

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



**Board of Scientific Counselors Meeting
May 29-30, 2008
Atlanta, Georgia**

Record of the Proceedings

TABLE OF CONTENTS

	<u>Page</u>
Attachment 1: List of Participants	A1-1
Attachment 2: Acronyms Used In These Meeting Minutes	A2-1
Executive Summary	-i-
Meeting Minutes.....	1
May 29, 2008	
Opening Session.....	1
Update by the NCEH/ATSDR Office of the Director	2
Update on the Formaldehyde and FEMA Trailer Study	4
Public Comment Session	12
Overview of the 2008 Draft Great Lakes Areas of Concern Report	12
Update on ATSDR's Toxicological Profiles	15
Proposed BSC Peer Review	18
Update on CDC's Climate Change Initiative	20
May 30, 2008	
Stakeholder Challenges to NCEH/ATSDR Programs	25
Draft Report by the BSC Peer Review Workgroup	29
Public Comment Session	38
BSC Business Session	38
Closing Session	39

ATTACHMENT 1

List of Participants

BSC Members

Dr. Alan Ducatman, Chair
Mr. Angelo Bellomo
Dr. Janice Chambers
Dr. Gary Evans
Dr. Jonathan Patz
Dr. Robert Rickard
Hon. Gerard Scannell
Mr. Matthew Stefanak
Dr. Andrea Taylor
Dr. David Wallinga
Dr. Cynthia Warrick
Dr. Paul Wax

Designated Federal Official

Dr. Mark Bashor, Executive Secretary

Ex-Officio Member

Dr. Hal Zenick (U.S. EPA)

CDC/NCEH/ATSDR Representatives

Dr. Henry Falk (CCEHIP Director)
Dr. Howard Frumkin
(NCEH/ATSDR Director)
Dr. Thomas Sinks
(NCEH/ATSDR Deputy Director)
Henry Abadin
Annabelle Allison
Michael Allred
David Ashley
Beth Blair
Robert Blake
Kayla Buchanan (Student Intern)
Sharunda Buchanan
Bernadette Burden
Tonia Burk
William Cibulas
Caroline Cusack
Scott Damon
Andrew Dannenberg
Kenneth Davis
Stephanie Davis
Scott Deitchman
Betsy Dunaway
Bruce Fowler

Paul Garbe
Michael Gressel
Hugh Hansen
Carolyn Harper
Olivia Harris
Michael Hatcher
Hilary Heishman
Dan Holcomb
Jim Holler
Ashley Hopkins (Student Intern)
Sandy Isaacs
Peter Kowalski
James Lando
Annie Latimer
Shirley Little
George Luber
Salvatore Lucido
Sandra Malcom
Stan Meiburg
Ted Meinhardt
Susan Metcalf
Daphne Moffett
Cory Moore
Teresa Morrison
Matthew Murphy
Edward Murray
Ken Orloff
James Pirkle
Tanja Popovic
Jamie Rayman (Student Intern)
Barbara Rogers
Helen Rogers
Michael Russell
Eric Sampson
Jay Sapp
Marissa Scalia
Joshua Schier
Eddie Shanley
Edwin Shourey
Dolly Sinha
Cassandra Smith
Anne Sowell
Scott Sudweeks
Rita Tallini
Jana Telfer

Carolyn Tylanda
Clement Welsh
Sharon Williams-Fleetwood
David C. Williamson (Student Intern)
G. David Williamson
Fuyuen Yip
Greg Zarus

Members of the Public

¹Pamela Bingham
(Bingham Consulting Services)
Roland Burse (Battelle Memorial Institute)
¹Walter Faggett (District of Columbia
Department of Health)
Dianne Farrell (Disaster Relief Housing
Task Force of the Recreation Vehicle
Industry Association)

Yona Hackl (Battelle Memorial Institute)
Jeff Inks (Manufactured Housing Institute)
¹Ronald Laessig (University of Wisconsin
Medical School)
Megan Latshaw (Association of
Public Health Laboratories)
Joe McDade (Battelle Memorial Institute)
Frank Pastor (Battelle Memorial Institute)
Eric Walcott (District of Columbia
Department of Health)
[via conference call]

¹Members of the Peer Review Panel
who joined the meeting by conference call

ATTACHMENT 2**Acronyms Used In These Meeting Minutes**

BSC	— Board of Scientific Counselors
CARB	— California Air Resources Board
CDC	— Centers for Disease Control and Prevention
COTPER	— Coordinating Office of Terrorism Preparedness and Emergency Response
DTEM	— Division of Toxicology and Environmental Medicine
EJ/HD	— Environmental Justice/Health Disparities
EPA	— U.S. Environmental Protection Agency
EPHTP	— Environmental Public Health Tracking Program
FEMA	— Federal Emergency Management Agency
GIS	— Geographic Information System
HHS	— Department of Health and Human Services
HRSA	— Health Resources and Services Administration
HUD	— U.S. Department of Housing and Urban Development
IOM	— Institute of Medicine
IPCC	— Intergovernmental Panel on Climate Change
LPT	— Lymphocyte Proliferation Test
MHI	— Manufactured Housing Institute
MRLs	— Minimal Risk Levels
NCEH/ATSDR	— National Center for Environmental Health Agency for Toxic Substances and Disease Registry
NIOSH	— National Institute for Occupational Safety and Health
OMB	— Office of Management and Budget
OTPER	— Office of Terrorism Preparedness and Emergency Response
PPB	— Parts Per Billion
PRWG	— Peer Review Workgroup
QA/QC	— Quality Assurance/Quality Control
SWOT	— Strengths, Weaknesses, Opportunities and Threats
THUs	— Temporary Housing Units
TPER	— Terrorism Preparedness and Emergency Response
VOCs	— Volatile Organic Compounds

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 May 29-30, 2008 in Atlanta, Georgia.

The Director of NCEH/ATSDR presented certificates of appreciation to the BSC Chair and three members whose terms would expire after the current meeting. The BSC welcomed 12 students who were selected as summer interns for NCEH/ATSDR's new "Collegiate Leaders in Environmental Health Program."

The Director of NCEH/ATSDR provided an update in three areas: (1) NCEH/ATSDR's major areas of focus and interest; (2) recent attention by Congress and the press in response to criticism that NCEH/ATSDR inappropriately conducted some activities; and (3) NCEH/ATSDR's ongoing efforts to advance and improve its overall performance as an environmental health agency.

The BSC applauded NCEH/ATSDR's efforts to benefit from criticism by Congress and the press by compiling lessons learned and taking concrete actions to improve its overall performance as an environmental health agency. The BSC made several suggestions for NCEH/ATSDR to consider in strengthening its public relations efforts.

A panel of NCEH/ATSDR staff presented an overview and updates on various components of the study on formaldehyde in Federal Emergency and Management Agency (FEMA) trailers: (1) the medical record review in Hancock County, Mississippi; (2) the investigation of health effects in children who lived in storm-damaged housing and temporary housing units (THUs) along the Gulf Coast; (3) the study to mitigate formaldehyde levels in FEMA-owned THUs; and (4) current efforts to determine the feasibility of developing a Gulf Coast Hurricane Registry. The BSC made a number of comments and suggestions for NCEH/ATSDR to consider in refining these projects.

ATSDR presented an overview of its 2008 Draft Great Lakes Areas of Concern Report. The overview included a detailed description of quality assurance/quality control measures that ATSDR implemented to improve and address concerns raised regarding the 2008 draft report. The BSC made several suggestions for ATSDR to consider while finalizing the 2008 draft report.

ATSDR presented an update on its toxicological profiles and asked the BSC to provide input on a proposed process to improve the development and maintenance of the profiles. ATSDR would use available data to create addenda for substances that were not selected for profile development. The addenda would supplement information in toxicological profiles with a background statement on the purpose and intent of the substance and relevant new studies. The BSC made a number of suggestions for ATSDR to consider in developing toxicological profile addenda and improving the external peer review process to evaluate the profiles.

The Designated Federal Official of the BSC and Associate Director for Science of NCEH/ATSDR asked the BSC to consider forming a workgroup to conduct a peer review of NCEH/ATSDR's internal clearance and external peer review processes. Several documents were

distributed to the BSC, including a proposed charge, to inform the decision-making process. Other issues that the workgroup would need to consider during the peer review were described as well. The BSC extensively discussed NCEH/ATSDR's proposal, particularly expertise and data that would be needed to conduct an adequate peer review. **The BSC agreed to conduct a peer review of NCEH/ATSDR's internal clearance and external peer review processes.**

NCEH presented an update on its climate change initiative, including recent activities by the Climate Change Workgroup; development of the CDC "Climate Change: The Public Health Response" policy; and NCEH's ongoing projects to support six of 11 priority health actions outlined in the climate change policy. The BSC made several suggestions for CDC to consider in its ongoing efforts to refine the climate change initiative.

The Deputy Director of NCEH/ATSDR provided an overview of NCEH/ATSDR's actions to achieve its mission to protect public health when stakeholders disagree with or desire different results. As an example of these efforts, a detailed description and timeline were presented on ATSDR's health study of potential beryllium exposure in an Elmore, Ohio community that eventually led to Congressional allegations in 2008.

The BSC made several conclusions based on the beryllium health study. NCEH/ATSDR appears to be applying the best possible approaches and should not allocate additional time or resources to incorporate other methods. NCEH/ATSDR did not present metrics for the BSC to determine the effectiveness of current methods to maintain objectivity and maximize trust. ATSDR's approach in the beryllium health study was problematic in some areas. The BSC made a number of suggestions for NCEH/ATSDR to consider in improving its interactions with external stakeholders in future health studies.

The BSC Peer Review Workgroup presented its draft report of the external peer review of NCEH/ATSDR's Terrorism, Preparedness and Emergency Response (TPER) Program. The Peer Review Panel that conducted the site visit evaluated strengths, weaknesses, opportunities and threats to make recommendations on NCEH/ATSDR's TPER activities in seven areas: strategic planning, communications, funding and resources, data management, workforce management, technology, and environmental justice/health disparities. The Panel also made a number of editorial comments, personal observations and disclaimers regarding the overall peer review process.

The BSC and NCEH/ATSDR applauded the Panel for its tremendous efforts in performing an extremely complex peer review, particularly under constraints that made this activity more difficult. The BSC engaged the Panel in an extensive discussion to obtain clarification on the peer review report, the overall peer review process, and the disclaimers.

The BSC asked the Panel to make the following revisions to the draft peer review report.

- The Panel should clarify activities that appear to be more "political than functional."
- The Panel should clarify whether GIS is described in the report as a method or tool of epidemiology or if NCEH/ATSDR actually has a gap in its GIS capacity.
- The Panel should clarify whether NCEH/ATSDR has gaps in its radiological expertise alone or if NCEH/ATSDR has equal gaps in both its radiological and chemical capabilities.
- The Panel should include new language in the executive summary to highlight the limitations of the overall peer review process.

- The Panel should ask NCEH/ATSDR to provide feedback on whether TPER is actually viewed as a “secondary” function to the “day” jobs of staff. The Panel should make this suggestion outside of the peer review report because this issue is beyond the scope of the charge.

The BSC accepted the NCEH/ATSDR Preparedness and Emergency Response Program Draft Peer Review Report with the revisions noted for the record.

Business items that the BSC raised over the course of the meeting were noted for the record and are outlined below.

Consensus Items:

- *The BSC agreed to conduct a peer review of NCEH/ATSDR’s internal clearance and external peer review processes.*
- *The BSC accepted the NCEH/ATSDR Preparedness and Emergency Response Program Draft Peer Review Report with the revisions noted for the record.*

Action Items:

- *Dr. Bashor will provide the BSC with CD-ROMs of ATSDR’s draft 2008 Great Lakes AOC report.*
- *Drs. Bashor and Fowler will develop and provide the BSC with a summary of the changes among the draft 2004, 2007 and 2008 Great Lakes reports.*
- *Dr. Bashor will provide the BSC with Dr. Lubert’s slides and CDC’s larger slide set on climate change.*
- *Dr. Bashor will place the following items on the next BSC agenda:*
 - *An overview of metrics for the BSC to determine the effectiveness of NCEH/ATSDR’s methods for maintaining objectivity and maximizing trust during its health studies.*
 - *Panel presentation on public health updates (rescheduled from the May 2008 meeting).*
 - *NCEH/ATSDR’s formal response to the Preparedness and Emergency Response Program Peer Review Report (extended agenda item).*

The Chair opened the floor for public comment at all times as noted on the published agenda. The next BSC meeting would be held on November 6-7, 2008.

**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
May 29-30, 2008
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 May 29-30, 2008 at the Atlanta Marriott Century Center Hotel in Atlanta, Georgia.

