



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
Healthy Homes/Lead Poisoning Prevention Branch**

**Advisory Committee on Childhood Lead Poisoning Prevention
Teleconference Meeting
January 4, 2012**

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) Healthy Homes/Lead Poisoning Prevention Branch (HHLPPB) convened a teleconference meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP).

The purpose of the teleconference meeting was for the ACCLPP membership to discuss and vote on the ACCLPP Report, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*. The teleconference meeting was held on January 4, 2012 from 1:00-1:49 p.m. EST.

OPENING SESSION

Mary Jean Brown, ScD, RN

Chief, Healthy Homes/Lead Poisoning Prevention Branch, NCEH, EEHS
Centers for Disease Control and Prevention
ACCLPP Designated Federal Official

Dr. Brown opened the teleconference meeting by conducting a roll call of the ACCLPP members and asking the members of the public to identify themselves and their affiliations for the record. The list of participants is set forth below.

Advisory Committee on Childhood Lead Poisoning Prevention	
Walter Alarcon, MD, MSc	<i>Ex-officio</i> , National Institute for Occupational Safety and Health
Mary Jean Brown, ScD, RN	Designated Federal Official
Carla Campbell, MD, MS	Liaison, American Academy of Pediatrics
Deborah Cory-Slechta, PhD	ACCLPP Voting Member, Blood Lead Level of Concern Workgroup co-Chair
Kim Dietrich, PhD	Voting Member

Warren Friedman, PhD, CIH	<i>Ex-officio</i> , U.S. Department of Housing and Urban Development
Perry Gottesfeld, MPH	ACCLPP Voting Member, Blood Lead Level of Concern Workgroup co-Chair
Kris Hatlelid, PhD, MPH	<i>Ex-officio</i> , U.S. Consumer Product Safety Commission
Sonya Hammons	<i>Ex-officio</i> , U.S. Department of State
Ezatollah Keyvan-Larijani, MD, DrPH	Liaison, Council of State and Territorial Epidemiologists
Michael Kosnett, MD, MPH	Voting Member
David McCormick	Voting Member
Linda McGinn (Representing Jan Towers)	Liaison, American Academy of Nurse Practitioners
Elizabeth McKee-Huger	Voting Member
Jane Malone	Liaison, National Center for Healthy Housing
Jacqueline Mosby, MPH	<i>Ex-officio</i> , U.S. Environmental Protection Agency
Ruth Ann Norton	National Coalition to End Childhood Lead Poisoning
Kimberly Hansen-Neumann, MD	Voting Member
Patrick Parsons, PhD	Voting Member
Brenda Reyes, MD	Voting Member
George Rhoads, MD, MPH	Chair
Walter Rogan, MD	<i>Ex-officio</i> , National Institute of Environmental Health Sciences
Cynthia Ruff	<i>Ex-officio</i> , Centers for Medicare and Medicaid Services
Megan Sandal, MD, MPH	Voting Member
Donald Simmons, PhD	Liaison, Association of Public Health Laboratories
Dana Williams	Voting Member
Members of the Public	
Mary Albert	Health Canada
Cristina Baker	Texas Department of State Health Services
Mary Ballew	U.S. Environmental Protection Agency Headquarters
Ben Bass	Congressional Quarterly
Deborah Bergin	Agency for Toxic Substances and Disease Registry
Patrick Bloomingdale	Texas Department of State Health Services
Jason Broehm	Centers for Disease Control and Prevention, Washington Office
Michelle Burgess	U.S. Environmental Protection Agency Headquarters
Ann Carroll	U.S. Environmental Protection Agency Brownfields Program
Tom Carroll	New York State Department of Health
Kathy Clement	Texas Health Steps Program
Margie Coon	Wisconsin Department of Health
Kimball Credle	Agency for Toxic Substances and Disease Registry
Helen Dawson	U.S. Environmental Protection Agency Headquarters
Jay Dempsey	Centers for Disease Control and Prevention
Jyothi Domakonda	City of Houston Health Department
Cynthia Driscoll, Ph.D.**	Jones Day
Chinyere Ekechi	Agency for Toxic Substances and Disease Registry
Barbara Ellis	Centers for Disease Control and Prevention
Daneen Farrow-Collier	Agency for Toxic Substances and Disease Registry
David Fowler	Agency for Toxic Substances and Disease Registry

