL HAZARDS AND HEALTH EFFECTS (EHHE)

A panel of EHHE leadership presented comprehensive responses to the peer review of three EHHE programs that the BSC conducted during the October 2010 meeting.

Response by the Environmental Health Tracking Branch (EHTB)

Len Flowers, MS
Acting Chief, Environmental Health Tracking Branch, NCEH/EHHE
Centers for Disease Control and Prevention

Ms. Flowers summarized the overall strengths and weaknesses the BSC identified during the peer review of EHTB. In terms of strengths, the BSC noted that the overall Tracking process is well defined, goal-oriented and executed reasonably well. The Tracking Network portal is operational with evidence of broad support and recognition. Very attractive interface and communication materials have been developed. The nice visual display is relatively easy to navigate. The commitment to continue to improve the interface is encouraging. EHTB's array of partners is impressive. EHTB has completed excellent work building the capacity of states to use environmental health data.

In terms of weaknesses, the BSC pointed out that the coverage of health effects needs to be expanded in the Tracking Network. Stronger linkages are needed to NHANES and USGS. The current design of the Tracking Network includes technologic functionality, but excludes scientific or epidemiologic functionality. The addition of data sources to the Tracking Network is somewhat slow at this time. Tracking Network data are not linked to national databases at this time. Analysis tools are needed to link more health conditions and better measures of environmental exposures.

Ms. Flowers presented EHTB's responses to the BSC's specific peer review recommendations. "EHTB is to be commended on building an EPH surveillance infrastructure that never before existed at CDC." EHTB responded that funding and support over the past nine years were instrumental in developing the Tracking Network at CDC and its 24 grantee partners. Efforts are ongoing at EHTB to add content, data updates and enhanced information technology (IT) functionality; increase utilization of data, including tools and linkages; and improve messaging and visualization of the content.

"Stronger efforts are needed to better envision and cultivate audiences for Tracking Network data portals, including the national one:

- The CDC national data portal should serve as the basis for delivering queriable data from a variety of CDC programs.
- The breadth of data in the portal is too narrow. Asthma, obesity, healthy homes, birth defects, NHANES, state biomonitoring data, climate-related illnesses, pesticides and community health should be included.
- The breadth of data in state portals is even narrower. EHTB should expect funded state health departments to develop state-specific indicators that ideally would be inclusive of some local indicators in addition to those at state and county levels.
- EHTB should quickly expand the Tracking Network to track and report indicators.
- Tracking activities should have a much closer relationship to NHANES environmental exposure work."

EHTB responded that five full-time health communications specialists strive to cultivate its audiences and partners. Efforts are underway to expand the Tracking venue for many CDC programs, including the addition of vital statistics, cancer registry, community design and climate change data. Additional data content is essential to the success of the Tracking Network. A great deal of progress has been made on the state portals since 2010. Asthma prevalence data and a community design module have been added since the BSC's peer review in October 2010.

A climate change module will be added in the summer of 2011 with an initial focus on heat events, heat-related mortality and factors that place populations at increased risk of heat-related health impacts. A developmental disabilities module will be added in the fall of 2011. New content is expected to be added at least twice per year. Pesticides, more water contaminants and an expansion of current hospitalization and emergency department data for other environmental health outcomes will be added in the future. Initiatives are ongoing with state grantees to gather data on private wells, radon and remote sensing.

NHANES biomonitoring data are being developed for use on the CDC National Portal. NHANES data are not the same geospatial context as other Tracking data, but provide baseline and benchmark data and begin to inform the conversation on biomonitoring data for environmental exposure assessment. Two academic partner projects are utilizing NHANES data to link air exposures and cardiovascular health outcomes.

"The original source of data should be displayed along with methods that were used to determine the selection of the data set and use of specific data." EHTB responded that the original source of data is currently available under links to indicator templates and links at the end of each content area. However, EHTB confirmed the data would be made more visible and accessible in the new IT platform.

"The data linkage abilities of the Tracking Network should be highlighted or improved." EHTB responded that this recommendation is the most critical next step for Tracking. The improved IT platform will better display multiple types of data. The next launch of the platform will include risk ratios linking temperature and mortality as a new indicator. Data for EPH professionals, the scientific community, policymakers and the public will be better visually linked.

"Collaborators of Tracking Network data should be identified." EHTB responded that this information is currently displayed in query notes, but additional locations will be explored to improve its visibility.

"Efforts should continue to be focused on making data available at the smallest geographic area possible. County-level data are often already available." EHTB responded that the new IT platform in 2011 allowed for improved data processing and displays, including census tracts, zip codes, and remote sensing or modeled grids for environmental health data at smaller geographic levels. However, the availability of health outcome data will remain at the county level due to confidentiality issues.

"More aggressive and rapid efforts should be made in adding data to the Tracking Network faster." EHTB responded that data are added to the site on a quarterly basis. Asthma

prevalence data and a community design module have been added since the BSC's peer review in October 2010. An entire module on climate change and heat-related mortality will be added in the summer of 2011. A developmental disabilities module will be added in the fall of 2011. NHANES biomonitoring data will be added in the future.

"CDC needs a clear strategy to communicate the value of the Tracking Network as an environmental surveillance system even if this resource does not meet the broader expectations of its constituents. CDC is not well positioned to address and temper Congressional and advocates' expectations for etiologic advances and cluster detection from this process."

EHTB responded that the expectations associated with having both secure and public portal components are a limitation. The secure portal was designed to provide a venue and tools for professionals to address complex concerns (e.g., etiology and small number clusters) in a collaborative venue. The public portal was designed for professionals to present results and findings. Activities conducted by professionals can be presented in a communications venue on the public portal. The public health actions of grantees are used to communicate the value and impact of the Tracking Network on public health.

"Productivity should be increased in terms of scientific publications. A manuscript describing the Tracking process, goals and milestones would significantly increase its visibility and transparency." EHTB responded that Tracking Network accomplishments have been published in multiple venues, including an *Environmental Health Perspectives* mini-monograph series of seven Tracking publications. The development of additional manuscripts is currently underway. With the launch of the Tracking Network, EHTB is better positioned to begin utilizing its data to examine geospatial trends, link health and environmental data, and generate specific research questions that can be explored.

"More detail should be included on the Tracking Network website or in communications materials about specific data that will be added and the expected time frame." EHTB responded that the addition of new data, activities and content are now communicated through the Tracking Network website and other venues within six-month time frames.

"The future funding value of leveraging the Tracking Network data infrastructure to promote internal evaluation of state and local environmental programs, health impact assessments and policy analysis should be recognized." EHTB responded that the Tracking Network has great potential to be used as an evaluation tool within and across states to compare the effectiveness of environmental health policies. Grantees are conducting policy analyses, such as evaluating the effectiveness of carbon monoxide detector statutes that differ across states and within other jurisdictions.

"The use of data in the project cities to impact public health policy should be prominently displayed." EHTB responded that New York City is the only non-state grantee. The New York City portal describes the implementation of policies derived from Tracking data, such as the New York City NHANES to inform policy (e.g., pesticide guidelines and restrictions, rodent advisories and bed bug policies). County-level data displayed on state and national portals also can inform local policies.

"EHTB and NCEH should consider reevaluating the mission, vision and goals of the Tracking Network since the portal is functional and other functions or capabilities may now exist." EHTB responded that many of its initial goals were accomplished. Communications reflecting updates are ongoing in multiple venues, including Twitter, Facebook, listserves, fact sheets, media announcements and interviews. The development of a new EHTB strategic plan is underway. During meetings with stakeholders, EHTB learned that its overarching mission and vision have not significantly changed. However, key objectives and milestones have changed reflecting accomplishments since EHTB's previous five-year strategic plan.

Ms. Flowers concluded her presentation by thanking the BSC for providing EHTB with insightful comments and recommendations during the peer review. She confirmed that EHTB found the BSC's peer review process to be extraordinarily useful.

The BSC thanked Ms. Flowers for presenting a detailed response to the peer review of EHTB. The BSC members made two suggestions for EHTB to consider in its ongoing efforts to refine and improve the Tracking Network. First, findings from the peer-reviewed literature should be added to the Tracking Network portal, such as data on well-defined cohorts.

Second, a public education program should be developed to widely publicize the availability and accessibility of the Tracking Network portal and provide instructions on its use. EHTB should closely collaborate with the American Library Association to ensure availability of the portal to low-income communities and communities of color that have a strong interest in Tracking data, but might have no or limited access to electronic data sources or social media.

Response by the Air Pollution and Respiratory Health Branch (APRHB)

Paul Garbe, DVM, MPH
Chief, Air Pollution and Respiratory Health Branch, NCEH/EHHE
Centers for Disease Control and Prevention

Dr. Garbe presented APRHB's responses to the BSC's specific peer review recommendations. "APRHB should develop a programmatic diagram to demonstrate the linkage among its six focus areas and illustrate the impact and evaluation outcomes of its interventions." APRHB responded that three diagrams were developed and distributed to the BSC for review. Dr. Garbe described each of the diagrams in detail.

The diagram of APRHB's strategic plan illustrates current efforts in four areas: increased knowledge, support and improvement of public health practice, service delivery, and coordination and leadership. The strategic plan outlines APRHB's partners at various levels, its three- to five-year vision, and core activities of implementation, translation, dissemination and evaluation.

The diagram of team relationships in implementing the APRHB strategic plan illustrates teams in six areas: Program Services, Surveillance, Evaluation, Communication, Epidemiology/

Research and Air Pollution Teams. All six teams are responsible for providing guidance and support to state programs and conducting emergency response activities.

For APRHB's remaining activities, three teams are responsible for conducting outbreak response activities, four teams are responsible for training public health professionals, five teams are responsible for translating and disseminating materials, five teams are responsible for collaborating with federal partners, two teams are responsible for leveraging partnerships, and three teams are responsible for monitoring progress.

The diagram of collaboration across APRHB in developing an Air Pollution Public Health Plan illustrates a comprehensive strategy for the Air Pollution Team to conduct research and translate findings to inform the design and development of interventions to reduce exposures to air pollution, including carbon monoxide. However, APRHB welcomes guidance from the BSC on modifying the Air Pollution Public Health Plan.

