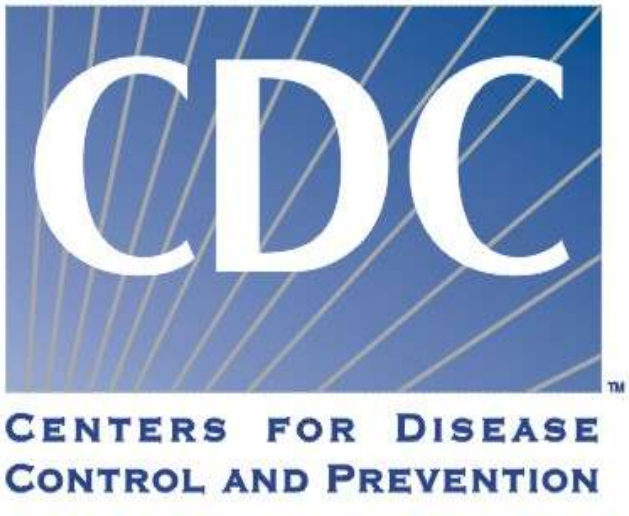
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry



Board of Scientific Counselors Meeting
October 29-30, 2009
Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

ATTACHMENT 1

List of Participants

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ATTACHMENT 2

Acronyms Used In These Meeting Minutes

ACCLPP	—	Advisory Committee on Childhood Lead Poisoning Prevention
ALF	—	Anthrax Lethal Factor
ALS	—	Amyotrophic Lateral Sclerosis
APHL	—	Association of Public Health Laboratories
BSC	—	Board of Scientific Counselors
CDC	—	Centers for Disease Control and Prevention
CLIA	—	Clinical Laboratory Improvement Amendments
CPSC	—	Consumer Product Safety Commission
DLS	—	Division of Laboratory Sciences
EEHS	—	Division of Emergency and Environmental Health Services
EHHE	—	Division of Environmental Hazards and Health Effects
EHSB	—	Environmental Health Services Branch
EIS	—	Epidemic Intelligence Service
EISs	—	Environmental Impact Statements
EJ	—	Environmental Justice
EPA	—	U.S. Environmental Protection Agency
EPH	—	Environmental Public Health
EPHRB	—	Environmental Public Health Readiness Branch
FDA	—	Food and Drug Administration
FTE	—	Full-Time Equivalent
HBCUs	—	Historically Black Colleges and Universities
HCDI	—	Healthy Community Design Initiative
HHS	—	Department of Health and Human Services
HIA	—	Health Impact Assessment
IDMS	—	Isotope-Dilution Mass Spectrometry
LPP/HHB	—	Lead Poisoning Prevention/Healthy Homes Branch
MOU	—	Memorandum of Understanding
NACCHO	—	National Association of County and City Health Officials
NBP	—	National Biomonitoring Program
NCEH/ATSDR	—	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NEPH	—	National Environmental Public Health Conference
NHANES	—	National Health and Nutrition Examination Surveys
TSAL	—	Tobacco and Smoking Addiction Laboratory
TSCA	—	Toxic Substances Control Act of 1976
VSP	—	Vessel Sanitation Program

EXECUTIVE SUMMARY

The Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a meeting of the Board of Scientific Counselors (BSC) on October 29-30, 2009 in Atlanta, Georgia.

The NCEH/ATSDR Director provided an update on several important developments that have occurred since the last BSC meeting in May 2009:

- CDC-wide organizational changes and five major priorities established by the new CDC Director.
- Key outcomes from the successful kick-off meeting of the National Conversation on Public Health and Chemical Exposures that was held in June 2009 in Washington, DC.
- NCEH/ATSDR's new Congressional appropriation in the FY2009 budget to conduct climate change activities.
- Increased funding in the FY2009 budget for the NCEH Division of Laboratory Sciences (DLS) to strengthen its Newborn Screening Program and National Biomonitoring Program.
- NCEH/ATSDR's role in new activities: reform of the Toxic Substances Control Act of 1976; more rigorous tobacco regulation by the Food and Drug Administration; and support to the Consumer Product Safety Commission in addressing ~60,000 homes containing Chinese manufactured drywall that have been built in the United States since 2006.

The BSC commended NCEH/ATSDR leadership and staff for convening the outstanding and informative 2009 National Environmental Public Health Conference. The BSC was particularly impressed with the high quality and diversity of the plenary and breakout sessions and speakers. The BSC also applauded DLS on leveraging increased funding for the Newborn Screening Program and the National Biomonitoring Program.

The Director of the NCEH Division of Emergency and Environmental Health Services (EEHS) presented a comprehensive overview to guide the BSC's external program peer review of four EEHS programs: Environmental Health Services Branch, Environmental Public Health Readiness Branch (EPHRB), Vessel Sanitation Program, and Healthy Community Design Initiative (HCDI). The overview covered a variety of areas, including EEHS's mission, staff, and ongoing and future activities.

Members of the BSC formed four breakout groups to review in-depth the four EEHS programs. The BSC was charged with addressing three key questions during the external program peer review of EEHS.

1. What are the current data gaps preventing EEHS from moving forward in providing services that promote public health?

2. What new or different activities can EEHS conduct to foster maximum support and benefit to state and local health departments?

3. Based on EEHS's mission and practice-based culture, what areas would the BSC (1) consider as markers of success in the next three to five years; (2) offer as meaningful strategies to measure impact; and (3) offer as advice on these indicators and initiatives?

In addition to providing EEHS with specific recommendations in response to the three peer review questions, the BSC also made general observations on two programs. The BSC viewed EPHRB's efforts and strategies as highly successful and effective because no accidents or contamination has occurred in communities. The BSC was extremely impressed with the breadth and scope of HCDI's activities. Despite the absence of a line item, HCDI has produced an extensive number of publications and developed several new tools for healthy community designs.

The BSC expressed overwhelming support of the new process of conducting external program peer reviews during meetings. However, the BSC noted improvements that should be made in several areas to refine the new process. A strategy should be developed for leadership and staff in NCEH/ATSDR programs to anonymously provide feedback on the effectiveness and value of the new peer review process. A mechanism should be created for the BSC to obtain input from NCEH/ATSDR's external partners and stakeholders and also to engage outside consultants to fill gaps in subject-matter expertise.

More time should be given for the BSC to meet with NCEH/ATSDR leadership and staff in programs that would be reviewed, compile key findings, and draft comprehensive and complete recommendations in response to the peer review questions. NCEH/ATSDR should provide the BSC with background materials well in advance of the peer review. The BSC Chair and NCEH/ ATSDR leadership proposed several options to address the BSC's concerns and improve the new process for the upcoming peer review.

The NCEH/ATSDR Acting Associate Director for Science described CDC's new clearance and peer review policies that will become effective on January 1, 2010. These policies address many of the recommendations in the BSC's peer review report of NCEH/ATSDR's peer review process and clearance policies. During the May 2010 meeting, NCEH/ATSDR would present its final program response to the BSC's report and also provide the BSC with both the revised clearance and peer review guidelines.

NCEH/ATSDR leadership provided updates on issues the BSC raised during previous meetings. These topics included:

- NCEH/ATSDR's outreach to Historically Black Colleges and Universities, Hispanic Serving Universities and Tribal Colleges to recruit a more diverse group of minority undergraduate students for the 2009 Collegiate Leaders in Environmental Health Internship Program.
- ATSDR's Amyotrophic Lateral Sclerosis Registry.
- The role of cross-cutting National Conversation themes (*i.e.*, agriculture, food, climate change, environmental justice and healthy community design) in informing NCEH/ ATSDR's ongoing and future activities.
- The "National Climate Change Research Agenda."

In preparation of the BSC's upcoming external program peer review during the May 2010 meeting, senior leadership provided a comprehensive overview of DLS and its three program areas: National Biomonitoring Program, Tobacco and Smoking Addiction Laboratory, and

Emergency Preparedness Laboratory, specifically its laboratory methods and research on botulism, anthrax and pandemic influenza. The overview covered a variety of areas, including DLS's staff, priorities, budget, and ongoing and future laboratory research and methods. The goals, objectives and overall process of the BSC peer review also were highlighted during the overview.

The BSC would be charged with providing DLS advice and recommendations in response to five peer review questions:

1. Are the DLS programs making contributions that are important and impact public health?
2. Are the anticipated growth areas important new directions for DLS's current programs?
3. What are potential barriers to DLS's projected growth and opportunities to overcome these challenges?
4. Are the new CDC project indicators and initiatives proposed by DLS adequate for their intended purpose?
5. Do the public health, regulatory and scientific communities fully utilize data produced by the DLS laboratories?

The BSC generally agreed on two issues for the upcoming peer review process of DLS: (1) DLS's proposed questions and overall process and (2) a deadline of January 1, 2010 to finalize the memberships of the four breakout groups for the DLS peer review.

The business items that the BSC raised over the course of the meeting are noted below for the record:

Action Items

- *NCEH/ATSDR will provide the BSC with advance notice via e-mail of registration deadlines and other important information related to EPH internship programs and training opportunities for both undergraduate and graduate students.*
- *NCEH/ATSDR will provide the BSC with the draft National Climate Change Research Agenda*.
- *NCEH/ATSDR will provide the BSC with PowerPoint slides of all DLS overviews presented during the meeting to assist the members in preparing for the upcoming external program peer review.*

Future Agenda Items

- *Update on joint activities conducted by FDA and the NCEH Tobacco and Smoking Addiction Laboratory*.
- *Tour of the NCEH laboratories [part of the DLS peer review during the May 2010 meeting.]*
- *Presentation on NCEH/ATSDR's internship programs for graduate students and other training opportunities for students*.

The Chair called for public comment at all times noted on the agenda published for the October 29-30, 2009 BSC meeting. The dates proposed for the next BSC meeting were May 6-7, 13-14, 20-21 or 27-28, 2010. NCEH/ATSDR would poll the members via e-mail to confirm the exact date.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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BOARD OF SCIENTIFIC COUNSELORS
October 29-30, 2009
Atlanta, Georgia

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 October 29-30, 2009 at the Sheraton Atlanta Hotel in Atlanta, Georgia.

Opening Session

Dr. Timothy Ryan, Chair of the BSC, called the meeting to order at 8:33 a.m. on October 29, 2009 and welcomed the attendees to the proceedings. He announced that BSC meetings are open to the public and all comments made are a matter of public record.

Dr. Ryan thanked Dr. Frumkin and other NCEH/ATSDR leadership and staff for convening the outstanding and informative 2009 National Environmental Public Health (NEPH) Conference. He noted that the BSC's attendance at the Conference would be extremely helpful in its ongoing role of providing advance and guidance to NCEH/ATSDR in its environmental public health (EPH) activities.

Dr. Ryan opened the floor for introductions and particularly recognized Dr. Frederick Angulo, Acting Associate Director for Science of NCEH/ATSDR, who has replaced Dr. Mark Bashor as the Designated Federal Official for the BSC. The list of participants is appended to the minutes as Attachment 1.