Caroline Grossman	Magellan Biosciences
Patricia Hyland	New Jersey Department of Health and Senior Services
Jeffrey Jarrett	Centers for Disease Control and Prevention
Claudine Johnson	Centers for Disease Control and Prevention
Steve Jones	Agency for Toxic Substances and Disease Registry
Vikas Kapil	Centers for Disease Control and Prevention
Veronica Kennedy	Centers for Disease Control and Prevention
Steve Kizinsky	U.S. Environmental Protection Agency, Region V
John Krupinski	Maryland Department of the Environment
Gladys Lewellyn	Centers for Disease Control and Prevention
Mark Maddaloni	U.S. Environmental Protection Agency, Region II
J.B. Manavati	New Jersey Department of Health and Senior Services
Andrea McKinsey	Health Canada
Fran Medaglia	Massachusetts Department of Public Health
Ray Meister	California Department of Public Health
Deborah Millette	Centers for Disease Control and Prevention
Nancy Minch	New York State Department of Health
Crystal Motlasz	New Jersey Department of Health and Senior Services
Jaydeep Nanavaty	New Jersey Department of Health and Senior Services
Sarah Nesland	Massachusetts Department of Public Health
Crystal Owensby	New Jersey Department of Health and Senior Services
Joe Pargola	New Jersey Department of Health and Senior Services
Anna Preiss	New Jersey Department of Health and Senior Services
Kathleen Raffaele	U.S. Environmental Protection Agency Headquarters
Ken Rose	Agency for Toxic Substances and Disease Registry
Adam Safruk	Intrinsic Environmental Sciences, Inc.
Lori Saltzman	U.S. Consumer Product Safety Commission
Joseph Schirmer	Wisconsin Department of Health
Lorraine Seed	Health Canada
Stephanie Shirley	Texas Commission on Environmental Quality
Bob Simmons	Iowa Public Health Laboratory
Thomas Sinks	Centers for Disease Control and Prevention
L.J. Smith	Texas Department of State Health Services
David Snell	Agency for Toxic Substances and Disease Registry
Janet Stetzer	Montana Department of Public Health and Human Services
Kara Stevens	Idaho Division of Health
Sheila Stevens	Centers for Disease Control and Prevention
Mark Stifelman	U.S. Environmental Protection Agency, Region X
Mike Stobbe	Associated Press
Marissa Sucosky	Centers for Disease Control and Prevention
Culan Sun	Texas Commission on Environmental Quality
Dan Symonik	Minnesota Department of Health
Thomas Talbot	New York State Department of Health
Jana Telfer	Centers for Disease Control and Prevention
Denise Tevis	Agency for Toxic Substances and Disease Registry
Tiffany Turner	Centers for Disease Control and Prevention
Will Wheeler	Centers for Disease Control and Prevention
Lynn Wilder	Agency for Toxic Substances and Disease Registry

****Counsels clients on legal and toxicological issues involving lead.**

Dr. Brown reminded the ACCLPP voting members of their responsibility to recognize potential conflicts of interest that may influence their votes and recuse themselves from participating in these matters.

Dr. Brown announced that the ACCLPP teleconference meeting is open to the public. The meeting notice and agenda were published in the *Federal Register* in advance of the meeting. A public comment session would be held after ACCLPP discussed and voted on the Level of Concern (LOC) document.