"APRHB should closely collaborate with Behavioral Risk Factor Surveillance System (BRFSS) staff to include cellular phones in the national sampling design." APRHB responded that the BRFSS program published a 2011 paper in the *American Journal of Epidemiology* evaluating a dual frame sampling method with both cellular phones and land lines. APRHB will collaborate with the BRFSS program to evaluate application of the dual frame sampling method for the BRFSS Asthma Call Back Survey.

"APRHB should develop a clear definition for 'asthma health disparities' with specific measures, objectives and outcomes to determine progress." APRHB responded that the disparities definition adopted by the Asthma Disparities Workgroup of the President's Task Force on Children's Health and Environment would be used. Measures to assess disparities that are consistent with Healthy People 2010 and 2020 would be used as well. Research is underway to develop additional measures, including rural-oriented metrics.

"APRHB should analyze metrics that are relevant to PHAs in deciding whether to use emission-based or observation-based models for outdoor air pollution." APRHB responded that HIAs are conducted in collaboration with EHTB, but APRHB does not conduct PHAs. APRHB will follow the BSC's advice to use observation-based rather than emission-based models to assess outdoor air pollution.

"APRHB should urge Washington State to review data to clearly demonstrate that the model tribal asthma home visit program will be transferable beyond the Port Gamble S'Klallam tribe." APRHB responded that a state program is collaborating with a second tribe to adapt the model over the next 12 months. APRHB will conduct a site visit with the state program on May 19, 2011 to assess progress in developing and adapting the model. APRHB will closely collaborate with the state program and two tribes to design a framework to transfer the model to other tribes in Washington State.

"APRHB should take a more strategic approach to encourage its grantees to collect data that would be more effective and relevant for targeting asthma interventions in communities bearing the greatest burden." APRHB responded that all grantees are expected to collect and use all

available data sources to evaluate their programs and improve interventions. Grantees also are expected to develop a strategic evaluation plan in close collaboration with APRHB.

The BSC gave an example of New York using State Children's Health Insurance Program (SCHIP) managed care plans to obtain data on prescription drugs to characterize chronic and acute asthma treatment among children. APRHB agreed that SCHIP data might be useful, but are not representative of state populations in a national surveillance system.

"APRHB should encourage or require state health department grantees to partner with state health services departments." APRHB responded that state asthma programs use many state data sources, but health services data are not fully comparable across states. National surveillance requires representative data systems. The Tracking Network now includes data on asthma hospitalizations and will soon add new data on asthma-related emergency department visits.

Dr. Garbe concluded his presentation by thanking the BSC for providing APRHB with extremely helpful comments and recommendations during the peer review. He was particularly pleased that the BSC commended APRHB on its leadership, guidance and technical assistance to state health programs on asthma surveillance, control and evaluation as well as other air pollution activities.

The BSC thanked Dr. Garbe for presenting a detailed response to the peer review of EHTB and distributing the informative diagrams. The BSC commended APRHB on its outstanding air pollution portfolio, particularly since APRHB receives no funding for these activities. The BSC members made two suggestions for APRHB to consider in its ongoing efforts to strengthen its programmatic activities, research and surveillance.

First, APRHB should expand its focus to address adverse health effects on the cardiovascular system from air pollution in addition to those on the respiratory system. The heart and lung have a strong relationship in the body. In response to this first suggestion, Dr. Garbe confirmed that APRHB would consult with and leverage expertise from the CDC Division of Heart Disease and Stroke Prevention on its existing activities to assess cardiovascular risks from air pollution.

Second, APRHB should compile, disseminate and promote best practices for assessing or estimating health effects from air pollution on cardiovascular and respiratory morbidity and mortality. For example, New York City recently released a report that estimated the annual burden of air pollution locally and calculated the benefits of specific policies. A similar report from APRHB at the national level would help states and municipalities to engage in efforts to improve air pollution policies at the local level. APRHB should collaborate with the Tracking Network to document and widely distribute air pollution best practices to states.

Response by the Climate Change Program (CCP)

George Luber, PhD
Associate Director, Climate Change, NCEH/EHHE

Centers for Disease Control and Prevention

Dr. Luber presented CCP's responses to the BSC's specific peer review recommendations. "CCP should expand its climate change activities to other parts of CDC, particularly the Tracking Network." CCP responded that the agency-wide Climate Change Task Force was formed in 2009 with leaders from a variety of CDC programs.

CCP is a member of the Tracking Network's Climate Change Workgroup and is developing climate change applications for the Tracking Network portal that will be launched in August 2011. CCP is pursuing a partnership with the ATSDR-/EPA-funded PEHSUs because young age is a critical risk factor for many health outcomes associated with climate change.

"CCP should develop a strategic plan to generate scientific information on climate change." CCP responded that its current intramural and extramural research projects will end in FY2011, but research would still be conducted on the health impacts of climate change. However, CCP's ability to conduct climate change research is restricted by funding and priority instructions from Congress.

CCP is directed to translate climate science for public health audiences and support capacity building of state and local agencies. CCP released "A Human Health Perspective on Climate Change" report in April 2010 to document research needs to help the public health community understand, mitigate and adapt to climate change

"CCP should elevate the significance of climate change-related health impacts among health professionals." CCP responded with its agreement that health professionals could play an important role in educating the public on the implications of climate change and behaviors to prevent related health impacts.

CCP is continuing to build and strengthen partnerships with the American College of Preventive Medicine, American Thoracic Society, other professional societies and non-profit organizations. CCP is continuing to pursue opportunities to make presentations at national meetings to raise awareness of climate change.

"CCP should improve training on climate change for the public health workforce." CCP responded that partner organizations (e.g., American Public Health Association (APHA), Association of State and Territorial Health Officials (ASTHO), and National Association of County and City Health Officials (NACCHO)) are funded to provide climate change training to public health professionals.

CCP's partners hosted a six-part webinar series in 2010 with 1,000 participants. The accredited series focused on the translation of science, mitigation and adaptation projects, and needs and vulnerability assessments. The series was adapted into a guide book that will be available within the next week for health departments to train their staff. The CCP Climate Ready States and Cities Initiative (CRSCI) Workgroup is developing a training module on the application of HIA methodologies for local public health agencies to engage the policy sector on climate change.

CCP will sponsor a training workshop on climate and health in July 2011 with a focus on state surveillance and responses to vector-borne diseases. CCP has trained interns, fellows and public health professionals in atmospheric and climate sciences through the Presidential Management Fellows Program and a two-year post-doctoral program with the National Center for Atmospheric Research. Opportunities will be explored to continue to award funding and collaborate with public health partners to provide and improve climate change training.

"CCP should develop rigorous outcome metrics to evaluate the impact and success of climate change activities at state and local levels." CCP responded that outcome metrics were developed in two categories to monitor and evaluate climate change activities. Grantees in CRSCI Category 1 (*i.e.*, assessment and planning) will be evaluated in the following areas: conducted comprehensive needs assessments and gap analyses for public health; developed a strategic plan to adapt health systems to climate change; participated on strategic planning groups; and considered public health within strategic plans for climate change.

Grantees in CRSCI Category 2 (*i.e.*, capacity building and public health adaptation) will be evaluated in the following areas: identified human health risks, vulnerable populations and vulnerable geographic areas; projected the estimated disease burden of health risks and vulnerabilities; and developed adaptations to address health risks for vulnerable populations.

"CCP should recruit staff with expertise in GIS." CCP responded that its personnel include one staff with a Master's degree in geography, three staff with training in the use of GIS applications, and additional staff with experience in built environment policy issues and extensive networks in the smart growth community. GIS and mapping applications are being developed at this time. Efforts are underway to build CCP's partnership base by outreaching to the American Planning Association, Smart Growth America and Congress for New Urbanism.

"CCP should reconsider its approach to developing the Alaska Surveillance and Response Toolkit." CCP responded that the systematic and scientific community-based participatory research (CBPR) model is being used to collect observational data on health impacts in Native Alaskan communities. In this initiative, trained local observers and a validated data collection instrument will be utilized to identify areas in which climate changes affect communities (e.g., impacts on subsistence food resources, food storage practices, community water resources and impacts on critical community infrastructure). Development of the toolkit will not be based on anecdotal reports.

"CCP should use CDC to redirect a portion of emergency preparedness (EP) dollars to broader preparedness activities." CCP responded with its support of incorporating climate change planning and response into EP operations, such as the inclusion of EP in climate change adaptation planning. State partners are being encouraged to develop strategies to leverage local dollars. To achieve this goal, CCP is building relationships with the public health and EP communities. These groups include State Directors of Public Health Preparedness through ASTHO's Climate Change Collaborative and Rear Admiral Ali Khan, MD, MPH, Director of CDC's Office of Public Health Preparedness and Response.

"CCP should consider the wider range of health risks that may emerge from extreme climate events and rising carbon monoxide levels." CCP responded that collaborations are underway

with state and local health agencies to (1) build overall capabilities to identify the impact of projected climate changes on injury and disease morbidity and mortality and (2) design and execute a course of action to best mitigate the projected additional burden of disease.

Various tools are being created to support assessments by state health agencies of potential health impacts. These resources include studies on the impact of the climate on pollen and asthma; projections of geographic distributions of health outcomes, injuries and deaths from heat events, cold events, wildfires and flooding; and collaborations on vector-borne disease initiatives.

"CCP should conduct a formal examination of interventions to reduce health impacts from climate change." CCP responded that because time scales associated with climate-related exposures complicate an evaluation of outcomes, evaluation activities must assess processes at the outset. An effective evaluation will require consideration of exposure characterization, attribution and exposure context.

The public health and climate change communities have initiated interactions and can learn from each other. A concerted effort is needed to evaluate CCP's impact on planned and autonomous adaptation methods. CCP is using the Tracking Network portal to develop strategies to monitor intervention outcomes.

"CCP should design an effective marketing strategy to address the future impact of the political environment on its climate change programs." CCP responded that its program is being re-branded as the "Climate and Health Program." The CCP website was updated with additional information on the health impacts of climate change and tools for health professionals to plan for climate change impacts.

A health communications specialist will be recruited to better frame climate change messages and engage other parts of CDC, health professionals and general public. CCP is participating in cross-agency communication and outreach workgroups, such as the U.S. Global Change Research Program's Communication Workgroup and the Outreach Workgroup of the Council of Environmental Quality's Climate Change Adaptation Task Force.