Dr. Ryan noted that the current agenda was structured differently than those in the past. The first day of the meeting primarily would be devoted to the BSC's external peer review of the NCEH Division of Emergency and Environmental Health Services (EEHS). To support this effort, the BSC members would meet in small breakout groups to engage in detailed discussions and provide input on four EEHS branches and programs. In response to the BSC's previous requests, an hour would be set aside on the following morning for the members to

discuss outstanding issues and for NCEH/ATSDR to present its responses to current recommendations.

NCEH/ATSDR Director's Report

Dr. Howard Frumkin, Director of NCEH/ATSDR, covered the following areas in his update. The Obama Administration appointed Dr. Thomas Frieden as the new CDC Director on May 15, 2009. Dr. Frieden recommended several organizational changes across CDC soon after he assumed his position in June 2009. The CDC Coordinating Centers will be eliminated. Efforts are underway to relocate Coordinating Center leadership and staff to other positions in CDC.

Associate Directors will serve as communication conduits between the National Center Directors and the Office of the CDC Director. The National Center for Public Health Informatics and the National Center for Health Marketing were established as new operating units under CDC's previous organizational structure. These two National Centers will be abolished and their functions will be returned to other organizational units in CDC.

Dr. Frumkin summarized the five major priorities Dr. Frieden has established for CDC. One, CDC will enhance its capacity in surveillance and epidemiology by establishing the Office of Surveillance, Epidemiology and Laboratory Services. The new office will be responsible for streamlining CDC's surveillance and epidemiology activities and also ensuring that solid data are collected and serve as the basis of sound public health decision-making. Two, CDC will strengthen its capacity in global health by establishing a new Center for Global Health. The International Emergency and Refugee Branch will be transferred from NCEH to the Center for Global Health.

Three, CDC will increase its support to state and local health departments. Four, CDC will enhance its focus on applicable, actionable and priority health problems that are relevant to policy actions. For example, CDC will emphasize cardiovascular disease, cancer, injuries and other diseases or conditions that are significant contributors to the burden of morbidity and mortality and result in tremendous gains or returns in the public health investment. Five, CDC will play a key role in engaging the public health community and incorporating prevention into health reform. The Obama Administration, HHS and CDC have identified health reform as a top priority.

For all five priorities, Dr. Frieden has reinforced the critical need for CDC to be held accountable for all of its activities and measure its impact. To support this effort, all CDC National Centers will be required to comply with the "Quarterly Performance Review." Leadership in each CDC National Center will present their ongoing programs and outcome metrics for each activity to Dr. Frieden and make improvements based on his feedback. Dr. Frumkin was pleased to announce that Dr. Frieden is aware and extremely supportive of NCEH/ATSDR's Health Impact Assessment (HIA) Initiative. As a result of this high-level support, NCEH/ATSDR has requested additional funding and expects to expand its HIA activities in the future.

Dr. Frumkin provided an update on the National Conversation on Public Health and Chemical Exposures. The kick-off meeting that was held in June 2009 in Washington, DC was extremely successful and reflected tremendous interest based on the participation of ~600 stakeholders from various sectors. NCEH/ATSDR and its federal partners made opening remarks during the meeting to emphasize that the National Conversation is a collaborative effort with strong support and endorsement of multiple agencies.

A number of community activists used the kick-off meeting as an opportunity to express their frustration with what they perceived as a lack of responsiveness to community concerns by ATSDR. Based on these comments, NCEH/ATSDR reaffirmed the critical need for extensive engagement of communities in all aspects of the National Conversation. Activities will be designed to assure public health protection from chemicals at all levels, including national policy reform at the top level and service to communities at the ground level.

Six expert workgroups were formed with ~30 members in each group to conduct specific activities in the National Conversation. The workgroup members were selected to reflect diversity in geographical locations, professional backgrounds, sectoral representation, gender and race/ethnicity. The functions of the six expert workgroups are highlighted as follows. The Monitoring Workgroup will collect information on chemical use, exposure pathways, exposure levels and health outcomes. The Scientific Understanding Workgroup will fill knowledge gaps on the health effects of chemicals.

The Policies and Practices Workgroup will reduce harmful chemical exposures and adverse health outcomes, eliminate inequities, and spur the development and use of safer alternatives. The Chemical Emergencies Workgroup will prevent, prepare for, and respond to acute chemical incidents. The Serving Communities Workgroup will address local chemical exposure concerns to promote environmental justice and improve health. The Education and Communication Workgroup will ensure a well-informed public and a competent network of healthcare providers.

NCEH/ATSDR staff members serve on each expert workgroup to take notes, collect information and provide other support as needed. All of the workgroups have convened conference calls and will hold face-to-face meetings in the near future. Each of the six expert workgroups will provide NCEH/ATSDR with recommendations over the next year, but most members are overwhelmed by their scope of activities, charges and tasks at this time. NCEH/ATSDR recognizes and appreciates the tremendous challenge in workgroup members with diverse backgrounds and perspectives attempting to provide federal agencies with focused, specific and actionable guidance in the extremely broad area of “public health protection from toxic chemicals.”

In addition to the six expert workgroups, a Leadership Council on Public Health and Chemical Exposures also was established with ~30 experts to oversee the entire process of the National Conversation. The Council members represent environmental agencies, industry, academia, and federal, state and local governments. NCEH/ATSDR was extremely pleased with the strong representation by the BSC members on both the Council and the six expert workgroups.

Dr. Frumkin highlighted key developments in NCEH/ATSDR's other EPH activities that have occurred since the May 2009 BSC meeting. NCEH/ATSDR received a new Congressional appropriation in the FY2009 budget to conduct climate change activities. NCEH/ATSDR used some of the new funds to build capacity by supporting ~22 intramural and extramural climate change research projects. Most of the intramural projects submitted by NCEH/ATSDR Investigators focused on vector-borne disease research relative to climate change, heat waves and climate change communications. Based on the extramural proposals that were submitted, NCEH/ATSDR expects to increase its public health role in both mitigation and adaptation policies for climate change.

NCEH/ATSDR allocated a large portion of the climate change appropriation to ~10 state and local health departments to pilot forecasting, modeling and preparedness initiatives related to climate change. NCEH/ATSDR hopes that additional funding will be available in the future to expand the climate change pilot projects to more areas of the country.

NCEH/ATSDR allocated the remainder of the new climate change appropriation to building an internal staff with responsibility for supporting conferences and partner organizations that will conduct activities in this area. Overall, NCEH/ATSDR is using the new funding to implement a solid Climate Change Strategic Plan, begin building a robust Climate Change Program, and play a critical role in the enormous interest in climate change at the White House and HHS levels.

The FY2009 budget included increased funding to strengthen the Newborn Screening Program and the National Biomonitoring Program within the NCEH Division of Laboratory Sciences (DLS). The Toxic Substances Control Act (TSCA) of 1976 is the major legal framework for regulating toxic chemicals in the United States. However, the public health, environmental health and industry communities view TSCA as an ineffective tool. Most notably, major legal burdens have allowed the U.S. Environmental Protection Agency (EPA) to only regulate five chemicals. Moreover, companies are not required to conduct pre-market testing or toxicity assessments before introducing new chemicals.

The current interest in harmonizing the approach to chemical regulation has led to the development of the "Kids Safe Chemical Act" within TSCA reform. This legislation might pass in the near future due to strong energy and interest in TSCA reform by the Obama Administration, EPA leadership, environmental groups and industry. Biomonitoring is a critical part of TSCA reform and calls for CDC to provide EPA with solid data on chemical burdens in the bodies of Americans. If the CDC biomonitoring program is expanded under TSCA reform, NCEH will have an opportunity to increase its expertise in geographic disaggregation.

More rigorous tobacco regulation by the Food and Drug Administration (FDA) will have implications for NCEH in the future. Most notably, the NCEH Tobacco Laboratory will be expected to greatly increase its analyses of specific contaminants and components in cigarette smoke. Dr. Frumkin confirmed that the BSC would receive more details in the future on collaborative efforts between FDA and the NCEH Tobacco and Smoking Addiction Laboratory. He also asked Drs. Angulo and Ryan to place a tour of the laboratory on the agenda for the next BSC meeting.

NCEH/ATSDR, EPA, and state health and environmental agencies are continuing to support the Consumer Product Safety Commission (CPSC) in addressing ~60,000 homes containing Chinese manufactured drywall that have been built in the United States since 2006. Public, political and media attention have focused on complaints submitted across the country regarding damage to home structures and a multitude of health symptoms, including respiratory irritation.

Federal and state agencies conducted a series of exposure studies to assess specific chemicals in Chinese manufactured drywall. CPSC will release results of the exposure studies on October 29, 2009 in Washington, DC. After exposures from Chinese manufactured drywall have been identified, NCEH/ATSDR will undertake several efforts if appropriate. Symptom-based or health-based studies will be conducted; health surveys will be administered; and assistance will be provided to CPSC in health communications activities.

In response to Dr. Frumkin's request for feedback, several BSC members who attended the 2009 NEPH Conference commented that many new NCEH/ATSDR employees were not familiar with environmental justice (EJ) or other EPH issues. The BSC members were pleased that the NEPH Conference provided an opportunity for new NCEH/ATSDR staff to interact with stakeholders from state and local agencies, professional organizations and communities.

The BSC members also were impressed by the high quality and diversity of the plenary and breakout sessions and speakers. These inspirational sessions and speakers covered several issues across multiple sectors, including transportation, housing, agriculture and energy. The NEPH Conference emphasized NCEH/ATSDR's strong collaborations with state and local health departments and allowed the BSC members to extensively network with these partners. The BSC members encouraged NCEH/ATSDR to replicate the successes of the 2009 NEPH Conference (*i.e.*, numerous networking opportunities and diverse speakers and sessions) while planning future conferences.

In response to Dr. Frumkin's update, the BSC commended NCEH/DLS on leveraging increased funding for the Newborn Screening Program and the National Biomonitoring Program and also for closely collaborating with the Association of Public Health Laboratories (APHL) and other partners to distribute these dollars. The BSC noted that additional resources for these programs would be extremely beneficial to state public health laboratories.

The BSC members made two key suggestions for NCEH/ATSDR to consider in enhancing its EPH activities. First, NCEH/ATSDR should not use the terms "mitigation" or "adaptation" when describing its climate change activities because CDC's mission focuses on different levels of "prevention." Instead, NCEH/ATSDR should define these activities as "climate change health prevention" at various levels. Second, NCEH should use TSCA reform as an opportunity to resolve the historical incompatibility between EPA and HHS/CDC databases for monitoring environmental exposures.

