EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMY K. POHL, an individual,

Plaintiff,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*.,

Defendants.

Civil Action No. 2:09-01480-WLS

ELECTRONICALLY FILED

DECLARATION OF PAM WIGINGTON

I, Pam Wigington, hereby declare and state:

1. I am the Freedom of Information Act (FOIA) coordinator for the Division of Emergency and Environmental Health Services (EEHS) in the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services (HHS). I have held this position since September 2004. I make this declaration in support of HHS's Opposition to Plaintiff's Motion for Attorneys' Fees in this proceeding. I make the following statements based upon my personal knowledge and information made available to me in my official capacity.

2. As the EEHS FOIA coordinator, I process incoming FOIA requests related to EEHS and work with branch and division staff to provide responses.

I. Receipt of the Jones Day Request

3. On June 12, 2008, the CDC FOIA office logged the August 9, 2007, request of Amy Pohl/Jones Day into its FOIA database, assigning it FOIA number 08-01169. The request was addressed to the U.S. Environmental Protection Agency (EPA). A true and correct copy of the request is attached as Exhibit A.

4. Additionally, attached to the request when I received it from the CDC FOIA Office was a January 26, 2007, memo from Zachary Pekar of EPA, and a February 14, 2008, letter from Kevin M. Miller, Assistant General Counsel at EPA. A true and correct copy of these documents is attached as Exhibit B.

5. The CDC FOIA Office also provided me with information relating to a letter it received dated May 29, 2008, from EPA with Ms. Pohl's request. This letter was addressed to a FOIA Officer at HHS, and referred Ms. Pohl's request to HHS for processing because a HHS grantee conducted the study which produced the records at issue. The CDC FOIA Office accepted the transferred request from EPA. A true and correct copy of this letter is attached as Exhibit C.

6. It is my understanding that the CDC FOIA Office sent Ms. Pohl an acknowledgment letter on June 17, 2008, which advised her about administrative details, provided the FOIA number, gave information about accessing the status of the request at any time on the CDC FOIA Office website, and requested more information/justification pertaining to the request for expedited processing. A true and correct copy of this document is attached as Exhibit D.

7. The request was then forwarded to my office (EEHS) for processing. On June 17, 2008, I personally received Ms. Pohl's request.

8. The request pertained to data produced under a project entitled "International Pooled Analysis of Lead-Exposed Cohorts." This project was incorporated into a report entitled "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" (EHP, Vol. 113, No. 7, July 30, 2007) by the grantee and cited by the Environmental Protection Agency (EPA) on its website, http//www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html.

9. It is my understanding that a denial of expedited processing response was sent to Ms. Pohl on June 30, 2008, along with a statement of her appeal rights. A true and correct copy of this document is attached as Exhibit E.

10. Also on June 30, 2008, I received a copy of the A-110 circular and spoke to the CDC FOIA office about this request. This was the first-ever A-110 request received by EEHS and so there was no policy or practice in place that instructed me how to process this request.

II. Initial Processing of the Jones Day Request

11. On July 9, 2008, I sent an e-mail request to a colleague at the EEHS Lead Poisoning Prevention Branch (LPPB) to determine the status of the FOIA request. LPPB was assisting with processing Plaintiff's request. I also inquired of the LPPB what funding CDC provided for the Cooperative Agreement, so that I could verify that Plaintiff's request satisfied the requirements of the A-110 circular. I also stated that we needed to ask the grantee how much it would cost to reproduce the data. A true and correct copy of this document is attached as Exhibit F.

12. On July 17, 2008, Samantha Harrykissoon, a fellow assigned to LPPB, was tasked with working the request. I asked Ms. Harrykissoon to determine the following:

a. what funding CDC provided for the Cooperative Agreement;
b. who the grantee was; and
c. how much it would cost the grantee to reproduce the data CDC paid for (estimates).

A. Initial Contact with Dr. Lanphear and Claim of Exemption

13. On or about July 21, 2008, Ms. Harrykissoon contacted Dr. Lanphear about Plaintiff's request. Dr. Lanphear was the Principal Investigator ("PI") on the CDC grant. In my division, the first point of contact about questions relating to Grant Awards is generally the PI, as named on the Notice of Grant Award. The PI is the "face" of the award and is closest to the information or data at issue. Furthermore, because the agency had questions regarding the amount of CDC funding that actually went toward the study at issue, the PI was the best person to specifically explain how the funding was accounted for. These questions stemmed from the funding acknowledgment in the article cited in the FOIA request: "This study was funded, in part, by the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency." Additionally, because the questions related to a specific data set, the PI was the person most likely to have an accessible copy of the data.

14. On July 21, 2008, I received a copy of the e-mail sent by Ms. Harrykissoon to Dr. Lanphear, informing him of a FOIA request for the study data and asking that Dr. Lanphear provide CDC with the amount of money received pursuant to the cooperative agreement and whether the funding was received directly from CDC or a

third party using CDC funds. A true and correct copy of this document is attached as Exhibit G.

15. Ms. Harrykissoon also provided a copy of Dr. Lanphear's response to her email. Dr. Lanphear responded that the funding from CDC "was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analysis." However, Dr. Lanphear also informed CDC in the response to Ms. Harrykissoon of the existence of a confidentiality agreement which prohibited release of the requested data under FOIA. A true and correct copy of this document is attached as Exhibit H.

16. Based on Dr. Lanphear's comments, I further investigated the issue of CDC funding. I determined the study combined and analyzed existing data sets from seven prospective international studies of children who had low blood lead levels. On July 25, 2008, we received the Notice of Grant Award showing that Dr. Lanphear received funding from CDC to conduct the analysis of these data. Pursuant to 45 C.F.R. § 74.36(d)(1), we proceeded to process the request.

B. Second Contact with Lanphear and Request for Confidentiality Agreement

17. On July 22, 2008, Ms. Harrykissoon responded to Dr. Lanphear's email and requested that he provide a copy of the confidentiality agreement. A true and correct copy of this document is attached as Exhibit I.

18. Dr. Lanphear responded on July 22, 2008, informing us that Jones Day, the law firm that filed the FOIA request, already had a copy of the confidentiality agreement. A true and correct copy of this document is attached as Exhibit J.

19. On or about July 22, 2008, Ms. Harrykissoon responded to Dr. Lanphear stating that CDC still needed to receive a copy of the confidentiality agreement. A true and correct copy of this document is attached as Exhibit K.

20. On July 23, 2008, I received a status report from Ms. Harrykissoon, stating that she had yet to hear back from Dr. Lanphear in response to a request for the confidentiality agreement. A true and correct copy of this document is attached as Exhibit L.

21. On July 30, 2008, I determined Dr. Lanphear had moved to Canada and was now affiliated with Simon Fraser University in Vancouver, British Columbia, Canada. CDC's efforts to obtain the data were frustrated by the fact that Dr. Lanphear had left the United States and CCHMC.

C. Contact with Cincinnati Children's Hospital Medical Center

22. On July 30, 2008, Ms. Harrykissoon called Connie Hopkins, Compliance Officer at CCHMC'S Research Division. CCHMC was Dr. Lanphear's employer at the time he received the CDC grant and the sponsoring institution on the CDC grant. Ms. Harrykissoon informed the CCHMC of a FOIA request for the study data and Dr. Lanphear's response. Ms. Harrykisson then followed up on this conversation by email, memorializing the conversation and requesting a copy of the confidentiality agreement. A true and correct copy of this document is attached as Exhibit M.

23. On August 12, 2008, Ms. Harrykissoon followed up by email with Ms. Hopkins at CCHMC. That same day, Ms. Hopkins emailed Ms. Harrykissoon to inform her that CCHMC located a box of grant records from the time of the CDC grant in an off-

site storage area and would review it as soon as it was received from storage. A true and correct copy of this document is attached as Exhibit N.

24. On August 19, 2008, Ms. Hopkins at CCHMC provided Ms. Harrykissoon with the information CCHMC located, but it did not include the confidentiality agreement or the data.