Opening Session

Dr. Alan Ducatman, Chair of the BSC, called the meeting to order at 8:37 a.m. on May 29, 2008. He welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Dr. Howard Frumkin, Director of NCEH/ATSDR, presented certificates of appreciation to four outgoing members in recognition of their service: Mr. Angelo Bellomo and Drs. Alan Ducatman, Gary Evans and Paul Wax. Dr. Frumkin also presented a separate token of appreciation to Dr. Ducatman in recognition of his service as the Chair of the BSC. The participants applauded the four outgoing members for their environmental health expertise and valuable contributions to CDC and the BSC.

Dr. Mark Bashor, Designated Federal Official of the BSC and Associate Director for Science of NCEH/ATSDR, explained the process to appoint new members. NCEH/ATSDR forwards a nomination package to HHS, but HHS can either accept or replace nominees that NCEH/ATSDR has suggested. After HHS makes its final selections, NCEH/ATSDR submits the final nomination package for approval. Current BSC members can serve an additional 180 days to fill gaps during the nomination process. NCEH/ATSDR has submitted the draft nomination package to HHS, but has not received a decision to date.

Dr. Bashor informed the BSC that a directive to abolish all federal advisory committees is typical with a new Administration. As a result, a significant number of advisory committees across the government traditionally have been dissolved and reconstituted under a new Administration. However, CDC has a history of minimizing disruption and maintaining strong scientific continuity with its existing federal advisory committees under a new Administration.

Dr. Frumkin was pleased to announce that 12 students were selected as summer interns for NCEH/ATSDR's new "Collegiate Leaders in Environmental Health Program." NCEH/ATSDR developed the internship program because many academic institutions that offer environmental studies and environmental sciences courses do not address the "health" component of environmental health. NCEH/ATSDR believes that the internship program will play a significant role in filling gaps in the current environmental health workforce.

Dr. Frumkin encouraged the BSC members to network with the summer interns over the course of the meeting. Dr. Ducatman added that NCEH/ATSDR would present results from the first cycle of the internship program during the next meeting.

Update by the NCEH/ATSDR Office of the Director

Dr. Frumkin covered three topics in his update. For topic 1, he described NCEH/ATSDR's major areas of focus and interest. Despite relatively flat funding and other challenges, NCEH/ATSDR has created a broad-based environmental health portfolio with new, emerging, ambitious and solid projects.

The climate change initiative is rapidly progressing and the built environment project is consistent with CDC's agency-wide healthy places goals. Preparedness, disaster response and recovery activities continue to be extremely important to NCEH/ATSDR. Solid science continues to pervade all of NCEH/ATSDR's activities, such as biomonitoring, health studies and toxicological profiles. Updates on some of these projects would be presented during the meeting.

For topic 2, Dr. Frumkin described recent attention by Congress and the press in response to criticism that NCEH/ATSDR inappropriately conducted some activities. Dr. Frumkin believed that the allegations were unfounded, but he acknowledged some areas of NCEH/ATSDR's environmental health portfolio could be improved. NCEH/ATSDR has held conference calls with the BSC to discuss these issues since the November 2007 meeting.

Two major issues have continued to attract attention by Congress and the press. NCEH/ATSDR's initial response to Hurricanes Katrina and Rita was to conduct acute and emergency response activities immediately after these disasters in late 2005. The issue of formaldehyde exposure in Federal Emergency Management Agency (FEMA) trailers arose in an unsystematic manner in early 2006.

Dr. Frumkin has publicly stated that NCEH/ATSDR could have been engaged earlier in the formaldehyde effort, released a work product with a broader focus, and performed a more rigorous review of materials prior to dissemination. Since that time, NCEH/ATSDR has developed a strong portfolio on formaldehyde exposure, post-disaster housing and other recovery issues and has also made a commitment to be more alert to emerging issues in future disasters.

ATSDR's draft report on the public health impacts of chemical exposures in the Great Lakes Basin was scheduled to be released in 2007, but a number of scientific shortcomings were identified. Dr. Frumkin directed ATSDR to delay the release of the draft report until these issues were addressed, but ATSDR was publicly criticized for inappropriately withholding the document for political and other non-scientific reasons.

ATSDR released the revised Great Lakes report for public comment and also forwarded the new draft to the Institute of Medicine (IOM) for an independent review of the scientific basis for the document. ATSDR requested formal and systematic oversight of the report and then posted the original draft on its web site along with critiques and a statement of scientific concerns. The accompanying documentation was also submitted to the IOM to inform the external review. ATSDR expects to receive the results of the IOM external review of the Great Lakes report in the summer of 2008.

In the interim, CDC and ATSDR have taken a number of steps to address the negative publicity on the Great Lakes report. The CDC Office of Enterprise Communications responded to press inquiries and ATSDR responded to all Congressional inquiries. ATSDR compiled and posted updated documentation on its web site to ensure that information on the report would be transparent and available to the public.

CDC and ATSDR commended staff for devoting a tremendous amount of time to provide documentation in response to inquiries and conduct other aspects of the investigation. The CDC Office of the Director provided ATSDR with strong support throughout this process.

For [topic 3](#), Dr. Frumkin described NCEH/ATSDR's ongoing efforts to advance and improve its overall performance as an environmental health agency. NCEH/ATSDR is taking advantage of opportunities to refine its scientific review and clearance processes to ensure that all activities are based on the best possible science and thoroughly reviewed by qualified scientists.

Questions were raised about the functionality of NCEH/ATSDR's internal clearance and external peer review processes following the Great Lakes report and post-Hurricane Katrina activities. As a result, the BSC would be asked during the meeting to conduct a formal review of these processes and particularly highlight areas of improvement. A presentation on this issue would be made during the meeting to inform the BSC's decision-making process.

NCEH/ATSDR is undertaking an internal management review to evaluate and improve its management and administration of the entire center and strengthen the scientific basis for all activities. NCEH/ATSDR has made several changes to date. Most notably, processes to track issues and clear documents are now more rigorous and systematic. NCEH/ATSDR will continue to review and refine its scientific clearance, management and other procedures to improve its overall performance as an environmental health agency one year from now.

The BSC applauded NCEH/ATSDR's efforts to benefit from criticism by Congress and the press by compiling lessons learned and taking concrete actions to improve its overall performance as an environmental health agency. The BSC also commended NCEH/ATSDR for formally

engaging the BSC in providing input on Congressional criticism and negative publicity following the Great Lakes report. Several members made suggestions for NCEH/ATSDR to consider in strengthening its public relations efforts.

- NCEH/ATSDR should compile and widely disseminate its lessons learned on continuous improvement activities because this information would be extremely useful to state and local environmental health programs.
- NCEH/ATSDR should increase outreach to “critics” and stakeholders. Face-to-face meetings should be convened to educate these groups on NCEH/ATSDR’s environmental health activities and ongoing improvements. This approach would serve as a solid companion to materials posted on the NCEH and ATSDR web sites and internal management reviews.
- NCEH/ATSDR should launch a major educational campaign to introduce its environmental health role, responsibilities, functions and accountability measures to the public. This strategy would increase general public knowledge of NCEH/ATSDR outside of its responses to natural disasters and other site-specific issues.
- NCEH/ATSDR should develop a formal process to identify priority issues that would need the BSC’s guidance and input during conference calls in between the biannual meetings.

Dr. Ducatman announced that the BSC extensively discussed public affairs issues during the conference calls with NCEH/ATSDR. He confirmed that the BSC would continue to revisit this topic on an ongoing basis during future BSC meetings.

Update on the Formaldehyde and FEMA Trailer Study

A panel of NCEH/ATSDR staff presented a series of updates on various components of the formaldehyde and FEMA trailer study.

Dr. James Lando described the results of a study that NCEH conducted at the request of FEMA to assess formaldehyde levels in occupied FEMA-supplied temporary housing units (THUs) in Louisiana and Mississippi from the period of December 21, 2007-January 23, 2008. NCEH designed the study with two key objectives: (1) determine formaldehyde levels in occupied THUs in Louisiana and Mississippi and (2) provide information to assist FEMA in making decisions on relocating residents. NCEH did not design the study to evaluate health effects.

NCEH initiated the study by thoroughly reviewing the characteristics and properties of formaldehyde. Formaldehyde is a colorless gas used to make many wood and consumer projects. Although formaldehyde is found in nature, the body, air along busy streets, and in nearly all homes throughout America, the chemical is at fairly low levels.

Formaldehyde levels are expressed in parts per billion (ppb). Levels starting at 10 ppb would present a low risk for health problems. Levels starting at 100 ppb would cause acute irritative health effects of mucous membranes in sensitized populations, such as elderly persons, young children, and persons with asthma and other health conditions. Levels starting at 1,000 ppb would result in acute health effects to nearly all persons.

To support the study, FEMA provided NCEH with a list of ~48,500 THUs in Louisiana and Mississippi that were still occupied ~2.5 years after Hurricanes Katrina and Rita in the Gulf Coast region. NCEH separated the THUs into 11 groups based on brand, type and most common use in the region.

The 519 THUs that NCEH selected for the study were categorized into six brands of travel trailers, two brands of park models, and two brands mobile homes. NCEH also designed the study with active air sampling using the National Institute for Occupational Safety and Health (NIOSH) standard, a walkthrough inspection for mold and other issues, and a questionnaire to residents.

Key findings of the study are summarized as follows. The mean formaldehyde level was ~77 ppb for all occupied THUs used in the region, but travel trailers had significantly higher levels than mobile homes and park models. By type of home, formaldehyde levels ranged from 3-590 ppb. By brand, formaldehyde levels were higher in Gulfstream travel trailers compared to other models. The mean formaldehyde level of this brand was 103 ppb, but 56% of Gulfstream models had levels >100 ppb and 8% had levels >300 ppb. Overall, formaldehyde levels >100 ppb were observed in all brands of THUs.

Elevated formaldehyde levels observed in many THUs could affect health, but these levels most likely under-represented long-term exposure due to a number of factors. Formaldehyde is released from materials through off-gases over time. The study was implemented in the winter. Formaldehyde levels experienced by residents closer to the time of the 2005 hurricanes and in hotter months were probably higher than levels observed in the NCEH study.

Higher indoor temperatures were associated with higher formaldehyde levels. Formaldehyde levels varied by the brand and type of mobile homes, park models and travel trailers. Travel trailers had significantly higher formaldehyde levels than mobile homes or park models on average. Travel trailers also had the highest percentage of formaldehyde levels >100 and 300 ppb.

Based on the findings of the study, NCEH advised FEMA to relocate residents before warmer weather according to the following priority: symptomatic residents, vulnerable populations and persons living in brands of THUs with higher formaldehyde levels.

NCEH recommended that federal partners establish multi-agency collaborations to (1) achieve safe and healthy housing for residents of the Gulf Coast region who were affected by Hurricanes Katrina and Rita; (2) assess the potential for formaldehyde exposure in other places and contexts; (3) consider the best strategies to provide necessary assistance to ensure

adequate follow-up for residents; and (4) consider supporting the establishment of a health registry of residents.

NCEH also formulated and targeted a number of recommendations to residents. The amount of time spent outdoors in fresh air should be increased and windows should be opened to let in fresh air. The indoor temperature should be maintained at the lowest comfortable level. Residents should not smoke, particularly indoors, because smoke contains very high levels of formaldehyde. A doctor or other medical professional should be seen to address health concerns.

At the conclusion of the study, NCEH and its federal partners hand-delivered general findings of the study and individual results to all 519 participants. Several public availability sessions were held in Louisiana and Mississippi. Information was distributed to healthcare providers and results of the study were presented to industry groups. Collaborations were continued with federal, state and non-governmental partners. The final report is expected to be released before the summer of 2008.

Dr. Teresa Morrison presented results of NCEH's medical record review in Hancock County, Mississippi. NCEH conducted the case series investigation in response to reports of increased respiratory illness among children who lived in THUs after Hurricane Katrina. The objectives of the study were to compare the proportion of healthcare visits among children with diagnoses potentially related to indoor air quality before and after Hurricane Katrina and characterize these proportions with regard to occupancy in THUs.

Data were collected from medical record reviews at one hospital and four pediatric practices in Hancock County. Medical records were identified by electronic queries of ICD-9 codes and abstracted based on specific selection criteria. Telephone interviews were also conducted with parents or guardians to obtain information on the child's THU occupancy and confirm the child's primary residence in Hancock County from August 29, 2004-August 28, 2007.

Selection criteria for the medical record abstraction included children 2-12 years of age as of August 29, 2004 who had visited one of the five healthcare facilities in the year before Hurricane Katrina, had a diagnosis included on the list of ICD-9 codes, and resided in Hancock County. Children were included in the study if their medical records had been abstracted, telephone interviews had been completed, information on THU occupancy had been obtained, and residence in Hancock County in the year before and the first and second years after Hurricane Katrina had been confirmed.

Of 934 children's records that were reviewed, 264 met the selection criteria. After completing 168 telephone interviews, 144 records met the inclusion criteria for analysis. Of the 144 medical records, 96 children lived in THUs and 48 children did not live in THUs. The data showed that a higher proportion of children 5-8 years of age did not live in THUs and a higher proportion of children 9-12 years of age lived in THUs. Proportions of race and gender were similar in both groups. Children who lived in THUs had a higher proportion of Medicaid coverage.

