DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION National Center for Environmental Health/

Agency for Toxic Substances and Disease Registry Lead Poisoning Prevention Branch





CENTERS FOR DISEASE CONTROL AND PREVENTION

Advisory Committee on Childhood Lead Poisoning Prevention October 21-22, 2009 Washington, DC

Record of the Proceedings

TABLE OF CONTENTS

Page

Attachment 1: List of Participants Attachment 2: Acronyms Used in These Meeting Minutes	A1-1 A2-1
Meeting Minutes	1
October 21, 2009	
Opening Session	1
Overview of the DC Department of the Environment	
Childhood Lead Poisoning Prevention Program	2
Update on CDC's Lead Poisoning Prevention and Healthy Homes Activities	7
Update by the Educational Intervention Workgroup	12
Update by the Lead in Consumer Products Workgroup	15
Overview of the Saliva Lead Testing Study	23
Public Comment Session	25
October 22, 2009	
Update by the Laboratory Methods Workgroup on Lead Poisoning Prevention	
Final Update by the Lead and Pregnancy Workgroup	
Update on CPSC Lead Poisoning Prevention Strategies	
ACCLPP Business Session	

 Public Comment Session
 40

 Closing Session
 40

ATTACHMENT 1

List of Participants

ACCLPP Members

Dr. George Rhoads, Chair Ms. Magaly Angeloni Dr. Deborah Cory-Slechta Dr. Lynn Gardner Dr. Kimberly Hansen Ms. Linda Kite Dr. Michael Kosnett Dr. Jessica Leighton Dr. Brenda Reyes Dr. Megan Sandel Mr. Dana Williams, Sr.

Designated Federal Official

Dr. Mary Jean Brown, Chief Lead Poisoning Prevention Branch, CDC

Ex-Officio and Liaison Members

Dr. Walter Alarcon (National Institute for Occupational Safety and Health) Dr. Helen Binns (American Academy of Pediatrics) Mr. Steve Hays (American Industrial Hygiene Association) Dr. Ezatollah Keyvan-Larijani (Council of State and Territorial Epidemiologists) Ms. Jane Malone (Alliance for Healthy Homes) Ms. Jacqueline Mosby (U.S. Environmental Protection Agency) Dr. George Rodgers, Jr. (American Association of Poison Control Centers) Dr. Walter Rogan (National Institute of Environmental Health) Dr. Phyllis Stubbs-Wynn (Health Resources and Services Administration) Ms. Dominique Williams (U.S. Consumer Product Safety Commission) Mr. Jonathan Wilson (National Center for Healthy Housing)

CDC Representatives

Dr. Sharunda Buchanan, DEEHS Director, CDC Sara Browning (CDC Contractor) **Barry Brooks** Charlotte Cloud-Williams Kimball Credle Jay Dempsey Qaiyim Harris Samantha Harrykisson Jeffrey Jarrett Robert Jones [via conference call] Claudine Johnson David Kyle [via conference call] Gerri Meadows Antonio Nerz **Barbara Rogers** Marissa Scalia Sucosky Connie Thomas Tiffany Turner Nikki Walker

Guest Presenters and Members of the Public

Joseph Battaglia (CLEARCorps USA) Linda Block (University of North Carolina-Asheville) Craig Boreiko (International Lead Zinc Research Organization & International Lead Management Center) Paul Cestone (U.S. Environmental Protection Agency) Maria Diaz Julie Emerv **Pierre Erville** (District Department of the Environment) Perry Gottesfeld (Occupational Knowledge International) Sue Gunderson (CLEARCorps USA) Teresa Holtrop (Children's Hospital of Michigan) Matthew Howsare (U.S. Consumer Product Safety Commission) Kelli Janowski Delaware Division of Public Health, Office of Lead Poisoning Prevention) Barbara Kelly (CLEARCorps USA)

Suzanne Lo

(Coalition to End Childhood Poisoning) Lucy Luta (Delaware Division of Public Health, Office of Lead Poisoning Prevention)

Anil Mangla (Georgia Department of Community Health) [via conference call] Robb Morse (ESA Biosciences) Patrick Parsons (New York State Department of Health) Donald Simmons (Association of Public

Health Laboratories)

Noel Stanton (Wisconsin State Laboratory of Hygiene) [via conference call]

ATTACHMENT 2

Acronyms Used in These Meeting Minutes

ABLES	Adult Blood Lead Epidemiologic and Surveillance
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
AFHH	Alliance for Healthy Homes
BEST	Better Environmental Sustainability Targets
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CFSA	Child and Family Services Agency
CLIA	Clinical Laboratory Improvement Amendments
CLPPP	Childhood Lead Poisoning Prevention Program
CMS	Centers for Medicare and Medicaid Services
CPSC	U.S. Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act of 2008
DDOE	District Department of the Environment
EBLL	Elevated Blood Lead Level
EIWG	Educational Intervention Workgroup
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GIS	Geographic Information System
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	Department of Health and Human Services
HUD	U.S. Department of Housing and Urban Development
IDEA	Individual with Disabilities Education Act
ILZRO	International Lead Zinc Research Organization
LMWG	Laboratory Methods Workgroup
LCPWG	Lead in Consumer Products Workgroup
LPPB	Lead Poisoning Prevention Branch
LPPP	Lead Poisoning Prevention Program
LSWP	Lead Safe Work Practices
LPWG	Lead and Pregnancy Workgroup
NCEH/ATSDR	National Center for Environmental Health/
	Agency for Toxic Substances and Disease Registry
NCHH	National Center for Healthy Housing
NHANES	National Health and Nutritional Examination Survey
NOFAs	Notice of Funds Available
OTI	Occupational Knowledge International
SAICM	Strategic Approach to International Chemicals Management
UN	United Nations
UNCA	University of North Carolina-Asheville
WHO	World Health Organization
WIC	Women, Infants and Children
XRF	X-Ray Fluorescence
L	

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry Lead Poisoning Prevention Branch

ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION October 21-22, 2009 Washington, DC

DRAFT 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), Lead Poisoning Prevention Branch (LPPB) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on October 21-22, 2009 at the Four Points by Sheraton Hotel in Washington, DC.

Opening Session

Dr. George Rhoads, Chair of ACCLPP, called the meeting to order at 9:00 a.m. on October 21, 2009. He welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as <u>Attachment 1</u>.

Dr. Rhoads announced that voting members with a real or perceived conflict of interest related to any item on the October 21-22, 2009 ACCLPP agenda would be responsible for identifying these issues and recusing themselves from voting on these topics or participating in these discussions.

Dr. Sharunda Buchanan, Director of the Division of Emergency and Environmental Health Services at CDC, thanked the ACCLPP members for their continued commitment, dedication and contributions to childhood lead poisoning prevention. She also expressed her appreciation to ACCLPP for undertaking a new role in providing solid guidance and recommendations to LPPB during its transition to healthy homes initiatives.

Dr. Buchanan confirmed that Dr. Mary Jean Brown, Designated Federal Official of ACCLPP and Chief of LPPB, provides regular updates to CDC on ACCLPP's activities and accomplishments.

She was pleased to note that ACCLPP's efforts over time have resulted in greatly advancing the science and practice of childhood lead poisoning prevention. Dr Buchanan concluded her opening remarks by inviting the ACCLPP members to attend CDC's National Environmental Public Health Conference on October 26-28, 2009 in Atlanta, Georgia.

Overview of the DC Department of the Environment Childhood Lead Poisoning Prevention Program

Mr. Pierre Erville, Esq., Associate Director of the District Department of the Environment (DDOE) Lead and Healthy Housing Division, explained that DC is a high-risk jurisdiction in terms of lead poisoning. Of ~275,000 housing units in DC, ~25,000 are vacant. Of DC's entire housing stock, nearly 90% is pre-1980 construction. Of this housing stock, ~51% is pre-1950 construction. Of all households in DC, >40% have an annual income <\$35,000. Of ~42,000 children <6 years of age who live in DC, at least 66% are eligible for or enrolled in Medicaid.

The DC screening law requires universal screening of all children 1 and 2 years of age. Children must be screened between 6-14 months of age for the first test and 22-26 months of age for the second test. Children >26 months of age who were not previously screened must receive a blood lead test before reaching 72 months of age and enrolling in a daycare or school. However, parents of school-age children can opt-out of this requirement for religious reasons.

DDOE's 2005-2008 screening data showed that screening rates ranged from 55% in 2005 to 46% in 2007 for children 12-23 months of age and from 55% in 2005 to 42% in 2007 for children 24-35 months of age. An additional 3,704 children 0-11 months of age were screened in DC in 2005 and 2007 and several thousand more children 36-71 months of age were screened annually as well.

DDOE's 2007-2008 elevated blood lead level (EBLL) data showed that 170 cases of EBLLs \geq 10 µg/dL were reported in 2007 and 2008. The rate of EBLLs \geq 10 µg/dL as a percentage of children tested was 0.68% in 2007 and 0.59% in 2008. In 2007 and 2008, 1,367 cases of BLLs 5-9 µg/dL were reported. The rate of BLLs 5-9 µg/dL as a percentage of children tested was 6.15% in 2007 and 4.14% in 2008.

Legislation was enacted that transferred authority of the DC Lead Poisoning Prevention Program (LPPP) from the health department to DDOE beginning on October 1, 2008. DDOE now has responsibility for the bulk of DC's LPPP components, including enforcement, permitting, accreditation, certification and the Childhood Lead Poisoning Prevention Program (CLPPP). Under this law, the DC mayor charged DDOE with coordinating DC's lead poisoning prevention strategy, chairing quarterly meetings of an Interagency Lead Task Force, and staffing meetings of the Lead and Healthy Housing Advisory Committee.

The DDOE Lead and Healthy Housing Division conducts lead poisoning prevention activities under two branches. The CLPPP and Healthy Housing Branch is supported by funding from CDC and local resources. Key activities of the branch are highlighted as follows. To promote lead screening and fill screening gaps, DDOE has a regular presence and makes presentations at a variety of outreach settings, such as meetings of the Mexico and El Salvador Consulates, health fairs, and events in Chinatown and the broader Asian community.

DDOE also uses the National Nursing Centers Consortium (also known as Lead Safe DC), the local chapter of the American Academy of Pediatrics, and the Lead and Healthy Housing Advisory Committee to provide education on the DC lead law, fill screening gaps and further promote lead screening to pediatricians, social workers, nurses, daycare centers and community organizations.

To collect and analyze data, DDOE sends annual reminder letters to laboratories to submit blood lead test results; uses DDOE staff, the Office of the Chief Technology Officer and an epidemiologist to refine and analyze data; and provides data to the Department of Health Public Health Tracking Advisory Committee as requested. DDOE also has expressed a strong desire to join the Adult Blood Lead Epidemiologic and Surveillance (ABLES) Program.

To manage cases, DDOE uses two nurses and three phlebotomists to investigate all children reported with BLLs $\geq 10 \ \mu$ g/dL. DDOE's protocol requires case managers to frequently interact with the family of each case, update the Leadtrax database, use the Lead Case Tracker database to check the status of actions taken to eliminate hazards in the home, and regularly communicate with providers via facsimile. The Lead Case Tracker database houses all information on a case in one location, allows case managers to monitor progress, and sends email alerts to case managers on significant developments.

To integrate healthy homes components into the Lead Program, DDOE is collaborating with the Air Quality Division to provide radon kits for testing homes and is partnering with Fire and Emergency Medical Services to install combination smoke/carbon monoxide detectors in homes at no charge. DDOE is leveraging its membership on the DC Control Asthma Now Steering Committee to further integrate healthy homes components into the Lead Program and also is actively seeking additional resources.

To conduct primary prevention activities, DDOE has a strong focus in four areas: children with BLLs 5-9 μ g/dL, expectant mothers, proactive identification and elimination of lead hazards, and education to contractors on lead safe work practices (LSWP) under a joint pilot project with the U.S. Environmental Protection Agency (EPA). DDOE awarded a subcontract to Lead Safe DC to visit the homes of children with BLLs 5-9 μ g/dL, provide one-on-one education and cleaning demonstrations to these families, collect dust samples, and perform HEPA vacuum cleaning in response to elevated dust wipe results. DDOE partnered with the DC Department of Health, Women, Infants and Children (WIC) Program, and Healthy Start Program to provide the same primary prevention interventions in the homes of expectant mothers.

Lead Safe DC visited 76 households of children with BLLs 5-9 μ g/dL from September 1, 2008-August 31, 2009. Of these households, 25 were non-English speaking and 76% had dust lead levels near or greater than the hazard level. These data showed that the homes of children with BLLs 5-9 μ g/dL were at significant risk of containing elevated levels of lead in household dust. Lead Safe DC also visited 179 households with expectant mothers during the same time period. Of these households, 9 were non-English speaking and 13% had dust lead levels nearer or greater than the hazard level.