UPDATE BY THE BLOOD LEAD LEVEL OF CONCERN WORKGROUP

Perry Gottesfeld, MPH

Executive Director, Occupational Knowledge International
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Deborah Cory-Slechta, PhD

Professor, University of Rochester School of Medicine
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Mr. Gottesfeld announced that after the November 2011 ACCLPP meeting, the workgroup revised the Level of Concern (LOC) document based on comments and feedback provided by the ACCLPP members. The document was further revised by an outside editor to ensure the accuracy of the references and refine the overall format.

A motion was properly placed on the floor and seconded by Mr. Gottesfeld and Mr. Dana Williams, respectively, for ACCLPP to approve the following resolution.

The Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) presents the statement, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*. ACCLPP requests that CDC and HHS adopt the recommendations outlined in the document. ACCLPP further requests that CDC report to ACCLPP on its progress in implementing the recommendations within 6 months.

The ACCLPP members made three key comments before voting on the resolution.

- A few sections of the LOC document that pertained to laboratory issues lost their clarity and meaning during the editing process. Dr. Patrick Parsons will provide the workgroup with revisions to address this issue.
- The existing draft document that is presented for ACCLPP's vote still needs small editorial changes. For example, some sections were repeated and "pediatrician" was used rather than "clinician" in some places. Dr. Megan Sandel will provide the workgroup with revisions to address this issue.
- Dr. Cory-Slechta will correct some of the references in the LOC document to be consistent with commentary submitted by Health Canada.

Dr. Brown clarified that if ACCLPP votes to approve the LOC document, small editorial changes or minor revisions to correct factually incorrect text could still be made. However, she emphasized that revisions to the document following ACCLPP's vote would not include new data, references or major changes. Dr. George Rhoads (ACCLPP Chair), Dr. Cory-Slechta and Mr. Gottesfeld (Workgroup co-Chairs) would make decisions on revisions that constitute "small editorial" versus "substantive" changes.

ACCLPP formally approved the resolution by a majority vote of 11 in favor and 1 opposed (Dr. Rhoads). Dr. Sher Lynn Gardner was unable to participate on the teleconference and vote on the resolution.

Mr. Gottesfeld and Dr. Cory-Slechta recognized several individuals for their outstanding contributions to the workgroup's 13-month effort of developing and revising the LOC document. Dr. Brown, Mr. Will Wheeler and other CDC staff provided tremendous oversight, technical assistance, data, and logistical and administrative support to assist the workgroup in its activities.

Mr. Gottesfeld and Dr. Cory-Slechta thanked the workgroup members and ACCLPP for their commitment, participation and expertise throughout the entire process.

George Rhoads, MD, MPH

Interim Dean, University of Medicine and Dentistry of New Jersey, School of Public Health
ACCLPP Chair

Dr. Rhoads opened the floor for ACCLPP to discuss the LOC document prior to its vote. A motion was properly placed on the floor by Dr. Cory-Slechta and Mr. Williams, respectively, for ACCLPP to approve the LOC document with minor editorial changes as noted by the members.

ACCLPP formally adopted the document, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*, by a majority vote of 11 in favor and 1 opposed (Dr. Rhoads). Dr. Sher Lynn Gardner was unable to participate on the teleconference and vote on the document.

Based on ACCLPP's formal adoption of the LOC document, Dr. Brown discussed CDC's internal process and next steps. The document will be submitted to Dr. Brown as the ACCLPP Designated Federal Official. CDC leadership will forward the document to the HHS Secretary. The HHS Secretary has 30 days to review and acknowledge receipt of the document.

CDC will review the recommendations and report its decisions to ACCLPP in writing within 90 days. CDC could concur with the recommendations, agree in principle, or deny the recommendations. "Agreement in principle" most likely would be based on resource constraints that would prevent CDC from acting on some recommendations. If the recommendations are denied, CDC would be required to provide ACCLPP with its rationale.