D. Third Contact with Dr. Lanphear

25. On or about August 27, 2008, the CDC Office of the General Counsel sent a letter to Dr. Lanphear at his office in Canada. That letter informed Dr. Lanphear that the research data at issue "is subject to OMB Circular A-110 and 45 C.F.R. section 74.36(d)." Furthermore, that letter informed Dr. Lanphear that "you are required to provide CDC with the research data so that the agency may be responsive to the FOIA request." A true and correct copy of this document is attached as Exhibit O.

26. On September 29, 2008, Dr. Lanphear responded to the August 27 letter via email. Dr. Lanphear stated that "the investigators provided the raw data with the stipulation that it would not be released or used for any other reason than the pooled analysis unless additional approval was sought and obtained from each investigator." Dr. Lanphear also attached an email from May 28, 2004, stating such an agreement. A true and correct copy of these documents is attached as Exhibit P.

E. Fourth Contact with Dr. Lanphear and Contact with Other Research Investigators

27. After Dr. Lanphear's response, the CDC FOIA Officer advised me to contact all the researchers involved in the study, including Dr. Lanphear, to get their

approval for release of the data. On October 24, 2008, I sent letters to all seven investigators and to Dr. Lanphear using Federal Express. An example of one such document is attached as Exhibit Q. I could not confirm that the package arrived in Mexico, and the University of South Carolina could not find Dr. Ernhart, so her package was returned to me.

28. On November 3, 2008, I received a response from one of the other seven researchers, Dr. Peter Baghurst. Dr. Baghurst stated that the "data you were seeking were not obtained using CDC funds" and therefore that the data was not subject the federal regulations at issue. Dr. Baghurst did not give permission to access his data. Dr. Baghurst's statement is accurate: The seven researchers had their own data that were not paid for by CDC. A true and correct copy of this document is attached as Exhibit R.

29. On or about November 3, 2008, one of the other seven researchers, Dr. Kim Dietrich, faxed me correspondence between Dr. Dietrich's attorney and Jones Day attorney Thomas S. Jones. That letter stated that Jones Day had subpoenaed Dr. Deitrich's data in 2006. That letter also stated that Dr. Dietrich's attorney had provided the data to Jones Day in 2006. A true and correct copy of this document is attached as Exhibit S.

30. On November 10, 2008, I received a response from one of the other seven researchers, Dr. Richard Canfield. Dr. Canfield stated that he was told by Dr. Lanphear that Dr. Lanphear had already provided CDC with the data. Also on November 10, 2008, I replied to Dr. Canfield informing him that Dr. Lanphear had not provided the data to CDC. A true and correct copy of these documents is attached as Exhibit T.

31. I did not receive any additional responses.

F. Fifth Contact with Dr. Lanphear

32. On November 13, 2008, I sent an e-mail to Dr. Lanphear. In that email, I asked him to confirm whether he was contending that the confidentiality agreement placed the data within an exception to the regulatory definition of "research data" 45 C.F.R. § 74.36(d)(2)(i)(A). Specifically, I asked him whether he was claiming that his data was trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected by law. A true and correct copy of this document is attached as Exhibit U.

33. Having received no response, on December 11, 2008, I sent a follow up e-mail to Dr. Lanphear, again requesting his response. A true and correct copy of this document is attached as Exhibit V.

34. On December 11, 2008, Dr. Lanphear responded via email, and contended that the exception to the definition of "research data" found in 45 C.F.R. § 74.36(d)(2)(i)(A) did apply to the requested data. A true and correct copy of this document is attached as Exhibit W.

III. CDC's Final Decision

35. The CDC FOIA Office advised me that Jones Day contacted CDC to inquire about the status of the request by letter dated December 2, 2008. A true and correct copy of this document is attached as Exhibit X.

36. The CDC FOIA Office advised me that CDC provided a "final response" to this request by letter dated December 16, 2008. That letter stated that CDC "staff

contacted the grantee regarding the availability of the data. The grantee's response is a claim of exclusion for the compiled dataset pursuant to 45 C.F.R. 36(d)(2)(i)(A)." A true and correct copy of this document is attached as Exhibit Y.

IV. Appeal of CDC's Decision

37. I was advised by the FOIA Office that Jones Day appealed the CDC decision by letter dated January 9, 2009. A true and correct copy of this document is attached as Exhibit Z.

A. Sixth Contact with Dr. Lanphear

38. After the FOIA Office received Jones Day's appeal, on February 20, 2009, CDC's Assistant General Counsel again contacted Dr. Lanphear. CDC informed Dr. Lanphear of Jones Day's appeal and stated that Jones Day argued that "the confidentiality agreement you entered into does not meet the criteria for the exclusion you claim." CDC also asked Dr. Lanphear to review his claim that the data was not "research data" within the meaning of the regulation and respond to Jones Day's argument. A true and correct copy of this document is attached as Exhibit AA.

39. My office did not receive any further response from Dr. Lanphear.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 28, 2011.

Pam Wigington
Health Communications Specialist

EXHIBIT

A

Wigington Declaration **EXHIBIT A**

To: NCEH/ATSDR

Request No.: 08-01169-FOIA

Requestor: Amy Pohl

Address/Affiliation: Pittsburgh, Pennsylvania Jones Day

Date Received: June 12, 2008 Due Date: July 9, 2008

Subject: documents related to grant awards titled International pooled analysis of lead-exposed cohorts for 2000/01 and 2001/02

Category: Commercial Organization

This letter authorizes your office to search for responsive documents for the attached request under the Freedom of Information Act. When documents are located please return as well as any instructions to our office. **IF THIS REQUEST SHOULD BE FORWARDED TO ANOTHER C/I/O FOR PROCESSING, PLEASE INFORM THE FOIA OFFICE.**

- Actual cost of fulfilling request -

To be completed by Program Staff - Please note time and grade of persons doing research

Invoiced Fees

	Time & Grade	Hourly Wage	Total
Read/Interpret Request...			
Clarifying/Negotiating...			
Searching for Records...			
Computer-based Data...			
Review/Edit/Delete...			
Materials...			
Other (specify) ...			

Are any responsive records covered by an assurance of confidentiality? Yes ___ No ___

Copying @ 10 cents per page

No. of pages _____ x .10 = _____ x No. of sets _____ = _____

To be completed by FOI Staff -

	Quantity	Unit Cost	Total
Logging/Tracking...			
Consultation...			
Clarifying/Negotiating...			
Review/Edit/Delete...			
Compose/Type Response...			
Other (specify) ...			

Copying @ 10 cents per page

No. of pages _____ x .10 = _____ x No. of sets _____ = _____

Mailing Costs: Postage: _____ Packaging: _____

Special Handling: _____ Other: _____

CDC 0.632 Rev.3/01 -- IF YOU HAVE QUESTIONS, PLEASE CALL THE FOI OFFICE AT P.I.

Wigington Declaration EXHIBIT A

~~FOIA~~ FOIA
6/12-7/3/08

JONES DAY

500 GRANT STREET • SUITE 3100 • PITTSBURGH, PENNSYLVANIA 15219-2502
TELEPHONE: 412-391-3939 • FACSIMILE: 412-394-7959

Direct Number: (412) 394-7263
akpohl@jonesday.com

JP420391/1162108v1
589170-096075

August 9, 2007

VIA FEDERAL EXPRESS

U.S. Environmental Protection Agency
National FOIA Officer
U.S. EPA, Records
FOIA & Privacy Branch
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: Freedom of Information Act ("FOIA") Request For Research Data Pursuant To 5 U.S.C. § 552, *et seq.* and 2 C.F.R. Part 215.36
EXPEDITED PROCESSING REQUESTED

Dear Sir or Madam:

This request for data is submitted pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, et seq. and the Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other non-Profit Organizations (OMB Circular A-110), at 2 C.F.R. Part 215.36.

The undersigned requests certain data related to and/or reported in the following report published by the Environmental Protection Agency ("EPA"): Lead Human Exposure And Health Risk Assessments For Selected Case Studies (July 30, 2007); and in the January 26, 2007 letter to Lead NAAQS Docket from Zachary Pekar (EPA OAQPS) regarding "Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implications for Pilot Risk Assessment." A copy of the report and supporting appendices, as well as the January 26, 2007 Correction notice, are published on the EPA's web site, at: *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html*

Kindly treat this FOIA request as a request for **expedited processing**. There is a compelling need for the information on an expedited basis. The data and information requested are needed for several pending civil litigation matter. Our client's constitutional due process rights to full cross examination of opposing expert witnesses may be impaired unless access to the requested data is provided in an expedited manner. In addition, it is necessary for us to have access to the data requested in this letter on an expedited basis so that we may meaningfully assess the report within the applicable public comment period set by the EPA. Expedited processing should be relatively easy and inexpensive as well -- because the data requested in this letter most likely exists in electronic format, the data may be easily transferable onto a disk or through email, with minimal effort or expense for the EPA.