DC's new lead law has allowed DDOE to undertake proactive hazard identification and control in large multifamily properties and geographic locations that are "hot spots" for lead poisoning in DC. DDOE will initiate a pilot project with the Weatherization Program to conduct dust testing after window replacements and other weatherization activities have been completed in 100 homes built prior to 1940. DDOE plans to require clearance of all weatherization activities if dust lead levels in the 100 pilot homes are found to be elevated. DDOE also will launch a project early in 2010 to analyze soil in community gardens owned by the DC government. DDOE intends to abate the soil if the levels are found to be elevated.

In March 2009, DC enacted one of the most promising, innovative and progressive lead laws in the country. The legislation presumes that all pre-1978 properties contain lead paint, provides DDOE with broad authority to inspect and issue orders, and requires the use of LSWP during renovation or abatement of all pre-1978 properties. DDOE's broad authority covers interim controls or abatement, relocation of families, cost reimbursement, penalties and referral of cases to the attorney general when necessary.

DC's new lead law extends far beyond federal disclosure requirements. The clearance at turnover provisions were written in three phases. Phase 1 was recently enacted and now requires property owners to produce clearance reports issued within the previous 12 months to prospective new occupants who are <6 years of age or pregnant. In phase 2, property owners will be required to produce clearance reports for all pre-1950 housing to all new occupants based on the results of phase 1 one year later. In phase 3, property owners will be required to produce clearance reports for all new occupants based on the results of phase 1 one year later. In phase 3, property owners will be required to produce clearance reports for all new occupants based on the results of phase 2 one year later. DC's new lead law was written with all of the same federal disclosure requirements and is enforceable at the local level.

DDOE's Compliance and Enforcement Branch is supported by funding from EPA and local resources. Key activities of the branch are highlighted as follows. The branch issues abatement permits, accredits training providers, certifies lead disciplines, uses a partnership with the Child and Family Services Agency (CFSA) to inspect prospective foster care homes for lead hazards, provide compliance assistance, and enforces DC's lead laws. As of October 2009, DDOE was given responsibility for conducting up to 190 risk assessments in the current fiscal year in the homes of prospective foster care parents. If hazards are identified in these homes, DDOE will issue orders, require clearance and refer cases to the DC Lead Hazard Control Grant Program.

To provide assistance with compliance, DDOE developed and posted a reader-friendly version of the DC lead law on its website and also distributed the law to training providers, abatement contractors, private-sector inspectors, risk assessors, and major property managers and owners. DDOE held one-on-one meetings with contractors, affected tenants and property managers to further explain the lead law. DDOE recently made a presentation to property owners and managers who are members of a large apartment owner association. To enforce the DC lead law, DDOE collaborates with EPA on disclosure enforcement requirements and the U.S. Department of Housing and Urban Development (HUD) on the Lead Disclosure Rule. DDOE receives support from the Office of the Attorney General and the Office of the Tenant Advocate to enforce EBLL cases and undertake proactive hazard identification and control.

DDOE's EBLL enforcement protocol requires an environmental investigation that includes water sampling, x-ray fluorescence (XRF) and environmental sampling of dust and soil. Property owners are given 30 days to comply with an EBLL enforcement order, but DDOE will issue an extension to the deadline if the owner demonstrates a good faith effort in abating the property. DDOE refers non-compliant property owners to the HUD Lead Hazard Control Grant Program and the Office of the Attorney General.

After the DC lead law was enacted in March 2009, DDOE closely collaborated with the Office of the Tenant Advocate to identify and send letters to major property owners and managers in DC wards at highest risk for lead poisoning. DDOE plans to expand and more effectively target its proactive enforcement efforts in the future by using geographic information system (GIS) indicators to identify specific jurisdictions that are "hot spots" for EBLLs. The GIS indicators also will be used to pinpoint neighborhoods with old housing stock, a large number of code violations and nuisance properties with visibility in the public right-of-way.

DDOE's dissemination of the DC lead law letter resulted in a 100% cooperation rate among property owners of 18 pre-1978 large multi-family properties containing 3,747 units. The owners hired contractors to inspect, assess risks and evaluate lead hazards in each property and unit. All of the property owners will submit copies of the hazard evaluation reports to DDOE. DDOE is currently entering the hazard evaluation reports into a database to monitor the status of lead hazards within the properties over time.

DDOE's current activities include modifying its strategic plan with a stronger focus on the elimination of lead poisoning and the promotion of healthy housing; developing a Medicaid reimbursement system; applying for authority from EPA to conduct a Renovation, Repair and Painting Program; creating a new partnership with the Legal Aid of DC if the EPA grant proposal is funded; and applying for a HUD Healthy Housing Grant.

DDOE hopes and intends to conduct a number of activities in the future. DDOE will improve and update its website with more targeted, visible and effective outreach components. DDOE hopes to become an ABLES jurisdiction; train code inspectors at the Department of Consumer and Regulatory Affairs; and provide LeadCare II units to health clinics to increase lead screening rates if the Health Resources and Services Administration awards DDOE's grant proposal for Title V funding.

DDOE hopes to lead the coordination and collaboration among all relevant DC agencies and a range of community partners. DDOE will strengthen its relationship with the DC Medicaid Agency because the vast majority of children <6 years of age who live in DC are Medicaid-eligible. DDOE hopes to fully fund financial assistance programs for property owners to abate

identified lead hazards. DDOE hopes to position DC as a model jurisdiction for the country that fully focuses on lead hazard elimination and ensures its residents live in healthy homes.

ACCLPP applauded DDOE on developing an extremely innovative Lead Poisoning Prevention Program, advancing DC's progressive lead law and serving as an example for the nation. The members were particularly impressed by DDOE's primary prevention focus areas of children with BLLs 5-9 μ g/dL and pregnant women; leadership in code enforcement; collaboration with the Weatherization Program to pilot the clearance project for dust testing; and the DC legislation that presumes all pre-1978 properties contain lead paint.

Several ACCLPP members expressed a strong interest in incorporating DDOE's primary prevention focus areas into all CDC-funded CLPPPs and encouraging other jurisdictions throughout the country to adopt the presumption that all pre-1978 properties contain lead paint.

The ACCLPP members made several comments and suggestions for DDOE to consider in further implementation of its lead poisoning prevention and healthy housing activities.

- DDOE should use its primary prevention focus area of children with BLLs 5-9 µg/dL to conduct research to determine the effectiveness of different interventions in various homes. The study should be designed with a comparison group. This research would play a key role in filling existing data gaps and identifying evidence-based interventions that are effective in reducing BLLs 5-9 µg/dL in children.
- DDOE should recognize the problems associated with office-based lead screening. Providers are less likely to report results to health departments with office-based lead screening. Moreover, the allowed variability of the LeadCare II instrument is <u>+6</u> µg/dL, but its performance is better than this limit. DDOE should develop a mechanism to ensure providers can easily report screening results from their offices. DDOE also should create protocols to ensure samples taken in the office are carefully monitored, handled and processed.
- DDOE should expand its lead screening promotion efforts to outreach to socioeconomic groups other than low-income and Medicaid populations. Most notably, affluent families who purchase old homes also could benefit from education on lead risks and hazards to young children and pregnant women during the renovation of these properties.

Dr. Brown congratulated DDOE on its new authority to enforce lead safety requirements in units before children achieve qualifying BLLs that trigger services. She pointed out an Epidemic Intelligence Service Officer would be available to LPPB for the next two years and could assist DDOE in designing ACCL PP's proposed study of lowering BLLs 5-9 ug/dL in children

Update on CDC's Lead Poisoning Prevention and Healthy Homes Activities

Dr. Brown covered the following areas in her update. On August 7, 2009, CDC published *Recommendations for Blood Lead Screening of Medicaid-Eligible Children Aged 1-5 Years: An Updated Approach to Targeting a Group at High Risk.* The paper recommended that state and local officials target screening to specific groups of children at higher risk for EBLLs in their

areas. The paper also supported targeted rather than universal screening because recent data indicate that BLLs are decreasing among children in low-income families and the EBLL disparity between Medicaid-eligible and non-Medicaid-eligible children is diminishing.

CDC developed a Healthcare Effectiveness Data and Information Set (HEDIS) measure for managed care organizations and healthcare providers to determine whether their Medicaidenrolled patients 2 years of age received a blood lead test. The HEDIS measure will determine whether their Medicaid-enrolled patients have received a blood lead test by 2 years of age. The review will be piggybacked on a similar measure of immunization status. Several CLPPPs have successfully linked Medicaid encounter data and blood lead testing data to distribute report cards or letters to healthcare providers regarding their individual performance in screening Medicaid-enrolled children. CDC expects the first provider-based data set from the HEDIS measure to be available early in 2010.

CDC sponsored a webinar with state and local health departments and also had discussions with advocates to clarify the updated recommendations on blood lead screening of Medicaidenrolled children. CDC and the Centers for Medicare and Medicaid Services (CMS) recently distributed a joint letter to state Medicaid Directors and regional CMS Coordinators to explain that a "targeted screening plan" must be supported by strong data. CDC also is urging its funded CLPPPs to adopt the HEDIS measure.

CDC's next steps in this initiative will be to update the *State Medicaid Manual* and collaborate with CMS to develop a joint framework to evaluate targeted screening plans submitted by jurisdictions. However, the current obligation to conduct blood lead testing of Medicaid-enrolled children 1 and 2 years of age will remain in effect until the *State Medicaid Manual* is revised.

CDC is continuing its efforts to promote Medicaid reimbursement of blood lead testing conducted by WIC programs. To support this initiative, CDC is compiling and will provide Medicaid Directors and regional CMS Coordinators with case studies of WIC programs that have implemented successful and creative strategies in conducting blood lead screening of Medicaid-enrolled children. The U.S. Department of Agriculture is coordinating with CDC and CMS in the effort to secure Medicaid reimbursement for blood lead screening conducted by WIC programs.

Dr. Brown reported on the status of three *Healthy People 2010* objectives and proposed *Healthy People 2020* objectives that are relevant to lead poisoning prevention and healthy homes. <u>One</u>, the current 2010 objective is to eliminate EBLLs in children with a target of 0%. The proposed 2020 objective will be to reduce BLLs in children by focusing on two sub-objectives: eliminate EBLLs in children and reduce the mean BLL in children. HHS's justification for the proposed 2020 objective is summarized as follows. The National Health and Nutritional Examination Survey (NHANES) is the data source for the 2010 objective, but does not have sufficient resolution to accurately provide population-based estimates of the number of children with EBLLs due to the small sample size of children <6 years of age.

NHANES has sufficient data to estimate the geometric mean of BLLs nationally and for targeted sub-populations. The addition of sub-objective 2, in combination with sub-objective 1, focuses

attention on reducing the central measure of BLLs in both the national population and subpopulations. Sub-objective 2 also addresses historic disparities in the geometric mean of BLLs in sub-populations and will help to focus attention on sub-populations with BLLs above the decreasing overall population mean.

<u>Two</u>, the current 2010 objective is to increase the proportion of persons living in pre-1950 housing that have been tested for the presence of lead-based paint. The proposed 2020 objective will be to (1) increase the proportion of pre-1970 housing that has been tested for the presence of lead-based paint, lead in dust or lead in soil and (2) decrease the number of U.S. homes identified with lead-based paint, dust lead hazards or soil lead hazards. CDC's next steps for the proposed 2020 objective will be to solicit public comment through the *Federal Register* and convene a series of public meetings beginning with Kansas City the week of October 19, 2009.

<u>Three</u>, the current 2010 objective is to reduce indoor allergen levels with the following targets: (1) Group I dust mite allergens exceeding 2 μ g/g of dust in the bed, (2) Group II dust mite allergens exceeding 10 μ g/g of dust in the bed, and (3) German cockroach allergens exceeding 0.1 unit per gram of dust in the bed. The proposed 2020 objective will be to reduce indoor allergen levels in cockroaches and mice.

CDC's justification for the proposed 2020 objective is summarized as follows. The most recent American Healthy Homes Survey did not collect samples from beds. Health-based threshold levels were dropped due to their uncertainty. Dust mite allergens were dropped due to their wide distribution both geographically and within homes. The possibility exists that these allergens could be endemic to some regions of the country. Cost-effective mitigation strategies for reducing whole-house levels need further development.

Dr. Brown summarized preliminary findings of two studies that were recently completed as a result of lead poisoning investigations. The Indiana State Department of Public Health investigated a cluster of unexplained lead poisoning cases among ~100 Burmese refugee children in Fort Wayne, Indiana. In general, the study showed that children who used Thanakha or Daw Tway were more likely to have EBLLs. In particular, children <1 year of age who used Daw Tway had an extremely high adjusted mean BLL of 24.6 μ g/dL and children \geq 1 year of age who used Daw Tway also had a significant adjusted mean BLL of 10.7 μ g/dL.

Daw Tway is a traditional medicine that is administered to infants as a digestive aid. The product was detected in four of the Fort Wayne cases and contained 480-560 ppm lead. Daw Tway was imported into the country by travelers from Southeast Asia, but its availability at local markets in Fort Wayne is unknown.

CDC investigated a cluster of lead poisoning cases among 30 Burmese refugee children <2 years of age in Tak Province Camps in Thailand. The most significant risk factors for lead poisoning in the study population were exposure to car batteries, iron deficiency and mouthing of non-foods. CDC issued several recommendations based on results of the study. Car battery exposure should be minimized or eliminated through education and administration of a household utilization survey. Micronutrient deficiencies of iron and calcium should be

addressed. Screening of all refugee children should be continued in accordance with CDC guidelines.