In terms of publication, the LOC document could be published as a CDC product in the *Morbidity and Mortality Weekly Report*. All persons who contributed to the document will be acknowledged. The document in its current form will remain on the CDC website with the "do not cite or circulate" disclaimer. After the document is revised with the minor editorial changes submitted by the ACCLPP members, the disclaimer will be removed and the final document will be placed in the public domain as an official ACCLPP product.

In terms of publicizing the document, Dr. Vikas Kapil is the Chief Medical Officer and Associate Director for Science in the CDC National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR). He will serve as CDC's spokesperson on the document to the press and Congressional officials. Dr. Rhoads will serve as ACCLPP's spokesperson on the document in his role as Chair. Other ACCLPP members are free to answer questions from the press or organizations as individuals with expertise in lead poisoning prevention, but none of the members other than Dr. Rhoads can speak for ACCLPP. CDC will not issue a press release on the document.

In terms of progress reports, Dr. Brown will provide an update at the next ACCLPP meeting on CDC's status in implementing the recommendations. At that time, CDC will solicit feedback from ACCLPP on strategies to improve implementation of the recommendations. Dr. Brown noted that a key component of the initial implementation process will be to accelerate the pace of the ACCLPP Educational Intervention Workgroup because the LOC document will greatly inform this process.

PUBLIC COMMENT SESSION

Dr. Rhoads called for comments by members of the public. (*Editor's Note:* The public comments set forth below are verbatim remarks and are not summarized.)

Cynthia Driscoll, PhD, JD
Jones Day

Thank you, Dr. Brown, and Dr. Rhoads and members of the Committee. I appreciate the opportunity to comment on the foundation underlying the workgroup's recommendation to eliminate 10 µg/dL as CDC's blood lead level of concern.

The workgroup is relying on Dr. Lamphear's published pooled analysis in its assessment of low-level lead effects and the workgroup admits that it has not analyzed the pooled analysis raw data; I have. Although our analysis is preliminary, it raises serious concerns about Dr. Lamphear's assessment. Given the weight attributed to Dr. Lamphear's pooled analysis in assessing low-level lead effects on IQ and given the significance of the actions that have been considered today by the Committee, I felt it was important to share concerns with your Committee.

I submitted a letter dated 12/22/11 to Dr. Rhoads and to Dr. Brown as the Chair of the Committee and the Chief of the Lead Poisoning Prevention Branch outlining some of our concerns about the pooled analysis and the conclusions that Dr. Lamphear and others make based on the pooled analysis.

I do not raise alarm bells lightly. Before reaching out to the Committee, I shared our analysis with a preeminent biostatistician and member of the Institute of Medicine's Academy of Sciences, Dr. Kramer, an Emeritus Professor at Stamford University. Dr. Kramer's credentials are impeccable. She has no financial or academic interest in lead. She receives no lead funding and she has not previously expressed any opinions about low-level lead effects.

Dr. Kramer's preliminary assessment of Dr. Lamphear's analysis reinforces and extends our concerns about drawing conclusions from the pooled analysis as analyzed, let alone using it to

influence policy decisions. With Dr. Kramer's reassurance and permission, my letter summarized some of our findings ahead of the release of the workgroup's report that came out just yesterday and the Committee's vote today.

Dr. Rhoads, I appreciated your reply in which you indicated that you shared my letter with the Committee. You indicated that my concerns and comments were not going to be incorporated into the workgroup's report because my concerns were not peer reviewed. There is no requirement that I know of that requires public comments to be peer reviewed nor is peer review a guarantee of quality or validity.

Regardless, the timing allowed for public comment on a report released as a draft less than two months ago, and again, just yesterday ahead of the opportunity for public comment today hardly affords such a luxury. Our analysis is still preliminary in part because Dr. Lamphear fought us for four years to deny us access to the federally-funded data and we only recently obtained it after we filed a lawsuit.

Nonetheless, peer reviewed or not, under these circumstances where the Committee is on the verge of making a significant policy recommendation, wouldn't it make sense to take the time to take a closer look at the concerns an impartial Dr. Kramer deemed to be credible? That seems not to be the case today.