JONES DAY

The above-cited report was drafted by the EPA in conjunction with ICF International, a recipient of federal funding, through Contract No. EP-D-06-115 and/or EP-D-06-115. Under FOIA, the EPA is required to provide access to the data requested below. None of the exemptions to disclosure set forth in FOIA (5 U.S.C. § 552(b)) preclude access to the data requested in this letter. In the event that the EPA does not possess the data requested in this FOIA letter, then the EPA is required to obtain all data requested in this FOIA letter from ICF International and to make the data available to the undersigned, under 2 C.F.R. Part 215.36(d). ICF International's Headquarters are located at 9300 Lee Highway, Fairfax, VA 22031, Phone (703) 934-3000; Fax (703) 934-3740.

The following data is requested:

1. A copy of all data related to the following study in the EPA report: Lanphear, *et al.*, "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," *Environmental Health Perspectives*, 113(7) (2005). The Lanphear, *et al.* 2005 study is identified at length in the EPA report. *See, e.g.*, Lead Human Exposure And Health Risk Assessments For Selected Case Studies (July 30, 2007), Section 4, pages 4-1 to 4-42; *see also, e.g.*, Appendix Sections G, H, J, L, M (citing Lanphear, et al. 2005 study throughout). It is apparent that EPA, in conjunction with ICF, utilized the data gathered by Lanphear et al. to provide its risk assessment model found in the EPA report. We note that EPA published a correction to Lanphear's study based upon its own review of the data on January 26, 2007. In addition, the underlying study was funded in part by the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention and the United States Environmental Protection Agency. As such, the data are available for public receipt.

2. A copy of the data collection forms and any software programs required to access and analyze the data identified in paragraph 1 in its computerized form, and

3. The data dictionaries for the raw data identified in paragraph 1.

The above-listed data and information should be provided in electronic, machine readable format, if available. It is our belief that the data should be readily accessible, easy to download on to storage media such as a CD or DVD and would be neither difficult nor time consuming to obtain. To the extent that the data contains subject names or other identifying information, we are willing to receive the data in a format without subject identifiers. Further, we are willing to pay a reasonable fee to obtain and/or produce the data requested. Please contact me with an estimate of the fee for this FOIA request.

We have copied Dr. Zachary Pekar, EPA Office of Air Quality Planning and Standards, on this FOIA letter, as Dr. Pekar is identified in the above-cited report as the contact person for questions and comments to the report. Dr. Pekar is likely to have access to the information requested in this FOIA letter, or information to permit the EPA to access the data requested from ICF International. The Lanphear, et al. data is addressed in the EPA's report, and it is apparent

JONES DAY

that the EPA authors and/or ICF International had access to some or all of the raw data from the Lanphear, *et al.* 2005 study. Further, in his letter dated January 26, 2007 (copy attached for convenience and also available at *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html*), Dr. Pekar referenced corrections in the 2005 Lanphear, et al. data, which further indicates that the EPA has access to or has the ability to obtain the raw data from the Lanphear, et al. study requested in this FOIA letter.

In the event you decline to comply with this FOIA request, please issue a written explanation detailing the reasons for your decision.

Please contact me with any questions. My telephone number is 412-394-7263.

Very truly yours,

Amy K. Pohl

cc: Dr. Zachary Pekar
U.S. Environmental Protection Agency
Office of Air Quality Planning & Standards
Mail Drop C504-06
Research Triangle Park, NC 27711
(via Fax: P.I.I. *and email:* P.I.I. *)*

EXHIBIT

B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
HEALTH AND ENVIRONMENTAL IMPACTS DIVISION
RESEARCH TRIANGLE PARK, NC 27711

January 26, 2007

TO: Lead NAAQS docket
FROM: Zachary Pekar (EPA OAQPS)
SUBJECT: Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implications for Pilot Risk Assessment

EPA has identified an error in the study titled "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis", (EHP, vol 113, No. 7, July, 2005). The error involves blood lead concentration ranges presented in Table 4 of the article. We have since received a corrected copy of Table 4 from Dr. Lanphear (presented below).

Values from the original Table 4 of the Lanphear et al. 2005 study were used in the pilot risk assessment. Specifically, two of the erroneous values in Table 4 (5th percentile concurrent and lifetime average blood Pb values) were used in deriving the cutpoints used in the pilot analysis. Consequently, these errors in Table 4 have an impact on our reported risk estimates, including those based on the concurrent and lifetime average blood Pb metrics. Specific results affected in the First Draft Staff Paper (December 2006) include those in Tables 4-13 through 4-17 (risk results) and Table 4-19 (sensitivity analysis results). Specific results tables affected in the supporting draft technical report ("Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas", December 2006) include Exhibits 6-1, 6-2, 6-4, 6-5 and 6-7 (risk results) and Exhibit 6-24 (sensitivity analysis results). In addition, Exhibits J-1 through J-5, the detailed risk results tables in the appendix to the risk assessment report, are also impacted.

The degree to which errors in Table 4 of the Lanphear et al. 2005 study impact pilot risk results is not clear without rerunning the risk analysis for both the concurrent and lifetime average blood Pb metrics. Assuming that the Table 4 values would play a role in the pending full-scale risk assessment, the corrected values would be used and reflected in those results.

Corrected Table 4 from Lanphear et al., 2005. *Corrected values are highlighted.*
(Note, corrected table obtained from Dr. Bruce Lanphear in a January 10th, 2007 e-mail)

Table 4: Mean Unadjusted and Adjusted Changes in Full Scale IQ Score associated with an Increase in Blood Lead Concentration (log scale), from the 5th to 95th percentile of the concurrent blood lead level at the time of IQ testing.

	Unadjusted Estimates	Adjusted Estimates	Blood Lead Concentration	IQ Deficits
Blood Lead Variable	β (95% CI)	β (95% CI)	5th to 95th %ile (µg/dL)	5th to 95th %ile (95% CI)
Early Childhood	-3.57 (-4.86, -2.28)	-2.04 (-3.27, -0.81)	4.0 - 34.5	4.4 (1.7, 7.0)
Peak	-4.85 (-5.16, -3.54)	-2.85 (-4.10, -1.60)	6.2 - 47.0	6.1 (3.4, 8.8)
Lifetime Average	-5.36 (-6.69, -4.03)	-3.04 (-4.33, -1.75)	4.1 - 34.8	6.2 (3.6, 8.8)
Concurrent	-4.66 (-5.72, -3.60)	-2.70 (-3.74, -1.66)	2.5 - 33.2	7.1 (4.4, 9.8)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 14 2008

OFFICE OF
GENERAL COUNSEL

Amy K. Pohl
Jones Day
500 Grant Street, Suite 3100
Pittsburgh, PA 15219-2502

Re: Freedom of Information Act Appeal HQ-RIN-01843-07 (HQ-APP-00009-08)

Dear Ms. Pohl:

I am responding to your October 18, 2007 Freedom of Information Act ("FOIA") appeal. You appealed the September 21, 2007 decision of Kelly Rimer for Stephen D. Page, Director, Office of Air Quality Planning and Standards, Office of Air and Radiation ("decision") of the U.S. Environmental Protection Agency ("EPA" or "Agency"), to deny the request you submitted to EPA on August 9, 2007. Your request sought the data underlying the July 2005 federally funded study, "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," reported in Environmental Health Perspectives ("Study"). The decision stated that your request was denied because (1) the Agency does not have the underlying data, and (2) because the draft report, "Lead Human Exposure and Health Risk Assessment for Selected Case Studies" ("Report"), which cites the Study, does not have the "force and effect of law" as required by 40 C.F.R. § 30.36. The decision also indicates that the Report in final form would not satisfy the "force and effect of law" requirement.

I have carefully considered your request, EPA's decision, and your appeal. For the reasons set forth below, I have determined that your appeal should be, and is granted in part and denied in part.