Community education should be conducted in refugee camps and safe housing should be provided. Continuity of care to Burmese refugee children should be enhanced by improving coordination both domestically and overseas. Follow-up testing should be conducted in Thailand and state Refugee Health Coordinators should be notified of U.S. arrivals. Domestic results should continue to be shared because no method has been established to date to collect health information on domestic refugee children.

Dr. Brown announced that CDC, EPA and HUD jointly sponsored a contest for high school students to develop lead poisoning prevention videos. The videos would be broadcast on You Tube, but the agencies also would develop a strategy to widely distribute the videos through other venues. An awards ceremony would be held during the 2009 National Environmental Public Health Conference to present college scholarships to the first-, second- and third-place winners. The videos of the three winners were presented to ACCLPP during the meeting.

Dr. Brown devoted the remainder of her update to CDC's healthy homes activities. On June 8, 2009, the Surgeon General issued a "Call to Action to Promote Healthy Homes" to focus attention on the public health impact of homes and outline a series of coordinated actions to improve the health of the nation's homes. The Call to Action outlines a society-wide approach to healthy homes that will result in the greatest possible public health impact and reduce disparities in the availability of healthy, safe, affordable, accessible and environmentally-friendly homes. The Call to Action has received a great deal of positive attention, interest and energy.

The Call to Action is based on three overarching premises. First, no one is immune from the effects of unhealthy and unsafe homes. This guiding principle focuses on indoor air quality, home design and resident behaviors, and accessibility and affordability of housing. Second, healthy homes lead to healthier lives. Third, communities, individuals, organizations, healthcare providers and government agencies can take actions to ensure healthy homes. CDC hopes that an interagency effort can be launched over the next two years to achieve the goal of testing building materials before their placement in housing.

An Interagency Healthy Homes Task Force was established with CDC, EPA, HUD, the U.S. Department of Energy, U.S. Department of Agriculture, Office of the Surgeon General, and National Institute of Standards of Technology. The purpose of the Task Force is three-fold. First, consensus will be achieved on the development of a "National Strategy to Promote Healthy Homes" that delivers safe and healthy housing for all citizens through collaborative efforts of federal, non-federal and private-sector leaders. Actions that federal agencies can take to advance the National Strategy are expected to be released by the end of November 2009.

Second, federal agencies will identify and leverage opportunities to eliminate barriers that impede collaboration and complicate providing assistance to persons in need of federal funding. For example, the federal partners are exploring creative strategies to develop criteria across agencies and jurisdictions for communities to apply for federal and state healthy housing funding in a more consistent and streamlined manner. Moreover, CDC and HUD are discussing

the feasibility of releasing joint notice of funds available (NOFAs) for healthy housing projects. Third, federal efforts will be joined with key non-federal and private-sector stakeholders to implement a rigorous healthy homes agenda at the community level.

The HHS and HUD Secretaries have been meeting to explore interagency strategies that could be developed and implemented to address three important housing agendas: homelessness; funding streams for elderly Americans and persons with disabilities to remain in their homes; and livable and sustainable communities with a health-promoting built environment at the macro level and healthy homes at the micro level. CDC is serving as the lead agency for these activities for HHS. Dr. Brown confirmed that she would provide an update to ACCLPP on initiatives under these housing agendas during a future meeting.

Dr. Brown highlighted awards CDC recently issued with its first healthy homes NOFA. The \$600,000 NOFA will support six planning grants over the next two years. The six grantees will use the funding to develop a blueprint for healthy homes activities in their respective jurisdictions. Because 64 applications were submitted, CDC used specific criteria (*i.e.*, diversity in geographic locations and types of institutions) to make the awards.

Impact Assessment, Inc., agent for the California Department of Public Health Division of Environmental and Occupational Disease Control, was awarded \$109,890 to assist local agencies with investigating and resolving hazards in the home and also to develop assessment, enforcement and compliance tools designed to help local housing and building agencies in all 61 jurisdictions in the state. During the two-year project period, California will measure trends and changes in health outcomes related to asthma and lead exposure.

The New York City Department of Health and Mental Hygiene was awarded \$110,000 to conduct evaluations of existing activities to reduce home health hazards, create a healthy homes action plan, and consolidate and analyze basic healthy homes information. The action plan will need to be adopted by local officials to lead the way in implementation of practices determined by the teams.

Environmental Health Watch in Cuyahoga County, Ohio was awarded \$82,095 to develop a "Healthy Housing Strategy Alliance" to convene key organizations in health, housing and other associated sectors to create and implement a healthy housing plan in conjunction with a broad range of additional stakeholders.

The University of Nevada-Las Vegas was awarded \$108,300 to conduct two major activities in years 1 and 2 of the project: (1) develop a plan to coordinate assessment and remediation activities to address housing-related health hazards and (2) begin conducting assessments and using remediation tools to reduce hazards known to impact the home environment.

The Oklahoma State Department of Health was awarded \$100,000 to administer the Tulsa Safe and Healthy Housing Project in Tulsa, Oklahoma with a goal of identifying, analyzing and prioritizing specific health and safety hazards found in home environments of the target population and implementing measures to reduce these hazards. During the two-year project period, Oklahoma will partner with the Children First Program to reduce health hazards found in ~500 homes of clients who live in pre-1950 housing.

The Rhode Island Department of Health was awarded \$109,402 to increase the availability of safe, healthy and affordable housing in the state and also to address targeted hazards in high-risk populations in the cities of Providence and Pawtucket. During the two-year project period, Rhode Island will target children who receive medical services at St. Joseph Hospital and Project Health Providence in Hasbro as well as refugee families and children.

Dr. Brown is collaborating with the Council of Foundations to identify resources to support some of the proposed projects that were not funded under CDC's healthy homes NOFA. She confirmed that over the next six to nine months, CDC would convene its six grantees and grantees funded by other agencies to share best practices and lessons learned in developing and implementing healthy homes projects.

Dr. Brown concluded her update by announcing that the city of Detroit recently passed a strong and proactive city ordinance. The new law is extremely protective of a lead paint abatement and lead poisoning prevention standard. The participants joined Dr. Brown in applauding Detroit's outstanding accomplishment.

ACCLPP was extremely impressed by the progress CDC and its federal partners have made over the past six months in advancing existing activities and developing new projects in the areas of lead poisoning prevention and healthy homes. The ACCLPP members made two key suggestions for CDC to consider in maintaining this momentum.

First, CDC should encourage its federal partners on the Interagency Healthy Homes Task Force to engage the architectural and engineering communities (*i.e.*, the American Institute of Architects, National Society of Professional Engineers, and National Institute of Building Sciences) in activities to impact the future housing stock. Mr. Steve Hayes is the ACCLPP liaison to the American Industrial Hygiene Association and offered to facilitate linkages and communications between CDC and these organizations.

Second, CDC and its federal partners should make stronger efforts to urge local agencies to collect and submit existing data on rodents, carbon monoxide/smoke detectors, and other healthy homes components. For example, the New York City Department of Health and Mental Hygiene has used grant funds from the CDC National Environmental Public Health Tracking Program to gather healthy homes data. Dr. Jessica Leighton is an ACCLPP member and Deputy Commissioner of the New York City health department. She offered to provide CDC with models in which local data from New York City were successfully applied to healthy homes projects.

Update by the Educational Intervention Workgroup (EIWG)

ACCLPP Meeting Minutes

Dr. Lynn Gardner is an ACCLPP member and chair of EIWG. She covered the following areas in her update. The EIWG members represent ACCLPP, CDC, academic institutions, CDC-funded CLPPPs, professional associations, community-based organizations, and parents of lead-poisoned children. ACCLPP charged EIWG with drafting recommendations to address the educational intervention needs of children with EBLLs. Dr. Gardner's summary of the structure of the draft educational intervention paper is outlined below.

The preface of the paper will focus on three distinct areas. First, EIWG's charge will be clearly defined. Existing evidence on deficits will be compiled. Parts B and C of the Individual with Disabilities Education Act (IDEA) will be reviewed. Specific action steps that can be taken by parents, clinicians, educators, community advocates and other groups will be described.

Second, EIWG's challenges in fulfilling its charge will be noted. The number of persons and groups needed to evaluate and manage the educational needs of lead-poisoned children and enroll this population into existing educational programs is quite large and will require a tremendous amount of coordination. No studies have been conducted and no evidence has been produced to demonstrate that educational interventions targeted to children with EBLLs are likely to improve children's academic outcomes compared to EBBL children who do not receive educational interventions have greater or lesser efficacy than those targeted to other children with developmental disabilities. However, research opportunities certainly exist in this area.

Third, the basis of the recommendations will be outlined. Clear evidence exists that early educational intervention services improve educational and behavioral outcomes for at-risk children. Clear evidence exists that an enriched environment for lead-exposed laboratory animals improves their ability to learn. Evidence also exists that EBLLs well below 10 μ g/dL are associated with educational and behavioral deficits in children.

The overview of the educational intervention paper will be divided into five sections. Section 1 of the paper will describe deficits that are known to be associated with EBLLs in children. The evidence shows that EBLLs are related to clinical deficits from a cognitive perspective, such as IQ and visual spatial skills. The 1995 Spreen, *et al.* study demonstrated that EBLLs also impact executive functions, such as strategic planning, impulse control, organized searching, flexibility of thought and action, and self-monitoring of one's own behavior.

The evidence shows that EBLLs are related to clinical deficits from a behavioral and social conduct perspective, such as restlessness, impulsivity, inattention and aggression. EBLLs also have been associated with educational deficits in reading, spelling and math, but EIWG is continuing to collect and review data in this area. Constructs that are used to organize learning profiles of students include attention, temporal-sequential ordering, spatial ordering, memory, language, neuromotor functions, social cognition, and higher order cognition. No studies have been conducted and no evidence has been produced to demonstrate that educational interventions targeted to children with EBLLs have greater or lesser efficacy than those targeted to other children with developmental disabilities. However, research opportunities certainly exist in this area.

Section 2 of the overview will describe assessment tools and clearly define triggers for assessment. Screening tools will be recommended as the first tier of an assessment. The paper also will recommend using BLLs $\geq 5 \mu g/dL$ detected during screening to warrant early intervention and enhancement for children <5 years of age and surveillance for specific deficits for school-age children. Deficit-specific assessment tools will be recommended as the second tier of an assessment.

EIWG is continuing to discuss coordination and consistency between recommendations in the paper and existing developmental screening requirements. Assessments require compliance with IDEA child identification/child find procedures. In accordance with IDEA Parts B and C federal regulations, schools are required to assume reponsibility for the location, identification and evaluation of all children from birth through 21 years of age who require special education and related services. All children who are suspected of having a disability and who are in need of special education are part of the child find process in a school district. Section 2 also will provide examples of assessment tools for cognitive, behavioral and educational functions.

Section 3 of the overview will describe educational interventions for children with EBLLs. Steps should be taken to immediately intervene upon identification of BLLs $\geq 5 \mu g/dL$ to prevent deficits by encouraging parent-focused enrichment activities and enrolling children in an Early Intervention Program. Educational and other interventions for deficits will be highlighted in Section 3, such as reading, math, spelling, speech therapy, physical therapy and nutrition.

Section 3 will describe the three major components of an effective Early Intervention Program: (1) parent skill-building and enrichment; (2) direct interaction with the child in a center-based or home-based model of early childhood education; and (3) well-defined objectives and well-designed evaluations as recommended by the National Research Council and Institute of Medicine in 2000.

Section 4 of the overview will cite laws for educational interventions for children with EBLLs. EIWG is currently reviewing existing laws that protect the rights of children with deficits related to EBLLs and also is identifying gaps in these laws. EIWG reviewed IDEA Part C that pertains to children 0-3 years of age. The law contemplates, but does not explicitly mention services based on lead poisoning. The regulation states that infants and toddlers who experience or have a condition that most likely would result in developmental delays are eligible for early intervention services. Based on this language, EIWG noted that children with EBLLs would fall under IDEA Part C.

EIWG also reviewed IDEA Parts B and C that pertain to autism, emotional disturbance, mental retardation, other health impairment, specific learning disabilities, and speech or language impairment. Based on the language in these sections, EIWG noted that children with EBLLs would fall under IDEA Parts B and C.

Section 5 of the overview will describe advocacy steps that communities can take to implement the recommendations, advance evidence-based policymaking and advocate for an educational intervention research agenda. EIWG acknowledges the need to widely distribute information to

parents, educators, physicians and community organizations after the educational intervention recommendations have been cleared for release.

ACCLPP commended EIWG on its tremendous progress in drafting the educational intervention paper over the past six months. The members made several comments and suggestions for EIWG to consider in its further development of the document.