Overview of the NCEH Division of Emergency and Environmental Health Services (EEHS)

Dr. Sharunda Buchanan, Director of EEHS, provided background information to guide the BSC's deliberations on the EEHS external program peer review. EEHS's organizational structure includes the Office of the Director, Environmental Health Services Branch (EHSB), Environmental Public Health Readiness Branch (EPHRB) [formerly the Chemical Weapons Elimination Branch], Vessel Sanitation Program (VSP), Healthy Community Design Initiative (HCDI), and Lead Poisoning Prevention/Healthy Homes Branch (LPP/HHB).

EEHS's multidisciplinary staff includes ~120 scientists, chemists, chemical engineers, public health advisors, environmental health officers, medical epidemiologists, veterinarians, behavioral scientists, sanitarians, and two Commissioned Corps Chief Professional Officers who provide expertise to CDC and the Commissioned Corps. The EEHS staff has expertise in diverse areas, such as lead poisoning prevention, food safety, HIAs, vector control, war-related injuries, cruise ship inspections, healthy homes and emergency preparedness.

EEHS's overall mission is to create and shape healthy communities through environmental health practice by revitalizing the EPH system, building capacity, developing policy, improving practice and sustaining health. EEHS's EPH activities are consistent with the priorities Dr. Frieden has established for CDC to strengthen capacity in surveillance and epidemiology; enhance capacity to support state and local public health; provide public health leadership in global health, health reform and other healthy policies; and better address the leading causes of death and disability.

Dr. Buchanan summarized three key questions the BSC would be charged with addressing during the external program peer review of EEHS.

1. What are the current data gaps preventing EEHS from moving forward in providing services that promote public health?

2. What new or different activities can EEHS conduct to foster maximum support and benefit to state and local health departments?

3. Based on EEHS's mission and practice-based culture, what areas would the BSC (1) consider as markers of success in the next three to five years; (2) offer as meaningful strategies to measure impact; and (3) offer as advice on these indicators and initiatives? Potential indicators or initiatives for the BSC to consider in evaluating EEHS's success and performance in providing both health and environmental benefits include:
   - the number of oversight inspections of Army facilities that stockpile chemical weapons;
   - the number of chemical agent releases beyond the boundaries of Army destruction facilities that have the potential to impact surrounding communities;
   - the number of cruise ships inspected quarterly;
   - continued decline of skilled EPH workers at state and local levels;

- efforts to define and market EPH services to policymakers and the public to gain support for these services at state and local levels; and
- insufficient funding for improving the science that supports EPH services at federal, state and local levels.

Dr. Buchanan explained that two branches would not be included in the BSC's external program peer review of EEHS. LPP/HHB obtains external advice from a separate committee chartered under the Federal Advisory Committee Act. The International Emergency and Refugee Health Branch would be transferred from EEHS to CDC's new Center for Global Health.

Dr. Buchanan noted that the BSC would meet in breakout groups to provide advice to EHSB, HCDI, EPHRB and VSP in response to the three key questions for the external program peer review of EEHS. She confirmed that leadership and staff in each of the four EEHS programs would be available to the BSC during the breakout groups to clarify issues or answer questions as needed. She highlighted the major activities of the four programs that would be included in the BSC's external program peer review of EEHS.

EHSB's environmental health officers, behavioral scientists, veterinarians, computer specialists and other staff provide technical assistance in the field to state and local environmental health programs; investigate multi-state and local disease outbreaks; serve as first responders to floods, hurricanes and other natural disasters; and assist in rebuilding capacity at state and local levels following emergencies. The EHSB website is www.cdc.gov/nceh/ehs.

HCDI's community planners, architects and other staff provide expertise and an evidence-based context to bridge the gap between health issues and the planning, design and use of land. HCDI's focus areas include science, partnerships, HIAs, education, training and communication. HCDI recognizes that healthy community designs can increase social capital and also can improve mental health, respiratory health, chronic disease and environmental health outcomes. EEHS has informed NCEH/ATSDR leadership of its strong interest in advancing HCDI from an initiative to a formal branch. The HCDI website is www.cdc.gov/healthyplaces.

EPHRB (formerly the Chemical Weapons Elimination Branch) is mandated to address public health and safety during weapons handling, disposal and destruction at Department of Defense stockpile sites. EPHRB also provides onsite medical response if necessary. The EPHRB website is www.cdc.gov/nceh/demil.

VSP's pay-for-service agreement with the private cruise ship industry is a unique funding stream in the federal government. VSP thoroughly inspects vessels; investigates outbreaks of disease or illness on cruise ships, and provides technical assistance to the cruise ship industry to minimize the risk for transmission of gastrointestinal diseases by safely providing food and water. The VSP website is www.cdc.gov/nceh/vsp and is one of CDC's most frequently visited websites.

Dr. Buchanan concluded her overview by emphasizing that EEHS's overarching goal is to weave science, policy and practice in all of its EPH activities. She confirmed that EEHS

welcomes the BSC's expert advice and recommendations on improving the effectiveness and efficiency of its EPH activities.

In response to specific questions posed by the BSC members during the discussion, Dr. Buchanan provided more details on EEHS in the following areas:

- Differences between the missions, functions and activities of EEHS and the NCEH Division of Environmental Hazards and Health Effects (EHHE).
- Levels of education and academic training among leadership and staff in each EEHS operating unit in the areas of EPH practice and science.
- EEHS's broad performance measure of the number of cruise ships inspected quarterly rather than more focused indicators, (*i.e.*, a reduction in the incidence of foodborne illness on cruise ships or a decrease in the number of non-compliant water systems).

Dr. Angulo made several remarks to provide the BSC with a clear context for the peer review of EEHS. CDC guidance for Boards of Scientific Counselors to conduct external research and scientific program reviews requires all programs to undergo external peer review at least once every five years through the BSC structure. Dr. Frieden has noted that the Boards of Scientific Counselors are an important asset to CDC and provide valuable advice to the HHS Secretary and CDC Director on strategies and goals for programs and research. Dr. Angulo pointed out that CDC's external program peer review policy and Dr. Frieden's written statement on the critical role of CDC's Boards of Scientific Counselors were distributed to the BSC for review.

Dr. Angulo provided the BSC with more specificity on its charge to conduct an external peer review of EEHS in response to comments Dr. Kegler made during the discussion. She conveyed that the BSC was charged with providing guidance to EEHS at the division level by responding to the three peer review questions, but the BSC members would meet in breakout groups to address these issues at the program level. Dr. Angulo acknowledged that the external program peer review was targeted to EEHS at the division level, but the BSC would need to first provide recommendations to EEHS by focusing on activities conducted at the program level.

Dr. Angulo explained that during the four breakout groups, EEHS leadership and staff at the program level would provide the BSC members with more information on their specific EPH activities. BSC members in each of the four breakout groups would discuss information presented by EEHS program staff, draft a brief and succinct one- to two-page summary of the key findings, and present the summary report to the full BSC.

The BSC would synthesize recommendations and findings from the four workgroup summary reports in order to draft a comprehensive peer review report to EEHS at the division level. However, the full peer review report would highlight key recommendations and findings the BSC members made during the four breakout groups of the EEHS programs.

Because the BSC would meet for less than 4 hours in the breakout groups, Dr. Angulo advised the members to focus their discussions on answering the three peer review questions Dr. Buchanan highlighted during her presentation. He also asked the members to provide feedback

on whether convening workgroups during formal BSC meetings would be an effective or ineffective approach in conducting external program peer reviews.

Dr. Angulo clarified that at this point, NCEH/ATSDR has not eliminated the BSC's current process of forming a peer review team, conducting a site visit of the program, and drafting and presenting a report outside of BSC meetings. However, he emphasized that an efficient and streamlined process must be implemented for the BSC to submit its peer review report to NCEH/ATSDR by the end of January. This timeline would allow the NCEH/ATSDR program that was reviewed to draft and present its formal response to the BSC peer review report during the May meeting.

Dr. Ryan concluded the discussion by encouraging the BSC members to use the background materials that were distributed to inform their deliberations during the breakout groups. These documents included comprehensive overviews of EEHS and the four EEHS programs the BSC would review, including their organizational structures, budgets and staff; EEHS publications from 2007 to the present; the BSC's peer review report of EHSB in September 2005; and EHSB's response to the BSC's peer review report in April 2006.

Dr. Ryan recessed the meeting for the BSC members to report to their respective breakout groups.

Reports by the BSC Breakout Groups

Environmental Health Services Branch (EHSB). Drs. Anna Fan, Andrea Kidd Taylor and Leonardo Trasande attended the breakout group meeting. Dr. Hal Zenick, the BSC *ex-officio* member for EPA, was absent. Dr. Timothy Ryan participated in another breakout group due to the absence of two members. Dr. Trasande's report of the breakout group's key findings of EHSB is outlined below.

Question 1: How should the impact of EHSB's activities be measured? The breakout group identified measures in several areas to address this question. Outputs should include the number of trainees who completed web-based training, the number of local and state health department representatives who completed the Environmental Health Training in Emergency Response Course, and the number of institutions that became certified in environmental health.

Capacity assessments should include documentation of expertise at state and local levels that is acquired over time in chemical hazards and other areas. This measure also should include areas where EHSB is able to, but is not providing training at the present time. Outcomes should include natural experiments documenting preventable events (ideally with risk reductions) as well as health outcomes and economic costs that could have been prevented.

Environmental health standards should be established for local and state health departments. This core function is not being accomplished at this time with the exception of a few food safety

standards under the purview of FDA. State and local stakeholders that have benefited from EHSB's efforts should be identified.

For example, the National Association of County and City Health Officials (NACCHO), National Association of Local Boards of Health, and Association of State and Territorial Health Officials should be engaged to communicate EHSB's successes and benefits to Congressional leadership, elected officials and stakeholders. EHSB should enhance linkages with ATSDR to harmonize an intra-agency approach to supporting local public health departments. The breakout group noted that EHSB would not need to allocate additional resources to implement this strategy.

Question 2: What strategies should be implemented to ensure that EHSB is involved earlier in Epi-Aid activities? The breakout group agreed that state and local health departments should request environmental health expertise. The CDC Epidemic Intelligence Service (EIS) Program also should be expanded to include environmental health practitioners who do not have the current requirement of a doctor of medicine, doctor of veterinary medicine or nursing degree.

Question 3: What actions should be taken to incorporate a solid line item for EHSB into the CDC budget? The breakout group agreed that local and individual impacts should be documented. Impacts at both state and program levels should be routinely measured even if resources must be diverted and intervention activities are limited as a result. Funding streams in the past have not required state and local programs to document and track impacts long-term.

A longer-term product should be developed for stakeholders to support new funding for EHSB. For example, a stronger focus should be placed on evidence-based metrics in FDA's new food safety guidelines. "Preventive Services Guidelines for Environmental Health" should be created to assess the usefulness of interventions. EIS case studies should be reviewed to compile lessons learned and document failures with an emphasis on secondary and tertiary prevention. Consideration should be given to changing the EIS Program to a "Prevention Intelligence Service" Program.