What if the red flags raised by our analysis were peer reviewed? Would the workgroup's policy recommendations stand? The pooled analysis data is now finally available for anyone to analyze. Why not take the time to conduct an independent, impartial, financially independent review or analysis before making policy recommendations based in large part on the pooled analysis which we and Dr. Kramer believe is flawed?

CDC's guidelines for ensuring the quality of information disseminated to the public states, "It is CDC's policy to ensure and maximize the quality, objectivity, utility and integrity of information that it disseminates to the public." A report and recommendations based on questionable science runs afoul of CDC's own policy.

Dr. Rhoads, in your response to my letter, you indicated that the ACCLPP is unable to include them in the report, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*. Whether the Committee is unable to incorporate them into the report remains a question, but they are at least unwilling to do so at this time. I submit that the Committee should postpone the vote to accept the workgroup's report until an independent, impartial, financially independent review or analysis is conducted. Given that you've already voted, that's a foregone conclusion. But it still could impact CDC's decisions to concur or deny recommendations.

Dr. Rhoads, you also indicated that I could offer the issues detailed in my letter during the public comment period. I request that my entire letter and these comments be made part of the record. You have my letter already and if it would be convenient, I could provide a written copy of my oral comments (See Appendix I).

Perry Gottesfeld, MPH

Executive Director, Occupational Knowledge International

[Response to Dr. Driscoll]: I find it completely unethical and personally offensive that you've come before the Advisory Committee on Childhood Lead Poisoning Prevention in a feeble attempt to raise questions about a peer-reviewed article without disclosing that you and your law

firm represent Sherwin Williams in ongoing litigation being brought by a group of county governments in California on behalf of the people in my state.

Millions of children are impacted by the past sales of lead paint that are known to cause exposures at levels that are harmful to children. And none of the claims you have made in your letter of December 22, 2011 negate this fact. Furthermore, Dr. Kramer's unpublished opinions have no place before this Committee. It is obvious that she is either a consultant to your firm, and/or your client, or an expert witness, or a soon to be named expert in this litigation in which this Committee and the Centers for Disease Control have no standing and no vested interest.

Therefore, it is completely inappropriate that you bring your propaganda to this body with the sole intent of generating doubt about a published epidemiological study by questioning the techniques used by Dr. Lamphear without addressing any of the underlying studies that he relies upon in his review.

It is completely naïve to think we would be concerned about your proposal to reanalyze the data from a single study when our Committee has relied on more than 90 references in its deliberations and has focused on the weight of evidence from all published literature on this topic. Given these facts, I believe you are misguided in bringing your claims to our Committee. And instead, I suggest you take your arguments to a jury in California. These opinions are my own and do not reflect the opinion of the CDC nor the ACCLPP Committee. Thank you.

In response to Dr. Driscoll's request, Dr. Brown confirmed that her December 22, 2011 letter and oral comments would be a part of the official record of the January 4, 2012 ACCLPP Teleconference Meeting and also would be available to the public.

Mr. Mike Stobbe is a reporter for the Associated Press. He requested interviews with Dr. Rhoads and other officials after the teleconference meeting was adjourned. Ms. Jana Telfer is the Associate Director of the NCEH/ATSDR Health Communication Science Office. She instructed Mr. Stobbe to contact the Office of Communication to coordinate interviews with CDC personnel and to schedule interviews individually with the ACCLPP members.

CLOSING SESSION

Drs. Rhoads and Brown thanked ACCLPP for developing and finalizing the LOC document and the members of the public for taking time from their schedules to participate in the teleconference meeting. Dr. Rhoads received a motion and a second from ACCLPP voting members to adjourn the teleconference meeting.