Of all 144 medical records included in the study, the total number of healthcare visits was 411 in the year before Hurricane Katrina, 272 in the first year after Hurricane Katrina, and 414 in the second year after Hurricane Katrina. Upper respiratory diagnoses accounted for the majority of healthcare visits in all three years compared to lower respiratory and allergy diagnoses.

Over the three study periods, upper respiratory diagnoses decreased from 63%-52%; lower respiratory diagnoses increased from 22%-31%; and allergy diagnoses were similar at 11% and 12%. The decrease in upper respiratory diagnoses and the increase in lower respiratory diagnoses were similar among children who lived and had never lived in THUs.

NCEH acknowledged several limitations of the study. The findings most likely did not represent all children in Hancock County because some medical records were destroyed, some children did not return, and only children with sick visits were included in the study. Missing records and the absence of denominator data prevented NCEH from estimating population-based rates.

Overall, the study showed that the multifaceted aftermath of Hurricane Katrina continued to affect Gulf Coast communities and affected children's health. Basic medical systems and services were severely compromised. Healthcare visits returned to pre-Hurricane Katrina levels in the second year after the hurricane. Diagnoses shifted from upper respiratory conditions in the year before Hurricane Katrina to lower respiratory conditions in the second year after the hurricane. This pattern was similar among children who lived and had never lived in THUs.

Dr. Fuyuen Yip described NCEH's investigation of health effects in children who lived in storm-damaged housing and THUs along the Gulf Coast. After the epidemiologic investigation was conducted in Hancock County, Mississippi, NCEH made plans to perform an assessment to measure formaldehyde concentrations in a random sample of occupied THUs to address ongoing concerns regarding long-term health effects in children from various indoor exposures.

NCEH is currently designing the study to determine if an association between the occurrence and severity of respiratory and dermal symptoms and occupancy in storm-damaged housing or FEMA-issued THUs as well as historic and ongoing exposures in the home. The study will be developed to describe the clinical and demographic characteristics of children, characterize environmental and behavioral risk factors, and formulate appropriate recommendations for public health strategies and messages.

NCEH proposes to use FEMA's National Emergency Management Information System to select study participants because this database includes all persons who requested or received aid from FEMA after Hurricanes Katrina and Rita. Examples of entries in the FEMA database include incident activities and preliminary damage assessments.

NCEH has proposed the following inclusion criteria for the study: children 0-12 years of age, a history of primary residence in a FEMA-issued THU or storm-damaged housing; a history of residence in Alabama, Mississippi, Louisiana or Texas at the time of recruitment; and residence in a household with a parent or guardian ≥ 18 years of age.

NCEH has proposed the following exclusion criteria for the study: children who never returned to or never resided in a storm-damaged house and was never issued a FEMA THU; refusal by the parent or guardian for the child to provide blood or urine samples; inability of the child to provide blood or urine; and residence in a household without a parent or guardian ≥ 18 years of age.

NCEH plans to recruit ~4,200 eligible children for the cohort study during a six-year project period with an option to continue the study for an additional six years. Environmental and health exposures will be assessed twice per year. The biannual evaluations will include baseline, health-based and mental health questionnaires; a medical component with a well-child examination, pulmonary function testing and sampling for biomarker analysis; and an environmental component with a home visual inspection and collection of air samples.

NCEH intends to focus on a number of biomarkers of exposure for the study, including cotinine, formaldehyde, serum, lead and various volatile organic compounds (VOCs). Indoor air quality will be measured based on one-week integrated air samples, dust samples taken during home visits, and one-week integrated samples for an indoor climate assessment. The indoor air quality measurement will focus on formaldehyde, nitrogen dioxide, mold, endotoxin, and other VOCs and allergens.

NCEH has proposed the following timeline for the study. Reviews by an expert panel, Institutional Review Board, and the Office of Management and Budget (OMB) will be completed in December 2008. Recruitment of participants, data collection and ongoing data analysis will be conducted from January 2009-December 2014. Data will be finalized and published from January 2015-December 2016.

Dr. Michael Gressel described NCEH's study to mitigate formaldehyde levels in FEMA-owned THUs. FEMA asked CDC to conduct this study to identify potential solutions to reduce or eliminate formaldehyde concentrations in THUs, including travel trailers. NIOSH staff members with expertise in exposure assessment and engineering controls were assigned to NCEH to assist in implementing the study.

NCEH initially designed the study to develop and evaluate cost-effective solutions to control or eliminate formaldehyde concentrations; identify characteristics that contribute to formaldehyde levels in THUs; and evaluate the efficacy of inexpensive direct-reading formaldehyde monitors. However, the initial priorities of the study were shifted because concentration studies already had been conducted and legal restrictions were placed on sampling in previously occupied travel trailers. Moreover, FEMA decided to discontinue the use of travel trailers in the event residents cannot be transferred from these units by June 1, 2008.

NCEH plans to conduct a separate study to evaluate the capacity of direct-reading instruments to monitor formaldehyde concentrations. Current validated analytical methods can be costly, need specialized equipment and require time-consuming laboratory analysis. NCEH will conduct the study in Selma, Alabama with FEMA trailers that have never been occupied and are not subject to current legal restrictions. Side-by-side samples will be collected using a validated analytical method and direct-reading monitors along with the NIOSH sampling method.

CDC and NASA have established an interagency agreement to take the following actions in the travel trailer mitigation study. Various solutions to reduce or eliminate formaldehyde concentrations in travel trailers will be identified and evaluated. Short-term solutions will be identified for residents who must remain in travel trailers beyond June 1, 2008. Long-term solutions will be identified for future residents of park model and manufactured homes if needed.

A total of 15 Gulfstream Cavalier models with the same floor plan, manufacturing date, plant and materials will be set up at the Stennis Space Center. Testing will include ~12 solutions, such as photocatalytic oxidation, ventilation and other sorbent materials. Ozone, treatments, plants, removal of materials, and temperature and humidity control will not be included in the evaluation. Solutions will be assessed over a two-month period. Air samples will be collected at regular intervals to identify formaldehyde and other VOCs. CDC and FEMA sampling of 519 occupied THUs and FEMA pre-deployment sampling of park model and manufactured homes will be used as data sources to determine the characteristics of THUs.

CDC established an interagency agreement with the Lawrence Berkeley National Laboratory to evaluate specific emission rates of materials for formaldehyde. The material-specific emission study involved air sampling of four different makes of travel trailers, collection of ventilation rate measurements using a carbon dioxide decay test, and chamber tests of building materials from the same four trailers. Testing of the materials showed aldehydes, including formaldehyde, and 80 different VOCs. To date, 45 of the 80 VOCs have been quantified and the acetic acid samples have not been run.

Samples from the trailers will be used to generate data on formaldehyde concentrations based on morning versus afternoon samples and differences in temperature and humidity. Data on other VOCs will be compared to previous studies that have been published on whole buildings. The ventilation rate will be determined to evaluate the amount of fresh that enters the trailers. Formaldehyde emission rates of 45 material samples that were tested will be compared to the standard established by the U.S. Department of Housing and Urban Development (HUD).

HUD established a building standard of 0.3 ppm for particleboard and 0.2 for hardwood plywood. However, the California Air Resources Board (CARB) has established building standards that are substantially lower than the HUD standard. An evaluation will be made during the materials-specific emission study to determine whether the HUD or CARB standard is sufficient for travel trailers.

NCEH is considering a number of activities to conduct in the future, including an assessment of ventilation solutions in park and manufactured homes, additional research on temperature and humidity effects, and more chamber studies. For all of the studies, NCEH will prepare and forward written reports to FEMA, post information on the CDC web site, and publish articles in peer-reviewed scientific journals.

Dr. David Williamson described ATSDR's ongoing strategic planning process to determine the feasibility of developing a registry of residents following hurricanes in the Gulf Coast in 2005. ATSDR is considering a number of factors in this effort. One, a "registry" is defined as a listing

of persons who share one or more characteristics, such as an exposure, disease or other factors. A registry might contain basic or more extensive information. The design of a registry directly affects its complexity, cost and utility. Participation in a registry is voluntary.

Two, different types of data can be collected for a registry, such as the individual's name, contact information, demographics, housing data, health data, and environmental exposure data. This information can be collected once at the outset or repeatedly. Three, the potential purposes of a registry include disseminating health education to participants; communicating housing, benefits and administrative information; and providing platforms for the distribution of benefits, provision of health care, and research to determine short- and long-term health effects.

Four, potential eligibility criteria for the Gulf Coast hurricane registry could include history of residence in the storm-affected area, history of being displaced following the hurricane, history of residence in a FEMA-owned THU, and history of certain medical conditions, such as pregnancy while living in a FEMA-owned THU. Additional eligibility criteria could include restrictions on age, geographic location and duration of residence.

Five, the time frame of the registry will be determined, such as start and end dates, the periodicity to collect follow-up contact and health information, and the duration to operate the registry. Six, the potential cost of the registry will be explored. A basic registry would have a lower cost and could be designed with restricted eligibility, demographic data only, and periodic communication with participants. A more elaborate registry would have a much higher cost and could be designed with broad eligibility; demographic, health and environmental data; regular updates; data analyses for research purposes; and regular communication with participants.

Seven, logistical challenges in developing a Gulf Coast hurricane registry will be taken into account. Most notably, the extremely large eligible population is widely dispersed and will increase the difficulty in obtaining an initial enumeration of residents who were affected by the hurricanes. Eight, various strategies will be considered to recruit participants for the registry, such as radio announcements and full-page advertisements in newspapers throughout the country; outreach activities developed by the CDC and FEMA communications offices; and innovative and effective approaches created by state and local health departments.

Nine, steps to actually implement the registry will be outlined. The purpose, eligibility criteria and time frame of the registry would need to be clearly defined. Operational mechanisms to implement the registry would need to be reviewed and established. Data sources from FEMA and state and local health departments would need to be evaluated.

Plans would need to be developed for data quality assurance, information technology, data analysis and communications. Regulatory and ethical issues would need to be investigated. External steering, scientific and community committees would need to be established to assist ATSDR in designing the registry.

The BSC members made a number of comments and suggestions for NCEH/ATSDR to consider in its ongoing efforts to refine the formaldehyde and FEMA trailer study.

- NCEH's recommendations to residents appear to be incomplete and inconsistent in some areas and indicate moderate risk. For example, opening windows while keeping the unit cool would not be possible in the south during the summer. NCEH should synthesize and make more definitive recommendations to assess the risk level to the public.
- NCEH should expand its literature review to refine the formaldehyde and FEMA trailer study. For example, California's extensive study on modular structures in schools generated solid data on formaldehyde in portable classrooms.
- CDC and its federal partners should jointly send a letter or launch a call to action to the manufactured housing industry. Federal agencies should ask industry to use results from CDC's comprehensive formaldehyde and FEMA trailer study to initiate additional research in a broader cross-section of manufactured housing across the country.
- NCEH should avoid making "alarmist" statements to the public that do not reflect the conclusions in its data sets. Based on the medical record review in Hancock County, for example, NCEH concluded that the aftermath of Hurricane Katrina affected children's health. However, this conclusion is broad-based, particularly since most health parameters of children in the study returned to normal or were not significantly higher after Hurricane Katrina.
- NCEH should take advantage of existing opportunities to expand the scope of the cohort children's health study. For example, more data could be collected on mental health, crowding, noise, stress hormones, psychosocial stressors and parent/child interactions among residents of FEMA-owned THUs. NCEH could use its existing access to families, urine and blood samples and other data to gather more information with minimal additional resources.
- NCEH's rationale for conducting a prospective study on formaldehyde in FEMA-owned THUs is unclear because primary prevention efforts to mitigate formaldehyde levels to the national standard would be less expensive than research. Moreover, public perception of the study might be negative for a number of reasons. Persons were exposed to high levels of formaldehyde in THUs supplied by a federal agency. THU residents who participated in the study might be viewed as "guinea pigs." Efforts to change engineering controls in THUs to minimize exposure to formaldehyde have been stalled.
- ATSDR should explore the possibility of linking existing data sets of CDC's Environmental Public Health Tracking Program (EPHTP) to the proposed Gulf Coast hurricane registry.

Dr. Frumkin provided additional details on the formaldehyde and FEMA trailer study in response to the BSC's questions and comments. CDC serves on an interagency workgroup to offer guidance on the safe and healthy use of manufactured structures. The federal partners are undertaking this effort to broaden the focus beyond formaldehyde in THUs and other post-disaster issues that are specific to Hurricane Katrina. In this activity, the federal partners are placing emphasis on more general healthy housing and healthy building issues, such as structural safety, the siting of structures and electrical safety.