Environmental Public Health Readiness Branch (EPHRB). Drs. Janice Chambers and Timothy Ryan attended the breakout group meeting. Dr. Darryl Barnett and the Honorable Gerard Scannell, BSC members, were absent. Dr. Chambers' report of the breakout group's key findings of EPHRB is outlined below.

Leadership and staff informed the BSC members that EPHRB emphasizes prevention with vigilance. EPHRB was formerly the Chemical Weapons Elimination Branch and receives the majority of its funding from the Department of Defense. A treaty and Congressional mandate authorize EPHRB to provide oversight of the Army for disposal of stockpiled chemical weapons, but this function does not include non-stockpiled chemical weapons. EPHRB's mission will decrease over time as the disposal of stockpiled chemical weapons is completed.

Question 1: What are the current data gaps preventing EPHRB from moving forward in providing services that promote public health? The breakout group noted the uncertainty in the

closure time of stockpile facilities. The original closure date was scheduled for 2007, but the five-year extension delayed the date until 2012. However, the breakout group did not find the extended date of 2012 to be feasible because two stockpile facilities planned for closure have not been constructed at this time.

Incineration traditionally has been used as the "best" disposal technology, but concerns have been raised about hazards with this method. Concerns also have been expressed as to whether new alternative technologies that are being developed will be as safe as incineration. Most notably, hydrolysis technologies have been found to result in more secondary waste stream.

The breakout group proposed that a risk assessment be conducted to compare incineration to alternative technologies to determine the best or most hazardous methods. EPHRB's mandate is limited to stockpiled chemical weapons, but 200,000 relatively small non-stockpiled case sets and other discarded chemical weapons are buried in known and unknown locations.

Question 2: What new or different activities can EPHRB conduct to foster maximum support and benefit to state and local health departments? The breakout group learned that because states have already deployed staff to disposal facilities, opportunities are limited for EPHRB to increase involvement of state and local health departments.

EPHRB has served as an "interpreter" to the public in the past on risks related to incineration technologies. The breakout group advised EPHRB to expand its interpretation role to inform the public about the relative safety and risks of new disposal technologies. Overall, the breakout group found EPHRB's efforts and strategies to be highly successful and effective because no accidents or contamination has occurred in communities.

Question 3: What areas would the BSC consider as markers of EPHRB's success in the next three to five years? The breakout group agreed that continued prevention of adverse impacts on communities would serve as a sound indicator of success. Because EPHRB considers workers to be part of the public, the breakout group suggested standard statistics of worker safety (*i.e.*, missed days or injury rates) as an additional marker of success. EPHRB should compare statistics between disposal facilities and other chemical management activities.

Question 4: What meaningful strategies should EPHRB use to measure impact? The breakout group agreed that the number of recommendations implemented by the Army to prevent contamination and accidents could be used as a strategy to measure the impact of EPHRB.

Question 5: What advice would the BSC offer on EPHRB's indicators and initiatives? The breakout group agreed that EPHRB has substantial and unique expertise in engineering, manufacturing and risk assessment. The EPHRB staff has a longstanding collaborative and cohesive relationship in addressing disposal of stockpiled chemical weapons.

The breakout group emphasized the critical need for EPHRB to maintain its specialized expertise as disposal facilities are closed over time. For example, EPHRB's collective expertise in risk assessments should be broadened beyond stockpiled chemical weapons disposal, such

as global contamination in the former Soviet Union and underwater disposed weapons that serve as risks to the public.

Vessel Sanitation Program (VSP). Drs. William Becker, Arthur Frank and Michelle Kegler attended the breakout group meeting. Dr. Lee Sanderson, the BSC *ex-officio* member for the National Institute for Occupational Safety and Health, was absent. Dr. Becker's report of the breakout group's key findings of VSP is outlined below.

VSP was established in 1970 with a mission to assist the cruise ship industry in preventing and controlling the introduction, transmission and spread of gastrointestinal illness on cruise ships from foreign to U.S. ports. The VSP staff of ~8 personnel inspects 140 ships twice per year and conducts ~300 additional inspections each year. VSP serves as an applied public health program with activities in five major categories: training, reviews of ships in the planning stage, consultation on ship construction, investigations and outbreak investigations.

VSP is a self-sustaining and fee-based program that has a tremendous partnership with and enormous trust of the vessel industry. VSP serves as a respected consultant to both the United States and other countries and has provided expertise for two Olympics, the World Health Organization, hotel industry and health departments.

Question 1: What are the current data gaps preventing VSP from moving forward in providing services that promote public health? The breakout group noted that VSP's current paper-based data collection system should be modernized. VSP's data are not fully communicated to other CDC programs. VSP has not bridged communication gaps with state and local health departments by providing a mechanism for real-time reporting of potential illnesses. VSP has not fully addressed the data needs of foreign vessel programs and governments.

Question 2: What new or different activities can VSP conduct to foster maximum support and benefit to state and local health departments? The breakout group advised VSP to improve communications with state and local health departments.

Question 3: What areas would the BSC consider as markers of VSP's success in the next three to five years? The breakout group noted that VSP currently uses the number of inspections and outbreaks per year as markers of success, but these indicators do not have sufficient details to demonstrate VSP's actual success. The breakout group advised VSP to collect and analyze its existing data as candidate markers of success.

Question 4: What meaningful strategies should VSP use to measure impact? The breakout group advised VSP to conduct evaluations and implement an outcomes-based process to measure its impact. For example, pre-/post-surveys could be administered to determine behavior changes among vessel personnel who attended a VSP training course and assess the impact of a VSP training course on inspection scores of cruise ships. The breakout group noted that the vessel industry would greatly appreciate annual evaluations to ensure the competency of VSP inspectors and a standardized approach to conducting inspections and complying with regulations.

Question 5: What advice would the BSC offer on VSP's indicators and initiatives? The breakout group advised VSP to fill its medical epidemiologist position that is vacant at this time. VSP should develop an evidence-based approach to better demonstrate the long-term public health benefits of its vessel inspections. This strategy might result in positive changes in VSP's current scoring system of vessels.

Healthy Community Design Initiative (HCDI). Dr. Jonathan Patz, Mr. Matthew Stefanak, and Drs. David Wallinga and Cynthia Warrick attended the breakout group meeting. Dr. Patz's report of the breakout group's key findings of HCDI is outlined as follows. The breakout group was extremely impressed with the breadth and scope of HCDI's activities. Despite the absence of a line item, HCDI has produced an extensive number of publications and developed several new tools for healthy community designs.

Question 1: What are the current data gaps preventing HCDI from moving forward in providing services that promote public health? The breakout group noted that the appropriateness of HCDI's name has not been formally evaluated in focus groups and research has not been conducted to determine whether HCDI's information and activities will resonate with end-users and communities. HCDI's original name was the "Built Environment Initiative."

The breakout group learned that HCDI is challenged by the lack of quantitative and qualitative indicators to clearly define a "healthy community." The breakout group noted that physical activity, mental stress and social capital could be used as health indicators in the future, but HCDI was encouraged to apply intermediate or surrogate indicators to clearly define a healthy community in the interim. The breakout group pointed out that existing databases in the business community track the number of persons who eat in fast food restaurants. Indicators in the smart growth movement are available as well.

The HCDI staff includes an urban planner, architect, EIS Officer, and communications and nutrition experts. The breakout group advised HCDI to expand its staff to include expertise in HIA, transportation, social capital, motor vehicle accident injuries, physical activity, EJ, and geographic information systems to determine geospatial relationships between communities and roads, parks and healthy foods in grocery stores.

Question 2: What new or different activities can HCDI conduct to foster maximum support and benefit to state and local health departments? The breakout group advised HCDI to conduct a comprehensive inventory of existing databases, such as the CDC Behavioral Risk Factor Surveillance System. HCDI should compile and disseminate findings of the database inventory to state and local public health departments.

HCDI should embed healthy community designs into the CDC National Environmental Public Health Tracking Program. HCDI should partner with areas that have Community Block Grant Development Programs and communities with existing momentum in EJ, community food security and similar areas. HCDI should make a strong case to demonstrate the benefits of healthy community designs beyond the health sector, such as local infrastructure and jobs.

HCDI should develop a broader and more diverse advocacy base. In addition to participating in the Congress for the New Urbanism, HCDI also should have strong representation at Annual Environmental Justice Conferences, Community Food Security meetings, Community Campus Partnerships for Health and NACCHO meetings.

HCDI should convene a session during the next Annual Environmental Justice Conference in May 2010 in Washington, DC. HCDI should continue to develop its healthy community design curriculum, but the curriculum should be incorporated into courses for undergraduate and graduate students at the MPH and MS levels to ensure training is provided to future health department officials in the pipeline.

HCDI should take advantage of language in the National Environmental Policy Act that requires health to be considered in environmental impact statements (EISs). HCDI provides input on EISs in accordance with its Congressional mandate, but has no full-time equivalent (FTE) or funding to support this activity.

The breakout group viewed this discrepancy as a missed opportunity and emphasized the critical need for HCDI to receive a Congressional appropriation to formally review EISs to determine health impacts. The breakout group considered this function to be one of HCDI's highest priorities and an important opportunity for NCEH/ATSDR to improve the public health of the nation.

The breakout group suggested targeting funding for HCDI to review transportation project EISs initially and then expanding these dollars to support EIS reviews for other projects in the future. The breakout group advised HCDI to partner with other federal agencies that have more funding for EIS reviews, such as EPA, the U.S. Department of Transportation, and U.S. Department of Housing and Urban Development. HCDI should determine whether linkages can be established with these agencies to demonstrate the benefits of healthy community designs in sectors beyond health.

Question 3: What areas would the BSC consider as markers of HCDI's success in the next three to five years? The breakout group proposed several indicators to measure HCDI's success, such as a multivariate index of healthy communities that could be ranked; a formal indicator in the *Healthy People 2020 Initiative*; full engagement of health officials in a number of city planning groups; the number of HIAs in new transportation projects; dedicated funding for health community design in the CDC budget; and adoption and implementation of a healthy community design toolkit by communities.

At the conclusion of the four breakout group reports, the BSC asked leadership and staff to provide additional information on activities in their respective EEHS programs. The discussion topics primarily focused on existing gaps in CDC's surveillance of vector-borne diseases and continued synergy, coordination and collaboration across the CDC National Centers in light of the elimination of the Coordinating Centers.

In addition to the peer review of a specific program, Dr. Frank questioned whether the BSC also should provide broader recommendations and advice on NCEH/ATSDR's current organizational

structure. For example, he noted that EPHRB and VSP function extremely well, but do not appear to be appropriately housed in NCEH/ATSDR due to their different funding streams, specialized expertise and unique activities in the areas of disposal of stockpiled chemical weapons and vessel sanitation, respectively.

In response to Dr. Frank's observations, Dr. Frumkin encouraged the BSC to provide guidance to NCEH/ATSDR based on the functional outcomes and impact of its operational units rather than organizational charts. For example, the BSC might see a need to suggest organizational changes for CDC to better coordinate water activities between the National Center for Zoonotic, Vector-Borne and Enteric Diseases and NCEH/EEHS and EHHE. The BSC also might advise CDC to implement organizational changes to strengthen synergies between EEHS and ATSDR in providing support to local EPH agencies.