- EIWG should include a description of the New York City model in the educational intervention paper. Organizations that receive state funding under contracts with the New York City health department to provide early intervention services are held responsible for conducting blood lead screening of all children who receive these services.
- EIWG should consider the difficulties in providing intervention services to older children ≥6 years of age with high BLLs who are already enrolled in school and exhibit learning disabilities, hyperactivity and other deficits as a result of severe lead poisoning.
- EIWG should include a flowchart in the educational intervention paper to organize the recommendations.
- EIWG should revise the legal section of the educational intervention paper with descriptions of 504 Education Plans and other legal mechanisms. The provision of early intervention services under IDEA is only triggered by the identification of medical conditions and might miss a critical group of children.
- EIWG should include nurses as another target group for the educational intervention paper.

Dr. Brown explained that Chicago, Rhode Island and other jurisdictions are reviewing and matching school administrative data sets and blood lead test results to determine whether children received Head Start or other early intervention services. Based on the timeline of these activities, she noted that EIWG might have an opportunity to include these data in the educational intervention paper.

In response to Dr. Rhoads' question, Dr. Brown confirmed that ACCLPP would have a more detailed discussion at the next meeting on EIWG's proposed recommendation to use BLLs \geq 5 µg/dL to warrant early intervention services. She emphasized that evidence has not been produced to date to demonstrate the effectiveness of an intervention to reduce, for example, a BLL of 7 µg/dL to 3 µg/dL.

Update by the Lead in Consumer Products Workgroup (LCPWG)

Dr. Michael Kosnett is an ACCLPP member and chair of LCPWG. He introduced a panel of two speakers who would make presentations on lead in consumer products to inform ACCLPP's discussion on this issue.

Ms. Linda Block is a Coordinator, Lead Risk Assessor and Healthy Homes Specialist at the University of North Carolina-Asheville (UNCA) Lead Poisoning Prevention Program (LPPP). She explained that the North Carolina Department of Environment and Natural Resources has received funding from CDC since 1997 to support the UNCA LPPP.

The mission of the UNCA LPPP is to proactively promote lead-safe environments for all residents of Buncombe and Henderson Counties through public education, home inspections, and professional training to healthcare providers, parents, pregnant women, realtors, property managers and construction contractors. BLLs $\geq 10 \ \mu g/dL$ trigger inspections by North Carolina health departments, but the UNCA LPPP has focused on and responded to all childhood BLLs 5-9 $\mu g/dL$ since its inception in 1997.

Lead continues to be a concern in the United States. Lower lead levels are known to be harmful. New immigrants and children adopted from foreign countries pose new risks for lead throughout the country. Adults who make lead-containing consumer products increase the risk for lead poisoning to children as a result of take-home exposures. Old homes and household products continue to serve as significant sources of lead in the United States. Ms. Block's description of consumer products that continue to be a concern for lead is outlined below.

<u>Product 1</u> is brass and brass keys, but most individuals are unaware that these products contain lead. Most adults and many children possess or handle keys daily without washing their hands afterwards. Some persons also place keys in their mouths, such as infants who are fascinated by keys and other shiny or jingly objects. Although keys are often used as toys for babies and infants, they are not considered or regulated as a "children's item."

A number of groups are affected by lead exposure from keys, including manufacturers of key templates, key cutters, locksmiths and their family members; all persons who handle keys; all persons who place keys in their mouths; and disposers of keys. The 2005 Kondrashov, *et al.* study assessed lead exposure risks in six professional locksmiths and six control volunteers. The study showed significant elevations in bone lead from past exposure and significant elevations in blood lead from current exposure.

Lead levels in keys can exceed 19,500 ppm and are much higher than the allowable limit of lead in children's items. The threshold was decreased to \leq 300 ppm in August 2009 and will be further reduced to \leq 100 ppm beginning in August 2011. The American Academy of Pediatrics has proposed an allowable limit of lead in children's items of \leq 40 ppm. Voluntary standard organizations have established \leq 90 ppm as the amount of lead that can migrate from toys. California Proposition 65 recommends lead exposure of <0.5 µg/day and a mandatory warning label for consumer products that exceed this limit. Lead consumption should be <15 µg/day to maintain BLLs <10 µg/dL.

UNCA conducted a study on the amount of lead that is transferred from keys to hands. The three phases of the study analyzed (1) daily handling and daily testing of five brands of new keys containing 1.4%-1.9% lead over five days; (2) long-term handling and periodic testing of new keys over four weeks; and (3) intensive handling of ten used keys over three days. The study showed that handling chrome-plated keys did not expose users to high levels of lead

based on the Proposition 65 level of >0.5 μ g/day. Handling non-plated brass keys over time appeared to expose users to concentrations of lead that might be harmful.

Other activities over the past 13 years that have focused on lead in keys are summarized as follows. In its 1996 report on lead in vinyl mini-blinds, the U.S. Consumer Product Safety Commission (CPSC) noted that 50% of lead on hands is transferred to the mouth. However, the amount of lead in the mouth if keys are placed directly in the mouth is unknown. The California State Attorney General sued 13 manufacturers of brass keys in 1999.

The San Diego Union Tribune published an article in October 1999 citing results from another key study. The study showed that lead from keys was deposited on fingers at amounts well above the safe level when keys were used as intended by being held for 15 seconds to open a lock. The study further demonstrated that some keys left lead up to 80 times more than the 0.5 μ g/day limit. The average lead level detected on hands was ~19 times above the "no significant risk level."

<u>Product 2</u> is vinyl-coated cords that often contain lead. Studies show that handling PVC cords leaves lead residue on hands. Many adults and teens handle cords on a daily basis from headphones, phone chargers, computers, hairdryers, coffee makers and cameras. Most individuals are not aware that vinyl-coated cords contain lead and do not wash their hands after handling these items. However, cloth-covered cords and other products have been manufactured as alternatives to vinyl-coated cords.

UNCA conducted an electric cord study to analyze routine handling of 40 phone and electric cords; determine initial and subsequent lead exposure on hands, and calculate daily exposure from routine handling. The study showed that most PVC cords, even from a single handling, exposed handlers to significant and sometimes relatively large quantities of lead. Based on results of the study, UNCA advised manufacturers to greatly reduce or discontinue the use of lead as stablizers of PVC.

UNCA conducted a PVC products study with seven vinyl children's products to analyze the rate of dust accumulation with induced degradation and determine whether lead dust levels >0.5 μ g/day or cadmium dust levels >0.05 μ g/day were produced. Children's products included in the study were raincoats, rain hats, backpacks, play tent poles and tote bags. The study showed that all seven products had lead exposures levels >0.5 μ g/day and all products tested for cadmium were >0.05 μ g/day. The study validated the concern that vinyl products might produce toxic lead and cadmium dust levels. All products tested in the study were found to be potential sources of lead or cadmium contamination for children.

<u>Product 3</u> is Mexican pottery that poses a risk to potters and families in Mexico and consumers in other locations who purchase these products. Labels in both English and Spanish that are misleading and confusing to consumers are one of the most significant concerns with Mexican pottery. For example, one manufacturer advertises all of its clay products in Spanish as "safe for preparing and storing food," but the English translation means that the products are "food contamination-free and dishwashable." In addition to misleading and confusing labels, Mexican pottery often has stickers or no permanent labels, no labels at all or labels in English only. UNCA performed tests on several different types of Mexican pottery to determine the amount of lead leached from these products. The "lead-free" label on one product passed the Food and Drug Administration (FDA) leach limit of 1 ppm, but failed the Proposition 65 leach limit of 0.1 ppm. Another product with no label failed both the FDA leach limit of 0.5 ppm and the Proposition 65 leach limit of 0.1 ppm.

Ms. Block reported that she discovered several myths associated with Mexican pottery during her recent site visit to Mexico. "Leaching diminishes to virtually no lead levels over time." "Lead in pottery can be cured with garlic and boiling water." "Lead has never affected relatives who have used Mexican pottery for generations." "Lead will burn off and disappear if Mexican pottery is heated to over 1,250 degrees." "Lead is safer from aluminum."

UNCA has made a number of recommendations for Mexican pottery based on the flawed labels, leach test results and longstanding myths. The sale of unsafe items should be discontinued and warnings about these products should be posted. Labeling requirements should be enforced and improved with clearer wording, labels in both English and Spanish, and permanent labels rather than stickers.

Collaborations should be established with Barro Sin Plomo in Mexico because this group is attempting to train local potters in producing lead-free pottery. Stronger efforts should be made in identifying sources of truly lead-free pottery in Mexico. UNCA should initiate a pottery cooperative with potters from Mexico who now live in Asheville, North Carolina and are selling pottery in local communities.

<u>Product 4</u> is carpet. The ASTM International Sports Equipment and Facilities Committee released a new standard for lead content in artificial turf fibers, but the standard does not cover carpet. Ms. Block tested tan carpet over concrete floors in the living room, hallway and bedroom of a home and found that lead levels ranging from 1.62-2.38 mg/cm² exceeded the lead-based paint limit of \geq 1 mg/cm². Tests of the carpet mesh in the home also exceeded the lead-based paint limit. Tests of dark brown and maroon carpet in another home showed non-detectable lead levels, but lead levels in the tan carpet still remained high at 1,380 ppm. However, none of these tests provided conclusive evidence of actual exposure to lead from carpet.

<u>Product 5</u> is other household items with lead levels ranging from 1,130-17,800 ppm and children's toys with lead levels ranging from 2.2-7.7 mg/cm². These items exceeded the lead-based paint limit of \geq 1 mg/cm². The items that were tested included a drinking glass, brass bell, jewelry and vinyl boots. CPSC informed UNCA that some of the toys are "antiques" and are not regulated as children's items. The manufacture and sale of lead-containing children's toys and household items will serve as a significant barrier to achieving the goal of BLLs <2 µg/dL in all children.

Ms. Block noted that the studies she presented on keys and vinyl-coated cords were released as technical reports. She offered to provide these studies to ACCLPP for review. She also

pointed out that UNCA's "Where Lead Hides" resource document was distributed to ACCLPP for review.

Mr. Perry Gottesfeld is the Executive Director of Occupational Knowledge International (OTI). He provided an international perspective on lead in consumer products. OTI conducts the majority of its activities in developing countries to build capacity in environmental health issues. As part of its mission, OTI is continuing to focus on the global lead poisoning epidemic.

The World Health Organization (WHO) estimates that 120 million persons are overexposed to lead and 99% of the most serious cases are in the developing world. Lead is commonly used in thousands of products, but lead batteries account for 80% of lead globally. Although the global lead poisoning epidemic occurs in every country in the world and impacts three times more persons than HIV/AIDS, this issue attracts minimal attention internationally. The *WHO 2002 World Health Report* ranked lead exposure as number 16 of the top 20 risk factors for the global distribution of burden of disease. However, lead exposure would be ranked as a top 10 contributor to the global burden of disease if all risk factors for nutrition were combined.

Developing countries are more susceptible to lead poisoning due to more opportunities for exposure, the continued sale of lead-containing consumer products and paints, and the increase of lead absorption as a result of poor nutrition. Developing countries also have no health screening programs; a higher proportion of lead; poor infrastructure and weak capacity for battery collection and recycling in modern or environmentally-efficient facilities; and a growth in the lead battery market. Lead batteries account for the vast majority of exposure, but cable sheathing, rolled and extruded products, shots and ammunition, alloys, pigments, other compounds and other miscellaneous items play a significant role in lead poisoning in developing countries as well.

The current practice in developing countries of welding battery plates together by melting lead with an open flame demonstrates no improvements in battery manufacturing since the 1914 Hamilton study on lead poisoning in the manufacture of storage batteries. Even in the most modern plants in developing countries, BLLs among workers exceed 50 μ g/dL on average and also are extremely high among children who live in communities near battery manufacturing plants.

In an effort to address these problems, OTI introduced the "Better Environmental Sustainability Targets" (BEST) Certification and Eco-Label Program to reward lead battery companies that meet specific emission targets and agree to accept used batteries for proper recycling. Companies that demonstrate compliance with the standard through annual audits can apply for the BEST Eco-Label for placement on their products. In cooperation with industry, OTI developed BEST as a minimum standard and launched the program in India in 2008.

Products other than lead batteries also contribute to the global lead poisoning epidemic. Mobile and fixed-line industries have rapidly grown 20%-30% each year throughout the world due to the increased use of mobile phones and fixed lines in developing countries. The battery company sector has greatly increased over the past ten years to meet the demand for the emerging mobile and fixed-line markets in these areas of the world.

Philanthropists and computer companies developed marketing plans to close the "digital divide" by using lead batteries to power the next billion computers in the developing world by 2015. OTI and the University of Tennessee recently conducted a life-cycle assessment that conservatively estimated lead emissions from batteries of the billion computers would exceed \sim 1.3 million tons of lead for computers sold by 2015.

In addition to lead batteries, other automobile components that contain lead are being sold in the developing world, including wheel weights, alloying agents, coatings, electronic applications, vibration dampers, automobile lighting, fuel hoses, PVC stabilizers, fuel tanks and brake linings. The 2005 Clark, *et al.* study, 2007 Adebamowo, *et al.* study, and 2007 Mathee, *et al.* study all reported significant lead levels in new residential paint in China, India, Malaysia, Nigeria, Singapore and South Africa. Lead levels found in these studies ranged from 9%-100% over 600 ppm and 0%-83% over 5,000 ppm. The 2008 Lin, *et al.* study and 2008 Gottesfeld study in China and India also showed significant lead levels in new residential paint ranging from 38%-50% over 600 ppm and 24%-28% over 5,000 ppm.