You assert in your appeal that EPA has not conducted a proper search for records responsive to your request. After receiving your appeal, I have confirmed that the Agency conducted a reasonable search for records responsive to your request, and am confident that the Agency does not have the requested data.

You also assert that Office of Management and Budget's ("OMB's") regulation at 2 C.F.R. § 215.36 requires the EPA to obtain a copy of the data and release the data under FOIA.[1] The Agency's regulation at 40 C.F.R. § 30.36(d)(1) states that "in response to a Freedom of Information Act (FOIA) request for research data relating to published

[1] EPA's version of the OMB regulation is found at 40 C.F.R. § 30.36.

research findings produced under an award that were used by the Federal government in developing an agency action that has the force and effect of law, the EPA shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA." "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined in the regulation as "when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law."

The original determination was correct that use of the Study in the Report does not obligate EPA to obtain the data underlying the study pursuant to 40 C.F.R. § 30.36(d)(1). However, since the time of that determination EPA has issued an Advance Notice for Proposed Rulemaking ("ANPR") for the lead National Ambient Air Quality Standards (NAAQS) revision (Federal Register publication December 12, 2007) which cited the Study in presenting and soliciting comment on evidence and risk-based considerations and regulatory options for the Administrator's review of the lead NAAQS. Furthermore, by court order, the Agency must, *inter alia*, issue its Proposed Rule for the lead NAAQS revision by May 1, 2008. In light of all of these facts and circumstances, I have determined that your request satisfies the requirement of 40 C.F.R. §30.36 and therefore, your appeal is granted on this ground.

In accordance with EPA's regulations, EPA will proceed to process your request in accordance with 40 C.F.R. § 30.36(d)(1), contact the grant recipient, and will request an estimate of fees for responding to your request. Per your original request, EPA will contact you with an estimate of fees before proceeding further.

This letter constitutes EPA's final determination on your appeal. In accordance with 5 U.S.C. § 552(a)(4)(B), you have the right to seek judicial review of this determination by instituting an action in the district court of the United States in the district in which you reside, or have your principal place of business, or in which the Agency records are situated, or in the District of Columbia.

Should you have any questions concerning this matter, please call Sara E. McGraw, at P.I.I.

Sincerely,

Kevin M. Miller
Assistant General Counsel
General Law Office

cc: HQ FOI Office

EXHIBIT C

Wigington Declaration **EXHIBIT C**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

MAY 29 2008

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

Mr. Robert Eckert
Freedom of Information Officer
U.S. Department of Health and Human Services
Mary E. Switzer Building, Room 5416
300 C Street, S.W.
Washington, D.C. 20201

Re: Freedom of Information Act Request EPA RIN-01843-07 – HQ-APP-00009-08

Dear Mr. Eckert:

I am referring the enclosed Freedom of Information Act request for processing by the U.S. Department of Health and Human Services (HHS). The request was submitted by Ms. Amy Pohl to the U.S. Environmental Protection Agency (EPA) pursuant to 5 U.S.C. § 552 et seq. and 2 C.F.R. § 215.36 for data (as well as data collection forms, any necessary software programs, and data dictionaries) for the study reported in "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," Environmental Health Perspectives, (vol. 113, no. 7, July 2005). The study was conducted by a grantee who received a grant from HHS.

I am also enclosing EPA's final determination on appeal concerning this request. EPA determined that, in light of the facts and circumstances, the request satisfied the criteria under EPA's regulations that correspond to 2 C.F.R. § 215.36. After consultation with Patricia Mantoan, EPA believes that is appropriate for the granting agency to be the point of contact with the grantee and coordinate the response to the request. Since HHS appears to have been the primary source of federal funding for this study, EPA is referring the request to HHS.

If you need any further information, please contact me or you may contact Sherry Russell of my staff at P.I.I.

Sincerely,

Stephen D. Page
Director
Office of Air Quality Planning
and Standards

Enclosures

cc: Amy Pohl
Larry Gottesman
Kevin Miller
Patricia Mantoan
Susan Cornell
Lynn Armstrong

EXHIBIT

D

Wigington Declaration **EXHIBIT D**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 17, 2008

Amy Pohl
Jones Day
500 Grant St.
Suite 3100
Pittsburgh, PA 15219-2502

Dear Ms. Pohl:

This letter is in response to your Freedom of Information Act (FOIA) request of August 09, 2007.

Your request has been received by the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) and will be sent to the area(s) which may have pertinent records. Program officials will initiate a search, and we will provide a copy of all releasable agency records as quickly as possible. All requests are handled on a first-in, first-out basis.

The FOIA sets out the standard for expedited processing requests at 5 U.S.C. 552(a)(b)(E). Your request for expedited processing asserts a due process interest, but does not provide sufficient information for this agency to make a determination. The due process interest must be substantial. Thus, a need for the information for use in civil proceedings has generally been held to be insufficient to require expedition. NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 243 (1978) (witnesses statements need *not* be released prior to an unfair labor practice hearing because "FOIA was not intended to function as a discovery tool"). If you believe your request rises to the level of a substantial due process interest, please provide further information to this office.

Your request has been assigned #08-01169-FOIA. You may check on the status of your case by going to our FOIA webpage at http://www2a.cdc.gov/od/foiastatus and entering this number. The fiscal year is the first two numbers and the request ID is the second set of numbers.

There may be a charge for processing your request.

Sincerely,

Freedom of Information Act Office
Office of the Chief Information Officer
[redacted] P.I.I.

EXHIBIT

E

Wigington Declaration EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 30, 2008

Amy Pohl
500 Grant Street
Suite 3100
Pittsburgh, Pennsylvania 15219-2502

Dear Ms. Pohl:

This letter is in response to your Freedom of Information Act (FOIA) request of August 09, 2007 pertaining to documents related to grant awards titled International pooled analysis of lead-exposed cohorts for 2000/01 and 2001/02.

Under the criteria set forth in the Freedom of Information Act, agencies may grant expedited processing of requests if the requester demonstrates a "compelling need." A requester can show "compelling need" in one of two ways: (1) by establishing that his or her failure to obtain the records quickly "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual"; or (2) if the requester is a "person primarily engaged in disseminating information," by demonstrating that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists.

Granting a request expedited processing gives that request priority over other requests, by moving that request ahead of others and correspondingly delaying the processing of earlier requests. Our review indicates that your request does not demonstrate a compelling need." The compelling standard is "intended to be narrowly applied." Al-Fayed v. CIA, 254 F.3d 300,310 (D.C.Cir.2001).

We carefully considered your request for "expedited" service but determined that the failure to obtain records quickly could not reasonably be expected to pose an imminent threat to the life or physical safety of an individual, that it is not of "current exigency," nor is it a matter of widespread and exceptional media or public interest. Therefore, the information requested does not meet the criteria set forth under the Act. While we are denying your "expedited processing" request, we are continuing to process your request.

You have the right to appeal this decision. Should you wish to do so, send your appeal, within 30 days from the date you receive this letter, to the Deputy Assistant Secretary for Public Affairs (Media), U.S. Department of Health and Human Services, Rm. 17A-46, 5600 Fishers Lane, Rockville, Maryland 20857. **Please mark both your appeal letter and envelope "FOIA Appeal.**

Sincerely yours,

Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of the Chief Information Officer

P.I.I.

08-01169-FOIA

EXHIBIT

F

Wigington Declaration EXHIBIT F

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Wednesday, July 09, 2008 7:44 AM
To: Brooks, Barry (CDC/CCEHIP/NCEH)
Subject: FW: Memo - Request for Documents 08-01169
Attachments: Memo - Request for Documents 08-01169.doc; Request Description.tif

Hi, Barry,

How is it going on this FOIA? (International pooled analysis of lead-exposed cohorts for 2000/01 and 2001/02)?

We need to find out what CDC paid for and go to the grantee and ask how much it will cost to reproduce those data.

(Estimates only at this point, not the data.)

THANKS!

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Dowling, Audrey (ATSDR/OPPE)
Sent: Wednesday, June 18, 2008 2:34 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Memo - Request for Documents 08-01169

Hi Pam, I really was not trying to send you anything:-) Please see below email from the FOIA office before processing this request.