"CCP should provide public health leadership for climate change and health and sustain relationships with state and local agencies and academia after the initial three-year funding cycle ends." CCP responded that its staff is engaging in cross-governmental climate change initiatives, providing education to raise awareness, distributing communication tools, supporting the use of HIAs, supporting the development of best practices and tools, encouraging CRSCI partners to collaborate with other sectors and government agencies on HIAs, and assisting in the creation of a "Community of Practice" for climate and health.

Dr. Luber concluded his presentation by thanking the BSC for providing CCP with insightful and thoughtful comments during the peer review. He emphasized that the BSC's guidance was particularly beneficial and timely to CCP because its formal establishment was only ~1.5 years prior to the peer review.

The BSC thanked Dr. Luber for presenting a detailed response to the peer review of CCP. The BSC members were particularly pleased that CCP is taking a CBPR approach to developing the Alaska Surveillance and Response Toolkit. The BSC noted that CBPR empowers communities to serve as true partners with agencies and organizations to conduct research and place a "human face" on health issues.

The BSC members made several suggestions for CCP to consider in its ongoing efforts to shift to the re-branded Climate and Health Program.

- CCP should include ethnographic approaches in the development of the Alaska toolkit to collect statistical data in addition to qualitative data and also to make the survey instrument "more scientific." Ethnographic narratives and case studies should be gathered to illustrate the use of the method and document the importance of climate change in public health. These approaches could help to address the BSC's peer review comment that the project design appears to be "unscientific."
- CCP should tailor the Alaska toolkit for use by other communities with underlying disparities related to climate change.
- CCP should engage external experts (e.g., APHA and the Association of Schools of Public Health (ASPH)) in developing an action-oriented strategic plan that would be designed to effectively re-brand, market and promote the health component of climate change. For example, CCP could engage affected communities to tell personal stories of the impact of climate change on their health through videos, photographs or documentaries.
- CCP should collaborate with APRHB to demonstrate the impact of chemical exposures and air pollution on climate change.
- CCP should ensure that the re-branded Climate and Health Program continues to emphasize the unequivocal scientific literature documenting actual health effects from climate change.
- CCP should link its activities to the HUD-Department of Transportation-EPA Partnership for Sustainable Communities that was announced in October 2010. The goal of this interagency initiative is to stimulate a new generation of sustainable and livable communities that connect housing, employment and economic development with transportation and other infrastructure improvements.

On behalf of the BSC, Dr. Ryan thanked EHHE leadership and staff for developing extensive responses to the three program peer reviews. The BSC appreciated the time and effort EHHE devoted to responding to all of the peer review recommendations.

Overview of NCEH/ATSDR Policies to Assure Quality in Science

Paula Burgess, MD, MPH
Senior Scientist, NCEH/ATSDR Office of Science
Centers for Disease Control and Prevention

Dr. Burgess presented a comprehensive three-part overview of NCEH/ATSDR's modified and new clearance, external peer review and priority-setting policies to assure quality in science. The impetus for the change in policies was based on four key factors. First, the BSC provided sound guidance during its program peer review of the NCEH/ATSDR clearance process. Second, the GAO report contained several recommendations directed to the ATSDR clearance process.

Third, Dr. Thomas Frieden, Director of CDC, established new eClearance requirements that call for a review of all documents produced by CDC National Centers through an electronic rather than a paper-based clearance process. The eClearance process must be completed at the National Center level in a two-week time frame. Fourth, Dr. Christopher Portier, Director of NCEH/ATSDR, provided valuable input to division leadership on improving existing policies.

Part 1: Clearance Policy. The clearance policy requires NCEH/ATSDR scientific documents intended for public use (or ~1,200 documents per year) to undergo an internal clearance process with the Documentum software. NCEH/ATSDR initiated a process in 2009 to update and revise the policy, obtain feedback and draft new iterations. After Dr. Portier gave final approval on January 10, 2011, the updated policy was implemented on January 17, 2011. Since that time, NCEH/ATSDR formed a workgroup to provide education and training to division and branch staff and make minor modifications to the clearance policy based on their input.

The major changes to the clearance policy related to science cover three areas. The first change is the addition of an independent review. The independent review is a pre-clearance function that must be completed before the clearance process is initiated. Division Directors, Associate Directors for Science or their designees identify and approve two scientists with no stake in the research or involvement in the development of the document to serve as independent reviewers. The independent reviewers conduct an overall review of the science, epidemiology, methodologies and conclusions to ensure the quality and integrity of the document.

The second major change is an elevation of three types of high-priority documents: PHAs, health consultations and ToxProfiles. Under the new clearance policy, Office of Science senior reviewers are required reviewers for all three document types. OD is a required reviewer for ToxProfiles and must receive informational copies of PHAs and health consultations. The Office of Communications and the Office of Policy, Planning and Evaluation must receive informational copies of ToxProfiles.

The third major change is a more robust clearance matrix in which OD receives informational copies of all documents at two different points beyond the division clearance level. This method allows OD to intervene and provide input earlier in the clearance process. Under the new clearance matrix, OD is a required reviewer for seven document types: Congressional materials and cover letters, editorials and op-ed's, *MMWR* articles, policy-related materials, press releases, Surgeon General reports, and toxicological/interaction profiles and addenda.

Part 2: External Peer Review Policy. NCEH/ATSDR acknowledged the need to improve its existing external peer review policy with better, clearer and more consistent guidance on documents that need to undergo this process and the selection of external peer reviewers. The

Office of Science developed a strawman of the external peer review policy and considered a number of issues in this effort.

NCEH and ATSDR have different requirements for and exemptions from external peer review based on their mandates. NCEH follows CDC guidelines for external peer review, while ATSDR must comply with the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA).

Research dictating external peer review must be clearly defined. Criteria must be established to determine specific cases in which external peer review would be more stringent or rigorous than CERCLA requirements. A process must be developed for external peer review of influential scientific information (ISI), highly influential scientific assessment (HISA) and high-priority documents. The Office of Management and Budget's *2004 Information Quality Bulletin for Peer Review* defined the ISI and HISA categories and requires rigorous external peer review of these types of documents.

For both NCEH and ATSDR, external peer review is required for all ISI and HISA documents that have subject matter related to a high-priority or high-visibility site or topic. ATSDR ToxProfiles are ISI documents that fall in this category. For ATSDR, CERCLA and SARA require appropriate peer review of all studies and results, but five types of documents potentially are exempted from this mandate: PHAs, non-research documents, emergency events and other exceptional circumstances with rapid turnaround times, presentations at meetings of draft research in progress, and manuscripts based on previously peer-reviewed research.

The Office of Science is currently reviewing comments and questions submitted by OD and program staff on the strawman of the external peer review policy. These issues include: (1) What is the mechanism of external peer review for protocols? (2) Should protocols for non-research (e.g., exposure investigations) undergo peer review? (3) Should all PHAs and health consultations or a subset of these documents undergo external peer review? (4) What are NCEH/ATSDR's criteria for defining "high-priority" documents?

Part 3: Priority-Setting Process. NCEH/ATSDR recognized the importance of creating a priority-setting process to support the more robust clearance matrix, identify documents for external peer review, directly respond to the GAO report, and address the impact of its documents on public health.

The development of the priority-setting process has been targeted to ATSDR to date due to the sole focus of the GAO report on ATSDR. ATSDR Division leadership and NCEH/ATSDR OD were engaged in a process for ~1.5 years to develop a prioritization scheme for site work with three major components: (1) strategies to enhance the effectiveness of ATSDR's site work and influence successful interactions with local communities; (2) mechanisms to assure effective management of available resources; and (3) approaches to ensure appropriate tracking, updates and timely completion over the lifespan of each project.

Internal policies and procedures were published in March 2011 to determine priorities and allocate funds to guide ATSDR's site-specific activities. Consistent approaches will be developed to address work at similar sites. Incoming work will be assessed and prioritized.

Achievable goals that clearly define the scope of site work will be established. Manageable timelines will be established and achieved. Appropriate management controls of site work will be assured. Appropriate expertise, knowledge and training of staff will be assured. Utilization of methods to address outcomes will be assured. Rigorous review, assessment and clearance of documents will be provided.

External policies and procedures were published in March 2011 to guide ATSDR's collaborations with federal and state partners and communities during site-specific activities. Requests for site work will be unambiguous and clearly defined at the outset of each project. Community expectations that ATSDR can meet will be established. A forum for open communications with engaged communities will be available. Coordination with other agencies involved at the site will be assured. A transparent, objective and collaborative approach will be taken to build trust with communities. Appropriate risk communication practices will be utilized.

ATSDR management developed a three-step process to assign a public health priority level to each request for site work. Step 1 is to determine the source of the request (e.g., federal or state public health or environmental agency, Congressional staff, municipality or private citizen). Step 2 is to use criteria in the "Public Health Priority Level Table" to assign a specific priority level to the site. Step 3 is to decide whether ATSDR will take action on the request, defer the request to gather additional information from federal or state partners, or refer the request to a more appropriate agency.

For step 2, ATSDR defined five priority levels as "urgent," "high," "medium," "low" and "refer." Sites will be prioritized in categories 1-4 based on whether a hazard is present, a human exposure pathway is present, a hazard is present at levels within an order of magnitude of health guidance values (HGVs), a hazard is present at levels greater than or equal to HGVs, a hazard is present with evidence of a health effect, or a hazard is present with a possible health effect. The fifth "refer" category will be reserved for requests beyond ATSDR's mandate that would be more appropriately addressed by another agency.

Several internal controls will be implemented to manage the prioritization and communication scheme for ATSDR site work. ATSDR OD and Division Directors will hold weekly meetings to review decisions made for high-priority sites and emergency response activities. Multiple ATSDR divisions will submit weekly reports to NCEH/ATSDR OD with a listing of high-priority sites, their public health priority levels and emerging issues. All incoming requests will be monitored through the ATSDR Sequoia tracking system. ATSDR Division Directors will hold weekly meetings to review the prioritization of requests.

The ATSDR prioritization scheme will be incorporated into the new and centralized Request-Track system that Dr. Portier described in detail during his Director's report. With Request-Track, NCEH/ATSDR OD will be given all work requests and projects in real time to provide high-level knowledge, offer input on the prioritization and selection of projects at various stages, and track the time flow and management of documents.