Dr. Frumkin agreed that science should be balanced with, but should not replace mitigation efforts. However, he clarified that CDC needs to allocate resources to the formaldehyde study because data have not been collected to date to determine a definitive association between exposure to formaldehyde in THUs and the onset of asthma or other conditions. Other data gaps that need to be filled in this area include short- versus long-term effects of formaldehyde and the role of other risk factors in THUs. CDC could use data from the study to inform parents of potential hazards in THUs and better focus efforts in the future.

Dr. Frumkin reported that resources have not been identified to date to implement the cohort children's study or the proposed Gulf Coast hurricane registry. NCEH/ATSDR is currently planning these activities, but actual implementation would require Congressional funding.

Public Comment Session

Mr. Jeff Inks is the Vice President of Regulatory Affairs for the Manufactured Housing Institute (MHI). He noted that industry recognizes the need to answer questions and reach consensus on health effects from formaldehyde and composite wood products in manufactured housing, recreational vehicles and park models. Specific actions that should be taken to address health concerns in different occupancy types should be identified as well, but these actions must be based on sound science and taken with caution.

Mr. Inks pointed out that the CDC web site references studies showing consistent formaldehyde levels between site-built housing and manufactured housing. As a result, the scope of concern of THUs should be expanded to include all occupancy types. Mr. Inks confirmed that MHI would submit more formal comments to the BSC in writing in the near future.

Overview of the 2008 Draft Great Lakes Areas of Concern (AOC) Report

Dr. Bruce Fowler is the Assistant Director for Science in the ATSDR Division of Toxicology and Environmental Medicine (DTEM). He presented an overview of ATSDR's report: *Selected Information on Chemical Releases With Great Lakes Counties Containing Areas of Concern*. The U.S.-Canada Great Lakes Water Quality Agreement defines "AOCs" as ecologically degraded geographic areas requiring remediation. Of 43 AOCs that were identified, 26 are in the United States, 12 are in Canada, and five are shared between the two countries. ATSDR's draft report covers the 26 U.S. AOCs.

ATSDR posted draft Great Lakes reports on its web site in 2004, 2007 and 2008 along with supporting documentation. ATSDR developed the 2008 draft report by forming a workgroup with subject matter experts from all four of its divisions. Quality assurance and quality control (QA/QC) were performed on all data presented in the report, particularly the updated site assessments and geographic information system (GIS) maps. Information on the number and

remedial status of site assessments in the 2004 and 2007 draft reports was updated for the 2008 draft report. Data sets that could not be verified were deleted from the 2008 draft report.

ATSDR collected and compiled environmental data for the 2008 draft report from four sources. Data on hazardous waste sites in AOC counties were collected from ATSDR's previous evaluations. Chemical release data were collected from the U.S. Environmental Protection Agency's (EPA) Toxic Release Inventory. Data on pollutant discharges were collected from EPA's National Pollutant Discharge Elimination System. Data on beneficial use impairments, such as wildlife and drinking water advisories, were collected from each of the Great Lake states. Data for each of the 26 U.S. AOCs are presented in the 2008 draft report as text, tables or GIS maps created by ATSDR.

ATSDR deleted information from the 2008 draft report in three areas. First, human health data collected by the Health Resources and Services Administration (HRSA) were outdated, county-specific and difficult to spatially link to AOCs. Second, data from ATSDR's HAZDAT database could not be verified. Third, beneficial use impairment data for beach closings were primarily due to coliform counts, but the 2008 draft report focuses on chemicals.

ATSDR improved the 2008 draft report in a number of areas. Chapter 1 more clearly presents methods by which the report was developed. Chapter 7 presents conclusions that are more directly linked to the data presented. Chapters 1 and 7 present additional information on the strengths and weaknesses of the report. Existing references were checked, updated and corrected and new references were added. QA/QC was performed on ATSDR's updated site assessments and GIS maps of AOCs.

The 2008 draft report contains the following key conclusions. Evidence shows current and past environmental pollution in the Great Lakes from >140 hazardous waste sites. Available information on environmental pollution in the Great Lakes region is limited, incomplete or does not provide insights into human exposure to pollutants. Health data are not well matched to exposure data. These reasons do not provide ATSDR with the ability to define threats to human health at this time.

The 2008 draft report also contains six major recommendations. More complete data on environmental contaminants are needed. Biomonitoring is needed to characterize the amounts of chemicals in persons in the Great Lakes region. More complete health data are needed. Data linkages to permit joint analyses of different data sets are needed. Analytical epidemiology studies are needed to test hypotheses. Exposure pathways need to be modeled.

The IOM is currently conducting an external peer review of the 2008 draft report and is expected to deliver its findings to ATSDR by June 30, 2008. The 2008 draft report has been posted on the ATSDR web site with a 60-day public comment period that will close on June 30, 2008.

Dr. Fowler emphasized that 81 staff members across all four divisions (or ~25% of the entire ATSDR workforce) participated in performing QA/QC and conducting other activities to improve the 2008 draft report. In addition to the diligent and extraordinary efforts of ATSDR staff, he also acknowledged exceptional cooperation and support from the following groups: leadership

in the Coordinating Center for Environmental Health and Injury Prevention and NCEH/ATSDR, the CDC Office of the Chief Science Officer, the ATSDR Office of Communication, and web management and communications outreach staff.

The BSC members made a number of suggestions for ATSDR to consider while finalizing the 2008 draft AOC report.

- ATSDR should include a summary of future research needs for the target AOCs in the executive summary of the report.
- ATSDR should explicitly state in the report that the Great Lakes region is one of the most hydrologically dynamic areas in the country in terms of future climate changes. Because of extremely heavy runoff and changes in the levels of Great Lakes that are projected, ATSDR should recommend additional assessments under different climate scenarios.
- ATSDR should include a description of environmental justice issues in the Great Lakes region in a prominent place in the report.
- ATSDR should compare the U.S. and Canada data because a formal benchmark assessment of the Canadian approach might provide the United States with insights on appropriate activities to conduct in the Great Lakes region long-term.
- ATSDR should leverage resources to perform epidemiological and biomonitoring studies in the Great Lakes communities with an appropriate reference or control group. ATSDR will run the risk of reaching erroneous or “alarmist” conclusions if this approach is not taken.
- ATSDR should partner with EPA to implement its recommendation to model exposure pathways. EPA has already developed elaborate models for pesticide transport in the environment.

Dr. Fowler provided more details on ATSDR’s 2008 draft AOC report in response to the BSC’s questions and comments. HRSA’s human health data are solid and accurate at the county level, but the information could not be geographically linked to the AOCs. Census tract, zip code or water district data in each AOC would be more appropriate for the Great Lakes report. However, ATSDR was sensitive in outlining its rationale in the report for deleting HRSA’s human health data.

Dr. Fowler informed the BSC that ATSDR has allocated ~\$32 million to the Great Lakes Human Health Research Program over the past 16 years. ATSDR has a longstanding commitment to address human health effects in the Great Lakes region and also has a strong desire to incorporate more data into the 2008 draft report, but resources are not sufficient at this time to support this effort. However, the report provides a solid foundation to conduct additional research on the AOCs in the future. ATSDR recognizes the need to leverage resources from EPA and other federal partners to gather more data.

Dr. Fowler confirmed that ATSDR’s updated site assessments have been the most helpful component of the report in terms of informing specific Great Lakes communities of actions to consider in addressing potential health effects in the target AOCs. For example, the report advises the Great Lakes states to collaborate in developing a uniform set of fish advisories.

However, ATSDR recognizes that state and local health departments would be the best entities to make decisions on follow-up of affected individuals.

Dr. Frumkin described lessons that NCEH/ATSDR learned from the negative publicity of the Great Lakes reports. NCEH/ATSDR must improve its internal processes to scrutinize and clear reports in a systematic and step-wise manner prior to public release. NCEH/ATSDR must develop reports to explicitly outline the methods and limitations of a study; deliver transparent messages to the public health community, policymakers and the general public; and present conclusions and recommendations that accurately reflect the data. NCEH/ATSDR must develop reports with a multidisciplinary team across divisions when necessary because this collaborative approach resulted in the production of a much better product.

Update on ATSDR's Toxicological Profiles

Dr. Edward Murray, Acting Director of the DTEM, explained that ATSDR develops toxicological profiles based on the following language in its Congressional mandate. A list of the most commonly found hazardous substances must be prepared in order of priority. The ATSDR Administrator shall prepare toxicological profiles using available toxicological information and epidemiologic evaluations. Toxicologic testing must be performed to identify adverse health effects in humans.

ATSDR designs the profiles to succinctly characterize toxicological and adverse health effects data; identify levels of exposure that present a significant risk to human health; and determine research areas or priority data needs to fill data gaps. The listing of chemicals, research and overall development of toxicological profiles play a key role in public health practice in terms of emergency responses, public health assessments and consultations, identification of priority health conditions, and dissemination of health advisories and environmental alerts.

Toxicological profiles have a number of unique aspects. Public health statements are produced in laymen's terms in both English and Spanish. ToxFAQs™ are question/answer documents that are also written in both English and Spanish. A quick reference is generated to identify relevant sections of toxicological profiles for healthcare providers.

Toxicological profiles support international chemical assessment documents and serve as a resource to guide decision-making on impacts to children's health, such as mercury and aluminum in vaccines, learning deficits related to lead, arsenic in pressure-treated wood, and malathion, pyrethrins and pyrethroids in mosquito spraying.

The entire process to initially develop and complete toxicological profiles requires ~2 years, including external peer review and public comment. This process is summarized as follows. The broad priority list of hazardous substances serves as the starting point for ATSDR to select chemicals to develop toxicological profiles. ATSDR uses the broad list to identify substances that should be evaluated, perform a literature review, conduct interagency and intra-agency

reviews, discuss the proposed substances with a workgroup, and release the proposed substances for public comment.

Based on the outcomes of this initial process, ATSDR selects ten chemicals from the broad priority list of hazardous substances, narrows the list to six or seven substances, updates existing toxicological profiles, and develops no more than two toxicological profiles of new substances.

ATSDR publishes notices in the *Federal Register* and posts announcements on its web site of substances that were selected for profile development. Draft 1 of the profile undergoes an internal review to determine health effects and minimal risk levels (MRLs) of the proposed substance. Draft 2 of the profile undergoes a second internal review along with an external review by an Interagency MRL Workgroup. Draft 2 is revised, reformatted as a camera-ready copy, approved by CDC and ATSDR leadership, and posted on CDC's web site. ATSDR's disposition of the peer review comments is posted on the OMB web site as well.

The camera-ready copy of the profile is released for a 90-day public comment through another *Federal Register* notice and web announcement. Public comments are classified and internally reviewed. The profile is revised based on the relevance of the comments. Another literature review is performed after the public comment period and another peer review is conducted if necessary. A report on responses to public comments is prepared. The final toxicological profile is released with a *Federal Register* notice and a web site announcement.

Other components of the toxicological profiles are described as follows. ToxGuides are new products that serve as a pocket guide for use in the field or healthcare providers who need a quick reference. ToxCABS are chemical agent briefing sheets that provide more scientific details on a particular substance.

ToxProfiles™ contain a search engine that allows users to search across various chemicals. The 2007 ToxProfiles™ CD-ROM is currently available and the 2008 CD-ROM will be available in the late fall of 2008. From May 2007-April 2008, ~1.8 million web hits were made to the ToxFAQs™ web page and 1.6 million web hits were made to the toxicological profile web page in Spanish.

ATSDR collaborates with a number of internal and external partners to develop, update and maintain toxicological profiles. ATSDR uses National Reports on Human Exposure to Environmental Chemicals developed by the NCEH Division of Laboratory Sciences to select profiles for development, incorporate biomonitoring data, and consider potential changes to the priority list of hazardous substances.

ATSDR and EPA established a memorandum of understanding in 2004 to leverage resources, harmonize assessment methods and more effectively communicate risks to the public with a unified voice. ATSDR and EPA also formed an interagency workgroup to oversee consolidation of administration and technical efforts. ATSDR's other federal partners in developing toxicological profiles include NIOSH, the Food and Drug Administration, the National Institute of Environmental Health Sciences, the Department of Defense and the Department of Energy.

ATSDR is proposing to modify its process of developing toxicological profiles by using available data to create an addendum for each substance that was not selected for profile development. ATSDR is considering this effort because Congressional legislation requires the ATSDR Administrator to establish and maintain an inventory of literature, research and studies on the health effects of toxic substances.

The addenda would supplement information in toxicological profiles with a background statement on the purpose and intent of the substance and relevant new studies. ATSDR would post addenda on its web site and update key literature in real-time. Dr. Murray presented a mock web site with an addendum for formaldehyde and asked the BSC to provide guidance on ATSDR's proposed process to create addenda for toxicological profiles.

Dr. Murray provided additional details on ATSDR's toxicological profiles in response to a number of questions the BSC members posed in the following areas: (1) the extent to which writing of the profiles is outsourced; (2) ATSDR's decision-making process to include or disregard certain studies in its literature reviews; (3) the process to prioritize new chemicals; (4) ATSDR's ability to be flexible in having more time in advance to determine emerging chemicals; (5) specific target audiences for the profiles; and (6) methods to disseminate the profiles beyond the ATSDR web site.