Thanks,
Audrey L Dowling
NCEH/ATSDR/OPPE
Centers for Disease Control
MS: F61
P.I.I.

-----Original Message-----
From: FOIA Requests (CDC)
Sent: Tuesday, June 17, 2008 3:14 PM
To: Dowling, Audrey (ATSDR/OPPE)
Subject: Memo - Request for Documents 08-01169

Wigington Declaration EXHIBIT F

Request for Documents for Case # '08-01169-FOIA'. Due date: July 09, 2008. Program must speak with Lynn Armstrong before processing this request. The second study cited in the second paragraph applies to CDC.

EXHIBIT

G

Wigington Declaration EXHIBIT G

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Monday, July 21, 2008 10:01 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

FYI

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted] P.I.I.
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Phone: [redacted] P.I.I.
Fax: [redacted] P.I.I.

Wigington Declaration EXHIBIT G

Email: P.I.I.

EXHIBIT H

Wigington Declaration EXHIBIT H

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Monday, July 21, 2008 10:01 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

FYI

-----Original Message-----
From: Bruce Lanphear [redacted]
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted]
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Phone: [redacted]
Fax: [redacted]

Wigington Declaration EXHIBIT H

Email: P.I.I.

EXHIBIT

I

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 9:02 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

FYI

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Tuesday, July 22, 2008 9:00 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Samantha:

If the legal firm that is requesting the agreement is Jones Day or if they were involved in the RI lead suit, they already have a copy of the agreement. It is also part of the official records of the RI suit.

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted] P.I.I.
>>> 07/22/08 8:19 AM >>>
Hi Bruce,

Would it be possible for you to send us a copy of the agreement that was made with the investigators to not share the data for our records?

Thanks in advance,

Samantha

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted]
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

[redacted]

EXHIBIT

J

Wigington Declaration EXHIBIT J

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 9:02 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

FYI

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Tuesday, July 22, 2008 9:00 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Samantha:

If the legal firm that is requesting the agreement is Jones Day or if they were involved in the RI lead suit, they already have a copy of the agreement. It is also part of the official records of the RI suit.

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted] P.I.I.
>>> 07/22/08 8:19 AM >>>
Hi Bruce,

Would it be possible for you to send us a copy of the agreement that was made with the investigators to not share the data for our records?

Thanks in advance,

Samantha

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted] P.I.I.
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

P.I.I. [redacted]

EXHIBIT

K

Ford, Kenya S. (CDC/OCOO/OGC)

From: Harrykissoon, Samantha (CDC/OD/OADP)
Sent: Tuesday, July 22, 2008 10:05 AM
To: 'Bruce Lanphear'
Subject: RE: Urgent CDC request

Hi Bruce,

The copy of the agreement is not for the law firm but for our FOIA office to retain in their records.

Thanks,

Samantha

-----Original Message-----
From: Bruce Lanphear [redacted P.I.I.]
Sent: Tuesday, July 22, 2008 9:00 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Samantha:

If the legal firm that is requesting the agreement is Jones Day or if they were involved in the RI lead suit, they already have a copy of the agreement. It is also part of the official records of the RI suit.

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted P.I.I.]
>>> 07/22/08 8:19 AM >>>
Hi Bruce,

Would it be possible for you to send us a copy of the agreement that was made with the investigators to not share the data for our records?

Thanks in advance,

Samantha

-----Original Message-----
From: Bruce Lanphear [redacted P.I.I.]
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" [redacted]
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

[redacted]
P.I.I.
[redacted]
[redacted]

EXHIBIT

L

Wigington Declaration EXHIBIT L

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Wednesday, July 23, 2008 2:43 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: Re: Urgent CDC request

Hi Pam

I still have not heard back from Bruce after I requested a copuy for his data agreement but it sound that PGO will be able to track down the contract now that you have the grantee number.

Sam

Sent using BlackBerry

----- Original Message -----
From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
To: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Cc: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Wed Jul 23 09:37:49 2008
Subject: RE: Urgent CDC request

No, I haven't. I was waiting to see whether the info I found would be useful.

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. P.I.I.
e-mail: P.I.I.
cell: P.I.I.

-----Original Message-----
From: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Sent: Wednesday, July 23, 2008 8:39 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Cc: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

This is great - it has everything PGO or MASO would need to find it. CFDA is the Catalog of Federal Domestic Assistance and the grant number is on his spreadsheet. Have you spoken with anyone at PGO? I was in the Healthy Homes meeting yesterday.

Joy Gulliksen
Public Health Analyst
CDC/NCEH/EEHS/LPPB
Phone: P.I.I.
Fax: P.I.I.

-----Original Message-----

Wigington Declaration EXHIBIT L

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 2:09 PM
To: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Cc: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

I was able to find some more info via the PGO Web site (I don't know who is in charge of coop agreements, but I guess PGO).

There's a link to HHS TAGGS (Tracking Accountability in Govt Grants), where I pulled up the attached. So now I have a CFDA number, but what's that? Do you know?

There's also an award number.

Does any of this help?

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. 9 [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 1:48 PM
To: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Cc: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Thanks, Joy. Do the proposal reviews state what the $$ is for? If so, that may be what we need at this point.

We're trying to determine what CDC paid for with this cooperative agreement.

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 1:46 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Cc: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Hi Pam,

This project began as an unsolicited proposal, was technically reviewed and awarded as a cooperative agreement to Children's Hospital Medical Center (I think it's in Cincinnati), for $42,140. Unfortunately since this was back in 2001 and probably only funded for 12 months, the file has long since been archived. PGO or MASO have the responsibility for permanently archiving/maintaining official files and should be the one to research this. I cannot find anything with a grant number which is how PGO tracks things. Also, I cannot remember if it was handled as an earmark since I don't think it was funded under our normal Program Announcement. I will ask our support group if we can retrieve the branch file. I vaguely remember that there really wasn't much in it. The only thing I can find electronically are the reviews of the proposal.

The Branch IV PGO people handling NCEH Cooperative Agreements are Tracey Coleman and Mildred Garner.

Joy Gulliksen
Public Health Analyst
CDC/NCEH/EEHS/LPPB
Phone: P.I.I.
Fax: P.I.I.

-----Original Message-----
From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 10:04 AM
To: Gulliksen, Joy (CDC/CCEHIP/NCEH)
Cc: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

Hi Joy,

I know you're super busy today but can you email Pam a contact person in PGO so that she can forward it on to the FOIA office.

Thanks in advance,

Sam

-----Original Message-----
From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 10:00 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Hi, Sam,

Answers to the two issues from this morning.

1. As I suspected, the FOIA office cannot contact Bruce. He needs to give us a copy of the agreement.

2. If Joy lets me know who she deals with in PGO, the FOIA office may be able to help with getting that information.

Thanks!

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 9:29 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: RE: Urgent CDC request

Also, I spoke to Joy this morning and she said it would be faster if the FOIA office got PGO to look up the grantee since they now know the grantee name and amount. Apparently PGO will look it up themselves if the request is from FOIA but won't do it for Joy so she would have to go to their office and look through the files. She's still going to try but I think the FOIA office should try also.

-----Original Message-----
From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 9:21 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

I am double-checking with the FOIA office, but I don't think they [the FOIA office] can contact him because he is not the FOIA requester. FOIAs are a lot of fun, I know. Each one is special in its own way. (You can thank Barry later!!)

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 9:15 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: RE: Urgent CDC request

I know but maybe the FOIA can send some sort of official request in writing to him.

-----Original Message-----
From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Tuesday, July 22, 2008 9:12 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Our FOIA office needs a copy of this. We do not have access to this information.

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health Division of Emergency and Environmental Health Services office phone: P.I.I. [Chamblee 106, room 6008]
e-mail: P.I.I.
cell: P.I.I.

Flexiplace phone: P.I.I. or P.I.I. (until 2:30 today)

-----Original Message-----
From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, July 22, 2008 9:02 AM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: Urgent CDC request

FYI

-----Original Message-----
From: Bruce Lanphear P.I.I.
Sent: Tuesday, July 22, 2008 9:00 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: Urgent CDC request

Samantha:

If the legal firm that is requesting the agreement is Jones Day or if they were involved in the RI lead suit, they already have a copy of the agreement. It is also part of the official records of the RI suit.