All requests entered into the ATSDR Sequoia tracking system will be reviewed to verify assignments of public health priority levels for each incoming request or project based on criteria from the table; assign deadlines for progress reports and other milestones based on the

designated priority level; and generate reports for NCEH/ATSDR OD to provide knowledge of ongoing projects, allocation of resources and efficiency of work.

Before opening the floor for the discussion period, Dr. Ryan recalled a major concern the BSC noted in its peer review report of the NCEH/ATSDR clearance process. Program staff informed the BSC that Documentum was too tedious for the clearance process and too expensive to change to adequately meet the needs of this process. Staff also pointed out that the system did not facilitate appropriate review of NCEH/ATSDR's documents.

Moreover, NCEH/ATSDR leadership informed the BSC that no further developments would be made on Documentum due to these problems. However, Dr. Burgess reported in her overview that NCEH/ATSDR is still using Documentum. Dr. Ryan questioned whether these issues were taken into account when the decision was made to continue using the system. He was concerned that regardless of future upgrades, Documentum might continue to have the same problems.

Drs. Burgess and Portier made several follow-up remarks to address Dr. Ryan's comments and concerns. NCEH/ATSDR is required to continue to use Documentum because this decision was made at the level of CDC OD. Since the BSC's peer review, however, Documentum has been upgraded with an improved user interface and other new features to support the CDC-wide eClearance process.

Moreover, the CDC Office of the Associate Director for Science has been providing technical assistance to NCEH/ATSDR to incorporate the new independent review process into an augmented version of Documentum. CDC also has expressed its willingness to allocate funds to upgrade and augment Documentum to support NCEH/ATSDR's new clearance policy.

At the National Center level, NCEH/ATSDR has improved training and education to staff on the use of Documentum. However, an assessment will be made in the future to determine the effectiveness of Documentum in the new NCEH/ATSDR clearance policy. For ATSDR, Sequoia is a separate system that is solely used to track site work as mandated by CERCLA and SARA. ATSDR will continue to use Sequoia for this purpose.

The BSC members made additional comments and suggestions on NCEH/ATSDR's clearance policy and priority-setting process.

- The BSC was pleased that NCEH/ATSDR gave considerable thought to and solicited broad input during the planning phase to develop and modify the clearance, external peer review and priority-setting processes. However, the BSC advised NCEH/ATSDR to obtain routine and continuous feedback from staff and launch prototypes of the policies during the implementation phase to make any necessary corrections early in the process.
- The BSC proposed additional criteria to prioritize ATSDR site work: (1) the potential to generalize findings of a site to other sites that are outside the National Priorities List, but have similar population characteristics, exposure pathways or contaminants and (2) the ability to detect exposures at a site.

- The BSC advised NCEH/ATSDR to develop a transparent and well-defined strategy to clearly communicate findings to communities, particularly those ranked as "low priority" sites. The Public Health Priority Level Table defines low-priority sites as the presence of a hazard, but the community might interpret the "low priority" ranking as an "unimportant issue" to ATSDR. The BSC believed the language and categories of the prioritization scheme most likely would be inappropriate and unacceptable to communities. The BSC proposed new language to add to the definition of low priority sites: (1) "ATSDR needs additional information to begin addressing potential health effects at this site." (2) "ATSDR concludes that the information collected to date shows this site has minimal probability of causing environmental health effects in the community."
- The BSC advised ATSDR to develop and distribute a toolkit to communities at the completion of site work. The toolkit should include clear guidance, risk communication and education strategies, training opportunities and other resources to (1) map local GIS data, (2) conduct environmental health assessments, and (3) access state and local partners in health departments, non-profit organizations and academic institutions. The BSC believed the toolkit might minimize historical mistrust and anger by communities at the completion of site work. Although ATSDR would conduct no further activities at the site, the resources and technical assistance in the toolkit could empower communities to take further action.

Dr. Portier thanked the BSC for its excellent feedback on NCEH/ATSDR's clearance policy and priority-setting process. He confirmed that NCEH/ATSDR would provide an update to the BSC to report its progress on implementing these suggestions.

Update on the National Conversation on Public Health and Chemical Exposures

Julie Fishman, MPH
Associate Director for Program Development, NCEH/ATSDR
Centers for Disease Control and Prevention

Ms. Fishman presented an update on the National Conversation that was launched in 2009. The vision of this initiative is to use and manage chemicals in a manner that is safe and healthy for all persons. The overarching goal of this initiative is to develop an Action Agenda with clear and achievable recommendations to help government agencies and other organizations strengthen their efforts to protect the public from harmful chemical exposures.

A number of components are needed to fulfill the vision of the National Conversation: accurate information, improved scientific understanding of the link between exposures and health outcomes, policies and practices that are protective of populations, prevention, preparedness and response approaches, elimination of inequities, improved engagement of the public and healthcare providers, and the development of networks to enhance collaboration and coordination among federal agencies.

The National Conversation complements and is consistent with the Open Government Initiative established by President Obama. A broad range of partners were involved in the National

Conversation, including RESOLVE, NACCHO, APHA, ASTHO, WebDialogues and the National Environmental Health Association.

In addition to partner organizations, public participation also was a key component of the National Conversation. In the summer of 2010, 52 community conversations were held with >1,000 participants in various locations across the country. A community toolkit was developed in both English and Spanish. In April 2010 and January 2011, two web dialogues were held and were open to any member of the public. ASTHO and NACCHO sponsored forums for state and local public health officials to describe their experiences in addressing chemical exposure issues. In addition, a public comment period was completed for the Action Agenda.

A Leadership Council was formed with representation by the BSC and other experts in the field to develop the Action Agenda. Workgroups were formed to prepare reports in six key areas: monitoring, policies and practices, chemical emergencies, scientific understanding, service to communities, and education and communication. The workgroup reports outlined the current state of each topic and formulated recommendations to inform the development of the Action Agenda.

The National Conversation reflected broad representation on the Leadership Council and six workgroups. The sectors represented included federal, state and local agencies, tribal governments and organizations, community and environmental justice groups, national non-governmental public health and environmental organizations, academia and industry.

Selected recommendations from each of the seven chapters are highlighted as follows. Chapter 1, "prevention of harmful exposures," recommends protecting children's health. Chapter 2, "monitoring of chemical exposures and health outcomes," recommends expanding biomonitoring capacity and using biomonitoring to prioritize public health actions. Chapter 3, "scientific understanding of chemicals and their health effects," recommends reviewing and improving the scientific methods ATSDR utilizes in community settings.

Chapter 4, "health and wellness in environmentally burdened communities," recommends broadening the scope of ATSDR's public health actions. Chapter 5, "the public's ability to make health protective decisions," recommends developing 21st century environmental and occupational health education. Chapter 6, "capacity of the public health and health provider workforce," recommends educating, mentoring and hiring environmental and occupational health professionals from under-resourced and historically marginalized communities. Chapter 7, "reduction in harm from chemical emergencies," recommends assessing and improving the healthcare response to hazardous chemical releases.

The next steps in the National Conversation will be to release the Action Agenda website on June 9, 2011 ; the website will include the Action Agenda, workgroup reports, web dialogue summaries, and individual reports from and a synthesis of the community conversations. The user-friendly website will be easy to navigate and will allow the Action Agenda to be searched by chapter and recommendations to be searched by sector. The website will be available at www.nationalconversation.us.

NCEH/ATSDR will review and address recommendations targeted to its agency, meet with partner agencies and stakeholders to discuss shared recommendations, and present the recommendations to existing federal committees (e.g., Children's Environmental Health, Environmental Justice, and Toxics and Risk Committees). NCEH/ATSDR will solicit input from the BSC on implementation of the Action Agenda and encourage its partner agencies to share relevant recommendations with their Boards of Scientific Counselors and advisory committees.

NCEH/ATSDR will support meetings and other efforts (e.g., the Interagency Workshop on Alternatives Assessment) to implement various recommendations. NCEH/ATSDR will make presentations at national conferences (e.g., the APHA 100th Anniversary of Environment Section) regarding the status and implementation of the recommendations.

Dr. Portier was pleased to announce that the Obama Administration invited NCEH/ATSDR to the Council of Environmental Quality to describe the tools, overall process and other aspects of the National Conversation as a model of the Open Government Initiative. He congratulated Ms. Fishman and her staff on this outstanding achievement.

The BSC members made three overarching suggestions for NCEH/ATSDR to consider in its ongoing efforts to implement the Action Agenda.

- The BSC was pleased that 52 community conversations were held with >1,000 participants in various locations across the country. However, some BSC members questioned whether these geographic areas were truly representative of environmental health concerns nationally. For example, a BSC member noted that community conversations were not held in chemical corridors near the Ohio River Valley or refinery communities in Texas. However, ~5 community conversations were held in Oregon, but this state has limited environmental health impacts from manufacturing. The BSC advised NCEH/ATSDR and its federal partners to hold community conversations in other impacted areas to obtain an actual representative sample of the country. If budget constraints do not permit additional community conversations, limitations of the National Conversation process in terms of public participation should be acknowledged and clearly communicated in the Action Agenda. (Ms. Fishman responded that the Community Conversations were just one component of the National Conversation and that there was broader geographic representation across all the components. She indicated she would add a map of all participant locations into the final Action Agenda.)
- The BSC advised NCEH/ATSDR and its partner agencies and organizations to jointly hold a series of town hall meetings in impacted communities across the country to broadly educate and engage the public and increase participation in the Action Agenda. ASPH should be extensively involved in this effort to target environmental health training programs to academia and students.
- The BSC advised NCEH/ATSDR and its federal partners to engage in dialogue to prioritize the 48 recommendations in the Action Agenda and determine concrete timelines to achieve goals. This approach will be critically important to meet the realities of current and future budget cuts, promote and publicize existing efforts that are responsive to the recommendations, and hold the agencies accountable to their individual and shared activities.

The BSC members also made two specific suggestions in response to the recommendation in Chapter 2 of the Action Agenda to expand biomonitoring capacity and use biomonitoring to prioritize public health actions.

- NCEH should apply the CBPR model to build capacity in communities to understand and gather data to address their exposures. DLS should develop a standardized protocol with appropriate quality assurance/quality control components to train "community scientists" in conducting biomonitoring. Communities that are trained to properly collect samples could help to meet the increased demand for biomonitoring and build local infrastructure for this activity in light of decreased federal budgets.
- EPA and the National Institute for Occupational Safety and Health (NIOSH) publish federal reference methods that carry a great deal of scientific weight and are considered to be the gold standard. DLS should take the same approach as EPA and NIOSH in publishing its biomonitoring data by informing the public that its methods are the best based on currently available science.