Dr. Ducatman summarized several overarching observations based on the BSC's questions regarding ATSDR's toxicological profiles. In general, the BSC members were impressed because the thorough documents are extremely useful at both national and international levels and are also universally viewed as strong products.

In particular, the BSC members advised ATSDR to clearly distinguish between "internal" and "external" reviews. In its current external review process, for example, ATSDR does not send toxicological profiles to persons with world-renowned expertise in a certain chemical. ATSDR should explore the possibility of asking experts to review the epidemiological or method section of a profile.

Some BSC members noted other flaws in ATSDR's external review process. For example, ATSDR's literature review to prioritize chemicals does not appear to account for the nature of a specific study and existing guidelines. This type of evaluation would be needed for ATSDR to identify studies that are most convincing or most commonly used nationally and internationally.

Some BSC members were not in favor of ATSDR convening world-renowned experts or an external panel to weigh and measure the evidence of studies that would be used to support toxicological profiles. The members noted that the entire process to develop and complete profiles now requires ~2 years, but the new approach would significantly increase this timeline.

Several BSC members supported a strategy of combining ATSDR's current external review process and the proposed approach of experts ranking the weight of the evidence for studies that would be used in the toxicological profiles. Dr. Ducatman raised the possibility of placing

this topic on a future BSC agenda or asking the BSC Peer Review Workgroup to address this issue.

Proposed BSC Peer Review

Dr. Bashor described a proposal for the BSC to establish a workgroup to conduct a peer review of NCEH/ATSDR's internal clearance and external peer review processes. He asked the BSC to consider five issues in deciding whether to undertake this effort:

1. Acceptance of the proposed peer review charge with or without modification.
2. BSC members to serve on the peer review workgroup.
3. A BSC member to chair the peer review workgroup.
4. Other external experts to serve on the peer review workgroup.
5. Data that NCEH/ATSDR would need to provide for the workgroup to conduct an adequate peer review.

Dr. Bashor noted that several documents were distributed to the BSC to inform its decision-making process: (1) the proposed peer review charge; (2) NCEH/ATSDR's clearance policy with a quick reference guide on all information products; (3) ATSDR's peer review policy; and (4) OMB's *Final Information Quality Bulletin for Peer Review*. In addition to these materials, the workgroup also would be provided with CDC and HHS peer review policies as references.

Dr. Bashor explained that the peer review charge described the background and need for this activity; the responsibilities, composition and specific charge to the peer review workgroup; the definitions and scope of NCEH/ATSDR's internal clearance and external peer reviews; and a proposed peer review schedule.

Dr. Bashor highlighted key components that the workgroup would need to consider during the peer review. At least two BSC members would need to serve on the workgroup for a total of eight reviewers. At least one workgroup member would need to be familiar with clearance processes of federal agencies. The workgroup would be asked to consider the appropriate balance between the robustness and thoroughness of the internal clearance and external peer review processes and NCEH/ATSDR's ability to generate final products.

NCEH/ATSDR's current workforce of ~1,200 full-time staff, fellows and interns would need to be taken into account as well. NCEH/ATSDR grouped the *Clearance Quick Reference Guide* into three product types: "required review," "discretionary review" and "information copy." The workgroup would be asked to determine whether the guide could be grouped into more effective or appropriate categories.

The workgroup would be asked to focus on a particular anomaly. The Office of the Associate Director for Science is responsible for all of NCEH/ATSDR's internal clearance and external peer review processes with the exception of DTEM's external peer reviews. NCEH/ATSDR recognizes the potential problem of DTEM handling its own external peer reviews. The

workgroup would be asked to discuss potential target audiences of products generated under NCEH/ATSDR's internal clearance and external peer review processes, including policymakers and Congressional staffers.

Dr. Bashor concluded that NCEH/ATSDR would ask the workgroup to complete all pre-meeting activities and conduct a two-day site visit in preparation of presenting a draft peer review report to the entire BSC during the November 2008 meeting.

The BSC's initial comments on the five issues that Dr. Bashor raised regarding the proposed peer review are outlined below.

- **Issue 1: The BSC agreed to conduct a peer review of NCEH/ATSDR's internal clearance and external peer review processes.** However, the BSC amended the proposed charge by agreeing to also focus on improving the quality and communication of science.

- **Issues 2 and 4:** BSC members and external consultants would need basic backgrounds, competencies or experience in the following areas:
 - Persons who have been editors or reviewers of peer-reviewed journals or major scientific documents.
 - Persons with knowledge of government processes to approve, clear and release documents.
 - Persons with a history of serving on government peer review panels.
 - Persons with management experience and logistical knowledge of a large organization due to the complexity of NCEH/ATSDR's infrastructure and the timeline involved in developing and releasing products.
 - A CDC Associate Director for Policy and an EPA staff member as informational resources only to avoid a potential conflict of interest.
 - Persons with scientific expertise in toxicology and both community-based and conventional epidemiology.
 - Persons with a community-based or non-technical perspective to provide guidance on the integrity of NCEH/ATSDR's internal and external review processes to the public.
 - Persons with public health experience at federal, state or local levels.
 - Persons who have no conflicts of interest in serving on the peer review workgroup.
 - Persons who are truly able to make a commitment to serve on the workgroup.

- **Issue 3:** The chair of the peer review workgroup should have been a project manager in the past or have strong management skills.

- **Issue 5:** NCEH/ATSDR should provide the peer review workgroup with the following information:

- Cost data in terms of actual dollars and the amount of time staff devotes to NCEH/ATSDR's internal clearance and external peer review processes.
- The current workload of staff.
- A strong commitment from NCEH/ATSDR leadership that staff will complete and return surveys in a timely manner.
- Primary and backup NCEH/ATSDR staff members who would be available to support the workgroup throughout the entire peer review.
- The entire "universe" of peer-reviewed publications and other products that are generated under NCEH/ATSDR's internal clearance and external peer review processes.
- Estimates of NCEH/ATSDR's internal and external inputs based on data from the document management system for 2007 and the first six months of 2008.
- The size and technical complexity of documents that are produced under NCEH/ATSDR's internal clearance and external peer review processes.
- Descriptions of specific situations when NCEH/ATSDR did or did not meet its metrics during internal clearance and external peer review processes.
- Descriptions of certain components of NCEH/ATSDR's internal clearance and external peer review processes, such as OMB requirements, that are not flexible and could not be changed with recommendations by the workgroup.
- Benchmark assessments of similar activities that have been completed by EPA, NIOSH and NCEH/ATSDR's other federal partners.
- A description of the number of times ATSDR did not follow its internal clearance and external peer review policies, reasons for this divergence, and documents showing the divergence.

Dr. Tanja Popovic, of the CDC Office of the Chief Science Officer, thanked the BSC for agreeing to undertake the peer review of NCEH/ATSDR's internal clearance and external peer review processes. She emphasized that the BSC's review would be extremely helpful to enhance the credibility of existing processes throughout CDC and ATSDR. She also noted that the BSC would establish a precedent for an external advisory body providing guidance on CDC's peer review process.

Dr. Megan Latshaw, of the Association of Public Health Laboratories, asked the BSC to consider inviting a laboratorian to serve on the peer review workgroup.

Update on CDC's Climate Change Initiative

Dr. George Luber, Associate Director for Global Climate Change at NCEH, explained that 2007 was a landmark year for climate change research. The Intergovernmental Panel on Climate

Change (IPCC) published three reports that unequivocally stated global warming is occurring at this time and human society needs to respond to this issue.

Other key points in the IPCC reports are highlighted as follows. Most global warming that has occurred over the past 50 years is very likely due to increases in greenhouse gases. Physical and biological systems on all continents and oceans have already been affected by climate changes. Even if current emission levels were capped, the effects of previous emissions will persist and cause global warming to continue over the next few decades.

Global destabilization of natural systems throughout the world is evidenced by ice cap and glacier melting, early arrival of spring, warming of oceans, rising sea levels, extreme weather patterns and coral reef disintegration. IPCC developed probability estimates to project climate changes in the future. An increase in the intensity and frequency of heat waves is very likely. An increase in the frequency of heavy precipitation events is very likely. An increase in the intensity of tropical cyclones with larger peak wind speeds and more heavy rainfall is likely. An increase in areas affected by drought is likely. An increase in the incidence of extremely high sea levels is likely.

Because global warming will not be uniform throughout the world, understanding of regional impacts of climate change will be critically important. From a public health perspective, extreme temperatures will impact individuals more than the increase in mean. Some occurrences will be well beyond historical experience, such as the 2003 heat wave in Europe that claimed >30,000 lives.

Urban built environments are a key factor in public health effects of climate change and an increase in vulnerable populations. Cities and climates are co-evolving in a manner that will place more populations at risk. The global population that currently lives in cities is >50% compared to 30% in 1950. The worldwide population of persons >65 years of age is projected to increase to 100 million more individuals by 2010. Many climate-sensitive health outcomes are associated with advanced age.

Urban heat islands can add 7-12°F to surrounding rural areas. Increased ozone concentrations play a significant role in more visits to emergency departments. A growing body of scientific evidence has demonstrated that global climate change is linked to the dramatic rise in allergies and asthma in the Western world. A 2007 published study showed a strong correlation between changes in average carbon dioxide levels and the production of pollen. This climate change indicates that growth of ragweed and other aeroallergens will be encouraged in many parts of the world.

A 1996 published study projected that warmer temperatures will encourage northward and upward migration of malaria-carrying mosquitoes. Based on dengue fever cases reported from 1980-1999, climate was found to be only one determinant of vector-borne disease incidence. More recently, climate change was reported to be a contributor to a deadly dengue fever epidemic in Mexico in 2007. A published study showed that rates of reported dengue fever between two nearly identical ecosystems were different by orders of magnitude.

Other published studies in the literature have described potential health effects of climate change, such as heat stress and cardiovascular failure from heat waves; injuries and fatalities from severe weather; and cardiovascular disease and asthma exacerbation from air pollution. Ecosystem changes also play a significant role in allergic, water-borne and vector-borne diseases. Other considerations of public health effects of climate change include significant regional variation and diverse differences in demographic groups that would be affected.

CDC established a Climate Change Workgroup to develop a set of priority actions to guide a public health approach. The workgroup convened a workshop in January 2007 with local and state public health officials, the national and international academic community, and other key partners and stakeholders. Recommendations from the workshop provided a foundation for CDC to develop its "Climate Change: The Public Health Response" policy. The policy can be viewed on the NCEH web site.

As a follow-up to the initial workshop, CDC sponsored additional workshops from October 2007-March 2008 to address specific aspects of climate change, including water-borne diseases; decision support and tools for local emergency preparedness of heat waves; effective health communication and marketing strategies to deliver climate change messages; and communities of color. CDC has planned or proposed additional workshops in 2008 to address the role of climate change in local public health preparedness and public health law.

NCEH is currently conducting activities to support six of 11 priority health actions outlined in the CDC climate change policy. One, CDC will serve as a credible source of information on the health consequences of climate change. To support this priority health action, NCEH will develop a climate change web site to engage and educate the public on this issue. NCEH will publish articles in peer-reviewed journals to provide the academic community with credible information on climate change. NCEH will continue its participation on the U.S. Climate Change Science Program to frame climate change as a public health issue.

Two, CDC will track data on environmental conditions, disease risks and disease occurrence related to climate change. To support this priority health action, NCEH will use the EPHTP to enhance and expand existing national disease surveillance systems by integrating infectious and environmental diseases and ecological parameters into a comprehensive database. Three, CDC will strengthen capacity for modeling and forecasting health effects that might be climate-related.

Four, CDC will identify locations and population groups at greatest risk for heat waves and other climate-related health threats. To support this priority health action, NCEH will conduct epidemiologic investigations and map vulnerable areas to assist local public health practitioners in effectively allocating resources to climate change activities. NCEH has developed neural network and census models to predict census blocks in cities that would most likely experience heat-related deaths.

NCEH is currently refining these models to identify risk factors, such as specific populations and geographical locations, and provide this guidance to emergency response personnel during heat waves. NCEH piloted the new model in Philadelphia with enormous success and hopes to

expand this effort nationally in the future. NCEH also used remote sensing and GIS technology in Chicago to identify areas of the city where individuals typically experience heat-related illness.

Five, CDC will communicate health-related aspects of climate change, including risks and strategies to reduce these threats, to the general public, decision-makers and healthcare providers. To support this priority health action, NCEH will develop and target heat wave messaging materials to a wide variety of audiences to emphasize the important need for communities to address heat as a critical health threat.

Six, CDC will provide technical advice and support to partners in developing and implementing response plans for health threats. To support this priority health action, NCEH and its federal partners created the *Excessive Heat Events Guidebook*. The document offers practical advice on developing city-specific heat response plans, such as strategies to assess vulnerability of a local population; options to characterize meteorological conditions associated with local morbidity and mortality; and approaches to develop effective heat wave notification and response plans.