APPENDIX I

JONES DAY

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December 22, 2011

VIA US MAIL AND E-MAIL

George C. Rhoads, MD, MPH
Dean, UMDNJ-School of Public Health
683 Hoes Lane West
Piscataway, NJ 08854

Re: Advisory Committee for Childhood Lead Poisoning Prevention

Dear Dr. Rhoads:

On November 14-16, 2011, I attended the public portions of the meeting of the Centers for Disease Control and Prevention's Advisory Committee for Childhood Lead Poisoning Prevention ("ACCLPP"). I enjoyed meeting you and I appreciated the hospitality afforded the attendees. It was an enlightening three days. Although a lawyer, I am also a PhD and I advise various clients on issues related to lead toxicology, exposure, and effects. Over the years, I have analyzed the methodologies used to assess whether various blood lead levels in children have measurable effects on IQ and behavior, as well as problems in the design, analysis and interpretation of lead studies.

While the ACCLPP meeting covered numerous topics related to children and lead, I was particularly interested in the proposal to eliminate the "level of concern" terminology and, in its place, institute a "reference level" of 5 µg/dL. Presenters to the ACCLPP continued to advocate for the recognition of low-level effects relying on studies that were in existence at the time of the ACCLPP's prior review in 2005, along with a few more recent studies. They continued to cite Lanphear et al., *Low-level environmental lead exposure and children's intellectual function: An international pooled analysis*, *Env'tl Health Persp.*, Vol. 113, 894-899 (2005) ("Pooled Analysis") as providing substantial support for the conclusion that IQ is significantly impaired at blood lead levels below 10 µg/dL. Indeed, while it now nearly seven years old, the Pooled Analysis continues to be the study on which many branches of the federal government focus and rely when considering health issues associated with lead.¹ Until recently, many of the analytical

¹ For example, on October 15, 2008, the United States Environmental Protection Agency ("EPA") signed into effect a new National Ambient Air Quality Standards for Lead ("NAAQS"). The supporting materials for the NAAQS termed the Pooled Analysis "the most compelling evidence for Pb effects at blood levels < 10 µg/dL" More recently, in May 2011, EPA released a draft Integrated Science Assessment for Lead. The leading study cited to support the effect of lead on the IQ of children was the Pooled Analysis. See EPA, *Integrated Science Assessment for Lead (Draft)*, p. 5-46 (2011). In October 2011, the National Toxicology Program ("NTP") issued its "Draft NTP Monograph on Health Effects on Low-Level Lead." In that paper, the NTP relied upon the Pooled Analysis, among other things, to conclude that there is "sufficient evidence that blood Pb levels < 10 µg/dL in children are associated with decreases in full-scale IQ (FSIQ) score" NTP Draft Monograph at 20. In fact, the

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and policy issues raised by the Pooled Analysis, including those cited in your prior editorial on the issue, Brown & Rhoads, *Responding to Blood Lead Levels < 10 µg/dL*, *Env'tl Health Persp.*, Vol. 116, p. A-60-61 (2008), and Dr. Ernhart's observations, *See Env'tl Health Persp.* Vol. 114(2) A85 (2006), could not be investigated further. However, four years ago, my colleagues initiated litigation under the Freedom of Information Act and the Shelby Amendment to obtain the Pooled Analysis data. In response, the federal government (which funded the study) indicated that Dr. Lanphear refused to turn over the data no fewer than six times and deemed his actions "recalcitrant." Finally, earlier this year, my colleagues prevailed in this litigation and obtained the data. The data is now also in the hands of other FOIA requestors and the EPA.