Dr. James Pirkle, Director of DLS, made several remarks in follow-up to the BSC's suggestions on the biomonitoring recommendation in the Action Agenda. DLS follows an evidence-based medicine approach to interpret biomonitoring data and express any uncertainties. DLS also develops reference ranges of chemicals in the U.S. population based on the 95th percentile of the general population and of age, race and gender subgroups.

Dr. Pirkle noted that DLS's reference ranges are extremely helpful for members of the public to understand whether levels of chemicals in their bodies are "unusual," "high" or "normal" in comparison to the general population and specific subgroups. DLS clearly delineates its action steps to address levels of chemicals in the body that are much higher than the 95th percentile.

Dr. Pirkle emphasized that DLS's laboratory methods and supporting scientific evidence are clearly explained in multiple studies, reports, publications and other products. This information is in the public domain on the CDC website. Moreover, any member of the public is welcome to contact DLS by telephone to obtain an explanation from a medical toxicologist about their individual measurements and potential health effects.

In response to the BSC's suggestion to replicate the EPA and NIOSH publication models, Dr. Pirkle explained that DLS publishes its methods to measure human exposure to environmental chemicals in an appendix of the National Report along with literature citations. DLS also sends supporting documentation upon request. Because EPA and NIOSH are regulatory agencies, their reference methods have a "mandatory" stature.

Because CDC is a non-regulatory agency, its biomonitoring methods are published as guidelines. However, Dr. Pirkle agreed with the BSC on the need to formalize and publicize DLS's biomonitoring methods as the gold standard. He confirmed that DLS would explore the possibility of highlighting its recommended methods in a separate and prominent area of the website.

Public Comment Session

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

With no further discussion or business brought before the BSC, Dr. Ryan recessed the meeting at 4:07 p.m. on May 18, 2011.

Opening Session: May 19, 2011

Dr. Ryan confirmed the presence of a quorum and reconvened the BSC meeting at 8:34 a.m. on May 19, 2011. He announced that in response to the BSC's request on the previous day for a completed HIA, NCEH distributed "Health Impact Assessment: A Tool for Promoting Health in All Policies." NCEH also distributed the "Healthy Community Design Initiative: Engaging Health Impact Assessment" packet with the following materials:

- a map of completed and ongoing HIAs;
- the web page of completed HIAs from a state Healthy Community Design Initiative (HCDI) grantee;
- a model of using an HIA in Tumalo (Deschutes County), Oregon to obtain federal funds for sidewalk infrastructure;
- an executive summary of EEHS's ongoing evaluation of its HIA pilot program; and
- PowerPoint slides of HIA activities conducted under the HCDI grant program.

Dr. Portier announced that the BSC agenda would be modified to accommodate a new item. Dr. Mary Jean Brown, Chief of the CDC Healthy Homes/Lead Poisoning Prevention Branch, would join the meeting to answer questions the BSC posed on the previous day regarding healthy homes issues.

Overview of the Literature Review for ATSDR Toxicological Profile Development

Ed Murray, PhD
Director, Division of Toxicology and Environmental Medicine
Agency for Toxic Substances and Disease Registry

Dr. Murray reported that ATSDR adopted NRC's 1984 *Guidelines for Assessing the Quality of Individual Studies* several years ago. ATSDR continues to utilize these guidelines to evaluate whether studies are relevant, acceptable and appropriate to be included and cited in ToxProfiles. ATSDR's study quality assessment process is a non-scoring and subjective review process that is based on pre-determined questions and statements.

In collaboration with the National Institute of Environmental Health Sciences (NIEHS), ATSDR is currently exploring the use of a numerical quantitative approach as its quality assessment of

studies for ToxProfiles. The proposed approach would include the development of a unified database of studies to be shared across agencies.

ATSDR's current approach to evaluate the quality of studies includes a well-established risk assessment framework with two major components. Hazard identification involves an evaluation to determine the potential of a chemical to be toxic and cause adverse effects. Data are collected from animal and human studies when available. The dose-response assessment involves a quantification of the hazard to determine the relationship between the dose and response.

The three major components of a systematic literature review are identification and location of studies; data extraction, synthesis and analysis; and data storage and organization. After the systematic review, a standardized filtering process must be implemented to determine whether articles and databases will be included or excluded.

As an initial step in modifying its current study quality assessment process, ATSDR reviewed an assessment of formaldehyde the National Academy of Sciences conducted utilizing EPA's draft Integrated Risk Information System (IRIS). The review showed that IRIS could serve as a solid road map to advance the development of ATSDR's proposed study quality assessment process for ToxProfiles.

EPA designed IRIS with exclusion criteria to discard low quality or inconsistent studies. IRIS's inclusion criteria and features are consistent with ATSDR's existing study quality assessment process (e.g, a systematic review to identify the available evidence, an evaluation to determine high quality studies, hazard identification using a weight-of-evidence approach, a dose-response assessment, and a calculation of the minimum risk level (MRL)).

ATSDR continued to search the literature to identify other study quality assessment models. The unique nature of ATSDR's CERCLA and SARA mandates makes its process more complex than IRIS. The literature search resulted in ATSDR's review of the 2009 Silbergeld paper, *Applying an Evidence-Based Approach: Arsenic as a Health Risk*. Similar to IRIS, ATSDR recognized that certain findings of the Silbergeld paper also would be important and relevant to modifying its existing study quality assessment process.

The Silbergeld paper specifies a strategy to search for evidence, including defined databases and search terms that permit replication by other groups. Evidence-based medicine offers systematic reviews and other tools that are applicable to toxicology. Preexisting conditions and criteria for weighing information are available to include or exclude information as solid evidence in systematic reviews. For example, reviews and editorials are considered to be inadequate. Standard analytical procedures and methodologies can be utilized in a review.

The *Cochrane Handbook for Systematic Reviews of Interventions* is available to the public at www.cochrane-handbook.org and was ATSDR's third resource in modifying its existing study quality assessment process. ATSDR reviewed the Cochrane evidence-based medicine approach to determine whether this methodology could be used in the quality assessment of studies for ToxProfiles. The handbook outlines the components of a systematic review and

provides similar guidance to the 2009 Silbergeld paper, but the Cochrane methodology is more complex.

The Cochrane methodology describes five major components of a systematic review. Objectives are clearly stated with predefined eligibility criteria for studies. The methodology is explicit and reproducible. The systematic search attempts to identify all studies that would meet eligibility criteria. The validity of findings of included studies is assessed through an evaluation of the risk of bias that can arise when evaluating the quality of studies. The characteristics and findings of included studies are compiled in a systematic presentation and synthesis.

The Cochrane methodology emphasizes that reporting biases occur when the nature and direction of results influence the dissemination of research findings (e.g., statistically significant results, "positive" results indicating the effectiveness of an intervention with more potential to be published, studies more likely to be published more than once, studies more likely to be published in high-impact journals, and studies more likely to be cited by others).

ATSDR's proposed approach includes criteria for assessing the quality of animal neurotoxicity studies, animal immunotoxicity studies, animal reproduction and developmental toxicity studies, and animal systemic toxicity studies. Forms to evaluate the quality of studies include a scoring system to quantify studies that will be included or excluded from ToxProfiles. The forms were distributed to the BSC for review and discussion.

ATSDR currently uses the EZ-Tox database to extract pertinent information from a study, such as the study description, dose, duration, species and parameters measured. The EZ-Tox database also allows ATSDR to extract information to develop supplemental documents for ToxProfiles. ATSDR's next steps in modifying its existing study quality assessment process are to collaborate with NIEHS on a Study Quality Workgroup and the development of a data extraction model and to finalize the study quality criteria.

Dr. Murray concluded his overview by asking the BSC to address three key questions during its discussion of ATSDR's study quality assessment process for ToxProfiles. First, is ATSDR's proposed approach defensible? Second, does ATSDR's proposed approach have "built-in" biases? Third, is the BSC aware of alternative approaches that are available to assess the quality of studies?

Overview of Quality Assessment and Other Changes in Office of Health Assessment and Translation (OHAT) Documents

Kristina Thayer, PhD
Director, NTP Office of Health Assessment and Translation
National Institute of Environmental Health Sciences
BSC Federal Expert Member

Dr. Thayer reported that harmonization between agencies of study quality assessment methods will be limited to some extent because ATSDR and NIEHS produce different conclusions in their

systematic reviews. The National Toxicology Program (NTP)-OHAT produces documents with five "level of concern" categories ranging from "negligible" to "serious" concerns for adverse effects. The five-point scale includes an additional category for "insufficient data" to determine a hazard or exposure.

OHAT reaches level of concern conclusions by integrating the weight of evidence for adverse developmental or reproductive effects in humans and animals, the extent of current human exposure and other factors. Because precise scientific definitions have not been established for the level of concern categories, OHAT is changing its current methodology to present data in a more transparent, consistent and clearer manner.

OHAT uses a seven-point hazard identification scale for the weight of evidence for adverse effects with categories ranging from "clear evidence of no adverse effects" to "clear evidence of adverse effects." Human and animal data are considered separately. Studies that are used to reach weight of evidence conclusions for adverse effects are based on "limited" or "high" utility. Studies of "no utility" are not considered, but "utility" has not been defined. The absence of a definition of utility has caused different expert panels and members of the same expert panel to evaluate studies differently.

In step 1 of OHAT's evaluation of the quality of bisphenol A studies in 2008, the weight of evidence for developmental and reproductive toxicity of the chemical was considered. The weight of evidence for animal studies was determined to be "limited" because the literature was based on low doses of 10 µg/kg/day for developmental effects. The weight of evidence for human studies was determined to be "insufficient evidence for a conclusion" due to the paucity of data.

In step 2, OHAT considered the extent of human exposure and other factors. The studies estimated intake of bisphenol A in infants to be 1-13 µg/kg/day. In step 3, OHAT used this information to document the level of concern as "some concern" for adverse effects in fetuses, infants and children.