CDC's public health response to climate change is closely aligned with the essential public health functions of assessment, policy development and assurance. NCEH will conduct seven key activities in its adaptation strategies for health:

- Track diseases and trends related to climate change.
- Investigate water-, food- and vector-borne disease outbreaks.
- Communicate effective climate change messages.
- Establish partnerships with the private sector, civic groups, the faith community, non-governmental organizations and other groups to conduct climate change activities.
- Focus on the most vulnerable populations in developing heat wave and severe storm response plans.
- Develop a public health workforce with solid capacity to respond to climate changes.
- Study and predict links between climate change and health.

Overall, climate change is now a mainstream issue and must be framed as a public health issue. The costs of not taking advantage of climate change opportunities will be high. Public health will play a key role in climate change by conducting science-based activities and delivering effective messages.

Drs. Luber and Frumkin provided additional details on CDC's climate change initiative in response to specific questions posed by the BSC.

- No new resources have been allocated for NCEH to conduct climate change activities.
- Efforts to separate climate change mitigation and adaptation strategies into two different groups are problematic for public health. CDC's role in addressing this issue at the federal level will be elevate discussions on the public health effects

- of climate change, widely promote the health benefits of mitigation strategies, and emphasize the negative consequences of not taking these actions.
- Participants in all of the climate change workshops have consistently advised CDC to focus on the mental health consequences of climate change. CDC will continue to engage its Mental Health Workgroup in future climate change workshops to assist in mobilizing a response to prepare for mental health effects related to climate change.
 - CDC is using the climate change initiative as an opportunity to integrate its existing faith-based and environmental justice activities.

The BSC commended CDC for developing thoughtful and well-designed approaches to climate change, particularly the primary prevention and preparedness strategies for state and local public health officials. The BSC was also pleased that CDC is using its “Healthy Healthcare Settings” goal to provide leadership and serve as a champion in greening the healthcare sector at the national level.

Several BSC members made suggestions for CDC to consider in its ongoing efforts to refine the climate change initiative.

- CDC should incorporate an assessment of the positive co-benefits of reducing greenhouse gases into its climate change adaptation strategies for health. This assessment could be extremely helpful in demonstrating to communities that the benefits far outweigh the risks.
- CDC should develop tools to assist clinicians, pharmacists and other healthcare providers in communicating the risks of heat waves and other climate changes to their vulnerable patients, particularly those who are elderly or have underlying medical conditions. CDC should use ATSDR’s environmental medicine case studies to offer continuing medical education on climate change to healthcare providers.
- NCEH should launch a CDC-wide effort to integrate climate change modules into other prevention areas. For example, NCEH should encourage the Chronic Disease Prevention, Injury Prevention and other CDC centers to prominently display climate change modules on their respective web sites. An integrated approach throughout CDC would help to remove silos and minimize public perception that climate change is solely an “environmental health” issue.
- CDC should engage the faith community, ministerial alliances and community health centers at the outset of developing heat wave messaging for elderly persons and other vulnerable populations.

With no further discussion or business brought before the BSC, Dr. Ducatman recessed the meeting at 4:37 on May 29, 2008.

Stakeholder Challenges to NCEH/ATSDR Programs

Dr. Ducatman reconvened the BSC meeting at 8:35 a.m. on May 30, 2008 and yielded the floor to the first presenter.

Dr. Thomas Sinks, Deputy Director of NCEH/ATSDR, described NCEH/ATSDR's actions to achieve its mission to protect public health when stakeholders disagree with or desire different results. A number of NCEH/ATSDR projects have resulted in interactions with external stakeholders ranging from constructive to disruptive. Examples of external interests with ATSDR projects include site-specific activities, toxicological profiles on certain chemicals and health studies. Examples of external interests with NCEH projects include the biomonitoring report, laboratory studies on smoking, formaldehyde in travel trailers and nutritional supplements.

To fulfill its mission to protect public health, NCEH/ATSDR takes an objective approach that is informed by the best available scientific information. NCEH/ATSDR maintains objectivity by being open-minded and listening to all points of view from communities, industry and other available stakeholders. Some interested stakeholders have a desire for NCEH/ATSDR to set aside objectivity or the best science to support their respective points of view. When NCEH/ATSDR arrives at a conclusion that does not support the point of view of an interested stakeholder, perceptions of undue influence may arise and lead to diminished trust.

Dr. Sinks described an example of an ATSDR project that differed from stakeholder interests. In 2001, an Ohio senator petitioned ATSDR to determine whether beryllium air emissions and offsite transport of beryllium dust on the clothing of workers of the Brush Wellman plant presented a health hazard to the community of Elmore, Ohio. In response to the petition, ATSDR performed a health consultation in 2002 and found that current air emissions did not pose a public health hazard. ATSDR further concluded that short-term beryllium release episodes and past violations of the EPA standard presented an indeterminate public health hazard.

ATSDR recommended follow-up environmental sampling and also noted that a few community members requested medical testing for beryllium sensitization. Brush Wellman representatives and county commissioners claimed that any follow-up was beyond the scope of the petition, unwarranted and lacked community support.

Despite these protests, ATSDR conducted several follow-up activities to the 2002 Brush Wellman health consultation. ATSDR proposed a plan to sample air, dust and soil in 60 homes from 2003-2005 and released the protocol for public comment. ATSDR was informed that soil and dust samples could not be interpreted to determine individual health risks for beryllium.

ATSDR revised its environmental sampling protocol based on these comments and convened a peer review panel. The panel recommended "aggressive" air sampling, but ATSDR did not pursue this advice due to ethical concerns associated with artificially placing beryllium in the air

of homes. The panel also found an inconsistency between ATSDR's 24-hour environmental sampling plan and the EPA standard of 30-day air sampling.

ATSDR shifted its focus from environmental sampling and placed more emphasis on medical testing of up to 200 persons from 2005-2006. ATSDR used the beryllium lymphocyte proliferation test (LPT) because the test is the most sensitive indicator of adverse effects of past beryllium exposure. ATSDR identified four at-risk groups and proposed to use the medical testing results to inform environmental sampling. However, community interest in the medical testing was uncertain and not quantified.

The timeline of the medical testing from March-July 2006 is summarized as follows. ATSDR briefed the senator's staff, county officials and Brush Wellman representatives on the proposed medical screening plan. ATSDR issued a media announcement and released the draft medical screening protocol for public comment.

An expert panel was convened to discuss the technical aspects of using the LPT and interpreting the test results. Members of the expert panel included a physician who represented the community interest group, industry and county commissioner representatives, and three respected experts in the field of beryllium disease and use of the LPT. A community involvement meeting was advertised in an Elmore, Ohio newspaper and resulted in participation of ~60 residents.

ATSDR responded to public comments on the draft medical screening protocol, revised the plan based on comments received, and released a final plan. ATSDR initiated testing and issued its final report in November 2006 with the following conclusions. Although ATSDR offered to screen up to 200 individuals and widely disseminated information about the medical testing, only 20 persons who were included in one of the four high-risk groups volunteered.

The LPT results showed that none of the 20 participants were sensitized to beryllium. However, one test result could not be interpreted because the participant had been diagnosed with sarcoidosis and was taking prednisone. ATSDR noted that other residents in the community who were eligible for medical screening, but chose not to be tested, might have been sensitized. ATSDR did not recommend additional environmental sampling and advised the local health department to distribute more information on beryllium sensitization and chronic beryllium disease to local physicians.

In April 2008, the Investigations and Oversight Subcommittee of the House Science and Technology Committee obtained documents and raised serious questions on whether politically-connected companies influenced ATSDR's 2006 health study in Elmore, Ohio and other potential public health hazards.

Documents the Congressional subcommittee obtained to make these allegations included correspondence to the Ohio governor and the HHS Secretary as well as a letter from a senior official at Brush Wellman stating that ATSDR's health investigations would have a negative impact on the company's plans to expand the Elmore plant. However, all of this correspondence was sent before ATSDR released its final medical screening protocol.

Dr. Sinks compared the Brush Wellman experience with NCEH/ATSDR's mission to protect public. ATSDR took an objective approach that was informed by the best available scientific information by deferring environmental sampling and performing medical screening. ATSDR listened to different points of view by revising the design and methods of the health study based on useful public and peer review comments that were submitted.

Some stakeholders rejected objectivity in favor of a finding that supported a one-sided position, but ATSDR stopped attempts by Brush Wellman and county commissioners for the community to oppose follow-up activities. ATSDR addressed public and peer review comments, documented community interest, and convened an expert scientific panel that represented all stakeholders. ATSDR maintained objectivity and maximized trust by meeting with county officials and the community. However, this trust was recently challenged by letters from Brush Wellman to high-level elected officials and political appointees.

ATSDR used all methods to maintain objectivity and maximize trust in the Brush Wellman health study. Meetings were convened with stakeholders in an effort to be transparent. All stakeholders were equally and fairly treated. The public was involved throughout the entire process with community availability sessions and public meetings. Internal clearance and external peer review processes were used for all products generated under the health study. A panel was convened with neutral experts who had no vested interest in the outcomes of the health study.

Overall, NCEH/ATSDR applies a number of guiding principles to convene meetings with stakeholders. NCEH/ATSDR will accommodate stakeholder requests for meetings, but the agency is not obligated to undertake this effort. During stakeholder meetings, NCEH/ATSDR listens to the issues and provides publicly available information without negotiating activities or engaging in scientific debate.

Stakeholder meetings may be held exclusively with the requesting party or other groups may be included based on mutual agreement. NCEH/ATSDR cannot require different stakeholders to meet. Stakeholder meetings are not confidential because information shared by an outside party is subject to the Freedom of Information Act. Notes are taken at all stakeholder meetings.

Dr. Sinks concluded his presentation by asking the BSC to consider three key questions during its discussion. First, should NCEH/ATSDR be open to concerns from all stakeholders? Second, are NCEH/ATSDR's methods for maintaining objectivity and maximizing trust effective? Third, what additional methods could NCEH/ATSDR use in this effort?

The BSC thanked Dr. Sinks for beginning and concluding his presentation with specific questions to consider. The members advised NCEH/ATSDR to use this format in all future presentations to the BSC. Initial responses to the questions by some of the BSC members are outlined below.

First, NCEH/ATSDR should be open to concerns from all stakeholders. Second, Dr. Sinks did not present results of a web-based survey or any other metrics for the BSC to determine the

effectiveness of NCEH/ATSDR's methods for maintaining objectivity and maximizing trust. Third, based on the Brush Wellman health study, NCEH/ATSDR appears to be applying the best possible approaches and should not allocate additional time or resources to incorporate other methods.

Several BSC members expressed concern about ATSDR's decision to conduct medical testing and not pursue environmental sampling in the Elmore, Ohio community. A number of BSC members made suggestions for NCEH/ATSDR to consider in improving its interactions with external stakeholders in future health studies.

- NCEH/ATSDR should link indeterminate findings of a study to the conclusions. This approach would be more transparent in informing the public that supporting data used in the study were not sufficient to reach conclusions. For example, ATSDR determined in the initial Brush Wellman health consultation that current air emissions did not pose a public health hazard. However, this finding most likely played a significant role in the lack of community interest and participation in follow-up activities.
- NCEH/ATSDR should improve its health communications to the community when changes are made to the design, methods or other aspects of a study. For example, ATSDR did not convene a public meeting or distribute materials at the outset to clearly explain its rationale for shifting from environmental sampling to medical testing of residents in the Elmore, Ohio community. ATSDR described the revised methodology in the medical screening protocol and medical testing fact sheets after its decision to change the focus of the study. Moreover, ATSDR did not clarify the difference between "research" and "service" in the Brush Wellman health study.
- NCEH/ATSDR should design health studies by focusing on its mission to protect public health. This approach would allow NCEH/ATSDR to honestly inform the community that current technology is not adequate to link an environmental substance to disease. This strategy also would allow NCEH/ATSDR to perform due diligence by addressing community concerns or anxiety regarding "safe" or "unsafe" levels of exposure to a substance in the home. Overall, NCEH/ATSDR should provide the community with a better context of multi-factorial issues that contribute to the limitations of environmental epidemiologic tools.
- NCEH/ATSDR should take caution in categorizing all interested parties as "stakeholders." "Community" stakeholders who are concerned about their health are not treated in the same equal and fair manner as "industry" stakeholders who have financial resources and economic power. Community residents and other private citizens typically have no time to attend meetings or participate in other aspects of the public process or have no resources to hire consultants to address health concerns. Community advisory panels that are convened for an indefinite length of time are problematic as well. NCEH/ATSDR should develop creative strategies to increase transparency and engage the public without burdening to the community. For example, public participation in health studies most likely would increase if community groups were formed with a clearly defined charge to address certain issues for a definitive period of time. NCEH/ATSDR should

review existing models of this approach. The Boston University School of Public Health developed a video in which community groups were convened with both scientists and residents to address toxic contamination issues. The community groups in this model met only a few times over one or two weekends.