We have had the opportunity to conduct preliminary analyses of the data. Our initial review confirms many of Dr. Ernhart's concerns and strongly suggests that the Pooled Analysis, as reported by Dr. Lanphear, may not be a reliable basis for addressing the question of effects on children's IQ below lead levels of 10 µg/dL. In particular, our preliminary analyses indicate several areas of concern, for example:

- **Unsubstantiated selection of the reported independent variable.** Although Dr. Lanphear calculated four separate blood lead measures for his subjects (early childhood average, peak, lifetime average, and concurrent), he reported results for only concurrent lead levels because, he claimed, concurrent lead levels showed the strongest relationship. However, analysis of the data show that early childhood average lead actually had the strongest relationship with IQ over the entire sample.
- **Most results do not confirm a statistically significant relationship.** Dr. Lanphear discusses four separate blood lead measures for two different subgroups: less than 10 µg/dL and less than 7.5 µg/dL. This creates eight possible analyses that might yield a significant relationship between blood lead levels and IQ. Only one, concurrent lead level for the less than 7.5 µg/dL subgroup, achieved statistical significance.
- **Childhood ingestion appears to be less important than previously thought.** Contrary to prior statements, ingestion during the "formative" years for children does not appear to be associated with later IQ.

(continued...)

NTP Draft goes on to conclude that the evidence remains "sufficient" at blood lead levels less than 5 µg/dL. Id. at XVI, Table 1.

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- **The Pooled Analysis was driven by the Rochester cohort.** The ostensible purpose of the Pooled Analysis was to use a larger group to “confirm” a relationship observed in the Rochester cohort and published in 2003. However, Rochester subjects included in the Pooled Analysis comprised 42% of the subjects in the less than 10 µg/dL group and 67% of the less than 7.5 µg/dL group. When the Rochester subjects were removed from the analysis of these low lead level subgroups, the one previously significant association between blood lead and IQ disappeared.
- **The “Effect” seen is implausibly large.** In the one analytical sample where a significant relationship between IQ and blood lead existed (concurrent blood lead less than 7.5 µg/dL), the relationship observed predicted that an increase of 1 µg/dL of blood lead would correspond to a loss of approximately 3 IQ points. Children with an elevation in blood lead from 1 - 7.5 µg/dL would be expected to lose approximately 19 IQ points.
- **Omission of an important and acknowledged confounder.** In each study done on his Rochester cohort, Dr. Lanphear and colleagues have found the income of the family to be an important covariate that attenuates the relationship between lead and IQ. In the Pooled Analysis, Dr. Lanphear did not use income (or any income proxy) as a covariate because data were not present for all of the studies. The effect of this omission would be to artificially strengthen the lead effect in the Rochester cohort which already dominated the analysis.

In light of these observations, the Pooled Analysis does not seem to be a sound basis for public policy or significant changes in lead guidance. As such, we are writing to you now to express our view that your Committee should not take action to address low lead level effects until further study of the Pooled Analysis is completed.

These data are being relied upon, perhaps unwittingly, by not only ACCLPP, but NTP, EPA and other federal, state, and international panels. The impact of this potentially misplaced reliance has far-ranging effects including changes to policies and regulations involving blood lead reference levels, air quality standards, US Housing and Urban Development and EPA clean-up levels, definitions of “lead poisoning,” childhood blood lead screening, and intervention levels.

In order to confirm that our findings were of sufficient import to bring to the attention of the ACCLPP, we contacted Dr. Helena Kraemer, a biostatistician and Professor Emerita at Stanford University. She is a Fellow of the American Statistical Association and of the American College of Neuropsychopharmacology and the author of more than 300 papers and four

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books, many of which address scientific research design and analysis issues. Dr. Kraemer has no previous involvement in issues related to lead.

Dr. Kraemer has agreed to let us share her preliminary assessment of Dr. Lanphear's analysis. She finds that the conclusions in the Pooled Analysis regarding low level lead effects on IQ as analyzed are unfounded. Although Dr. Kraemer has not had an opportunity to conduct a full analysis, her preliminary review reinforces and extends our concerns.

By this letter, I request the opportunity to meet with you to discuss these matters further so that you might be able to share them with other members of the ACCLPP. I look forward to hearing from you in advance of the ACCLPP meeting in January.

Sincerely,

A handwritten signature in black ink that reads "Cynthia D. Driscoll". The script is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Cynthia D. Driscoll, PhD, JD

cc: Mary Jean Brown, ScD, RN