Findings from the five studies conducted in 2005-2008 raised the question of whether an international ban on lead in paint could be achieved. Supporters of this initiative acknowledged that the International Labour Organization of the League of Nation called for an international ban on white lead in paint 88 years ago, but the ban was never formally ratified. To renew this effort, Toxics Link called for a ban in 2008 that was backed by Nigeria, Germany, the United States and other countries. The Strategic Approach to International Chemicals Management (SAICM) also approved the call to eliminate lead in paint and form an international partnership.

During the joint United Nations (UN)/SAICM conference that was held in May 2009, a formal resolution was passed to establish a partnership on the global phase-out of lead in paint by conducting five major projects: (1) raise awareness of toxicity to human health, the environment and alternatives; (2) provide guidance and assistance to identify potential lead exposure; (3) assist industry, including manufacturers, wholesalers and retailers; (4) establish prevention programs to reduce exposure; and (5) promote national regulatory frameworks. EPA also played an instrumental role in passing the resolution on the global phase-out of lead in paint at the international level. ACCLPP and the paint industry submitted letters in support of the resolution as well.

Mr. Gottesfeld highlighted practices in two countries that account for the largest proportion of lead-poisoned persons. A recent study showed that despite the ban on lead in gasoline, 35% of children in Southern India still have BLLs >10 μ g/dL. Vehicle production has rapidly grown in India and has doubled in the past five years to 35%-40% lead consumption. The two-wheeler segment has had the highest growth rate of >32%. Backup power accounts for 35% of lead consumption and continues to grow at 12% per year. The per capita paint consumption in India is only 1/20th of the use in the United States. India has no regulations on lead paint levels.

The 2009 He, *et al.* study showed that despite the ban on lead in gasoline, 23.9% of children in China still have BLLs >10 μ g/dL. Lead production in China has rapidly grown and now accounts

for 40% of global lead production. Battery sales as a result of increased demand for electric bicycles are expected to rapidly grow to 35.6% by 2012.

The 2008 Frost and Sullivan/Liber Research study showed that revenues from the sale of electric bicycles have been doubling in China every two years since 2003. Batteries in the bicycles are the same size as those in automobiles, but only last for ~12 months. Mass lead poisoning incidents have been documented in a number of provinces throughout China over the past five years related to smelters and lead battery manufacturing facilities. The per capita paint consumption in China is only 1/10th of the use in the United States.

OTI will conduct and participate in several projects in the future to decrease lead poisoning in China. Collaborations will be formed with local partners to provide outreach and education on lead poisoning prevention in China. The California Department of Public Health Environmental Health Program and the China CDC in the Shanghai and Guangzhou Provinces will convene a joint conference in April 2010 to publicize the lead poisoning epidemic in China.

In coordination with the Vehicle Emissions Control Center and the China Automotive Technology and Research Center, outreach, education and training will be provided to lead battery companies and vehicle manufacturers to facilitate enforcement of pollution controls. A voluntary environmental certification program will be launched for low-level lead paint.

Dr. Kosnett devoted the remainder of the presentation to LCPWG's draft charge that was distributed to ACCLPP for review, discussion and formal approval. [*Editor's Note*: Due to ACCLPP's upcoming vote on this issue, the draft charge reflects no editorial changes and is captured below as read verbatim into the record by Dr. Kosnett.]

- 1. "Building upon the formal liaisons that now exist between the CDC Advisory Committee on Childhood Lead Poisoning Prevention and other federal agencies such as the Consumer Product Safety Commission, the Food and Drug Administration, and the National Institute for Occupational Safety and Health, the Work Group will recommend and foster collaborative efforts to enhance awareness of the public health community and the public at large of methods to identify, reduce, and prevent childhood lead exposure from consumer products. These collaborative efforts might include, but not be limited to, development of web-based documents and educational resources, participation in educational symposia and conferences, and consideration of domestic and international policy recommendations. Particular attention might be devoted to the development of a web page on the ACCLPP website that highlights the hazards posed by lead in consumer products, and educates public and private sector lead poisoning prevention programs at the local and state level on steps that may be taken to facilitate international awareness and cooperation on the elimination of lead hazards.
- 2. Working with parties in the public and private sector, the Work Group should pursue efforts that support the convening of an international conference, possibly in China, that addresses advances in the recognition, management, and prevention of lead poisoning in children and adults. Featuring invited contributions by health professionals, environmental scientists, public health officials, industrial hygienists, industry

representatives and other interested parties, the conference may have the following specific aims:

- To foster an international consensus on the health risks posed by low and moderate levels of lead exposure, especially as demonstrated by recent epidemiological and clinical research; and
- To identify and promote public health strategies to reduce lead poisoning in children and adults, including health surveillance in communities and workplaces, educational outreach, pediatric case management, improved public health laboratory infrastructure, and primary prevention
- To identify innovative approaches that can reduce lead exposure through voluntary certification programs and the reduction of nonessential uses of lead."

Dr. Kosnett emphasized that LCPWG's proposal to convene a bilingual international conference in the spring of 2011 would be feasible if efforts were made at this time to identify potential funding sources from both public and private sectors in the United States and China. He noted that LCPWG's activities would result in two tangible products: (1) recommendations and publications from the international conference and (2) the development of a web page to serve as a resource for international sources of lead poisoning.

Dr. Brenda Reyes is an ACCLPP member and Bureau Chief of the City of Houston Health and Human Services. She noted that Houston has been closely collaborating with manufacturers of Mexican pottery and FDA to address the problems Ms. Block outlined in her presentation. To advance LCPWG's efforts related to Mexican pottery, she offered to provide Dr. Kosnett and Ms. Block with contact information at FDA and data Houston has collected in this area to date.

In terms of LCPWG's draft charge, some ACCLPP members noted differences in typical workgroup charges. For example, most workgroups are charged with reviewing the literature and formulating recommendations on a specific issue, but LCPWG's draft charge focuses more on activities that will be conducted.

In response to the panel presentations, several ACCLPP members made comments and suggestions for LCPWG to consider in its ongoing efforts.

- LCPWG and UNCA should collaborate in conducting additional research to determine the bioavailability of lead exposure from keys.
- CDC should explore the possibility of inviting major trading partners outside of the United States to serve as liaison members on ACCLPP. For example, health professionals and other groups in China, India and Mexico are extremely knowledgeable of the lead poisoning epidemic and are attempting to address the same problems globally.
- To forge stronger alliances in addressing lead in consumer products both domestically and internationally, LCPWG should link to ongoing and future efforts (*i.e.*, the joint UN/SAICM initiative to establish an international partnership on the global phase-out of lead in paint and the upcoming joint conference by the California Department of Public Health and China CDC).

- LCPWG should engage native-speaking researchers who received training on lead poisoning in China, but now reside and are practicing in the United States.
- LCPWG should identify and prioritize the top consumer products and focus its efforts on those that pose the greatest risk for lead exposure.

Dr. Brown made several remarks in follow-up to ACCLPP's discussion. The Federal Trade Commission (FTC) has expressed a strong interest in pursuing cases of Mexican pottery with ineffective or inaccurate labeling or those involving fraud. She confirmed that she would provide Ms. Block with contact information for FTC officials during the meeting.

In response to the suggestion to invite major trading partners outside of the United States to serve as liaison members on ACCLPP, Dr. Brown clarified that CDC's Congressional line item and ACCLPP's charter are limited to domestic lead poisoning prevention activities. However, she was extremely supportive of the proposal and made a commitment to explore mechanisms for persons representing international organizations to serve on ACCLPP as liaisons.

As potential international liaison members, Dr. Brown suggested representatives from China CDC, the United Nations Environment Programme, or the new international partnership on the global phase-out of lead in paint. In the interim, she announced that the U.S. Department of State would be invited to join ACCLPP beginning with the next meeting

Dr. Brown concluded the discussion by asking the ACCLPP members to review LCPWG's draft charge overnight for final deliberations and a formal vote during the business session on the following day.

Overview of the Saliva Lead Testing Study

Dr. Gardner presented preliminary data from a study the Emory University School of Medicine and its colleagues conducted to determine the accuracy of oral fluid lead testing. The incidence of lead poisoning has decreased in the United States, but ~250,000 new cases occurred in 2008. Lead poisoned children are at higher risk for having neurodevelopmetnal deficits and various behavior problems. Current screening practices are complicated by the need to obtain blood from young children. Oral fluid can be used *in vitro* to appropriately measure lead in a laboratory setting, but this matrix has not yet been tested in a clinical setting with a large number of children.

The study methods included the collection of oral fluid samples from 500 children 6 months to 5 years of age in a hospital-based primary care clinic. All children who already had venous BLLs drawn for routine screening purposes were eligible for the study. BLLs were measured using a standard methodology at a laboratory certified by Clinical Laboratory Improvement Amendments (CLIA).

Oral fluid levels were measured using inductively coupled plasma-mass spectrometry (ICP-MS). Oral fluid samples were collected from 50 children twice to validate internal controls, but were only counted once. Pearson correlations, scatter plot and linear regression were used to analyze data. The mean absolute difference between the sample groups was determined to test the hypothesis that group means were equal.

Results of the study are summarized as follows. All 500 eligible patients agreed to participate in the study. Of the entire sample, 474 patients had both blood and oral fluid samples available for analysis and the remaining 26 patients had no blood samples available. Of 474 patients who had both blood and oral fluid samples available, 455 had BLLs <5 μ g/dL and all of these patients had corresponding oral fluid lead levels <5 μ g/dL. The remaining 19 patients had BLLs \geq 5 μ g/dL and all of these patients had corresponding oral fluid lead levels <5 μ g/dL.

The authors reached several conclusions based on the study results. Oral fluid appeared to be a reliable medium to use when screening children for lead exposure. Oral fluid lead levels $\geq 5 \mu g/dL$ should be confirmed by a venous blood sample. The sample size of 19 children who had oral fluid levels $\geq 5 \mu g/dL$ was inadequate to draw conclusions on oral fluid reliability at these levels. As a result, further studies are being conducted. The convenience of lead screening with oral fluid measurements should improve the success of screening by reducing parental refusal and eliminating the inability to obtain adequate samples. This method of screening will allow very large groups of children to be screened more quickly and easily than conventional methods.

Dr. Anil Mangla is the Chief Lead Epidemiologist for the Georgia Department of Community Health and one of the authors of the saliva lead testing study. He joined the ACCLPP meeting by conference call to provide additional details on the study. He explained that data from the study were submitted to the University of Georgia Department of Biostatistics for independent validation, analysis and comparison of the results. At the completion of the independent review, the study would be submitted for publication in a peer-reviewed journal over the next month. The complete data analysis of the study also would be presented at the 2009 National Public Health Environmental Conference.

In response to Mr. Gottesfeld's question, Dr. Mangla emphasized that the methods of the saliva lead testing study have no connection to the LeadConfirm Professional[™] saliva lead screening kit. He contacted the company and requested predictive values, cutoff points, false-positive/ false-negative rates, sensitivity/specificity rates and other supporting data for the test. Dr. Mangla has received no response to his request from the company to date.

In response to Dr. Cory-Slechta's question, Dr. Mangla explained that the manufacturer plans to market the saliva lead test for ~\$35-\$40. However, he acknowledged the need to reduce this cost, particularly if the test is first piloted in the high-risk Medicaid population.

Dr. Patrick Parsons, of the New York State Department of Health, is chair of ACCLPP's Laboratory Methods Workgroup on Lead Poisoning Prevention. His position was that feedback on the saliva lead testing study would be premature at this point without ACCLPP's review and examination of the data from both clinical and analytical perspectives. For example, he noted

enormous uncertainty associated with the density and volume of saliva collected on the sample preparation slides.

Dr. Parsons also expressed concern about the extraordinary capability required to measure low concentrations in saliva lead while avoiding contamination. The peer-reviewed literature documents that saliva lead closely follows plasma lead and would only represent a small fraction of blood lead concentrations. In addition to contamination controls for low saliva lead levels, he emphasized that questions also need to be answered regarding traceability of the measurements and reference materials for saliva lead need to be collected.

Similar to Dr. Mangla, Dr. Parsons announced that the New York State Department of Health also contacted the manufacturer of the LeadConfirm Professional[™] saliva lead screening kit and requested the validation package for independent verification of the validity of the test. Because the company refused to submit the validation package due to the proprietary nature of the data, the LeadConfirm Professional[™] saliva lead screening kit cannot be marketed in New York without open and transparent review of the data.

Dr. Parsons reiterated the need for ACCLPP to determine the role of the saliva lead testing study in a public health context only after the independent review and validation of the data have been completed. To assist ACCLPP in this effort, he conveyed that the Laboratory Methods Workgroup would propose conducting research on saliva and other alternative matrices for assessing exposure to lead.