OHAT will change its documents for the modified study quality assessment process. The documents will be shorter and more interactive without jeopardizing the quality of the scientific review. Graphics will be used to display data with filters and sorting capabilities to more easily and rapidly assess the quality of studies. Consideration is being given to deleting a category from the five-point level of concern scale (e.g., "serious concern," "some concern" or "concern").

Dr. Thayer presented a demonstration of the Forest Plot Viewer that will be used to make OHAT's documents more interactive. The demonstration featured a collection of studies analyzing the relationship among persistent organic pollutants, diabetes and related health indices (e.g., glucose intolerance and insulin resistance). An expert panel used the software to review an extremely complex dataset of ~500 findings in a relatively short period of time. The experts were able to determine indications of a positive association between certain types of polychlorinated biphenyls and diabetes. A similar software program will be available to review the quality of animal studies.

OHAT will replace descriptors in its seven-point hazard identification scale with descriptors similar to those used by the International Agency for Research on Cancer (IARC). "Clear" will be changed to "sufficient." "Some" and "limited" will be changed to "limited." "Insufficient" will be changed to "inadequate." "Clear," "some," and "limited evidence of no adverse effects" will be changed to "evidence of lack of toxicity." OHAT's goal is to align its modified descriptors with terminology in the Globally Harmonized System to the extent possible.

IARC evaluations consider the weight of evidence for cancer in humans and in experimental animals separately, mechanistic data and other relevant evidence. An assessment of mechanistic evidence determines whether data are "weak," "moderate" or "strong" and if the mechanism is likely to be operative in humans. IARC evaluations categorize conclusions in five groups. Group 1 is "carcinogenic to humans." Group 2A is "probably carcinogenic to humans." Group 2B is "possibly carcinogenic to humans." Group 3 is "not classifiable as to its carcinogenicity to humans." Group 4 is "probably not carcinogenic to humans."

OHAT will convene a public meeting in the fall of 2011 to compare approaches for study quality assessment. A pre-meeting workshop will be held for experts to evaluate the same core set of experimental animal data and human observational studies using a variety of approaches. The workshop will provide the experts with an opportunity to share experiences, make modifications to the approach, and analyze inter-rater agreement within and across approaches.

During the public meeting, the experts will discuss and present recommendations on OHAT's approach for study quality assessment. OHAT will apply the recommended approach to a collection of animal, human and mechanistic studies for a weight of evidence/level of concern case study during a meeting that will be held in the spring of 2012.

OHAT's conceptual approach for study quality assessment will adopt concepts used in clinical epidemiology, such as the Cochrane systematic review and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method. These methods are analogous to the weight of evidence approach used in toxicology. The conceptual approach for study quality assessment is not an "off-the-shelf" solution for NTP. However, evidence streams for toxicology are different than those for clinical epidemiology due to the use of animal studies.

No consensus has been established on quality assessment of observational human studies, but OHAT will focus on the "most recommended" approaches. OHAT will assess the quality of studies with a "domain-based" approach. Single summary scores of the quality of studies are strongly discouraged because this approach requires weighting and serves as a source of subjectivity.

The Cochrane "Risk of Bias" table is used to determine whether individual studies have a "low," "high" or "unclear" risk of various types of biases. A selection bias includes random allocation to a group and allocation concealment. A performance bias includes blinding of participants and personnel. A detection bias includes blinding of outcome assessments. An attrition bias includes incomplete outcome data. A reporting bias includes selective outcome reporting. The table separates the risk of bias from the quality assessment.

OHAT is conducting experiments at this time to determine whether the Cochrane table can be used to evaluate the risk of bias, reporting quality and generalizeability of animal studies. OHAT modified the Cochrane table with new bias domains for reporting quality and generalizability of animal studies (e.g., utility of the animal model for health conditions, relevance of the route of administration, and relevant timing of exposure and outcomes). OHAT is aware that some of the clinical epidemiology domains (e.g., allocation of concealment) might not be relevant to animal studies.

The risk of bias across a collection of studies would be captured in the limitations category of the GRADE evidence profile table. Other categories of the GRADE table include inconsistency of findings, indirectness of populations, imprecision of results with wide confidence limits, publication bias and other considerations (e.g., a large magnitude of effect or indications of a dose-response). Findings in all of these categories would be used to determine whether the quality of evidence is "high," "moderate," "low" or "very low."

Dr. Portier provided additional details on IARC's evaluation of the weight of evidence that uses animal, human and mechanistic studies to make final decisions on the carcinogenicity of compounds. He emphasized that mechanistic data can be pivotal when human data are not conclusive.

Dr. Portier supported IARC's evaluation of the weight of evidence for ATSDR's proposed study quality assessment approach. He found the IARC process to be extremely well structured and suited to make clear and defensible statements on grouping studies in one of the five categories of carcinogenicity.

Dr. Portier made additional remarks for the BSC to consider during its discussion. The study quality assessment for ToxProfiles that Dr. Murray presented is a proposed approach at this point. ATSDR would use the BSC's feedback to revise the proposed approach and solicit the BSC's formal vote and approval to proceed.

Dr. Portier asked the BSC to target its responses to the questions posed by Dr. Murray to both agencies to the extent possible. He noted that efforts would be made in the future to harmonize quality assessment methods across all HHS agencies up to the point of hazard identification.

The BSC commended ATSDR and NTP-OHAT on their proposed approaches to assess the quality of studies. The BSC noted that the unified database of studies would have a great deal of potential beyond systematic reviews conducted by ATSDR and NTP-OHAT. Responses by the BSC members to Dr. Murray's questions are outlined below.

Question 1: Defensibility

- Both the ATSDR and NTP-OHAT proposed approaches are defensible overall.
- The solid and excellent Cochrane approach for systemic reviews is more comprehensive than any other method, but its limitations should be acknowledged. For example, the position of some study authors is that the Cochrane approach focuses on medical interventions and would not be effective in assessing the quality of animal studies.
- The agencies should clearly articulate studies that were excluded from a systematic review and criteria utilized to assess an individual study.

- The agencies should register their systematic reviews in the Cochrane Collaboration to broaden access to their methodologies.

Question 2: Biases

- Application of the proposed approaches with epidemiologic observational studies is questionable and will be much more difficult than with animal studies. The agencies should give careful thought to this issue and develop similar approaches to assess the quality of epidemiologic observational studies.
- The unified database of studies should be designed to reflect the public health goal of protecting health.

Question 3: Alternative Approaches

- CDC's highly-respected systematic review process to develop the *Guide to Community Preventive Services* should be considered as an additional model.
- The proposed approaches should be applied in a retrospective review to test their efficacy. This assessment should include a benchmark, chemicals with known adverse effects (e.g., vinyl chloride and benzene), and chemicals with limited concern for adverse effects.
- ATSDR should factor in complexities associated with the collection and assurance of data that will drive the decision-making process in the development of ToxProfiles.

Dr. Vincent Cogliano is the Director of the IRIS Program at EPA. He supported the agencies' domain-based approach because this method would facilitate a tradeoff of strengths and limitations from an individual study to another study. He advised the agencies to consider using specific components from multiple approaches. For example, both the domain-based and quantitative methods might be needed to achieve the goals of the study quality assessment. Dr. Cogliano advised NTP-OHAT to use its upcoming workshop as a forum to discuss the strengths and limitations of various approaches.

Overview of Experimental Mixtures Strategies

Christopher Portier, PhD
Director, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Portier explained that the purpose of his overview would be to delineate an experimental risk assessment approach to include mixtures in ATSDR's ToxProfiles. Individual exposure to more than one substance continues to be a major problem in communities visited by NCEH/ATSDR. However, most studies in ATSDR's database address exposure to a single compound.

Action levels are expressed as exposure to a single compound and are not associated with a stated risk. For example, water contamination in a community could include four agents that are all 10% above the MRL. A single contaminant might not be at a level requiring action, but the aggregate risk to the community might be unacceptable. Multiple chemicals might interact to increase risk, but no methods exist to address this problem.

Dr. Portier developed a potential risk assessment approach that would allow ATSDR to formally analyze the impact of mixtures in communities. The experimental solution to this approach would be to assign risk to the action level. The MRL is ATSDR's action level and would be used for this purpose. After making this assumption, a smooth curve would be drawn between 0 added risk at 0 exposure and the risk at the point of departure (POD) (e.g., the lowest observed adverse effect level (LOAEL) or benchmark dose (BMD)) that runs through the risk at the MRL for each chemical. The curve would be used to evaluate risks at the actual exposure for each chemical. Risks would be aggregated to estimate risks for the entire population.

MRLs are derived by dividing the POD by modifying and uncertainty factors. The POD is effective for both epidemiologic and animal data and can be determined with several methods. The BMD is the preferred approach, but the LOAEL or no observed adverse effect level also could be utilized. Modifying and uncertainty factors are based on scientific judgment and are guided by several documents. The factors are both context and POD-type specific.

Dr. Portier outlined ATSDR's standard operating procedure in using the BMD method to determine MRLs. The exposure is displayed on the x-axis and added risk from the exposure is displayed on the y-axis. Experimental laboratory data or observational data from an epidemiologic experiment are used to provide solid exposure information. Standard regression techniques are used to incorporate a dose-response curve.

To estimate the BMD, the benchmark response (BMR) is specified and advanced at 1%, 5% or 10%. ATSDR typically uses 5% or 10% as the BMR depending on the endpoint, but 1% is used for human data. The BMR is correlated to the dose-response and exposure curves to determine the BMD. Based on the BMD and BMR, a 95% confidence region is calculated. Variances are observed in the probability of risk at the dose and also in the actual dose associated with a 10% risk. The BMD lower bound (BMDL) is the POD to calculate the MRL. Modifying and uncertainty factors are applied to the BMDL to calculate the MRL.

Dr. Portier proposed his experimental approach to risk assessment using the MRL, small added risk, BMD and BMDL. The curve is dependent on and sensitive to the size of the added risk. The BMDL is used to obtain an upper bound of the risk at a new exposure with "pseudo-confidence." In the mathematical description of the experimental risk estimation, the small added risk is expressed as ε and actual exposure in a population is expressed as E.

The function used to interpolate between the BMD and 0 added risk is $R_D = \alpha D^k$. At the BMD, the risk is already specified as $R_{BMD} = \alpha BMD^k$. The response at the MRL is given by $\varepsilon = \alpha MRL^k$ where ε is very small. Since the value of α is the same for equations 2 and 3, an algebraic formula would be used to solve for k. These results then would be used to solve for α. Similar algebraic formulas would be used to calculate the upper bounds.