In response to Dr. Trasande's question, Dr. Frumkin explained that he was unaware of any plans at this time to merge the BSC and NCEH/ATSDR's other advisory group, the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP).

Dr. Angulo further clarified that the Office of the Chief Science Officer views BSCs as the premiere advisory body for CDC. As a result, advisory committees are expected to report their findings to BSCs and BSCs should feel comfortable in reviewing the recommendations of advisory committees. During a future meeting, Dr. Angulo was interested in exploring a process to bridge gaps and strengthen relationships between the BSC and ACCLPP. He pointed out that the minutes of the March 2009 ACCLPP meeting were distributed to the BSC for review.

Dr. Ryan opened the floor for the BSC to provide any of the four EEHS programs with additional input on their activities. The BSC made four key suggestions in this regard.

- EEHS should recruit students to work in EHSB, EPHRB, VSP and HCDI during summer internships. For example, VSP could instruct students on analyzing existing data because the staff does not have sufficient time to undertake this effort on a regular basis. Summer internships also could enhance the pipeline of future EPH professionals.
- EEHS should collaborate with the Pan American Health Organization to compile lessons learned and best practices in disaster preparedness from other countries.
- HCDI should closely collaborate with EHHE on the Climate Change Initiative. The two programs could utilize this partnership to help communities in preparing for future environmental stresses, such as the urban heat island effect, natural disasters, extreme and intense rainfall events, and storm runoff.
- HCDI should ensure that its communications and messages are framed to generate interest in healthy community design among communities with no first-hand experience or knowledge of this concept. For example, HCDI's communication materials should be designed with more pictures than words to clearly convey the purpose and intent of a "healthy community."

Dr. Ryan opened the floor for the BSC to comment on the new peer review process. The BSC expressed overwhelming support of the new process for conducting external peer reviews of NCEH/ATSDR programs and made several comments on this issue. BSC members who

served on peer reviews in the past noted that the previous process was extremely lengthy, time-consuming and resource-intensive for both the BSC and NCEH/ATSDR staff. The BSC was in favor of refining and applying the shorter and more intense process to future peer reviews.

Some members believed the new peer review process gave the BSC an opportunity to make a greater contribution to improving NCEH/ATSDR programs and provide meaningful feedback more rapidly. Several members also noted that the new peer review process served as a more efficient and productive use of the BSC's time and expertise.

Before the new peer review process is institutionalized, however, the BSC emphasized the critical need for EEHS leadership and staff to provide their feedback and perspectives on the value and benefits of this approach. EEHS should anonymously submit comments on whether the new peer review process allowed the BSC to provide concrete recommendations on improving its programs. The BSC also asked NCEH/ATSDR to reevaluate the success of the new peer review process based on the accuracy and content of the full peer review report to EEHS.

The BSC members also pointed out the need to address and resolve four issues regarding the new process before the next peer review is conducted.

- The new peer review process did not include two extremely important components from the previous process: (1) a full-day site visit for the BSC to meet with NCEH/ATSDR leadership and staff in the program that would be reviewed, and (2) conference calls for the BSC to obtain input from NCEH/ATSDR's external partners and stakeholders.
- The new peer review process allotted <4 hours for the BSC members to engage in dialogue with program leadership and staff and compile key findings during the breakout groups. This time was insufficient for the breakout groups to draft comprehensive and complete recommendations in response to the peer review questions.
- The new peer review process did not allow the BSC to engage external subject-matter experts. Existing expertise on the BSC might be inadequate for each NCEH/ATSDR program that will be reviewed. For example, no analytical chemists serve on the BSC, but expertise in this area will be critical for the upcoming peer review of the NCEH Division of Laboratory Services.
- The new peer review process did not provide adequate time for NCEH/ATSDR to distribute sufficient background materials to the BSC well in advance of the meeting. For example, the breakout group for VSP used a significant portion of its time in listening to a "VSP 101" presentation.

Drs. Ryan and Thomas Sinks, Deputy Director of NCEH/ATSDR, proposed several options to address the BSC's concerns with the new peer review process. EEHS leadership and staff could provide Dr. Ryan with anonymous comments on the BSC's new peer review process by the end of the day. EEHS's feedback would be included in the BSC's discussion of outstanding issues on the following morning.

Overviews of NCEH/ATSDR programs that precede the BSC's onsite peer reviews could be modified to include comments and perspectives by key external partners and stakeholders.

External subject-matter experts could be identified prior to onsite peer reviews and assigned to serve on breakout groups along with BSC members as appropriate.

Dr. Ryan described the next steps in the BSC's external program peer review of EEHS. Key findings generated by the four breakout groups will be compiled into an initial draft summary report in January 2010. The initial draft will be distributed to the full BSC for review, comments and revisions. The final draft summary report will be submitted to EEHS for a formal response and presented at the next BSC meeting in May 2010. In terms of the new peer review process, Dr. Ryan was pleased that the BSC supported this approach. He confirmed that the BSC's comments and concerns would be taken into account to refine the process for future reviews.

With no further discussion or business brought before the BSC, Dr. Ryan recessed the meeting at 4:49 p.m. on October 29, 2009.

Discussion of Outstanding BSC Issues and NCEH/ATSDR Responses to BSC Recommendations

Dr. Ryan reconvened the BSC meeting at 8:05 a.m. on October 30, 2009. He opened the floor for a discussion on NCEH/ATSDR's responses to the BSC's previous recommendations and outstanding BSC issues.

TOPIC 1: NCEH/ATSDR's Responses to BSC Recommendations. Dr. Angulo explained that CDC policy requires each National Center to archive and formally respond to recommendations made by all BSCs. He noted that the BSC was provided with the home page of the NCEH/ ATSDR Office of Science Intranet site for peer reviews of intramural programs. The website outlines CDC's current policy for peer review of research and also contains PDF files of the BSC's past peer review reports and NCEH/ATSDR's responses to each report.

Dr. Angulo informed the BSC of recent developments that are relevant to the BSC's 2008 review of NCEH/ATSDR's peer review process and clearance policies. Dr. Frieden established three new priorities for clearing documents across CDC that will become effective on January 1, 2010. All CDC National Centers will be required to use Documentum in the electronic clearance (E-clearance) process. First authors will be required to input citations and PDF files of each peer-reviewed and published manuscript into Documentum to allow for real-time accounting of CDC's publications.

All CDC National Centers will be required to adhere to standards of four weeks for clearance of documents and two weeks for cross-clearance of documents. Dr. Frieden will receive quarterly reports outlining the status of each National Center in complying with these timelines. The quarterly reports also will compare performance across National Centers to assure timeliness and accountability for clearing documents.

Dr. Angulo described actions that are being taken to refine NCEH/ATSDR's peer review process and clearance policies. The clearance guidelines and companion matrix are being revised at

this time to incorporate the E-clearance process and highlight several major changes. Editing will be completed before documents are entered into the clearance process to ensure that E-clearance is not used for major rewrites of documents.

A new parallel process will be implemented to allow documents to be cross-cleared in multiple NCEH/ATSDR divisions at the same time. Poorly written documents will be rejected and returned to primary authors for editing outside of the E-clearance process. To improve the quality of documents, a scientific writing expert will convene seven three-day scientific writing courses over the next six months. To date, >100 NCEH/ATSDR scientists have registered to attend the courses.

During the scientific writing courses, Editorial Services will make presentations on common mistakes in documents that are submitted to the E-clearance process. The Office of Communication also will emphasize the responsibilities of primary authors in ensuring that documents are well written before being submitted to the E-clearance process. Overall, the scientific writing courses will attempt to promote a standardized approach to writing documents across all NCEH/ATSDR divisions.

Dr. Angulo summarized NCEH/ATSDR's responses to recommendations in the BSC's report of NCEH/ATSDR's peer review process and clearance policies.

1. "*Ensure ongoing monitoring to strike an appropriate balance between science and policy*." NCEH/ATSDR has consulted with the Office of Communication and Editorial Services to remove the editing component from the E-clearance process.

2. "*Review and update the description of clearance and external review processes, including the complex grid*." NCEH/ATSDR has shortened the grid from six pages to one page to minimize its complexity. Definitions in the grid have been improved and are more clearly articulated.

3. "*Delegate more clear authority for final reviews to division management*." NCEH/ATSDR will revisit this issue after the revision of the clearance guidelines has been completed. Associate Directors for Science will continue to be extensively engaged in this process.

4. "*Upgrade or replace Documentum with a system that is more user-friendly and can track useful metrics*." NCEH/ATSDR and all other CDC programs have adopted Documentum in the E-clearance process. Tools and software other than Documentum are being explored at this time and might replace Documentum in the E-clearance process in the future. The NCEH/ATSDR E-clearance Coordinator serves as a resource to all divisions and other National Centers by answering questions and providing training to ensure compliance to CDC's new clearance policies that will become effective on January 1, 2010.

5. "*Identify the need for cross-clearance as early in the process as possible*." NCEH/ATSDR's new parallel process for cross-clearing documents in multiple divisions at the same time will address this recommendation.

6. "*Eliminate the requirement for documents to be externally peer reviewed before submission to journals*." NCEH/ATSDR will thoroughly consider and determine whether this recommendation can be adopted during upcoming discussions on the revised peer review process.

7. "*Consider whether to establish a formal process for dispute resolution on scientific issues arising during the clearance and review process*." NCEH/ATSDR will include specific language in the revised clearance guidelines to address this recommendation.

8. "*Develop and use metrics of accountability on the conduct and progress of internal and external peer review processes*." "*Attempt to minimize exceptions to routine peer review policies, but monitor any such exceptions*." NCEH/ATSDR will formally adopt both of these recommendations in the revised peer review process.

During the May 2010 meeting, Dr. Angulo planned to present the final program response to the BSC's report of NCEH/ATSDR's peer review process and clearance policies and also provide the BSC with both the revised clearance and peer review guidelines.

Dr. Chambers co-chaired the BSC workgroup that conducted the review of NCEH/ATSDR's peer review process and clearance policies. She commended NCEH/ATSDR on being extremely responsive and taking actions that exceeded the BSC's recommendations.

TOPIC 2: Discussion of Outstanding BSC Issues. Dr. Warrick was pleased that the meetings would be restructured for the BSC to conduct external program peer reviews. Based on the schedule of the six upcoming BSC meetings in 2010-2012, however, she was concerned that the BSC's role would be limited to conducting the current peer review and planning for the upcoming peer review. Dr. Warrick emphasized the critical need for NCEH/ATSDR to continue to provide regular updates on important EPH topics and seek the BSC's advice, guidance and technical expertise on non-peer review issues.