Dr. Robert Jones, of CDC, also joined the ACCLPP meeting by conference call. He encouraged the authors of the saliva lead testing study to review the National Committee for Clinical Laboratory Standards. He pointed out that guidelines 9-A specifically provide guidance on comparing different laboratory methods and might serve as a useful resource in validating the conversion from oral fluid lead levels to BLLs.

ACCLPP shared many of the concerns Dr. Parsons raised regarding the saliva lead testing study. Several members emphasized that obtaining corresponding lead levels in blood and oral fluid in the same patient would be impossible. Some members also were concerned about the inconsistency and discrepancy between these findings and rigorous laboratory studies with well-controlled study designs that have been recently documented in the published literature.

ACCLPP agreed with Dr. Parsons on the need to reserve its input on the saliva lead testing study until after the supporting data were submitted and thoroughly reviewed. In the interim, however, the members made a suggestion for the authors to consider before presenting the study at the 2009 National Environmental Public Health Conference the following week. ACCLPP advised the authors to thoroughly review and revise the conclusions. For example, the authors concluded that oral fluid appeared to be a reliable medium to use when screening children for lead exposure. However, this conclusion conflicts with the recommendation to confirm oral fluid lead levels $\geq 5 \mu g/dL$ with a venous blood sample.

Dr. Rhoads concluded the discussion by describing ACCLPP's next steps on the saliva lead testing study. The Laboratory Methods Workgroup would be charged with conducting a detailed

analysis of the study. The authors would facilitate this effort by providing the workgroup with raw results from the ICP-MS, the algorithm that was used to convert oral fluid lead levels to BLLs, and data from all 474 patients who had both blood and oral fluid samples available.

Public Comment Session

Ms. Jane Malone is the ACCLPP liaison to the Alliance for Healthy Homes (AFHH). She announced that the International Code Council would hold a hearing on November 4, 2009 to update and approve model codes for adoption by states and jurisdictions. ICC would consider two major issues during the hearing. First, the International Property Maintenance Code would be revised to require LSWP for the repair of deteriorated paint in pre-1978 properties. Second, EPA's new Renovation Rule requirements would serve as the standard of practice for all repairs, alterations and renovations to existing properties and would be enforced by building officials throughout the country.

Mr. Perry Gottesfeld, of Occupational Knowledge International, was pleased that the saliva lead testing study had no relationship to the LeadConfirm ProfessionalTM saliva lead screening kit. The company is marketing the test as an "FDA-approved collection kit that is reliable as blood laboratory tests." Mr. Gottesfeld found this advertisement to be deceptive because only the saliva collection method, not the LeadConfirm ProfessionalTM kit itself, is FDA-approved.

In response to Mr. Gottesfeld's comments, Ms. Kite expressed an interest in ACCLPP revisiting the deceptive advertising practices of the LeadConfirm Professional[™] saliva lead screening kit at a future meeting. She raised the possibility of ACCLPP educating parents who have purchased the test and also taking formal actions with FDA to force the company to clarify its website.

Mr. Craig Boreiko is a Research Administrator at the International Lead Zinc Research Organization (ILZRO). He explained that ILZRO and the Basel Secretariat of the United Nations Environment Programme have been collaborating over the past six years to develop cooperative regional strategies for the end-of-life disposition of batteries in developing countries. The most significant problem in this initiative is that many countries in the developing world do not have sufficient throughput or volume of materials to maintain an economically viable recycling infrastructure. Moreover, efforts to develop cooperative regional strategies have been blocked by current international regulations on the transport of hazardous materials.

ILZRO and the Basel Secretariat have piloted battery recycling programs in the Caribbean and Latin America and hope to expand the pilot to Africa and Southeast Asia based on UN funding. A meeting was held with representatives of Chinese industry in September 2009 and initial memoranda of understanding were established to explore various avenues for the transfer of technology and expertise. Despite ongoing cultural and political barriers, China has recognized its severe lead poisoning problem and is anxious to achieve a formal resolution. Mr. Boreiko was pleased to announce that a number of other organizations have joined the outreach efforts in China and similar progress in India is expected in the near future.

Dr. Brown pointed out that a table was distributed outlining the status of comments submitted by ACCLPP on the July 8, 2009 version of the draft lead and pregnancy paper. She asked the members to review the table overnight in preparation of ACCLPP's voice vote on the paper that would be taken on the following day.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 4:35 p.m. on October 21, 2009.

Update by the Laboratory Methods Workgroup on Lead Poisoning Prevention

Dr. Rhoads reconvened the ACCLPP meeting at 9:04 a.m. on October 22, 2009 and yielded the floor to the first presenter.

Dr. Patrick Parsons is the chair of the Laboratory Methods Workgroup (LMWG). He covered the following areas in his update. LMWG's nine members represent ACCLPP, CDC, state health departments, academic universities and a commercial laboratory. LMWG is requesting ACCLPP's guidance at this time on whether its existing membership should be confirmed and/or expanded. LMWG has already identified two potential new members: Dr. Donald Simmons as a liaison to the Association of Public Health Laboratories and Dr. Michael Kosnett as another ACCLPP member who also would provide expertise to LMWG based on his position as a medical toxicologist at the University of Colorado Health Sciences Center.

LMWG convened two meetings in March and June 2007 and used its last meeting in July 2007 to draft and circulate a report. However, no progress was made on these initial efforts because ACCLPP did not give LMWG a formal charge and CDC had no budget to support additional meetings. LMWG plans to hold meetings in the future pending a formal charge from ACCLPP and support from CDC.

ACCLPP previously approved the establishment of LMWG due to the need to more closely focus on proficiency testing limits for blood lead and achieve "consensus" on tighter requirements at low BLLs. The position of the clinical laboratory community is that the limit of $\pm 4 \mu g/dL$ established by CLIA more than ten years ago is overly generous. The clinical laboratory community also believes that the limit of $\pm 4 \mu g/dL$ is not consistent with current technology and a limit of $\pm 3 \mu g/dL$ would be feasible at this time.

During its initial meetings, LMWG agreed that improvements in laboratory accuracy to achieve the limit of $\pm 3 \mu g/dL$ would not result in a measurable impact on the number of laboratories failing proficiency testing. LMWG noted that a limit of $\pm 2 \mu g/dL$ might be possible after a few years. LMWG recognized the need for ACCLPP to send a formal letter or statement to CMS recommending a change in the regulations to permit flexibility for proficiency testing providers to establish limits that are consistent with program and medical needs and current laboratory capabilities.

ACCLPP also approved the establishment of LMWG due to the need to analyze and provide guidance on proficiency testing issues regarding the LeadCare instrument. This point-of-care blood lead testing device is being used more frequently across the country, but the instrument is being implemented with minimal training and oversight. In an effort to improve this area, New York State developed and widely shared practice standards with regulated full-service laboratories, laboratories in physicians' offices and limited testing laboratories.

CLIA classified the original non-automated hand-held LeadCare device as "moderately complex" and "waived" the newer non-automated device. The difference between the two devices emphasized a strong need for standards. In response to this issue, New York State developed the following practice standards for the LeadCare instrument. Manufacturer's instructions should be followed. Only fresh whole blood should be analyzed.

Aged blood older than 24 hours, refrigerated blood and frozen samples should not be analyzed. Samples from patients with BLLs $\geq 8 \mu g/dL$ should be referred to a certified laboratory for analysis using a reference method. Test results should be used for screening purposes only. All blood lead test results should be reported to the health department. Staff should be trained to ensure competency. LeadCare results should be maintained for record keeping.

Dr. Parsons proposed several new activities LMWG could conduct at the direction of ACCLPP. For <u>activity 1</u>, LMWG could undertake a systematic review of the literature on saliva lead, assess new testing approaches that might be promoted by commercial companies, and formulate recommendations in this area.

For <u>activity 2</u>, LMWG could validate other new clinical tests based on robust peer-reviewed publications in appropriate journals (*i.e.*, *Clinical Chemistry* or *Clinica Chemica Acta*) or based on regulatory oversight and approval as a result of federal or state requirements. LMWG could use New York State's validation requirements for clinical tests as a model in this effort. New York State requires the rationale and utility of each clinical test to be justified with a strong basis or comparison to a reference method. New York State must be provided with a validation package that addresses pre-analytical, analytical and post-analytical issues.

The performance of the clinical test must be demonstrated. At the clinical level, data must be provided on the diagnostic specificity and sensitivity of the test as well as its false-positive and false-negative rates. At the analytical level, data must be provided on the detection limit, measurement precision, repeatability, reproducibility, accuracy and traceability of the test. The interpretation, reference interval and reporting units of test results must be submitted. New York State's validation requirements for clinical tests can be viewed on the website of the New York State Department of Health Wadsworth Center at <u>www.wadsworth.org</u>.

For <u>activity 3</u>, LMWG could analyze other biomarkers of lead exposure in packed red cells, hair, nails, breast milk or sweat. However, the challenges in analyzing these biomarkers include limited capacity to accurately convert different units and ranges to whole blood; the absence of proficiency testing requirements, certified reference materials and quality assurance/quality control measures; and contamination issues.

For <u>activity 4</u>, LMWG could perform environmental analyses to address the disconnect between acceptable lead limits established by multiple agencies. These differences include lead levels in drinking water, soil in play areas and dust established by EPA; various lead levels in food established by FDA; the residential wall paint lead level established by HUD; and various lead levels in consumer products established by CPSC. Moreover, many of the existing lead level limits established by federal agencies that are harmful to children are based on old data.

LMWG's environmental analyses could validate "promises" by manufacturers of the ability of their new devices to better detect lead in paint, toys and other consumer products in the field. LMWG recognizes the need to educate users on the limitations of these new technologies. Because federal regulations are now requiring lead measurements at lower levels, LMWG could conduct research to determine whether current analytical methods are adequate for testing samples of paint and other consumer products for lead content.

LMWG's environmental analyses also could include regulatory oversight; standards developed by the National Environmental Laboratory Accreditation Conference and the NELAC Institute; and new CPSC regulations requiring International Organization for Standardization certification of laboratories that test consumer products.

The Consumer Product Safety Improvement Act of 2008 established new limits on lead concentrations in paint of 90 ppm following the 2007 recall of millions of toys produced in China that were contaminated with lead >600 ppm. This legislation also decreased the total lead content to 300 ppm beginning in August 2009 and will further reduce the total lead content to 100 ppm beginning in August 2011. Dr. Parsons showed photographs and briefly described the new devices.

Mr. Jeffrey Jarrett, of the Division of Laboratory Science at CDC, presented analytical considerations and other issues related to saliva lead measurements based on a recent review of the literature. The interest in saliva testing for multiple applications has greatly increased over time. Since 1982, >2,500 articles have been published in the peer-reviewed literature reporting the use of saliva as a diagnostic fluid. These papers have covered a wide range of biomonitoring issues, including drug monitoring, hormone testing, validation of self-reported frequency of smoking, estimates of dietary intakes, genetic testing, and detection of various systemic maladies. The number of publications related to saliva lead measurements has increased from 0 in 1981 to ~50 at the present time.

Saliva is a complex mixture before and after entering the mouth and includes water, multiple glycoproteins, blood cells, microorganisms, epithelial cells, food debris and upper-airway secretions. The production of saliva varies throughout the day and depends on the nature, duration and intensity of the stimulus. Low pH levels, high-frequency chewing and high bite force increase output and must be taken into consideration when collecting saliva samples. Individuals produce 0.5-1.5 liters of saliva per day. The submandibular glands produce 50%-75% of saliva; the parotid gland produces 20%-50% of saliva; and the sublingual and other glands produce 5%-10% of saliva.

Mr. Jarrett summarized key findings that have been documented in the literature regarding saliva lead measurements. The collection of saliva lead samples is non-invasive and less traumatic for patients. A sufficient volume of 1-5 mL of saliva is typically easy to collect in five minutes. Saliva lead testing costs less than traditional testing because no specialized training is necessary. Other benefits of saliva lead testing that have been reported include no risk to patients of infection, anemia or thrombosis and a safer method than blood collection for health professionals.

Saliva lead testing reflects real-time levels of biomarkers of lead because lead in saliva is the direct excretion of the diffusible lead fraction in plasma that is not bound to proteins. Some researchers have suggested that this fraction is highly associated with the toxic effects of lead. The question has been raised in the literature about whether saliva would be considered as medical waste and could benefit from disposal costs.

Issues or limitations that should be considered in sampling saliva lead measurements include variations of saliva composition throughout the day. These differences are influenced by circadian rhythms, medications, stimulation methods, gender, age, gland size, psychological effects, health and nutrition. The susceptibility of contamination is amplified by low saliva lead concentrations.

Environmental contamination can be minimized with a clean and controlled environment to collect saliva samples and rigorous methods to pre-screen all collection supplies. Intra-oral contamination can be minimized with fasting and mouth rinse with water prior to saliva collection to reduce the impact of lead in metallic dental restorations and also to remove food debris, blood in saliva and smoking residue.

Issues or limitations that should be considered in analyzing saliva lead measurements include extremely low levels that limit the range of suitable analytical techniques. To date, CLIA has not approved any standard or certified reference materials for quality assurance of saliva lead measurements. To date, CLIA has not approved an external quality assurance or proficiency testing program for saliva lead measurements.