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" P.I.I.
>>> 07/22/08 8:19 AM >>>
Hi Bruce,

Would it be possible for you to send us a copy of the agreement that was made with the investigators to not share the data for our records?

Thanks in advance,

Samantha

-----Original Message-----
From: Bruce Lanphear P.I.I.
Sent: Monday, July 21, 2008 9:38 AM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: Urgent CDC request

Samantha:

It has been awhile and I am currently working out of boxes having recently relocated to Vancouver, BC. As I recall, it was somewhere between $10,000 to $30,000 to hold a workshop or conduct the analyses.

In the end, it doesn't really matter because the stipulation and agreement I had with the other investigators who shared their raw data was that the data would not be shared with any other party for any other reason. The legal firm who is requesting the data is aware of this because they have tried to get it through a court order, the US EPA and now the CDC.

Best regards,

Bruce

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" P.I.I.
>>> 07/21/08 9:15 AM >>>
Hi Bruce,

The Lead Poisoning Prevention Branch received a FOIA (Freedom of Information Act) request concerning your paper "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis" published in 2005. Your study was partially funded by CDC. If possible could you provide us with the amount of money that was received from CDC and whether this was a direct contract with the CDC or if you were funded by a third party with CDC funds. Any clarification on the funding process for you study will be helpful.

Thanks you in advance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Phone: P.I.I.
Fax: P.I.I.
Email: P.I.I.

EXHIBIT

M

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, August 12, 2008 3:31 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: CDC Grant request

Pam, FYI about the FOIA.

From: Connie Hopkin[redacted] P.I.
Sent: Tuesday, August 12, 2008 3:28 PM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: CDC Grant request

Samantha,

I have located the box with the grant information. This box is located at an off-site storage area. I have requested the information to be sent to my building. I should have this in the next day or two. This information goes back to a grant for the time period 9/30/2001-9/29/2002.

Connie

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" <[redacted] P.I. 8/12/2008 9:04 AM >>>

Hi Connie,

I'm following up to see if you were able to find any information or someone that may be able to help us answers the questions below.

Thanks for your assistance,

Samantha

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Wednesday, July 30, 2008 11:29 AM
To: 'connie.hopkins@cchmc.org'
Subject: CDC Grant request
Importance: High

Hi Connie,

Per our conversation this morning The CDC is trying to fulfill a FOIA (Freedom Of Information Act) request concerning funding given to Children's Hospital Medical Center.

Grantee: Children's Hospital Medical Center
3333 Burnet Ave
Cincinnati, OH 45229
Grant No R01/CC521049-01
Grant Period: 9/30/01 to 9/29/02
Title of Project: International Pooled Analysis of Lead-Exposed Cohorts
P.I. : Bruce P. Lanphear

We are looking for an agreement between Bruce Lanphear and the other investigators that the data would not be shared. In order to fulfill the FOIA request CDC needs a copy of this agreement.

Thanks for your assistance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Phone: P.I.I.
Fax: P.I.I.
Email: P.I.I.

EXHIBIT

N

Wigington Declaration EXHIBIT N

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Tuesday, August 12, 2008 3:31 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FW: CDC Grant request

Pam, FYI about the FOIA.

From: Connie Hopkins [P.I.I.]
Sent: Tuesday, August 12, 2008 3:28 PM
To: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: RE: CDC Grant request

Samantha,

I have located the box with the grant information. This box is located at an off-site storage area. I have requested the information to be sent to my building. I should have this in the next day or two. This information goes back to a grant for the time period 9/30/2001-9/29/2002.

Connie

>>> "Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)" <[P.I.I.]> 8/12/2008 9:04 AM >>>

Hi Connie,

I'm following up to see if you were able to find any information or someone that may be able to help us answers the questions below.

Thanks for your assistance,

Samantha

From: Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Sent: Wednesday, July 30, 2008 11:29 AM
To: 'connie.hopkins@cchmc.org'
Subject: CDC Grant request
Importance: High

Hi Connie,

Per our conversation this morning The CDC is trying to fulfill a FOIA (Freedom Of Information Act) request concerning funding given to Children's Hospital Medical Center.

Grantee: Children's Hospital Medical Center
3333 Burnet Ave
Cincinnati, OH 45229
Grant No R01/CC521049-01
Grant Period: 9/30/01 to 9/29/02
Title of Project: International Pooled Analysis of Lead-Exposed Cohorts
P.I. : Bruce P. Lanphear

We are looking for an agreement between Bruce Lanphear and the other investigators that the data would not be shared. In order to fulfill the FOIA request CDC needs a copy of this agreement.

Thanks for your assistance,

Samantha

Samantha Harrykissoon, JD, MPH
Policy Analyst/ORISE Fellow
Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Phone: P.I.I.
Fax: P.I.I.
Email: P.I.I.

EXHIBIT

O

Wigington Declaration **EXHIBIT O**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Public Health Division
CDC/ATSDR Branch
1600 Clifton Road, N.E., MS D53
Atlanta Georgia 30333
P.I.I. [redacted]

August 27, 2008

Dr. Bruce Lanphear
Simon Fraser University
Faculty of Health Sciences
Blusson Hall, Room 11300
8888 University Drive
Burnaby, B.C.
V5A 1S6

Re: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CCS21049-01

Dear Dr. Lanphear:

I am writing in follow-up to your discussions with staff in the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health, (NCEH) Lead Poisoning Prevention Branch (LPPB) regarding a Freedom of Information Act (FOIA) request that CDC received in relation to Cooperative Agreement (CA) number R01/CCS21049-01, awarded to the Children's Hospital Medical Center to fund the project entitled "International Pooled Analysis of Lead-Exposed Cohorts," of which you were the principal investigator. As you have been informed by CDC staff, the FOIA request specifically seeks data collected pursuant to the above-mentioned CA and subsequently published by the Environmental Protection Agency (EPA) on July 30, 2007 in the report, "Lead Human Exposure and Health Risk Assessment for Selected Case Studies," as well as in the January 26, 2007 EPA letter to Lead NAAQS Docket from Zachary Pekar (EPA OAQPS) regarding "Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implication for Pilot Risk Assessment."

Because the data sought by the FOIA request was collected under a CA funded by CDC, the research data is subject to OMB Circular A-110 and 45 C.F.R. section 74.36(d). 45 C.F.R. section 74.36(d)(1) states:

> In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under FOIA....

Wigington Declaration **EXHIBIT O**

The data that you collected pursuant to CA R01/CC521049-01 was published by the EPA in reports placed on its website. More importantly, the research findings were cited in an EPA Advance Notice for Proposed Rulemaking (ANPR) for the lead National Ambient Air Quality Standards revision. The use of the data in this manner satisfies the "published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law" requirement of 45 C.F.R. 74.36(d). Therefore, in accordance with this regulation you are required to provide CDC with the research data so that the agency may be responsive to the FOIA request.

You have indicated to CDC staff, however, that you are unable to provide such data because you signed a confidentiality agreement with the other investigators of CA R01/CC521049-01 prohibiting the release of the data. CDC staff has repeatedly asked you to provide a copy of this agreement so that we may attempt to use the reasoning of the agreement to deny the FOIA request outright or withhold the raw data in whole or in part in accordance with any applicable FOIA exemptions. You have thus far refused to provide a copy of the agreement.

Please keep in mind that the closeout of the CA does not affect the continuing property management requirements of 45 C.F.R. sections 74.31-74.37 that you agreed to upon acceptance of the CA funding. Award recipients are required to retain records for three years following the conclusion of the award; therefore, while we realize that you may no longer have the data, you have not indicated that that is the case. In fact, you have indicated that the reason for not releasing the data to CDC is not that you no longer possess it, but that you signed a confidentiality agreement. Therefore, if you are still in possession of the data, you must comply with the requirements of 74.36(d).

I have enclosed a copy of 45 C.F.R. 74.36(d), the FOIA request and EPA's determination regarding the data for your review. Please contact the Office of the General Counsel or NCEH/LPPB staff should you have questions or wish to discuss the matter further. Otherwise, please promptly provide the data as requested by LPPB and required by 45 C.F.R. section 74.36(d).