ATSDR tested the efficacy of Dr. Portier's proposed approach with 23 completed ToxProfiles that were developed with the BMD method. Various datasets were included in the experiment, such as oral and inhalation routes of exposure; acute, intermediate and chronic exposures as the length of time; and quantal and continuous data. MRLs, BMDs and BMDLs were previously calculated and were available in the completed ToxProfiles.

The BMR that ATSDR utilizes to determine MRLs as well as modifying and uncertainty factors were included. The small added risk of "k" was established at 10^{-5} (or a 1 in 100,000 chance of risk of exposure to a substance at the specified MRL). With the exception of vanadium compounds at a risk of 2.42 and boron compounds at a risk of 2.02, risks for other substances in the remaining 21 ToxProfiles were <2.00. Other data in the experiment of Dr. Portier's proposed approach included the upper bound risk at the MRL, α and α-upper bound.

For compounds in the 23 completed ToxProfiles, ATSDR incorporated all of these factors into the experiment of Dr. Portier's proposed approach to determine values for k (*i.e.*, the small added risk); the relative risk at twice the MRL to the risk at the MRL; and the relative risk at 5 times the MRL to the risk at the MRL. The experiment did not show significant differences in the risk of exposure at twice the MRL, but dramatic changes of up to 30- to 40-fold were observed at 5 times the MRL with ε at 10^{-6} versus 10^{-4}.

The next step in the experiment of Dr. Portier's proposed approach was for ATSDR to assess the impact of the differences. ATSDR found that the relative risk rather than the absolute risk detected at sites should be expressed in the context of taking action. To incorporate mixtures into ATSDR's ToxProfiles, calculations should be made to determine the probability of disease based on different exposures and an assumption of an independent action between chemicals.

Dr. Portier summarized ATSDR's new risk assessment methodology based on his proposed approach. Estimations would be made for α, k and α-upper bound for each chemical. The population would be evaluated and exposures to the population would be estimated for each compound. The risk for each exposure to the population would be calculated. Risks would be combined using Dr. Portier's proposed formula. The results would be compared to the target risk for the population to analyze the relative risk and make decisions on whether or not to take action.

Dr. Portier described an example of applying his proposed approach to express a mixture of cadmium, uranium and barium salts in ATSDR ToxProfiles. The population would be exposed to 0.001 mg/kg/day of cadmium (or twice the MRL), 0.0015 mg/kg/day of uranium (or slightly below the MRL), and 0.1 mg/kg/day of barium salts (or 50% of the MRL). The combined risk for these three compounds would be 3.9×10^{-5}.

ATSDR resolved two major issues to apply Dr. Portier's proposed approach to express mixtures in ToxProfiles. First, some ToxProfiles are not created with the BMD method, but uncertainties in deriving MRLs from LOAELs have been addressed. Second, chemicals might be expressed independently rather than as similar modes of action. Equivalence factors and risk assessment solutions have been developed to solve this problem (e.g., binding of dioxins to age receptors that are linked to their toxicity).

ATSDR is aware of the need to address outstanding issues to refine and apply Dr. Portier's proposed approach to express mixtures in ToxProfiles. The choice of ε (*i.e.*, the small added risk) is sensitive. The proposed approach appears to be accurate for curves, calculated risks and confidence bounds, but the scientific certainty of these findings are implied rather than real.

Dr. Portier welcomed the BSC's suggestions on effectively communicating "soft" results of the MRL.

Dr. Portier concluded his overview by describing the next steps in his proposed approach to evaluate mixtures at sites and include these data in ToxProfiles. ATSDR will apply the methodology to conduct experiments with completed evaluations of various sites that had multiple compounds. ATSDR will determine whether the methodology resulted in the same or different findings as the original site evaluations. Based on these results, ATSDR will either continue to conduct experiments or formally adopt the methodology to guide decisions made at sites.

If the methodology is found to have a significant impact on evaluating mixtures at sites, ATSDR will publish a *Federal Register* notice, open a public comment period, convene a meeting with experts and stakeholders to obtain broad input, and solicit the BSC's formal vote and approval for implementation.

Dr. Vincent Cogliano, Director of the IRIS Program at EPA, recognized the importance of Dr. Portier's proposed approach to assess mixtures at sites. He noted that similar to ATSDR, EPA also computes risks at sites. Unlike ATSDR, however, EPA has a federal mandate to analyze the cost-benefit ratio of each risk assessment method, place a dollar value on reducing environmental health effects from exposures to substances, use its regulatory authority to make decisions on cleanup actions at sites, and establish standards.

Dr. Cogliano was pleased that Dr. Portier highlighted the limitations of the proposed approach and outlined the relative risk of exposure at different MRLs. He emphasized that the use of relative risk is a sound approach to communicate risks to communities. Dr. Cogliano raised the possibility of ATSDR conducting another type of sensitivity analysis that would be stratified by uncertainty factors. Overall, he noted that ATSDR's proposed approach to evaluate mixtures at sites would fill critical data gaps and needs in this area.

Dr. Ryan asked the BSC members to thoroughly review Dr. Portier's slides and the meeting minutes that would be distributed. He noted that the BSC's review of these documents and Dr. Portier's update would prepare the BSC to provide substantive input to ATSDR and formally approve the proposed approach to evaluate mixtures at sites during a future meeting.

Overview of the CDC/NCEH/ATSDR Japan Response

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

Dr. Kapil described NCEH/ATSDR's role in CDC's response to an earthquake, tsunami and radiation release in Japan. The earthquake occurred in Japan on March 11, 2011 and registered at 9.0 on the Richter magnitude scale. The earthquake was the largest in Japan's

history and the fourth largest in the world. The epicenter of the earthquake was 25 miles off the coast of Japan. The resulting tsunami produced waves as high as 45 feet and penetrated remarkable distances of 6 kilometers inland. Dr. Kapil presented a map illustrating the U.S.-recommended evacuation zone in Japan.

The Fukushima Daiichi Nuclear Power Plant has six boiling water reactors. The earthquake and resulting tsunami led to a loss of external power, containment and backup generators that are used to cool water in the reactors. Seawater that was used to cool the material resulted in releases of hydrogen, pressure buildup and explosions at some reactors. Periodic airborne releases of radioactive materials primarily included iodine-131 and cesium-137, but releases also occurred in water that was used for cooling.

CDC immediately activated its Emergency Operations Center (EOC) in response to the tragedy in Japan. NCEH/ATSDR has lead responsibility for a number of CDC's emergency response activities and assigned an incident commander to the response. In addition to NCEH/ATSDR, other parts of CDC were actively involved in the response (e.g., NIOSH, the Center for Global Health, Division of Global Migration and Quarantine (DGMQ), Office of Public Health Preparedness and Response, and the Strategic National Stockpile). NCEH/ATSDR accounted for at least 50% of ~200 CDC staff assigned to the response.

In terms of external partners for the response, CDC collaborated with professional organizations and numerous agencies at federal, state and territorial levels. CDC's federal partners in the response included HHS (e.g., National Institutes of Health, Food and Drug Administration, and Substance Abuse and Mental Health Services Administration), NRC, EPA, Department of Homeland Security (DHS), Department of Defense, Department of Energy (DOE), Department of State, Occupational Safety and Health Administration, and the White House National Security staff. The agencies provided expertise in several important areas, including radiation health, food safety, border protection, emergency response and worker exposures.

NCEH/ATSDR's specific role in the response was to support the U.S. government and the government of Japan on public health aspects of the event. NCEH/ATSDR closely collaborated with federal, state, territorial and organizational partners to coordinate activities related to health messaging, radiation health issues, risk assessment and communication, surveillance and monitoring, worker safety, laboratory assessment capacity with radionuclide screening, and countermeasures. NCEH/ATSDR's other major focus area during the response was to assess gaps and lessons learned to strengthen domestic preparedness. NCEH/ATSDR also deployed staff to Japan, NRC and the White House during the response.

The Joint Information Center (JIC) developed strategies to effectively communicate and deliver messages on several priority issues, such as travelers' health, potassium iodide (KI), American citizens in Japan and the United States, U.S. preparedness, and CDC's responses activities and priorities. NCEH/ATSDR's key messages are highlighted as follows. "The United States has no health risks associated with the radiation release in Japan, but appropriate monitoring is underway." "No individual in the United States needs to take KI." "Food safety is being closely monitored." "The public should be prepared for any type of natural or manmade disaster."

JIC's communication strategies targeted two key audiences with different needs. For Japanese citizens in Japan, the messages focused on heat, food, water and sanitation needs directly due to damages from the earthquake and tsunami as well as food and water safety and KI issues due to the radiation release. For American citizens in Japan, the messages focused on the availability of KI to all American citizens. Outreach was conducted via the U.S. Embassy in Japan, a clinician's network, businesses and social media.

In collaboration with the American Association of Poison Control Centers, NCEH/ATSDR used the National Poison Data System to track calls to U.S. Poison Control Centers related to the earthquake, tsunami, radiation exposure and nuclear incident in Japan. Calls to the data system were coded as "requests for information only" or "suspected or known exposures."

Epidemiologic and surveillance data showed that the number of calls to U.S. Poison Control Centers dramatically peaked the day after the earthquake on March 12, 2011, but remarkably declined beginning on March 19, 2011 after CDC implemented its health messaging and risk communication efforts. The CDC BioSense surveillance system showed that no emergency department visits were made to federal or non-federal hospitals in the United States related to KI following the earthquake in Japan on March 11, 2011.

President Obama was briefed by public health experts and informed the public on March 17, 2011 that harmful levels of radiation were not expected to reach the United States. He further informed the public that beyond staying informed, precautionary measures were not advised for persons in the United States.

The EPA RadNet surveillance system conducts real-time air monitoring, collects precipitation data, and gathers information on potentially contaminated drinking water and milk at ~200 sites in every state. The RadNet system was an extremely valuable and credible data source for the federal agencies to communicate that releases from the catastrophic events in Japan were not expected to result in significant health risks to populations.