Issues or limitations that should be considered in utilizing saliva lead measurements include the absence of reliable published correlations between lead levels in saliva and those in blood or plasma. Reliable reference saliva lead values for human populations have not been produced to date. Both of these limitations increase the difficulty of interpreting the health significance of observed saliva lead concentrations.

Mr. Jarrett cited excerpts from three review articles on saliva lead measurements that are documented in the literature. The 2005 Barbosa, *et al.* review article concluded: "In the absence of consistent and dependable saliva lead measurements, it is not generally accepted as a reliable biomarker of lead exposure. Uncontrolled variation in salivary flow rates, lack of standard or certified reference materials and absence of reliable reference values for human populations are major factors that limit the utility of saliva lead measurements."

The 2007 Koh review article concluded: "In practice, the use of saliva lead in biomonitoring is probably limited to situations of higher levels of lead exposure and blood contamination of saliva is a potential problem. Measurement of lower levels of lead in the saliva can also pose technical challenges." The 2009 Esteban review concluded: "The disadvantage of saliva is related to its flow, which is influenced by many factors. Saliva flow does not influence all substance concentrations to the same degree, so it can still be a useful matrix for non-flow-dependent chemicals."

Mr. Jarrett described two commercial saliva lead test kits that are currently on the market, but he clarified that the mention of company or product names does not constitute endorsement by HHS, CDC or NCEH. In 2004, American Medical Saliva Testing, Inc. stated: "Using Oral Fluid ELAN DRCc ICP Mass Spectrometer testing, one obtains similar information on the status of a person as one can obtain from whole blood." This test was marketed for whole saliva collection with a sample collection time <2.5 minutes. The manufacturer provided information for users to submit samples to an EPA-approved and CLIA-certified laboratory for analysis by ICP-MS with "capabilities as low as 30 ppt."

The LeadConfirm Professional[™] saliva lead screening kit can be purchased from Confirm Biosciences at <u>www.amazon.com</u>. The test is marketed for "convenient saliva collection at home" with the capability of producing an "affordable and comprehensive lead report from a CLIA-accredited laboratory" that uses state-of-the-art liquid high-performance chromatography with mass spectrometry. The manufacturer claims the test is 99.9% accurate, FDA-approved and as reliable as blood laboratory tests. The manufacturer claims 100% correlation between lead levels found in saliva and blood,

The manufacturer further claims that "analyzing saliva is an effective means to establish body lead, especially if this test is viewed as a screening method with the recommendation of a physician involved in the event results exceed a certain level." The manufacturer also describes the ease in using the test by placing a sponge applicator in the mouth for saturation by saliva. Instructions are given on mailing the applicator to the laboratory and receiving full results of lead levels in the body in two days.

Dr. Parsons concluded the update by presenting LMWG's proposed charge. In general, he emphasized that ACCLPP should clearly define the scope of advice solicited from LMWG. CDC also should provide administrative support to enable LMWG to meet and produce a document that addresses laboratory methods issues. In particular, Dr. Parsons proposed activities in five categories and requested ACCLPP's guidance on prioritizing these issues. He noted that LMWG would use ACCLPP's feedback to clearly define its next steps and future direction.

1. Proficiency Testing Limits

 LMWG will address whether blood lead proficiency testing acceptability limits should be more stringent than the current CLIA 1988 standard of <u>+4</u> µg/dL or <u>+10%</u>, whichever is greater, and if so, what these limits should be.

- LMWG will draft ACCLPP's letter to the appropriate federal agency recommending that a change in the CLIA 1988 regulations be implemented to tighten the minimum acceptable proficiency limits for blood lead.
- 2. Practice Standards for Point-of-Care Lead Testing
 - LMWG will address the need for recommended standards of practice for those using point-of-care blood lead testing.
- 3. <u>Alternative Matrices for Assessing Exposure to Lead</u>
 - LMWG will investigate and report to ACCLPP the reliability and validity of measuring lead in saliva as an index of lead exposure.
 - LMWG will investigate and report to ACCLPP the reliability and validity of measuring lead in proposed matrices, [*i.e.*, saliva, sweat, hair, packed red cells or nails] as an index of lead exposure.
- 4. Environmental Lead Analytical Issues
 - LMWG will investigate and report to ACCLPP the reliability of current technologies for assessing lead content of paint, plastics and other environmental samples, existing laboratory capacity and capabilities for handling samples.
- 5. <u>Reference Intervals for Adult Lead Exposure</u>
 - LMWG will investigate and report to ACCLPP approaches clinical laboratories should take to report the reference interval for adult lead exposure. Many laboratories now report BLLS <20 µg/dL and <30 µg/dL as "normal" for adults.

To compliment LMWG's proposed activities, Dr. Brown asked ACCLPP to consider writing a guidance document for CLPPPs during a future meeting. The document ideally would contain a list of questions for CLPPPs to ask vendors who sell new commercial lead screening kits for saliva, nails, sweat or any other matrix. ACCLPP's guidance document to CLPPPs also would contain a set of appropriate responses from vendors.

Mr. Jonathan Wilson is the ACCLPP liaison to the National Center for Healthy Housing (NCHH). He announced that NCHH and AFHH recently sent a petition to EPA requesting a reduction in floor dust lead levels to 10 μ g/sq. ft and window sill lead levels to 100 μ g/sq. Dr. Brown confirmed that CDC would provide ACCLPP with information on this activity to ensure the members had an opportunity to respond to EPA in a timely fashion.

Ms. Jacqueline Mosby is ACCLPP's *ex-officio* member for EPA. She announced that EPA is in the process of developing an accreditation program or registry for portable devices (*i.e.*, XRF and spot test kits) to test lead in paint, dust, soil and water. She clarified that EPA will not use the accreditation program for products. EPA expects to finalize the accreditation program some time in FY2010. Ms. Mosby anticipated being able to provide an update on this initiative during the last ACCLPP meeting in 2010.

In response to a request by Dr. Kosnett, Ms. Mosby confirmed that EPA also would make a presentation during the March 2010 ACCLPP meeting. EPA is reviewing its lead hazard standards and recent data to determine whether a new metric should be used to evaluate screening and intervention values for lead in environmental media with BLLs <10 μ g/dL. Ms. Mosby conveyed that EPA would welcome input from ACCLPP on appropriate changes to its current lead hazard standards.

Ms. Dominique Williams attended the ACCLPP meeting on behalf of Dr. Kristina Hatlelid, ACCLPP's *ex-officio* member for CPSC. She made a commitment to provide ACCLPP with an update on CPSC's progress in utilizing XRF and other alternative methods to test consumer products for assessing lead exposure.

ACCLPP made several comments and suggestions on LMWG's proposed charge in response to Dr. Parsons' request for input and guidance.

- The current practice by many laboratories of reporting BLLS <20 µg/dL and <30 µg/dL as "normal" for adults should not be considered as a part of LMWG's charge.
- LMWG's charge should include a review of filter paper technology.
- LMWG should develop a paper that describes alternative matrices for assessing exposure to lead in general and includes a critical review of each matrix. LMWG should not develop an analytically detailed document on specific products because this activity would fall beyond the scope of ACCLPP's charter.
- LMWG's top three priority charges should be proficiency testing (#1), practice standards for point-of-care lead testing (#2), and reference intervals for adult lead exposure (#5).
- LMWG's actions on proposed charge #3 (alternative matrices for assessing exposure to lead) should be limited to immediately producing a cautionary statement. For example, LMWG could clearly articulate the limitations of saliva lead testing and submit this information to CDC for immediate posting on the ACCLPP web page.
- LMWG should add "efficacy" or "feasibility" after "reliability and validity" in the second bullet under proposed charge #3.
- LMWG's proposed charge #4 (environmental lead analytical issues related to consumer products) should be prioritized because the identification of environmental pathways plays a critical role in solving clinical problems related to lead. If ACCLPP approves charge #4 as a priority, LMWG should explore the possibility of providing oversight to the program developed by the Toy Industry Association. If ACCLPP approves charge #4 as a priority, LMWG should ensure that all activities are conducted in close collaboration and coordination with CPSC and EPA.
- LMWG's proposed charge #5 (reference intervals for adult lead exposure) should be prioritized due to previous successes in this area at the state level. For example, Michigan recommended that its laboratories strengthen reference intervals for adult BLLs and all laboratories in the state were able to comply with this standard as of 2007. Michigan's accomplishment could be used as an opportunity for healthcare providers to make an important change in lead poisoning prevention practices.

A motion was properly placed on the floor and seconded by Drs. Sandel and Reyes, respectively, for ACCLPP to formally charge LMWG with conducting the proposed activities in all five categories as outlined by Dr. Parsons.

Dr. Rhoads made a friendly amendment to the motion to provide LMWG with more specificity and direction on the charge based on ACCLPP's discussion. LMWG's top four priorities would be tighter proficiency testing limits (proposed charge #1); practice standards for point-of-care testing (proposed charge #2); development of a statement on reference values for adult lead exposure (proposed charge #5); and development of a statement on the use of saliva for assessing exposure to lead (proposed charge #3). LMWG would provide regular updates to ACCLPP to obtain guidance on the feasibility of analyzing and making recommendations on other matrices in the future. LMWG would coordinate its activities with ongoing efforts by CPSC and EPA.

Drs. Sandel and Reyes accepted Dr. Rhoads' friendly amendment. **ACCLPP unanimously** approved the motion as modified with no further discussion.

Final Update by the Lead and Pregnancy Workgroup (LPWG)

Dr. Brown confirmed that in response to ACCLPP's previous comments, changes related to chelation during pregnancy were made in the text of the July 8, 2009 version of the draft lead and pregnancy paper. The same revisions would be made to Table 6 subsequent to the meeting.

Dr. Cory-Slechta expressed concern regarding Dr. Kosnett's proposed change to add "certain" before "cells" on page 11, line 22 of the paper. The original sentence was: "Lead appears to be preferentially accumulated by cells in the brain, perhaps disrupting the blood brain barrier." Dr. Brown proposed the following language to resolve this issue: "The brain is the target organ for lead and lead in the brain may disrupt the blood brain barrier." Both Drs. Cory-Slechta and Kosnett agreed with this language.

A motion was properly placed on the floor and seconded by Drs. Sandel and Cory-Slechta, respectively, for ACCLPP to approve the lead and pregnancy paper with the change noted for the record. ACCLPP approved the motion with a majority vote, one abstention (Rhoads) and no further discussion.

Ms. Nikki Walker, of LPPB, described CDC's plans to rollout *Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women* in the spring of 2010. Outreach and communication to providers would include newsletters, listservs, placement of the lead and pregnancy logo in journals, and op-ed articles in journals of professional organizations.

The LPWG members made commitments to publish op-ed articles of the lead and pregnancy paper in the journals of their respective organizations, including the American Academy of

Family Medicine, American College of Nurse Midwives, American Academy of Pediatrics, and American College of Obstetricians and Gynecologists.

Outreach and communication to CLPPPs would include a webinar, newsletters and listservs to assist CLPPPs in answering questions from their constituents. Other components of the communication rollout would include fact sheets to providers, public health professionals and the general public; a web spotlight and podcast; and announcements on Facebook, Twitter, blogs and other social media. The lead and pregnancy document also would be linked to the websites of other CDC National Centers, particularly the pregnancy website of the National Center for Birth Defects and Developmental Disability.

Dr. Jessica Leighton, an ACCLPP member and chair of LPWG, described issues in the lead and pregnancy paper that most likely would cause concern: issues related to BLLs 5 μ g/dL versus 10 μ g/dL; Occupational Safety and Health Administration recommendations; general screening recommendations for pregnant or lactating women in high-risk communities; the calcium recommendation of 2,000 mg; and the calculation used to arrive at BLLs \geq 40 μ g/dL as a caution for breastfeeding.

Ms. Walker added that CDC would develop and post a question/answer sheet on its website to specifically address the major issues Dr. Leighton described and other highly technical or scientific questions CLPPPs or healthcare providers might have difficulty in answering. The web site also would provide a toll-free telephone number at 1-800-CDC-INFO for persons to obtain additional information.

In terms of dissemination, Ms. Walker conveyed that CDC would develop and distribute all materials associated with the lead and pregnancy paper in both English and Spanish. She encouraged ACCLPP to provide her with additional suggestions on the rollout of the lead and pregnancy paper at <u>mwalker@cdc.gov</u>.

ACCLPP made several comments and suggestions for CDC to consider in the rollout and dissemination of the lead and pregnancy paper.

- CDC should link the lead and pregnancy paper to the websites of the National Institutes of Health (*i.e.*, the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences), other federal partners, the Institution of Higher Education and advocacy groups.
- CDC should provide CLPPPs with "sound bites" or other information to respond to questions and concerns regarding payment to conduct blood lead testing of pregnant women.
- CDC's rollout of the lead and pregnancy paper should be designed to deliver messages to the most at-risk populations, such as pregnant women and women of child-bearing age who are renovating old homes.
- CDC should link the lead and pregnancy document to the websites of occupational organizations, such as the American College of Occupational Environmental Medicine, Adult Blood Lead Epidemiologic and Surveillance Program, Association of Occupational

and Environmental Clinics, and American College of Medical Toxicology. CDC should submit op-ed articles to the journals of these organizations as well. CDC should use Dr. Walter Alacon, ACCLPP's *ex-officio* member for the National Institute for Occupational Safety and Health, as well as Drs. Kosnett and Rhoads as resources in outreaching to the occupational community. Dr. Kosnett offered to contact an organization in the United Kingdom that will soon release a similar document on lead in pregnancy to explore the possibility of this group writing an editorial on ACCLPP's paper.