Sincerely,

Kenya S. Ford
Senior Attorney
HHS Office of the General Counsel

Cc: Pamela Wigington, NCEH
Samantha Harrykissoon, NCEH
Enclosures

by Federal statute as long as the Federal Government retains an interest in the supplies.

(2) If the supplies are owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the HHS awarding agency.

(3) User charges shall be treated as program income, in keeping with the provisions of § 74.24.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996]

§ 74.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."

(c) The Federal Government has the right to:

(1) Obtain, reproduce, publish or otherwise use the data first produced under an award; and

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d)(1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the HHS Awarding Agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) The following definitions apply for purposes of this paragraph (d):

(i) *Research data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). *Research data* also do not include:

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(ii) *Published* is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(iii) *Used by the Federal Government in developing an agency action that has the force and effect of law* is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(3) The requirements set forth in paragraph (d)(1) of this section do not apply to commercial organizations.

(e) Title to intangible property and debt instruments purchased or otherwise acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use that property for the originally—authorized

purpose, and the recipient shall not encumber the property without approval of the HHS awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of § 74.34 (g) and (h).

[59 FR 43760, Aug. 25, 1994, as amended at 68 FR 14407, 14418, Mar. 25, 2003]

§ 74.37 Property trust relationship.

Real property, equipment, intangible property and debt instruments that are acquired or improved with Federal funds shall be held in trust by the recipients as trustee for the beneficiaries of the project or program under which the property was acquired or improved, and shall not be encumbered without the approval of the HHS awarding agency. Recipients shall record liens or other appropriate notices of record to indicate that real property has been acquired or constructed or, where applicable, improved with Federal funds, and that use and disposition conditions apply to the property.

PROCUREMENT STANDARDS

§ 74.40 Purpose of procurement standards.

Sections 74.41 through 74.48 set forth standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are established to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. The standards apply where the cost of the procurement is treated as a direct cost of an award.

§ 74.41 Recipient responsibilities.

The standards contained in this section do not relieve the recipients of the contractual responsibilities arising under its contract(s). The recipient is the responsible authority, without recourse to the HHS awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

§ 74.42 Codes of conduct.

The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipients.

§ 74.43 Competition.

All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The recipient shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and/

EXHIBIT

P

Wigington Declaration EXHIBIT P

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Ford, Kenya S. (CDC/OCOO/OD)
Sent: Monday, September 29, 2008 5:22 PM
To: 'Bruce.Lanphear@cchmc.org'
Cc: Mantoan, Patricia (HHS/OGC); Armstrong, Lynn (CDC/OD/OCS); Wigington, Pamela S. (CDC/CCEHIP/NCEH); Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: FW:
Attachments: Pooled Analysis Agreement.pdf

Mr. Lanphear:

I have not actually ever spoken with you on the telephone; this matter was referred to me internally by CDC staff. I have only communicated with you through the one letter to which you refer below. I am not sure with whom at CDC you have previously spoken regarding this matter; perhaps NCEH staff.

Thank you for providing the attached, as requested by my letter to you. CDC will be in touch with you should further information be needed.

Kenya S. Ford
HHS Office of the General Counsel

Kenya S. Ford
Senior Attorney
HHS Office of the General Counsel
CDC Branch

-----Original Message-----
From: Bruce Lanphear [redacted] P.I.I.
Sent: Monday, September 29, 2008 4:59 PM
To: Ford, Kenya S. (CDC/OCOO/OD)
Subject:

Kenya:

I received your nice note this morning about the FOIA request related to data collected pursuant to CDC Cooperative Agreement Number RO1/CC521049-01.

As I indicated when we talked on the telephone, Jones-Day already has a copy of the agreement I made with each of the co-investigators (see attached). They received it during the Rhode Island Suit against the paint and pigment industry. Indeed, they used it to successfully argue against my testifying at the trial even though I released all of the raw data from my own studies.

As indicated in the letter, the investigators provided the raw data with the stipulation that it would not be released or used for any other reason than the pooled analysis unless additional approval was sought and obtained from each investigator.

You (or Jones-Day) can, of course, seek approval from each investigator.

Please let me know if you have any additional questions.

Bruce

Kimberly Yolton - Pooled Analysis - Use of the Data

From: Kimberly Yolton
To: LeadPooledGroup
Date: 5/28/2004 10:02:46 AM
Subject: Pooled Analysis - Use of the Data

Pooled Analysis Investigators:

See the following request from Bruce Lanphear regarding a request to use the Pooled Analysis data in another paper. You may respond to me or Bruce on this.

From Bruce:

Steve Rothonberg, one of the co-authors on the pooled data study, is writing a commentary paper on the effects of the functional form of the lead term in human health effects lead study models. He wants to statistically determine if natural log lead terms better fit data sets than linear lead terms. He will also use the two lead specifications to examine their effect on the outcome of lead-reduction benefit models already published. He will use the lead coefficients from the pooled analysis for this work as presented in the manuscript and from a newly constructed model using a linear lead term. He will not use the data set in any other way. He will cite the current manuscript in his commentary article.

As we agreed at the outset of our collaboration, data from the pooled data analysis would be available to the co-authors for other studies, but only if the co-authors give permission.

Please indicate if you give Steve permission to use the pooled analysis data set in this way.

Bruce Lanphear

Kimberly Yolton, Ph.D.
Research Assistant Professor of Pediatrics
General & Community Pediatrics Research
Children's Environmental Health Center
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue, ML 7035
Cincinnati, OH 45229-3039

Delivery address (FedEx, UPS, etc.):
2800 Winslow, Room 5213
Cincinnati, OH 45206

P.I.I. [redacted]

Jane KHOURY - Pooled Analysis

From: Bruce Lanphear
To: Claire Ernhart; David Bellinger; Dietrich, Kim (DIETRIKN); Gail Wasserman; GCOONEY@ted.educ.mq.edu.au; Herbert Needleman; Jane KHOURY; Joe Graziano; Lourdes Schnaas; Peter Baghurst; Rick Canfield; Rick Hornung; Robert Bornschein; Russell Roberts; Steve Rothenberg; Tom Greene
Date: 5/29/2000 4:10 PM
Subject: Pooled Analysis

Dear colleagues:

I have now recieved a formal letter of support from each of the PI's and Co-PI's for the 8 cohorts involved in the pooled analysis. This collaboration will examine an estimated 1,951 children, 37 months to 120 months of age, from 7 countries.

The first meeting is planned to be held during the 18th International Conference on Neurotoxicology to be held in Colorado Springs, Colorado from September 23rd to the 26th. The actual meeting of the pooled analysis will be held on Saturday September 23rd, so investigators will need to arrive on Friday September 22nd. I am trying to confirm funds from NIEHS for travel and consultant fees to cover this meeting.

I have also submitted a letter of intent to the March of Dimes to conduct the analysis, pay consultant fees and travel costs for the second meeting, to be held in 2001. The second meeting will ideally be held in Australia.

I will let each of you review the March of Dimes proposal, if a full proposal is requested.

Please review and file the attached, revised proposal. It incorporates most of the suggested revisions many of you recommended. Further revisions will be made during the meeting in Colorado.

After I have confoirmed funds for consultant fees and travel costs for the first meeting, I will send out a request for data sets with specified variables. In that request, I will include a letter stating the purpose of the analyses and indicating that the data will not be used for any other purpose without the formal approval of the responsible investigators.

Sincerely,

Bruce

EXHIBIT

Q

UNIVERSITY OF SOUTH CAROLINA BEAUFORT

October 31, 2008

RE: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01

Enclosed is the document sent to Claire B. Ernhart, University of South Carolina Beaufort, South Campus, 1 University Blvd., Bluffton, South Carolina 29909. I am returning this document as there is no employee at the University of South Carolina Beaufort Campus by this name and the requested information, "data collected pursuant to Dr. Lanphear's study…" is not familiar to this campus. Perhaps the request should have been directed to another campus in the USC system.