NCEH/ATSDR and DGMQ collaborated on developing traveler screening protocols for use by U.S. Customs and Border Protection. The protocols were cleared by HHS and vetted through a number of groups (e.g., ASTHO, NACCHO, DHS and the Council of State and Territorial Epidemiologists). Consideration was given to enhanced border screening due to the potential for alternative scenarios. NCEH/DLS partnered with DGMQ in providing laboratory capacity in the event that mass evacuation of American travelers from Japan became necessary.

NCEH/ATSDR noted several challenges with the federal response to the tragedy in Japan. The availability of staff with expertise in radiation health was found to be extremely limited at CDC and other federal agencies. Interagency coordination, collaboration and communication were difficult in terms of providing technical data in a timely manner, accurately interpreting data, and creating a cohesive approach to communicate consistent findings and recommendations without causing confusion. Radiologic event capacity and related laboratory services were found to be minimal at state and territorial levels.

In addition to these challenges, NCEH/ATSDR also identified key gaps in science. Standards, units and assumptions to measure radiation exposures vary within and across countries. "Safe"

levels of exposure to radiation have not been defined to date. Guidance on the distribution, dosage, initiation and duration of KI is incomplete, inconsistent and differs within and across countries. Recommendations on sheltering, evacuation and re-occupancy triggers are limited and inconsistent. Existing capacity for monitoring radiation exposures in air, water and food is limited in terms of frequency of testing, protocols to determine the operation of monitors, and rapid turnaround times to produce data.

Dr. Kapil presented a map illustrating nuclear power plants in North America (e.g., Canada, Mexico and the United States). Many of these plants have multiple reactors and are located in areas where natural disasters occur. As a lesson learned from the catastrophic events in Japan, the locations of these nuclear power plants must be considered in efforts to improve domestic preparedness in the United States.

Overall, the response to the tragedy in Japan involved NCEH/ATSDR's leadership of CDC's significant and multifaceted federal response. The catastrophe resulted in ~12,000 confirmed deaths to date, but experts estimate that the actual number of deaths is closer to ~27,000. The discrepancy between the confirmed and estimated deaths is due to the inability to locate ~15,000 "missing" persons.

The response to the tragedy in Japan provides a unique opportunity for CDC to evaluate and enhance domestic preparedness for radiation events in the United States. NCEH/ATSDR and other parts of CDC are closely collaborating with partners within and outside the U.S. government to improve their ability to respond to similar events in the future.

Dr. Kapil concluded his overview by informing the BSC that NCEH/ATSDR is developing CDC's after-incident report of its response to the tragedy in Japan. The report will be submitted to the HHS Secretary in June 2011 and will highlight important public health issues, communication strategies and lessons learned from the Japan response to improve domestic preparedness. The HHS Secretary will use CDC's report as a foundation to closely collaborate with other federal agencies in creating and implementing a U.S. government preparedness plan. Dr. Kapil raised the possibility of the BSC making a site visit to the EOC during a future meeting.

The BSC was impressed by CDC's immediate mobilization of its internal assets and rapid efforts to collaborate with external partners at all levels to respond to the catastrophe in Japan. The BSC also commended CDC for quickly assuring its state and local partners that national leadership and resources for the response would be provided.

The BSC members made two key suggestions for CDC to consider in strengthening its role to improve domestic preparedness and response capacity.

- CDC should have presented a map with its official logo during the height of the Japan response illustrating geographic areas where radiation releases were detected. CDC is viewed as the premiere public health agency to provide unbiased and trustworthy information to the public. Maps presented by the media most likely were from inaccurate sources and confirmed to the public that the United States has no coherent and coordinated system available at this time to detect radiation releases. To the extent possible, CDC should use its international stature, influence, recognition and brand to

present national environmental health data to the public during an event. For example, President's Obama's national address on March 17, 2011 would have been stronger and more credible if he informed the public that his messages related to the tragedy in Japan were based on public health expertise from CDC.

- CDC should ensure that its risk communication messages delivered to the public during an event are consistent at all levels of public health. During the Japan response, for example, federal agencies advised President Obama to inform the public that precautionary measures were not recommended for persons in the United States beyond staying informed. At the local level, however, New York City made a definitive statement that advised individuals in the United States not to take KI.

Dr. Portier informed the BSC that following the tragedy in Japan, he and Dr. Frieden met with the NRC Safety Commission to discuss the important role of health in establishing mass evacuation plans, distributing KI, and addressing health issues related to nuclear power plants. The discussion also focused on the capacity of communities to respond to mass exposures to large populations. Dr. Portier confirmed that as a result of this discussion, CDC, NRC and other federal partners are developing a strategy to ensure the health and safety of persons in the United States during an event.

Overview of the CDC Healthy Homes Portfolio

Mary Jean Brown, ScD, RN
Chief, Healthy Homes/Lead Poisoning Prevention Branch
Centers for Disease Control and Prevention

Dr. Brown joined the meeting to present an overview in response to questions the BSC raised on the previous day. The BSC requested additional details on CDC's interagency collaborations with EPA and HUD on healthy homes issues. The BSC questioned whether CDC's individual healthy homes portfolio or its joint efforts with other agencies are designed to address healthy school environments and weatherization issues.

Dr. Brown informed the BSC that a Federal Interagency Workgroup was established with representation by CDC, EPA, HUD, DOE, the U.S. Department of Agriculture and other agencies to closely collaborate and coordinate healthy homes issues. CDC also requires its state cooperative agreement grantees to share data with EPA, HUD and the Department of Justice on properties with a past history of lead poisoning cases to facilitate enforcement at the local level.

Because the Healthy Homes/Lead Poisoning Prevention Program is not solely supported by CDC dollars, CDC leverages resources from EPA and HUD and also obtains funding from DOE to address weatherization issues. However, HUD is the major contributor to CDC's healthy homes research and training initiatives. The CDC National Healthy Homes Training Center and Network provides training to healthy homes and lead poisoning prevention professionals on weatherization issues. CDC expects to engage the NIEHS Radon Training Program in this effort over the next two to three months.

Dr. Brown informed the BSC that funding for the CDC Division of Adolescent and School Health has been removed from the President's FY2012 budget, but its function will be reorganized and redistributed in other parts of the agency. In an effort to address this gap, NCEH could provide healthy school environment toolkits to EPA.

Dr. Brown further informed the BSC that if Congress approves the 50% decrease in funding proposed in the President's FY2012 budget request, most jurisdictions will be unable to adopt the more holistic healthy homes approach. The vast majority of localities will be limited to meeting their statutory and mandatory obligations to address the needs of children identified as lead poisoned. Other potential implications of the budget cut include a 48% decrease in funding to grantees and CDC's inability to continue to fund large cities.

Dr. Brown concluded her remarks by informing the BSC that CDC and other agencies are sponsoring a healthy homes conference on June 20-23, 2011 in Denver, Colorado. The HHS Secretary is expected to be one of the keynote speakers. The registration is still open for any BSC member with an interest in attending the conference.

The BSC thanked Dr. Brown for joining the meeting on short notice to provide an overview of CDC's healthy homes portfolio. The BSC members made two key suggestions for CDC to consider in preparation of a severe budget cut. First, CDC should link its healthy homes/lead poisoning prevention activities to the President's "Race to the Top" Initiative. This effort is designed to assure educational attainment and advancement among children with lead poisoning exposures.

Second, the relationship between education and health reflects fragmented linkages, limited access, and minimal cross-fertilization to collaborate on healthy school environments. CDC should make stronger efforts to engage the Department of Education in its healthy homes activities at the outset.

Public Comment Session

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

BSC Open Discussion

Dr. Ryan led the BSC in an open discussion for the members to make comments on any aspect of the current meeting or propose suggestions to improve future meetings.

For topic 1, the BSC emphasized the need for an extensive discussion during the next meeting to propose strategies to increase public participation at future meetings. For example, the existing momentum and current base of stakeholders for the National Conversation could be

used as a mechanism to more effectively engage the public. The BSC noted that the high level of security at the Chamblee Campus might serve as a barrier to the public attending meetings.

Based on the BSC's comments, Dr. Portier confirmed that "public participation" would be placed on the agenda for the next meeting. This item would include an overview by NCEH/ATSDR on its previous public meetings and a discussion with the BSC on potentially changing the location of future meetings and publicizing meetings beyond *Federal Register* notices. Dr. Portier also confirmed that in the future, the BSC would be notified of public meetings NCEH/ATSDR holds in various areas of the country.

For topic 2, some BSC members raised the possibility of shortening future meetings to 1.5 days, but other members were in favor of maintaining a two-day meeting to account for the extensive content and substance of specific agenda items. During the current meeting, for example, some BSC members were interested in engaging NCEH/ATSDR in a more detailed discussion on alternative toxicological evaluation protocols.

For topic 3, the BSC asked NCEH/ATSDR to place three items on future meeting agendas:

- an update on the environmental investigation at the Vieques, Puerto Rico site;
- a detailed presentation independent of the Director's report on NCEH/ATSDR's PHA of contaminated drywall; and
- status reports on ATSDR's proposed approaches to (1) assess the quality of studies for inclusion in ToxProfiles and (2) evaluate mixtures at sites to incorporate these data into ToxProfiles.

Closing Session

Dr. Ryan announced that the next BSC meeting would be held in either the last two weeks in October 2011 or the first week in November 2011. The Office of Science staff would poll the BSC members, Designated Federal Official and NCEH/ATSDR Director by e-mail to determine their availability and confirm the date.

Dr. Portier thanked the BSC for providing valuable input to NCEH/ATSDR on its portfolio of EPH activities, projects and research over the course of the meeting. To assist in developing the next agenda, he encouraged the BSC members to contact Drs. Kapil and Ryan with additional suggestions on future topics.

Dr. Kapil thanked the Office of Science staff (Ms. Sandra Malcom, Executive Coordinator for the BSC and Ms. Shirley Little) for continuing to provide outstanding administrative and logistical support for the BSC meetings. Dr. Kapil also recognized Dr. Paula Burgess, Ms. Lindsey Horton, Ms. Whitney Neal and Mr. Ken Rose for providing excellent technical support to ensure a successful and productive BSC meeting. The BSC applauded the Office of Science staff for their efforts.

With no further discussion or business brought before the BSC, Dr. Ryan adjourned the meeting at 1:41 p.m. on May 19, 2011.

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

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Date

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Timothy J. Ryan, PhD
Chair, Board of Scientific Counselors