Dr. Brown made several remarks in response to ACCLPP's comments and questions. In terms of payment, blood lead testing of pregnant women should be considered a part of usual and customary care. The position of CDC and experts in the field is that blood lead testing should not be viewed as a special test or exception to routine care of pregnant women.

With respect to early distribution of the document, Dr. Brown would determine the point at which ACCLPP members could share a draft version of the lead and pregnancy paper with colleagues prior to publication. In the interim, however, ACCLPP members could reference the document as a draft that has been submitted to CDC for final approval and clearance.

The participants applauded Drs. Leighton and Brown for their outstanding leadership over the past few years and also commended the diligent efforts of Dr. Adrienne Ettinger, other LPWG members and CDC staff for their tremendous accomplishment of completing the lead and pregnancy document.

Update on CPSC Lead Poisoning Prevention Strategies

Mr. Matt Howsare, Esq. is the Legal Counsel to the Chairman of CPSC. He presented CPSC's updated strategies and approach to address lead poisoning prevention. Following the 2007 recall of lead-contaminated toys produced in China, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was developed with stricter lead standards. Since that time, CPSC's primary focus areas in lead poisoning prevention have been implementation and enforcement of the new CPSIA standards and education to domestic and foreign manufacturers and consumers in complying with these laws.

Mr. Howsare highlighted key components of CPSIA. CPSIA reduced the lead in paint standard for children's toys and furniture from 600 ppm to 90 ppm. CPSIA's stricter standards on leachable lead from children's metal jewelry allowed CPSC to enforce a lead content standard of 300 ppm for a consumer product or any of its parts. However, the lead content standard will be further reduced to 100 ppm beginning in August 2011 if CPSC determines the standard is technologically feasible.

The lead content standard is restricted to children's products, but CPSC is currently developing a rule to clearly define "children's products." The existing statute defines "children's products" as those primarily intended for children \leq 12 years of age. New CPSIA testing and certification requirements require third-party independent testing for compliance with standards, regulations

and bans enforced by CPSC, including the lead in paint and lead content standards. These requirements are expected to become effective in February 2010. CPSC also enforces ASTM International Standard F963. This mandatory toy safety standard is covered by CPSIA and requires testing of lead and five other heavy metals in the surface coating of children's toys.

Mr. Howsare summarized CPSC's five major compliance strategies. <u>One</u>, CPSC monitors U.S. ports to prevent dangerous products, including those containing excessive amounts of lead, from entering the marketplace. CPSC uses the XRF device to test products for lead at ports. Dangerous products are destroyed at U.S. ports or sent to the CPSC laboratory for further testing and are not returned for sale in other countries under any circumstance.

<u>Two</u>, CPSC is continuing its retail surveillance with 100 field investigators who visit the marketplace, collect samples of products, and send samples to the CPSC laboratory for testing to confirm compliance.

<u>Three</u>, CPSC is strengthening and expanding its partnerships with state attorney generals, poison control centers, state health departments and other reporting agencies. CPSC and several state attorney generals across the country recently convened a joint meeting to explore collaborative strategies to improve the enforcement of lead limits in the United States.

CPSC is continuing to send letters or issue press releases to notify foreign countries or counterparts when products have been recalled or recalled products that violate lead standards have been distributed. CPSC welcome reports from CDC, its partners and grantees at state and local levels, and other concerned parties about any products distributed in the United States that violate lead limit standards. CPSC will continue to aggressively pursue and investigate laboratory findings from lead testing of products that demonstrate violations of lead standards.

<u>Four</u>, CPSC expects testing and certification to be tremendous enforcement tools after these requirements become effective in February 2010. Importers and manufacturers will be required to certify that their products are in compliance with CPSIA based on a testing program. Under CPSIA, CPSC will be authorized to issue civil penalties to any importer or manufacturer that submits a false certification of a product.

<u>Five</u>, CPSC requires self-reporting within 24 hours of products that "might" violate CPSC bans and standards or "might" pose a substantial hazard to consumers. For extremely complex situations, however, CPSC will allow the reporting firm to self-report in ten days. CPSC's award-winning Fast Track Recall Program has been extremely effective in removing dangerous products from the marketplace and enforcing lead limits.

Mr. Howsare reported that CPSC increased education and training to foreign government officials and suppliers after CPSIA was passed to ensure compliance with lead limits and other regulations. CPSC recently installed new video conferencing software to facilitate broadcasts of webcasts, webinars and training seminars in two languages simultaneously without the need for staff to travel overseas and overcome language barriers. However, CPSC still deploys staff overseas on a regular basis to train and educate foreign officials and suppliers on the importance of complying with U.S. lead laws and other consumer product safety regulations.

CPSC posts all guidance documents on its website in Mandarin and Vietnamese to eliminate the need for China and Vietnam to translate CPSC documents. CPSC outreaches to importers and foreign suppliers to facilitate compliance with lead limits and other CPSIA requirements. CPSC will develop and distribute a handbook to importers within the next year and continues to disseminate a handbook to small businesses and resellers. CPSC hopes to create and provide hand crafters with a similar handbook in the near future. CPSC will continue to participate in official meetings with foreign government officials and various economies to emphasize the critical need for compliance with U.S. lead laws and other consumer product safety regulations.

CPSC leadership and senior management are currently attending the U.S./China Consumer Product Safety Summit to discuss compliance with the new CPSIA lead limits and other requirements. The Lead in Children's Products Workgroup is one of six workgroups that will be convened during the summit. The workgroup will focus on lead in toys, identify concrete steps to take at the regulatory expert level, and advance full compliance with CPSIA lead limits. Action steps developed by the workgroup are expected to target production, testing, certification and enforcement practices.

CPSC has focused its domestic educational activities on ensuring that manufacturers comply with CPSIA's new lead limits and informing consumers of the new lead laws. CPSC now utilizes Face Book, Twitter, Flicker and other social media outlets to widely publicize its consumer product safety messages and rapidly inform the public about dangerous products that have been recalled.

CPSC convenes public meetings and broadcasts webinars to engage consumers in dialogue and provide education on complying with the new lead limits. CPSC's website and recalls of dangerous products in the marketplace also serve as effective educational tools. CPSC is holding Public Commission hearings to more actively engage stakeholders in the regulatory process and reinforce its educational messages.

The CPSC Chairman has expressed a strong desire to convene a full Commission hearing on childhood lead poisoning prevention to publicize the dangers of lead to children. Mr. Howsare encouraged the ACCLPP members to attend the hearing and make a presentation to the full Commission. He emphasized that ACCLPP's subject-matter expertise during the hearing would be extremely beneficial to Commissioners who have an interest in learning more about lead in consumer products and childhood lead poisoning prevention.

Mr. Howsare conveyed that CPSC has planned several activities in the future to strengthen compliance with and education of CPSIA regulations. Most notably, CPSC will respond to three recommendations the U.S. Government Accountability Office recently issued related to CPSC's Import Surveillance Program.

CPSC was advised to quickly implement CPSIA requirements for imports by developing a substantial products hazards/generic defects list and creating import risk strategies in collaboration with U.S. Customs and Border Protection (CBP). CPSC is partnering with CBP to develop these strategies and also is undergoing the rule-making process to prevent the import

at U.S. ports of entry of drawstrings on children's outerwear and other generic defects that pose a risk.

CPSC was advised to take action on targeting shipments, including updating information sharing agreements with CBP and ensuring a presence at the CBP Targeting Center. CPSC has completed both of these activities. CPSC was advised to update its strategic plan with import strategies. CPSC expects to begin responding to this recommendation within the next few weeks.

CPSC's other future activities include enforcement of CPSIA testing and certification requirements to further promote lead poisoning prevention. CPSC will launch a new public database over the next 18 months to enhance the collection of information on potentially dangerous products. CPSC will partner with industry, consumer groups and other stakeholders to ensure the accuracy of information that is submitted.

After the database is launched, CPSC will convene a series of meetings with stakeholders from multiple sectors, including industry, consumer groups, and federal and state agencies, to ensure the data are effectively used and widely disseminated to protect consumers. CPSC also will use software that will mine information from the database to identify problematic products, patterns, trends and emerging hazards.

Dr. Brown noted that CPSC uses the handheld XRF to test products for lead at U.S. ports. However, data have shown a strong correlation between this device and false-negative results or non-detectable limits even for products with high lead levels. She offered to collaborate with CPSC on developing more effective methods to test products for lead at ports.

Dr. Brown conveyed that CDC-funded CLPPPs have informed CDC of their difficulties over a number of years in attempting to navigate and access CPSC's cumbersome reporting process. She offered the services of Ms. Samantha Harrykisson, of LPPB, to closely collaborate with CPSC in streamlining its reporting process for CLPPPs in the field to more easily use this system.

ACCLPP thanked Mr. Howsare for providing an extremely comprehensive and informative update on CPSC's lead poisoning prevention strategies. The ACCLPP members looked forward to additional reports on CPSC's ongoing and future activities and also welcomed the opportunity to provide assistance and guidance to advance these efforts, particularly during the upcoming Commission hearing on childhood lead poisoning prevention.

ACCLPP Business Session

Dr. Brown noted that EIWG's draft charge was distributed to ACCLPP for review, discussion and a formal vote. [*Editor's Note*: Due to ACCLPP's upcoming vote on this issue, the draft charge reflects no editorial changes and is captured below as read verbatim into the record by Dr. Gardner.]

"The Educational Interventions for Lead-Exposed Children Work Group, in conjunction with the committee, will implement the following charges as provided by the ACCLPPP during the March 2008 meeting and as further discussed during the October 2008 meeting: Compile existing evidence; Review IDEA parts B and C, Special Education and model regulations to provide guidance to state and local governments; and describe specific action steps for parents, clinicians and educators.

To implement the committee charges, the workgroup will focus on the following activities: (1) make recommendations regarding developmental assessment, intervention and special education services for children with elevated blood lead levels; (2) inventory the existing regulatory and policies that support provision of assessment and educational interventions and mechanisms for ensuring that children with a history of elevated blood lead levels receive the services they are entitled to; (3) provide guidance to state and local governments, parents, pediatric health care providers, lead poisoning prevention programs, educators, and others who work with young children. The work group, in conjunction with the committee, will make a summary of the recommendations for publication."

A motion was properly placed on the floor and seconded by Ms. Kite and Mr. Williams, respectively, to accept the Educational Intervention Workgroup charge with ACCLPP's two suggested revisions: change "inventory" to "review" and "regulatory" to "regulations." **ACCLPP unanimously approved the motion with the changes noted for the record.** There was no further discussion.

Dr. Brown returned to LCPWG's draft charge Dr. Kosnett read into the record on the previous day. ACCLPP made three key suggestions that should be considered in LCPWG's ongoing activities and future direction.

- LCPWG's draft charge should be revised to more broadly focus on "developing countries" rather than specifically focusing on China.
- LCPWG should be charged with investigating and posting lead-containing consumer products of concern on the CDC website with oversight by ACCLPP.
- LCPWG should use the international conference to form an ongoing global partnership to maintain long-term momentum on lead in consumer products.

A motion was properly placed on the floor and seconded by Drs. Sandel and Reyes, respectively, to accept the Lead in Consumer Products Workgroup charge. **ACCLPP unanimously approved the motion.** Dr. Brown confirmed that ACCLPP's suggestions on LCPWG's proposed charge would be taken into consideration.

Public Comment Session

Mr. Boreiko noted that the International Organization for Standardization Secretariat issues standards, particularly for items containing lead. These products include food, contact surfaces, crystal, ceramic ware, PVC and water pipes. He pointed out that the European Union has been extremely attentive to issues related to these products.

Mr. Boreiko announced that the European Union is currently revising occupational exposure standards in collaboration with industry and ILZRO. He hoped CDC would make the draft version of the lead and pregnancy paper available in the near future to inform this process.

Closing Session

The participants joined Dr. Rhoads in applauding Mr. Barry Brooks, Ms. Claudine Johnson, and other CDC staff and contractors for providing outstanding administrative support and making logistical arrangements for the ACCLPP meeting. He announced that the next ACCLPP meeting would be held on March 18-19, 2010 in Atlanta, Georgia.

Dr. Brown thanked the ACCLPP members for their continued energy, commitment and support to childhood lead poisoning and healthy homes.

With no further discussion or business brought before ACCLPP, Dr. Rhoads adjourned the meeting at 12:20 p.m. on October 22, 2009.

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

Juns Malan

<u>1/11/2010</u> Date

George G. Rhoads, M.D., M.P.H. Chair, Advisory Committee on Childhood Lead Poisoning Prevention