- NCEH/ATSDR should determine the feasibility of collecting data when facilities are initially sited or permitted.

Draft Report by the BSC Peer Review Workgroup (PRWG)

Dr. Janice Chambers is a member of the BSC and co-chair of the PRWG. She presented a draft report of the PRWG's external peer review of NCEH/ATSDR's Terrorism, Preparedness and Emergency Response (TPER) Program. The PRWG selected two BSC members and eight external consultants to serve on the Peer Review Panel. The Panel conducted a site visit on January 25-26, 2008 to listen to presentations by NCEH/ATSDR staff; meet with various representatives; and convene a closed executive session to analyze the information and begin to formulate recommendations.

The Panel was charged with the following tasks. NCEH/ATSDR would be reviewed and assessed based on TPER goals and objectives of units, divisions and offices; the quality of science and public health impact of TPER activities; and overall TPER accomplishments. NCEH/ATSDR's capacity to effectively respond to environmental, chemical and radiological hazards from natural, terror-based, technological and transportation events would be evaluated. Recommendations would be made on the future directions and priorities of NCEH/ATSDR's TPER activities.

The Panel also reviewed NCEH/ATSDR's functional objective areas and the divisions' routine core business functions, such as health monitoring and surveillance; epidemiology, exposure and other assessment sciences; public health laboratory science and service; response and control; and public health system support. Due to the complexity in evaluating NCEH/ATSDR's TPER functions that cut across seven different divisions, the Panel agreed to use a traditional "strengths, weaknesses, opportunities and threats" (SWOT) analysis to ensure consistent and concise identification, evaluation and communication of issues.

The Panel found NCEH/ATSDR's TPER activities to be excellent overall and commended the staff for producing high-quality products. However, the Panel noted several areas in NCEH/ATSDR's TPER activities that could be improved. The Panel focused the review on optimizing NCEH/ATSDR's current efforts to provide a basis for aligning limited resources with successful completion of its TPER mission.

Dr. Chambers used the SWOT analysis to summarize the Panel's overarching findings that were highlighted in the executive summary of the peer review report.

- *Strengths:* NCEH/ATSDR has an extensive track record in TPER and an excellent reputation as a national public health agency and resource. Staff and

management are dedicated, hard working and experts in the field. The creation of the Office of Terrorism Preparedness and Emergency Response (OTPER) demonstrates CDC's recognition of the need to coordinate TPER efforts. The NCEH Division of Laboratory Services has both basic and response capacity and could serve as a model for other divisions. The success of TPER activities is frequently based on staff relationships with external customers and stakeholders.

- *Weaknesses:* A TPER strategic plan has not been developed to date. Staff members are relatively unaware of activities conducted by OTPER and other divisions. Short-, mid- and long-term goals and ongoing projects for the seven divisions are not clearly defined. Performance criteria for TPER activities are not identified. The Panel was uncertain whether NCEH/ATSDR has developed an overall plan to manage an incident. The details and usefulness of surveys that were completed by staff and submitted to the Panel widely varied. A TPER communication plan has not been created for staff, customers, clients and stakeholders. The current focus on "terrorism" rather than "all hazards" limits emergency response capacity. TPER activities are not implemented to a great degree at state and local levels.
- *Opportunities:* An all-hazards strategy would be most effective from a management perspective. OTPER could create a TPER mission and vision throughout NCEH/ATSDR with an approach that cuts across traditional boundaries. For internal use only, OTPER could create an NCEH/ATSDR-wide organizational chart that eliminates duplication and maximizes resources. Core functions and TPER expectations as well as staff expectations of multiple priorities for routine and TPER functions should be clearly defined. State and local capacity in TPER should be developed with appropriate training.
- *Threats:* Inadequate resource allocation to TPER could result in failure to effectively and efficiently respond to emergencies. NCEH/ATSDR's reputation could be compromised by an inadequate response. Failure to develop state and local capacity in TPER will diminish potential opportunities to leverage resources. Management of resources will be difficult without clear expectations. Current staffing levels might limit TPER capacity. The dual use of staff in routine tasks in addition to TPER activities might overextend national resources. Based on prior events, resources might not be sufficient to respond to emergencies in the future. Failure to define TPER capacity and resource needs could lead to rapid response capabilities that are not flexible or effective.
- *Overarching Recommendations:* As NCEH/ATSDR's focal point for TPER activities, OTPER should articulate its daily responsibilities; implement a matrix management approach to TPER across the divisions; and create an internal cross-divisional organizational chart for TPER activities to improve integration. The names of OTPER in NCEH/ATSDR and the Coordinating Office of Terrorism Preparedness and Emergency Response (COTPER) in CDC lead to confusion. NCEH/ATSDR should take caution to ensure that customers do not confuse the

OTPER and COTPER functions. Lessons learned and after-action reviews, if mandated, should be utilized.

- *Specific Recommendations:* A cross-cutting inter-divisional strategic planning process should be initiated. A communications process should be implemented with appropriate mechanisms. OTPER should be designated to receive annual programmatic funding for critical core functions. The competitive grant process should be reserved for projects that are more appropriate for short-term funding. The expansion and improvement of GIS capacity should be prioritized for data acquisition and management. Special compensation should be given to staff members who are active in TPER and have a 24-day/7-week on-call schedule. A pipeline should be developed to replace staff members who resign or retire. Technology capabilities and interoperability should be assessed and improved throughout NCEH/ATSDR. Environmental justice and health disparities (EJ/HD) issues should be integrated into TPER and coordinated throughout NCEH/ATSDR.

In addition to its overarching conclusions, the Panel also evaluated NCEH/ATSDR's TPER activities in seven areas. For each of these issues, Dr. Chambers provided a brief introduction, summarized the outcomes of the SWOT analysis, and highlighted key recommendations.

Strategic Planning

- *Introduction:* Strategic planning is extremely important for a variety of reasons, such as defining future directions; establishing goals; developing strategies and actions; making tactical and operational decisions; allocating human and capital resources; taking steps to align management and staff; and creating a framework for program evaluation and performance improvement.
- *Strengths:* Strategic planning is one of OTPER's roles. CDC's TPER goals assist in guiding the project approval process. CDC's strong public health foundation serves as the basis for TPER and is critical in aligning TPER strategies with daily activities.
- *Weaknesses:* Evidence of strategic planning in OTPER and strategic alignment across NCEH/ATSDR is minimal. Staff was not aware of NCEH/ATSDR's TPER vision and goals.
- *Opportunities:* Strategic planning and evaluation processes should be included in OTPER without regard to NCEH/ATSDR's traditional roles. NCEH/ATSDR divisions, partners and stakeholders should be involved in this effort. A "matrix management" approach should be taken to cut across traditional divisional barriers and lead to more effective TPER activities. A strategic plan should be developed, shared and emphasized with staff, partners and stakeholders both internally and externally to ensure endorsement.
- *Threats:* NCEH/ATSDR and OTPER will be unsuccessful in coordinating TPER activities across the divisions without a strategic plan. The absence of a strategic plan will also increase the potential for inadequate emergency response; present a disorganized appearance; minimize NCEH/ATSDR's organizational credibility

and reputation; and alienate staff, partners and stakeholders. The absence of an evaluation process will not allow OTPER to monitor assess activities.

- *Recommendations:* Strategic planning and evaluation processes should be initiated for the TPER functional area. Matrix management techniques should be developed for cross-cutting TPER functions. A strategic plan should be created without regard to NCEH/ATSDR's traditional roles.

Communications

- *Introduction:* Communications are important to distribute clear, accurate and timely information; make decisions at all levels; increase public health protection and injury prevention; reduce anxiety levels of communities that are affected by emergencies; and facilitate relief efforts. Strong communication channels should be developed well in advance of an emergency with involvement of both internal and external stakeholders.
- *Strengths:* NCEH/ATSDR has created strong formal communication networks with state and local health departments and has also established informal collegial relationships with local and regional staff. NCEH/ATSDR has developed TPER web sites and participates on the 24-hour/7-day on-call center housed in the CDC Director's Emergency Operations Center.
- *Weaknesses:* Some of the networks are based on personal relationships between NCEH/ATSDR staff and local or regional staff. With the exception of personal contacts, external partners had limited knowledge of mechanisms or appropriate staff members to contact. NCEH/ ATSDR's web sites are difficult to navigate. Internal communications appear to be weak.
- *Opportunities:* A communications planning process with specific action steps should be rapidly included in OTPER by involving NCEH/ATSDR divisions, COTPER, and other partners and stakeholders. Regular communications should be instituted and maintained with internal and external stakeholders as well as state and local environmental health agencies.
- *Threats:* "Personal contacts" will weaken existing networks in the field when staff members resign or retire. Poor communications can lead to insularity and a disenfranchised culture if NCEH/ATSDR staff is not aware of policies, activities and important developments. The absence of a strong communications plan can result in a disorganized appearance.
- *Recommendations:* Internal and external partners should be informed of NCEH/ ATSDR's roles, responsibilities, capabilities, processes and points of contact. A single point of contact should be assigned to address the needs of external partners. Protocols should be established for internal partners. Information should be made accessible on NCEH/ATSDR's web sites.

Funding and Resources

- *Introduction:* A significant percentage of NCEH/ATSDR's funding for TPER activities is based on one-year grants that are administered and apportioned under an internal competitive process.
- *Strengths:* The competitive process has a tremendous amount of flexibility that allows the potential for new TPER projects to be funded each year. Moreover,

the competitive process is conducive to high-risk and high-reward projects; allows activities to be shifted relatively quickly if needs and priorities change; and provides opportunities for scientists to initiate ideas and demonstrate creativity.

- *Weaknesses:* One-year project funding is allocated to support NCEH/ATSDR's critical programmatic functions, including OTPER's workforce of 26 staff, the GIS mapping program and various epidemiologic surveillance systems. The one-year competitive process increases the risk of core functions being terminated; limits cross-cutting teams and integration; does not provide opportunities for external stakeholders to provide input on critical needs; and promotes low morale among staff due to uncertainty and lack of direction. The Panel was unable to determine whether NCEH/ATSDR submitted grants to COTPER for funding or if submitted grants were not funded.
- *Opportunities:* OTPER should obtain guidance from COTPER and external stakeholders to identify core programs, such as GIS and surveillance systems, that are essential and critical to NCEH/ATSDR's mission to ensure consistent funding. OTPER should articulate short-, mid- and long-term goals, its mission, vision and priorities for non-core programs and direct sub-units to develop and implement projects for support. A percentage of funds should be set aside for scientists and investigators to conduct "futures-type" projects of high interest. Integration and collaboration among divisions should be strongly encouraged to address funding and resource issues. An evaluation of this process should be incorporated into both programs and projects.
- *Threats:* Critical core programmatic functions might not be funded under a one-year competitive process. The current funding approach might stifle coordination and integration among divisions. The process gives the appearance that core programmatic functions are not critical to the mission. A continuous grant writing process is inefficient, burdensome and detracts from NCEH/ATSDR's actual mission.
- *Recommendations:* OTPER should be designated to receive annual program funding rather than relying on project funding under a competitive grant process. OTPER should establish NCEH/ATSDR's programmatic priorities. The one-year competitive process should be reserved for "futures-type" research projects of high interest, but should not be used to fund critical programmatic functions. OTPER should encourage collaboration and integration across divisions. An evaluation process should be implemented to assess funding and resource issues in all NCEH/ATSDR programs and projects.

Data Management

- *Introduction:* Data acquisition, organization, analysis and interpretation are critical to characterize and respond to environmental emergencies. Data collection should be routine, broad-based and targeted. Information should be gathered in real-time. The transfer, storage and accessibility of data should be rapid, easy, confidential and interoperable.
- *Strengths:* NCEH/ATSDR has extraordinary expertise and a proven track record in data acquisition and management. Current surveillance systems span a

variety of substantive areas. The world-class Laboratory Program and strong GIS capacity are major assets for NCEH/ATSDR.

- *Weaknesses:* Some activities appear to be more political than functional. Existing surveillance systems do not appear to integrate expertise. GIS activities appear to be insular and lack strategic plans. Current GIS capacity is not sufficiently focused on issues and data that are relevant to TPER. The Panel was unable to determine whether the GRASP GIS database is at the cutting edge.
- *Opportunities:* Surveillance programs, including interoperability across NCEH/ATSDR, should be routinely evaluated. Existing surveillance technologies that are used in current public health information network systems should be expanded. Existing subject matter expertise throughout CDC should be more engaged in NCEH/ATSDR's TPER activities. Technical staff should be cross-trained to establish integrated teams.
- *Threats:* The absence of solid data acquisition and management processes could result in non-interoperable systems, loss of information and confidentiality of data, lack of adequate data security, and limited collaboration across CDC centers.
- *Recommendations:* NCEH/ATSDR should take advantage of its ideal position as a leader in the development and application of preparedness surveillance methodologies. Expansion and improvement of GIS capabilities should be prioritized. NCEH/ATSDR should take advantage of the opportunity for the GRASP GIS database to become an even greater asset throughout CDC.