In response to Dr. Warrick's concerns, Dr. Frumkin confirmed that he would continue to provide the BSC with regular updates on all of NCEH/ATSDR's EPH activities during his "Director's Reports." Moreover, Dr. Ryan encouraged the BSC members to send him e-mail messages describing non-peer review topics of interest. He and Dr. Angulo would make every effort to place these topics on future BSC agendas.

Dr. Warrick made a suggestion during the May 2009 BSC meeting for NCEH/ATSDR to closely collaborate with academic institutions that have well-established relationships with CDC and offer internships to undergraduate students at Historically Black Colleges and Universities (HBCUs).

In response to this suggestion, Dr. Frumkin informed the BSC that NCEH/ATSDR extensively outreached to HBCUs, Hispanic Serving Universities and Tribal Colleges to recruit a more diverse group of undergraduate students for the 2009 Collegiate Leaders in Environmental

Health Internship Program. However, only one or two of the 12 undergraduate students in the 2009 internship program were minorities.

NCEH/ATSDR intends to increase its outreach to minority serving academic institutions to recruit more minority students in future internship programs. To facilitate this effort, Dr. Frumkin urged the BSC members to provide NCEH/ATSDR with contact information of their colleagues in minority serving academic institutions.

Dr. Frumkin confirmed that two actions would be taken in response to requests by Drs. Patz and Kidd Taylor. First, NCEH/ATSDR would present its internship programs for graduate students and other training opportunities for students at the next meeting and solicit advice from BSC to improve these initiatives. Second, NCEH/ATSDR would e-mail announcements to the BSC of registration deadlines and other important information related to internship and training programs. Advance notice of these opportunities would allow the BSC members to play a stronger role in NCEH/ATSDR's recruitment efforts.

In response to Dr. Warrick's request, Dr. Frumkin provided an update on ATSDR's Amyotrophic Lateral Sclerosis (ALS) Registry. Based on strong interest by Congressional members and advocacy groups, ATSDR conducted a series of pilot studies to determine the feasibility of identifying and registering ALS cases. During a stakeholder meeting, ATSDR announced that ascertaining and registering ALS cases would be possible based on results of the pilot studies. ATSDR is now launching the ALS Registry.

In response to Dr. Wallinga's question, Dr. Frumkin described the role of cross-cutting National Conversation themes (*i.e.*, agriculture, food, EJ, climate change and healthy community design) in informing NCEH/ATSDR's ongoing and future activities. The National Conversation is designed to inform NCEH/ATSDR's structural and organizational components. For example, the workgroups might advise ATSDR to revise its product lines or improve its approaches to serving communities.

The workgroups also might advise NCEH to expand its biomonitoring and geographic disaggregation research. Overall, NCEH/ATSDR will be in a better position to determine the role of the cross-cutting National Conversation themes in guiding its programs and activities after the workgroups produce their recommendations in 2010. NCEH/ATSDR will then focus on implementing the workgroups' recommendations to strengthen existing policies and practices.

In response to Dr. Patz's question, Dr. Frumkin announced that multiple federal agencies collaborated to develop the "National Climate Change Research Agenda." The research agenda will cover major diseases and pathways of exposure and is being finalized at this time. However, the research agenda does not identify specific agencies with lead responsibilities for activities and funding of various climate change research domains. CDC also is continuing its extensive involvement in ongoing climate change activities led by HHS, the White House and the U.S. Global Change Research Program. Dr. Frumkin confirmed that NCEH/ATSDR would provide the BSC with the draft research agenda.

Public Comment Session

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

Overview of the NCEH Division of Laboratory Sciences (DLS)

Dr. Ryan prefaced the overview by explaining that this topic was placed on the agenda because the BSC would conduct an external peer review of DLS during the May 2010 meeting. He yielded the floor for senior leadership to provide overviews of DLS and its program areas that would be included in the BSC peer review.

Division of Laboratory Sciences (DLS). Dr. Eric Sampson, Director of DLS, reported that DLS's broad laboratory portfolio includes emergency response to chemical and radiation events, the National Biomonitoring Program, Tobacco and Smoking Addiction Laboratory, Newborn Screening Program, as well as nutrition and selected chronic and infectious diseases.

DLS conducts activities through 23 laboratories with >90% of intramural funding. The majority of measurements on human blood and urine samples makes DLS unique compared to other federal agencies. DLS has a strong emphasis on analytical chemistry and its laboratories promote scientific synergy and shared services. DLS serves as a laboratory for other CDC National Centers and a tremendous resource to state public health laboratories and the international community. As a result, quality is a major focus for DLS staff at all levels, including leaders, chiefs, supervisors and laboratory personnel.

DLS is certified under the Clinical Laboratory Improvement Amendments (CLIA) and undergoes independent inspections of its laboratory methods and processes every two years. DLS has never received a CLIA citation. DLS's programs touch every stage of life. DLS performs at least ten times more laboratory measurements for the National Health and Nutrition Examination Surveys (NHANES) than any other laboratory. NHANES is the only survey approved by the Office of Management and Budget for the administration of questionnaires and the collection of human blood and urine samples at the national level. All samples that DLS uses to develop the Exposure and Nutrition Reports are collected from NHANES. NHANES serves as DLS strongest internal partner at CDC.

Congress and external partners rely on DLS's laboratory science for a number of reasons. DLS has unique expertise in responding to public health and national security emergencies, including chemical and radiologic events. DLS trains and transfers technology to state public health laboratories and also serves as a leader in measuring human exposure to environmental chemicals.

DLS conducts ongoing assessments of the U.S. population's exposure to priority environmental chemicals; provides exposure assessments in human studies of health effects; evaluates the effectiveness of interventions and regulations to reduce exposures; determines reference

ranges for human exposure levels; and builds capacity in state public health laboratories. DLS serves as the nation's only tobacco laboratory. DLS measures addictive and toxic substances in tobacco products and persons and also identifies changes in tobacco product construction that increase the delivery of addictive substances. DLS has a memorandum of understanding (MOU) with FDA to provide technical expertise in this area.

DLS is the only comprehensive program in the world that is devoted to ensuring the accuracy of newborn screening tests. DLS provides quality assurance to state and international newborn screening programs for >50 newborn diseases; improves screening methods to detect newborn diseases; and supports state newborn screening laboratories to undertake pioneering research projects, including the use of DNA technology. DLS's Newborn Screening Program is one of the most successful public health initiatives due to its tremendous accomplishment of preventing deaths or mental retardation in 6,500 children each year. In 2007, DLS received a $7 million Congressional appropriation to enhance the Newborn Screening Program.

DLS is a leader in laboratory measurements of nutrition and selected chronic diseases. DLS conducts ongoing assessments of nutritional indicators in the U.S. population; provides nutritional indicator data on nutrition and health studies; evaluates the efficacy of interventions and regulations to improve health; and standardizes key laboratory measurements in chronic diseases. State public health laboratories serve as DLS's strongest external partner in all of its program areas.

DLS has specialized the use of analytical laboratory techniques for public health. DLS develops innovative laboratory measures for the diagnosis, treatment and prevention of selected environmental chronic and infectious diseases. DLS also standardizes and improves the quality of laboratory measurements. DLS's 176 mass spectrometers exceed those of most countries and any other institution in the world.

The key features of DLS's laboratory measurements include a strong focus on isotope-dilution mass spectrometry; the development of first-time methods; high-quality accuracy and precision; excellent analytic sensitivity with low limits of detection; capacity to measure multiple chemicals per method and a large number of samples per day with a short time to receipt of the first result; and extensive expertise in reference methods and the provision of laboratory quality assurance programs.

DLS has had tremendous growth in three key areas over the past ten years. The DLS budget dramatically increased from $10.5 million in 1999 to $73.5 million in 2009. DLS receives $32 million of its total budget from four other CDC programs, five interagency agreements and four program agreements using the CDC Foundation. The DLS staff has rapidly grown from 134 personnel in 1999 to 400 personnel in 2009. The current staff reflects 247 FTEs, 153 non-FTEs, 102 PhDs and seven MDs.

Most personnel remain in DLS their entire careers and work in the laboratories. The majority of personnel initially begin their careers with DLS as temporary Oak Ridge Institute for Science and Education Fellows, contractors or staff fellows before being hired as FTEs. DLS rewards entrepreneurial activities conducted by staff. Emerging leaders become "DLS leads" on major

national and international studies and interact with senior scientists. Overall, the scientific staff is highly trained, diverse, friendly and collaborative.

DLS's laboratory space has markedly increased from 60,000 square feet in 1999 to 143,000 square feet in 2009. All laboratory buildings are full at this time, but CDC policy requires all of its laboratories to be located on CDC property. The next DLS laboratory building is expected to be completed in 2017.

DLS has planned a number of activities in all of its program areas over the next five years. For radiation preparedness, methods will be developed for the 20 leading radionuclides and capacity will be built in state laboratories. DLS expects its budget to increase from $2 million to $5-$16 million per year in this program area. For the National Biomonitoring Program, cooperative agreements will be awarded to state laboratories to build capacity. DLS expects its budget to increase from $5 million to $10-$20 million per year in this program area.

For the National Children's Study, new research will be initiated to follow 100,000 children over 20 years. This research initiative will serve as the largest study linking genetics, health and the environment. Of $190 million in the FY2010 budget for the study, DLS expects to receive at least $5 million per year. DLS also will expand the National Biomonitoring Program to provide support to EPA in TSCA reform. DLS expects the budget for this major program area to be large.

For the Tobacco and Smoking Addiction Laboratory, support will be provided to FDA on the new Tobacco Regulation Act in which $700 million will be collected in taxes of cigarette products over the new few years. DLS expects its budget to be $20-$40 million per year in this program area. For nutrition and chronic diseases, the Nutrition Report will be expanded and laboratory methods for selected chronic diseases will be improved. DLS expects its budget to increase from $1.5 million to $6-$20 million per year in this program area.

For the Newborn Screening Program, activities will be expanded to include more conditions in collaboration with the HHS Secretary's Advisory Committee. DLS expects its budget to increase from $7 million to $20-$40 million per year in this program area. For infectious diseases, innovative laboratory technologies will be applied to revolutionize influenza virus and vaccine development activities. DLS expects its budget to increase from $2 million to $3-$5 million per year in this program area.

Over the next five years from 2009-2014, DLS projects an increase in its total budget from $73.5 million to $150 million; an increase in staff from 400 to 600 personnel; and an increase in laboratory space from 143,000 square feet to 240,000 square feet. In addition to professional judgment, DLS's five-year forecast also is based on priorities established by Dr. Frieden, Congress, APHL, EPA, the National Association of Chronic Disease Directors and the CDC Influenza Program; funding by Congress and the CDC Coordinating Office for Terrorism and Preparedness Response; and MOUs with FDA and the National Institute of Child Health and Development.

National Biomonitoring Program (NBP). Dr. James Pirkle, Deputy Director for Science of DLS, reported that ~90% of DLS's activities, including NBP, are required by Congressional mandates or directives from the CDC Director. NBP focuses on pathways of exposure and health effects, including external doses from air, water, food, soil and dust through inhalation, ingestion and skin absorption as well as internal doses from blood, serum, urine and tissue. Biomonitoring measures chemicals in blood and urine in the human body because measurements of other matrices have been inadequate in demonstrating relationships between exposures and human health effects.

NBP applies four essential public health actions to successfully prevent disease from exposure to toxicants and identify gaps: detect exposure or disease, assess health risks, develop and apply treatment and prevention, and assure effective treatment and prevention. Biomonitoring is a valuable resource in achieving the public health action of assessing health risks due to its capacity to produce excellent and high-quality human data that markedly reduce uncertainty in human health risk assessments. The use of rat, mouse or primate data requires the incorporation of a number of other factors to estimate human health risks.

NBP targets both the general population and vulnerable groups in its activities. For the general population, NBP produces the *National Report on Human Exposure to Environmental Chemicals* every two years to assess exposure to >300 priority chemicals in the entire U.S. population. Chemicals featured in past Exposure Reports include carcinogens, lead in gasoline and secondhand smoke exposure. For vulnerable groups. NBP conducts 50-75 studies each year of exposure and health effects in newborns, women of childbearing age, elderly and underserved populations, and higher exposed groups.

NBP currently has capacity to measure >450 environmental chemicals in blood or urine in a number of categories: metals, environmental phenols, perfluorinated compounds, phthalates, polybrominated diphenyl ethers, tobacco smoke, polycyclic aromatic hydrocarbons, acrylamide and glycidamide hemoglobin adducts, organophosphate insecticides, halogenated phenol compounds and polychlorinated napthalenes.

NBP will release the Fourth Exposure Report in December 2009 with data on 212 chemicals in blood and urine based on samples collected from 2,400 persons in the 2003-2004 two-year period. Nationally representative samples in the Fourth Exposure Report will cover the years 1999-2000, 2001-2002 and 2003-2004. Exposure Reports can be used for several public health actions, such as measuring chemicals that actually enter the human body, identifying at-risk populations, detecting trends in exposure over time, evaluating the effectiveness of public health efforts, and establishing priorities for human health effects research. All Exposure Reports and NBP's recent publications can be viewed on www.cdc.gov/exposurereport.

Data tables presented in previous Exposure Reports described (1) the geometric mean and selected percentiles of cadmium in urine concentrations for the U.S. population ≥6 years of age based on 1999-2002 NHANES data; (2) serum cotinine levels among 11,800 persons to measure tobacco smoke exposure in the U.S. population from 1988-1991; (3) serum cotinine levels in the U.S. population based on the number of hours non-tobacco users are exposed at

work; and (4) the decline in exposure to environmental tobacco smoke among the U.S. population as a result of public health interventions and smoking restrictions.

In addition to measuring metals, radionuclides, small compounds and peptides, NBP also has developed some of the most advanced techniques in the world to measure proteins. NBP created new markers that help determine the actual contribution of air, water or other sources to exposure. Most notably, NBP's urine arsenic measurements separate food arsenic from water arsenic. Moreover, NBP's blood mercury measurements make a clear distinction among inorganic, methyl and ethyl mercury.

Dr. Pirkle summarized NBP's other major activities that have public health significance. NBP was extensively involved in a study to detect unusual levels of exposure among 370 firefighters who served as first responders to the World Trade Center following the 9/11 terrorist attacks. Blood and urine samples were collected from firefighters while the fires still burned and 110 fire-related chemicals were tested.

NBP's funding opportunity announcement to build state capacity in biomonitoring generated tremendous interest. Of 33 states that applied for funding, NBP awarded grants totaling $5 million to California, New York and Washington State. The expansion of biomonitoring grants to other states is a top priority for DLS leadership.

NBP's unparalleled and innovative laboratory response to chemical terrorism includes a rapid toxic screen that quantitatively measures 150 chemicals in blood and urine from nerve agents, nitrogen and sulfur mustards, Lewisites, ricin, saxitoxin, incapacitating agents, tricothecene mycotoxins, hydrogen cyanide, cyanogens chloride, toxic metals, volatile toxins and selected toxic industrial chemicals.

NBP is continuing its strong focus on radiologic terrorism from a "dirty bomb" or nuclear explosion, such as an attack on a nuclear facility, an improvised nuclear device or nuclear weapon. To fill data gaps in radiologic terrorism, NBP is developing the Urine Radionuclide Screen (URS) at this time using mass spectrometry and selective radiation detection to quantify radionuclides. The URS will be able to rapidly measure $\geq$22 radionuclides in urine, but this laboratory project is severely under-funded at this time because CDC is not receiving additional bioterrorism funds.

Tobacco and Smoking Addiction Laboratory (TSAL). Dr. David Ashley, Chief of the Emergency Response and Air Toxicants Branch in DLS, reported that TSAL has focused on tobacco exposure biomarkers since 1984 and tobacco products since 1994. TSAL performs laboratory experiments with seven smoking machines that can smoke 1-20 cigarettes at one time. TSAL uses the smoking machines to collect and analyze particulate matter and gas phase samples in order to determine the role of the design of tobacco products in producing toxins and addictive compounds.

TSAL is the only laboratory that measures addictive and toxic chemicals in tobacco products, in emissions, as biomarkers and the topography of tobacco use. In its unique role, TSAL analyzes

tobacco emissions, the use of tobacco products, biomarkers in serum, blood, urine and saliva, and biomarkers of effect.

TSAL's research has shown that cigarettes are highly engineered delivery devices and contain a complex mix of components. The tobacco industry has engineered cigarettes to ensure that measurements of tar and nicotine in mainstream cigarette smoke result in low determined levels, but current standard measurement techniques do not show actual exposures of toxic chemicals to smokers.

There are approximately 1,500 different brand variants marketed in the United States. A normal blend cigarette in the United States contains different types of tobacco, including 30%-40% from bright tobacco, 20%-30% from burley tobacco, 2%-10% from stems, 10%-15% from oriental tobacco, and 5%-15% from reconstituted tobacco. Reconstituted tobacco is made from tobacco dust, diammonium phosphate and other chemicals. It is formulated in ways that promote the addictive characteristics of the product. TSAL's research has shown that the design of tobacco products is modified to increase the levels of the form of nicotine known as "free nicotine", which is more addictive than ionized nicotine, in a similar way that "crack cocaine" is more addictive than cocaine. Tobacco companies have developed a number of "modified risk products" and smokeless tobacco products to ensure that health conscious smokers continue to smoke.

TSAL conducted a study that showed free nicotine in U.S. smokeless tobacco brands ranges from low concentrations in the low pH "starter" brands for youth to brands with much higher free nicotine concentrations in the higher pH brands with levels intended to maintain addiction over time. TSAL's investigation showed that the free nicotine concentrations of Skoal Bandits changed from a starter brand to one which had much higher free nicotine concentrations between August 2004 and December 2006 with no notification to users or submission of reports to FDA.

TSAL recently published a study describing the impact of factors other than cigarettes smoked per day on biomarkers of exposure to smokers. By race/ethnicity, the study showed that the number of cigarettes smoked per day was 16.6 among non-Hispanic whites, 10.4 among non-Hispanic blacks and 6.5 among Mexican Americans. Non-Hispanic blacks smoked fewer cigarettes per day than non-Hispanic whites, but had higher serum cotinine levels. By gender, the study showed that the number of cigarettes smoked per day was 13.1 among males and 12.5 among females.

TSAL conducted a study by collecting cigarette butts to determine certain factors (*i.e.*, stress or job activities) that influence smoke intake from individual cigarettes. Findings from the study will assist TSAL in developing more effective smoking cessation measures. In addition to addiction, TSAL also conducts research on toxicity from tobacco. Tobacco-specific nitrosamines (TSNAs) are known carcinogens that are formed from nicotine and other alkaloids in tobacco.

TSAL conducted a study that showed both smokers and non-smokers are exposed to carcinogenic TSNAs. TSAL demonstrated wide variation in the levels of carcinogenic TSNAs in cigarettes in countries around the world. Other studies further showed a direct association between carcinogenic TSNAs and levels in smokers. Studies by other researchers

demonstrated an association between concentrations of NNAL in urine, a biomarker of TSNA exposure, and lung cancer. Because of the way U.S. cigarettes are designed, American smokers have higher urinary concentrations of NNAL. The design of American cigarettes may be leading to increased lung cancer in the United States.

The 2009 Family Smoking Prevention and Tobacco Control Act became effective in June 2009 and gave FDA regulatory authority over all tobacco products. Under this legislation, FDA will receive reports on ingredients of tobacco products, receive and evaluate health information, develop product standards, evaluate new tobacco products, assess "modified risk products," and design new warning labels. The legislation also might provide FDA with regulatory authority to restrict promotion and advertising.

TSAL's role in the 2009 Family Smoking Prevention and Tobacco Control Act will be to develop and evaluate testing methods and product standards; utilize surveillance to evaluate the impact of tobacco product regulation; provide oversight of product testing quality assurance; and create measures that can be used to assess "modified risk products" and new products to achieve reduced emission levels, substantial reductions in exposure and a decline in biomarkers of long-term disease.

TSAL has grown in three major areas over the past ten years from 1999-2009. The budget has increased from $1 million to $5.6 million. The staff has increased from 10 personnel to 29 personnel. Laboratory space has increased from 5,000 square feet to 12,500 square feet. TSAL has projected additional increases in its infrastructure over the next five years from 2009-2014. The budget is estimated to increase to $45 million. The staff is estimated to increase to 130 personnel. Laboratory space is estimated to increase to 57,500 square feet.

TSAL projected the $44 million increase in its budget over the next five years based on proposed funding and professional judgment. The current Senate version of the FY2010 appropriations bill proposes $4 million to TSAL. TSAL expects to receive $40 million for supporting FDA activities under the 2009 Family Smoking Prevention and Tobacco Control Act.

***Emergency Preparedness Laboratory*.** Dr. Pirkle described DLS's laboratory methods and research on botulism, anthrax and pandemic influenza. DLS applies four essential public health actions in its response to prevent botulism: diagnose and detect disease in populations, assess health risks, develop and apply treatment and prevention, and assure effective treatment and prevention.

DLS identified tremendous gaps in the public health action to diagnose and detect disease in populations. The time to obtain the first mouse bioassay result typically is two to three days. The mouse bioassay detects only four of six botulinum types and has an extremely slow throughput. The mice supply is very limited and the animal rights movement prevents mice from dying of botulism. DLS also identified gaps in the public health action to develop and apply treatment and prevention. The benefit of the botulism antitoxin is questionable and no quantitative method has been developed to date to evaluate an antitoxin.