Workforce Management

- *Introduction:* A well-trained, knowledgeable and committed staff is critical to any unit or agency. Staff members should have knowledge of their respective duties, responsibilities, flexibility, and available career advancement opportunities.
- *Strengths:* Staff members who met with the Panel were impressive in terms of their competency, commitment, enthusiasm, knowledge of their specific duties and effectiveness in performing their jobs. The staff also presented a wealth of information and has established an impressive roster of contacts.
- *Weaknesses:* Nearly all staff members who met with the Panel were overburdened and viewed TPER activities as a secondary function to their "day" jobs. In some instances, only one trained individual has been assigned to a particular capability. A "pipeline" has not been established to replace staff members who resign or retire. The lengthy lead time to replace staff further weakens NCEH/ATSDR's capacity.
- *Opportunities:* The pipeline issue should be addressed by planning for the replacement of staff members who resign or retire. A commitment should be made to cross-train staff to ensure that more than one individual can handle specific activities. A more formal career development plan should be provided to staff.
- *Threats:* The absence of a pipeline to replace staff members who leave or retire could result in the loss of critical functions and inadequate emergency responses in the future. "Burnout" is a strong possibility if staff members feel overburdened

or under-appreciated. The new generation of workers might be less amenable to a long-term commitment to one organization.

- *Recommendations:* Mechanisms should be enhanced to assure staff members that their commitment and value are appreciated. Special compensation should be given to staff members who are on call 24-hours/7-days and spend time responding to emergencies. Approaches should be created to overcome the perception among staff that TPER is a secondary function. A five- to ten-year pipeline should be established to replace staff members who resign or retire to maintain existing TPER capacity. TPER tasks should be redistributed among staff members to maximize and not duplicate their expertise and abilities. NCEH/ATSDR should be mindful that staff members with a “packed bag” at the office in preparation of a two-hour notice before deployment have an additional stress and should be appreciated for this effort.

Technology

- *Introduction:* Technology must be used to maximize the efficiency of TPER activities; develop appropriate responses to emergencies with the best health information; and facilitate technology transfer functions and GIS capacity in laboratories.
- *Strengths:* NCEH/ATSDR’s laboratory capability is truly outstanding and has a strong focus on the need for GIS capacity. NCEH/ATSDR makes a significant investment in current technology.
- *Weaknesses:* Redundant capacity has not been developed for critical laboratory functions to ensure the availability of multiple staff members or cross-train personnel at a minimum. The GIS program is not institutionalized or sufficiently staffed throughout NCEH/ATSDR. Limited availability of uniform data collection instruments could lead to inadequate and inconsistent data at the national level. Capacity in radiological and chemical surveillance instrumentation appears to be lacking.
- *Opportunities:* Partnerships in technology transfer between NCEH/ATSDR-states and state-local agencies should be strengthened. An assessment should be performed to identify technologies that can be accessed from other agencies. GIS research opportunities should be created. Technology opportunities should be leveraged with CDC- and HHS-funded academic institutions. Sources throughout CDC and HHS should be engaged to make data for populating GIS databases for TPER activities accessible.
- *Threats:* The lack of interoperable systems and cross-training will be a major threat during an emergency. Strong GIS capacity might be lost despite resource allocations to develop staff. Emergency notifications by e-mail or e-blasts without multiple backup processes might be unavailable or fail in critical situations. Key personnel might have limited knowledge of using the Internet or might be unable to check e-mail messages on a routine basis during an emergency. Staff might be unavailable in an emergency if personnel are not cross-trained.
- *Recommendations:* Technology-related resources within NCEH/ATSDR should be fully accessible across divisions. Technologies that exist in other parts of

HHS and are necessary to access information should be identified. GIS capacity should be developed and integrated across NCEH/ATSDR.

EJ/HD

- *Introduction:* Vulnerable populations will be at risk during an emergency due to inadequate planning, limited involvement of affected communities, and failure to appropriately address cultural issues. These deficiencies could result in inequitable public health protection and inconsistent access to available resources within agencies that are charged to conduct TPER activities.
- *Strengths:* NCEH/ATSDR has a solid history of prior experience, relationships and collaborations with vulnerable populations at state and local levels as well as an extensive data set on these groups. NCEH/ATSDR also has a strong cadre of professionals with subject matter expertise in EJ/HD and access to CDC's health disparities funding.
- *Weaknesses:* Staff members do not view EJ/HD as a part of their individual TPER responsibilities. Staff does not appear to have a clear understanding of or plan for EJ/HD issues in the context of TPER. EJ/HD issues have not been fully integrated into NCEH/ATSDR's routine operations or ongoing public health responsibilities.
- *Opportunities:* NCEH/ATSDR should take advantage of several legislative initiatives that are available to address the public health needs of vulnerable populations. State and local health departments should be used as conduits to better inform target populations of an event. Vulnerable populations should be identified as a part of NCEH/ATSDR's initial emergency response assessment.
- *Threats:* Inadequate attention to EJ/HD issues during an event will result in adverse health impacts on vulnerable populations, negative media attention, criticism by policymakers, and weakened credibility. NCEH/ATSDR will be ineffectual without solid communications to address vulnerable populations before, during and after an event.
- *Recommendations:* GIS mapping should be utilized when assessing TPER infrastructure gaps and limitations within at-risk communities. NCEH/ATSDR's planning efforts should include activities to improve state and local environmental health capacity to assure equal protection of vulnerable populations.

Dr. Chambers made a number of editorial comments, personal observations and disclaimers regarding the overall peer review process. The 1.5-day site visit was not sufficient for the Panel to fully evaluate NCEH/ATSDR's broad-based TPER activities that cut across seven different divisions. The complex review included an enormous amount of background materials for the Panel to digest.

The BSC has only a few precedents for conducting cross-cutting functional reviews, particularly at the level of complexity as the TPER review. The Panel had conference call discussions with only a few external partners and only met with ~12 staff members during the site visit. Because of these limitations, Dr. Chambers was not completely confident of some of the Panel's conclusions.

Dr. Chambers concluded her presentation by thanking Dr. Bashor, Ms. Dolly Sinha, other staff of the NCEH/ATSDR Office of Science, and OTPER staff for their outstanding support during the peer review process.

The BSC and NCEH/ATSDR applauded the Panel for its tremendous efforts in performing an extremely complex peer review, particularly under constraints that made this activity more difficult. Dr. Ducatman welcomed three Panel members who joined the meeting by conference call: Dr. Ronald Laessig, chair of the Panel, Ms. Pamela Bingham and Dr. Walter Faggett.

Dr. Laessig made a number of clarifying remarks on the draft peer review report. NCEH/ATSDR should view the recommendations as a tool to “fine-tune” its existing TPER activities rather than perform a major overhaul. The Panel did not see a need for either NCEH or ATSDR to change its fundamental or core functions. The Panel’s overarching recommendation was for NCEH and ATSDR to consider the TPER function in a new paradigm and use OTPER to direct activities across all divisions. This synergistic and integrated approach would ensure that NCEH/ATSDR, rather than NCEH alone, would be viewed as making valuable contributions to TPER.

The BSC engaged the Panel in an extensive discussion to obtain clarification on the peer review report, the overall peer review process, and the disclaimers Dr. Chambers made. In addition to these issues, the Panel also noted that NCEH/ATSDR did not provide adequate staff support or produce sufficient data for an activity as complex as the TPER peer review. Moreover, the Panel used questionnaires that were completed by staff as the basis for the peer review, but extremely limited information in some of the questionnaires was a major problem for the Panel.

Several BSC members were concerned about the disclaimers regarding the overall peer review process. Most notably, the Panel determined that the 1.5-day site visit did not allow sufficient time for a full evaluation of NCEH/ATSDR’s TPER activities. As a result, some BSC members were uncertain whether the major deficiencies noted in the report were factual or if the Panel was not adequately informed due to the lack of time to gather and review data. The BSC members also noted that if the report was intended to provide NCEH/ATSDR with guidance to “fine-tune” its TPER activities, the Panel would need to change the tone of the document.

Dr. Scott Deitchman, Associate Director for Terrorism Preparedness and Emergency Response in NCEH/ATSDR, thanked the Panel for conducting a comprehensive and honest peer review. He acknowledged that some of the problems identified in the report were accurate, but he appreciated the Panel’s recognition of the limitations of the overall peer review process.

Dr. Deitchman planned to read the report in more detail to engage NCEH/ATSDR leadership and staff in thoughtful discussions. He would present NCEH/ATSDR’s formal response to the peer review report during the next meeting.

Based on the BSC’s discussion, Dr. Ducatman asked the Panel to make the following revisions to the draft peer review report.

- The Panel should clarify activities that appear to be more “political than functional.”
- The Panel should clarify whether GIS is described in the report as a method or tool of epidemiology or if NCEH/ATSDR actually has a gap in its GIS capacity.
- The Panel should clarify whether NCEH/ATSDR has gaps in its radiological expertise alone or if NCEH/ATSDR has equal gaps in both its radiological and chemical capabilities.
- The Panel should include new language in the executive summary to highlight the limitations of the overall peer review process.
- The Panel should ask NCEH/ATSDR to provide feedback on whether TPER is actually viewed as a “secondary” function to the “day” jobs of staff. The Panel should make this suggestion outside of the peer review report because this issue is beyond the scope of the charge.

The next steps to finalize the draft peer review report would be for Dr. Ducatman to provide the revisions in writing to Dr. Bashor; Dr. Bashor to forward the revisions to Dr. Laessig; and Dr. Laessig to incorporate the revisions into the peer review report one week after receipt.

The BSC accepted the NCEH/ATSDR Preparedness and Emergency Response Program Draft Peer Review Report with the revisions noted for the record.

Public Comment Session

Dr. Ducatman opened the floor for public comments; none of the participants responded.

BSC Business Session

A panel presentation was scheduled on the agenda for NCEH/ATSDR staff to provide public health updates in three areas. Due to Dr. Chambers’ comprehensive presentation and the BSC’s extensive discussion to accept the draft peer review report, the panel presentation was rescheduled for the next meeting. Dr. Frumkin thanked the staff for preparing for the panel presentation and apologized for the abrupt change in the agenda.

Dr. Frumkin confirmed that NCEH/ATSDR would make strong efforts to improve the overall peer review process. Future panels would be provided with sufficient staff support, data and time and also would be given a better estimate of the magnitude and scope of the review.

Business items that the BSC raised over the course of the meeting were noted for the record and are outlined below.

Consensus Items:

- *The BSC agreed to conduct a peer review of NCEH/ATSDR's internal clearance and external peer review processes.*
- *The BSC accepted the NCEH/ATSDR Preparedness and Emergency Response Program Draft Peer Review Report with the revisions noted for the record.*

Action Items:

- *Dr. Bashor will provide the BSC with CD-ROMs of ATSDR's draft 2008 Great Lakes AOC report.*
- *Drs. Bashor and Fowler will develop and provide the BSC with a summary of the changes among the draft 2004, 2007 and 2008 Great Lakes reports.*
- *Dr. Bashor will provide the BSC with Dr. Lubert's slides and CDC's larger slide set on climate change.*
- *Dr. Bashor will place the following items on the next BSC agenda:*
 - *An overview of metrics for the BSC to determine the effectiveness of NCEH/ATSDR's methods for maintaining objectivity and maximizing trust during its health studies.*
 - *Panel presentation on public health updates (rescheduled from the May 2008 meeting).*
 - *NCEH/ATSDR's formal response to the Preparedness and Emergency Response Program Peer Review Report (extended agenda item).*

Closing Session

Dr. Ducatman thanked Dr. Bashor for providing his technical expertise and guidance to ensure that all BSC meetings are productive. He also acknowledged Ms. Sandra Malcom, the BSC Committee Management Specialist, and other staff in the NCEH/ATSDR Office of the Director for providing the BSC with tremendous support for each meeting.

Dr. Ducatman recognized the BSC members for contributing even more of their valuable time over the past six months to participate on conference calls and provide input to NCEH/ATSDR on its negative publicity regarding the Great Lakes report and post-Hurricane Katrina activities.

Dr. Frumkin also thanked the BSC members for contributing their valuable time and expertise to strengthen CDC's environmental health programs, research and other activities. The BSC applauded Dr. Ducatman's outstanding management skills and leadership as chair over the past two meetings.

The next BSC meeting would be held on November 6-7, 2008. Ms. Malcom would e-mail this date to all of the BSC members as a reminder.

With no further discussion or business brought before the BSC, Dr. Ducatman adjourned the meeting at 11:53 a.m. on May 30, 2008.

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

Date

Alan M. Ducatman, M.D.
Chair, Board of Scientific Counselors