To fill gaps in botulism laboratory methods, DLS developed a mass spectrometry botulinum neurotoxin assay that has sound specificity and is 1- to 20-fold more sensitive than the mouse bioassay. With DLS's assay, the time to obtain the first result has been shortened to three to four hours; 300-500 assays can be run each day; and all six botulinum types and 16 of 17 botulinum subtypes can be detected. DLS's mass spectrometry botulinum neurotoxin assay has been extremely well received by the international community and will soon be transferred to states, particularly Alaska and New York.

DLS will take several actions to further refine its botulism laboratory research and activities. Split samples with the mouse assay will be continued for all CDC botulism measures. A major project will be launched with the Army to develop a new antitoxin with recombinant DNA technology in yeast that will bypass Fc fragment side effects and produce large amounts of antitoxin. DLS's assay will be the only assay with capacity to assess the effectiveness of antitoxin to ensure correct antitoxins are selected for production.

High throughput capacity will be maintained in DLS as part of CDC's current response plan. Training and proficiency testing will be provided to meet the substantial demand to transfer botulism technology to state public health laboratories, particularly those in large states. Many state laboratories have already implemented DLS's method development for API 4000 to improve sensitivity of instruments. Research will be conducted to replace all feces analyses with serum analyses, improve the milk assay, and develop assays for other environmental matrices. The botulism method will be optimized for simultaneous measurement of botulinum types C and D with A, B, E and F.

Similar to botulism, DLS also identified significant gaps in the four essential public health actions to respond to anthrax. Cultures are negated by antibiotic therapy and culture-negative clinical cases have been detected. The wait for culture results is lengthy. Particle sizes are poorly measured and have a major effect on the delivery of spores. The benefits of immunoglobulin treatment are uncertain. Dosing and timing of immunoglobulin are not well determined due to the absence of rigorous evaluation tools.

To fill gaps in anthrax laboratory methods, DLS developed a mass spectrometry assay to measure anthrax lethal factor (ALF). The ALF assay uses substrates to detect cleavage products. DLS was able to apply its assay to the field by measuring ALF in plasma and serum of a patient in New York. The assay was extremely valuable in this case by allowing the patient's physicians to more clearly distinguish between the effectiveness of treatment and potential new complications. DLS's ALF assay also was tremendously important to clinicians who conducted a study with Rhesus Macaque monkeys to determine serum lethal factor levels following inhalation exposure.

DLS's ALF assay does not interfere with antibiotics; has capacity to detect disease at least one day earlier than culture in monkeys; has the ability to detect disease ~12 hours before fever in rabbits; accurately detects toxin even with early clinical improvement; and effectively tracked the clinical course of a patient.

DLS will take several actions to further refine its anthrax laboratory methods and research. The efficacy of anthrax immune globulin will be evaluated in Rhesus Macaques. The ALF assay will be applied to each new clinical case of anthrax to guide treatment decisions. Analytical throughout will be maintained to handle terrorist events. The ALF assay will be transferred to state public health laboratories and proficiency testing will be conducted to assure quality. The efficacy of new anthrax treatments, including antibiotics, will be evaluated.

Similar to botulism and anthrax, DLS also identified significant gaps in the four essential public health actions to respond to pandemic influenza. The six- to eight-month process to produce vaccine is lengthy. Manufacturers have major problems in measuring correct doses. Vaccine strains of interest might not be the most important from a public health protection perspective. Some components of the vaccine production process can completely fail due to reliance on antibodies from goats. Some segments of the public are suspicious of vaccine safety and effectiveness.

Hemagglutinin plays in important role by helping to transfer virion into the host cell, but techniques to measure the 16 types of hemagglutinin were developed in 1955 and are outdated. Neuraminidase also plays an important role by helping to transfer newly made virion out of the host cell to infect other cells. However, no methods have been developed to date to measure the nine types of neuraminidase.

To fill gaps in pandemic influenza laboratory methods, DLS developed the isotope-dilution mass spectrometry (IDMS) assay that tremendously improves the existing radial immunodiffusion assay in six major areas. The accuracy of the IDMS assay is traceable to National Institute of Standards and Technology standards by amino acid analysis. The precision of the IDMS assay has a relative standard deviation of 3%-7%. The time to measurement with the IDMS assay is ~4 hours. The IDMS assay routinely measures three strains, but has the ability to measure up to 15 strains. The IDMS assay has no dependence on antibodies on goats and can measure hemagglutinin in new adjuvant vaccines.

DLS is aware that growing viruses faster for vaccine production is particularly a problem with the recent H1N1 influenza strain. The reassortant gene approach yields ~10-16 strains. Hemagglutinin in egg allantoic fluid must be measured to identify strains that grow most rapidly. The current hemagglutinin test does not have adequate sensitivity for early detection of rapidly growing stains. Reliance on goat antibodies delays results for 10-12 weeks. DLS's IDMS assay can resolve these problems due to its effectiveness in using egg allantoic fluid, sensitivity in measuring hemagglutinin after ~1 day of growing, and capacity in analyzing 10-16 strains in one to two days.

To address issues related to early identification of dangerous influenza strains, vaccine safety and drug resistance, DLS is applying mass spectrometry characterization of post-translational modifications. This technique will better identify virulent and transmissible influenza strains and also will play an important role in assuring vaccine safety.

DLS's analysis of neuraminidase most likely will better identify drug-resistant influenza strains. DLS is partnering with FDA in an effort to change methods for measuring hemagglutinin and

revise vaccine production systems with a basis on mass spectrometry in the United States, United Kingdom and Japan. DLS has $1.5 million remaining in its FY2009 budget for pandemic influenza, but a new appropriation in the FY2010 budget for these activities is uncertain.

***BSC Peer Review of DLS*.** Dr. Sampson described the next steps in the BSC's external program peer review of DLS. During the May 2010 meeting, the BSC members would meet in breakout groups to listen to short overviews and tour the laboratories of the four proposed program areas that would be reviewed: (1) National Biomonitoring Program; (2) Emergency Preparedness Laboratory for chemical and radiological events, toxins and pandemic influenza; (3) Tobacco and Smoking Addiction Laboratory; and (4) newborn screening, nutrition and selected chronic diseases. DLS branch chiefs, laboratory chiefs and office staff would provide the BSC with all requested materials and also would be available for the entire peer review.

The BSC would conduct the peer review in laboratory conference rooms to provide DLS with advice and recommendations in response to five key questions:

1. Are the DLS programs making contributions that are important and impact public health?
2. Are the anticipated growth areas important new directions for DLS's current programs?
3. What are potential barriers to DLS's projected growth and opportunities to overcome these challenges?
4. Are the new CDC project indicators and initiatives proposed by DLS adequate for their intended purpose?
5. Do the public health, regulatory and scientific communities fully utilize data produced by the DLS laboratories?

The BSC was impressed by DLS's phenomenal growth of its budget, staff and laboratory space over the past ten years. The BSC also commended DLS on its tremendous and successful partnerships with state public health laboratories. The BSC noted that state laboratories greatly value and appreciate DLS's development of laboratory methods, preparedness activities, and quality assurance programs for biomonitoring, newborn screening and other program areas.

The BSC generally agreed with the questions and overall peer review process for DLS. The BSC members made one suggestion for DLS to consider in refining its laboratory methods, research and activities prior to the peer review in May 2010. DLS should explore the option of awarding contracts or cooperative agreements with institutions and organizations outside of state public health laboratories that have capacity to conduct analytical chemistry research at both national and international levels.

Drs. Angulo, Ryan and Sinks described the next steps in the external program peer review of DLS from the BSC's perspective. The members would volunteer to serve on one of the four breakout groups well in advance of the May 2010 meeting and inform Drs. Angulo and Ryan of their choices via e-mail. However, Dr. Ryan would take the Chair's prerogative in making adjustments to self-selections by the BSC members to ensure that the four breakout groups were equally balanced.

To minimize document production and review, the BSC members would only receive and review PowerPoint slides, publications and other background materials for their respective breakout groups. To make the most efficient use of time during the peer review, the BSC members would only tour the laboratories for their respective breakout groups.

DLS confirmed that the BSC members would be given materials well in advance of the peer review. DLS also would identify staff to facilitate ongoing communications with the BSC members in each breakout group in terms of answering questions, clarifying issues or providing additional materials prior to the peer review.

Drs. Frumkin and Sinks urged the BSC members to volunteer to serve on one of the four breakout groups as soon as possible. The terms of some BSC members have expired and the specific expertise of the incoming members is unknown. NCEH/ATSDR would need time to identify and recruit non-BSC members to serve on one of the four breakout groups to fill gaps in expertise. However, NCEH/ATSDR would rely on input from the BSC in determining gaps in expertise for the DLS peer review.

Dr. Ryan and NCEH/ATSDR leadership emphasized the critical need for the BSC breakout groups to convene conference calls with DLS over the next few months to resolve any issues related to materials and recruitment of both internal and external experts. **The BSC generally agreed to finalize the memberships of the four breakout groups by January 1, 2010.**

BSC Business Session

The business items that the BSC raised over the course of the meeting are noted below for the record:

Action Items

- *NCEH/ATSDR will provide the BSC with advance notice via e-mail of registration deadlines and other important information related to EPH internship programs and training opportunities for both undergraduate and graduate students.*
- *NCEH/ATSDR will provide the BSC with the draft National Climate Change Research Agenda*.
- *NCEH/ATSDR will provide the BSC with PowerPoint slides of all DLS overviews presented during the meeting to assist the members in preparing for the upcoming external program peer review.*

Future Agenda Items

- *Update on joint activities conducted by FDA and the NCEH Tobacco and Smoking Addiction Laboratory*.
- *Tour of the NCEH laboratories [part of the DLS peer review during the May 2010 meeting.]*
- *Presentation on NCEH/ATSDR's internship programs for graduate students and other training opportunities for students*.

Closing Session

The dates proposed for the next BSC meeting were May 6-7, 13-14, 20-21 or 27-28, 2010. NCEH/ATSDR would poll the members via e-mail to confirm the exact date.

Dr. Frumkin thanked the BSC for attending the NEPH Conference and conducting a thorough peer review of EEHS with an entirely new process. While drafting the EEHS peer review report, he advised the BSC not to limit its guidance to the overviews that were presented during the meeting and breakout groups. Instead, he encouraged the BSC to provide NCEH/ATSDR with recommendations on broad issues at all levels, such as new projects, innovative activities, different organizational structures or new funding line items for the EEHS programs. Dr. Frumkin confirmed that the BSC's suggestions would be taken into account in NCEH/ATSDR's ongoing efforts to refine the new process for future peer reviews.

The participants joined Dr. Frumkin in commending Dr. Angulo's outstanding efforts in his new role as the Acting Associate Director for Science of NCEH/ATSDR. The participants also applauded the Office of Science staff (Ms. Dolly Sinha, Team Lead; Ms. Sandra Malcom, Committee Management Specialist for the BSC; and Ms. Shirley Little) for providing excellent administrative support and making logistical arrangements for the BSC meeting.

With no further discussion or business brought before the BSC, Dr. Ryan adjourned the meeting at 12:15 p.m. on October 30, 2009.

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