From: Origin ID: MGEA (770)488-4024
Pam Wigington
CDCNCEHDECHS
4770 Buford Highway
MS-F60
Atlanta, GA 30341

Ship Date: 24OCT08
ActWgt: 1 LB
CAD: 3867277/INET8091
Account#: S*********

Delivery Address Bar Code

Ref #
Invoice #
PO #
Dept #

SHIP TO: 843-208-8000 BILL SENDER
Claire B. Ernhart
University of SC Beaufort
1 UNIVERSITY BLVD
SOUTH CAMPUS
BLUFFTON, SC 299096085

MON - 27OCT AM
PRIORITY OVERNIGHT

TRK# 0201 7906 1162 5799

XX SAVA

29909
SC-US
SAV

After printing this label:
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Wigington Declaration EXHIBIT Q

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

October 24, 2008

Claire B. Ernhart
University of South Carolina Beaufort
South Campus
1 University Blvd.
Bluffton, South Carolina 29909

Re: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CCS21049-01

Dear Dr. Ernhart:

I am writing to you about data used by Dr. Bruce Lanphear in a study funded by the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health, (NCEH) Lead Poisoning Prevention Branch (LPPB) titled International Pooled Analysis of Lead-Exposed Cohorts.

CDC has received a Freedom of Information Act (FOIA) request that specifically seeks the data collected pursuant to Dr. Lanphear's study and that was subsequently

- Published by the U.S. Environmental Protection Agency (EPA) on July 30, 2007, in its report titled Lead Human Exposure and Health Risk Assessment for Selected Case Studies
- And published in the January 26, 2007, EPA letter to Lead NAAQS Docket from Zachary Pekar (EPA OAQPS) titled Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implication for Pilot Risk Assessment.

Because the data sought by the FOIA request were collected using CDC funds, the research data are subject to OMB Circular A-110 and 45 C.F.R. section 74.36(d). 45 C.F.R. section 74.36(d)(1) states:

> In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under FOIA....

Dr. Lanphear's research findings were cited in an EPA Advance Notice for Proposed Rulemaking (ANPR) for the lead National Ambient Air Quality Standards revision. The use of the data in this manner satisfies the underlined portion of 45 C.F.R. 74.36(d).

Therefore, in accordance with this regulation, Dr. Lanphear is required to provide CDC with the research data so that the agency may be responsive to the FOIA request. However, he has provided us with a copy of the confidentiality agreement with other investigators prohibiting the release of your data. We are asking for your permission for Dr. Lanphear to release your data to us.

Enclosed are copies of

- 45 C.F.R. 74.36(d),
- the FOIA request, and
- EPA's determination regarding the data for your review.

Please contact NCEH staff if you have any questions. Otherwise, please give us your permission in writing so we can obtain a copy of your data from Dr. Lanphear.

Thank you for your cooperation in allowing Dr. Lanphear to provide CDC with this required information.

Sincerely,

Pamela S. Wigington

Pamela S. Wigington
Health Communications Specialist
Division of Emergency and Environmental
Health Services
National Center for Environmental Health
MS F-60
4770 Buford Highway NE
Atlanta, GA 30341-3717
P.I.I.
Ph

Enclosures

cc:
Dr. Bruce Lanphear
Kenya Ford, CDC Office of General Counsel
Lynn Armstrong, CDC FOIA Officer
Samantha Harrykissoon, CDC Lead Program

by Federal statute as long as the Federal Government retains an interest in the supplies.

(2) If the supplies are owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the HHS awarding agency.

(3) User charges shall be treated as program income, in keeping with the provisions of § 74.24.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11757, Mar. 22, 1996]

§ 74.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."

(c) The Federal Government has the right to:

(1) Obtain, reproduce, publish or otherwise use the data first produced under an award; and

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d)(1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the HHS Awarding Agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) The following definitions apply for purposes of this paragraph (d):

(i) *Research data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). *Research data* also do not include:

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(ii) *Published* is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(iii) *Used by the Federal Government in developing an agency action that has the force and effect of law* is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(3) The requirements set forth in paragraph (d)(1) of this section do not apply to commercial organizations.

(e) Title to intangible property and debt instruments purchased or otherwise acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use that property for the originally-authorized

purpose, and the recipient shall not encumber the property without approval of the HHS awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of §74.34 (g) and (h).

[68 FR 43760, Aug. 25, 1994, as amended at 65 FR 14407, 14418, Mar. 16, 2000]

§ 74.37 Property trust relationship.

Real property, equipment, intangible property and debt instruments that are acquired or improved with Federal funds shall be held in trust by the recipients as trustee for the beneficiaries of the project or program under which the property was acquired or improved, and shall not be encumbered without the approval of the HHS awarding agency. Recipients shall record liens or other appropriate notices of record to indicate that real property has been acquired or constructed or, where applicable, improved with Federal funds, and that use and disposition conditions apply to the property.

PROCUREMENT STANDARDS

§ 74.40 Purpose of procurement standards.

Sections 74.41 through 74.48 set forth standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are established to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. The standards apply where the cost of the procurement is treated as a direct cost of an award.

§ 74.41 Recipient responsibilities.

The standards contained in this section do not relieve the recipients of the contractual responsibilities arising under its contract(s). The recipient is the responsible authority, without recourse to the HHS awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of statutes are to be referred to such Federal, State or local authority as may have proper jurisdiction.

§ 74.42 Codes of conduct.

The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipients.

§ 74.43 Competition.

All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The recipient shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and/

Wigington Declaration **EXHIBIT Q**

JONES DAY

500 GRANT STREET • SUITE 3150 • PITTSBURGH, PENNSYLVANIA 15219-2502
TELEPHONE: 412-391-3939 • FACSIMILE: 412-394-7959

Direct Number: (412) 394-7763
akgrob@jonesday.com

JP42019/1/1162108v1
589170-0900/5

August 9, 2007

VIA FEDERAL EXPRESS

U.S. Environmental Protection Agency
National FOIA Officer
U.S. EPA, Records
FOIA & Privacy Branch
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: Freedom of Information Act ("FOIA") Request For Research Data Pursuant To 5 U.S.C. § 552, *et seq.* and 2 C.F.R. Part 215.36
EXPEDITED PROCESSING REQUESTED

Dear Sir or Madam:

This request for data is submitted pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, et seq. and the Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other non-Profit Organizations (OMB Circular A-110), at 2 C.F.R. Part 215.36.

The undersigned requests certain data related to and/or reported in the following report published by the Environmental Protection Agency ("EPA"): Lead Human Exposure And Health Risk Assessments For Selected Case Studies (July 30, 2007); and in the January 26, 2007 letter to Lead NAAQS Docket from Zachary Pekar (EPA OAQPS) regarding "Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implications for Pilot Risk Assessment." A copy of the report and supporting appendices, as well as the January 26, 2007 Correction notice, are published on the EPA's web-site, at: *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html.*

Kindly treat this FOIA request as a request for expedited processing. There is a compelling need for the information on an expedited basis. The data and information requested are needed for several pending civil litigation matter. Our client's constitutional due process rights to full cross examination of opposing expert witnesses may be impaired unless access to the requested data is provided in an expedited manner. In addition, it is necessary for us to have access to the data requested in this letter on an expedited basis so that we may meaningfully assess the report within the applicable public comment period set by the EPA. Expedited processing should be relatively easy and inexpensive as well -- because the data requested in this letter most likely exists in electronic format, the data may be easily transferable onto a disk or through email, with minimal effort or expense for the EPA.

Wigington Declaration **EXHIBIT Q**

The above-cited report was drafted by the EPA in conjunction with ICF International, a recipient of federal funding, through Contract No. EP-D-06-115 and/or EP-D-06 115. Under FOIA, the EPA is required to provide access to the data requested below. None of the exemptions to disclosure set forth in FOIA (5 U.S.C. § 552(b)) preclude access to the data requested in this letter. In the event that the EPA does not possess the data requested in this FOIA letter, then the EPA is required to obtain all data requested in this FOIA letter from ICF International and to make the data available to the undersigned, under 2 C.F.R. Part 215.36(d). ICF International's Headquarters are located at 9300 Lee Highway, Fairfax, VA 22031, Phone (703) 934-3000; Fax (703) 934-3740.

The following data is requested:

1. A copy of all data related to the following study in the EPA report: Lanphear, *et al.*, "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," *Environmental Health Perspectives*, 113(7) (2005). The Lanphear, *et al.* 2005 study is identified at length in the EPA report. *See, e.g.*, Lead Human Exposure And Health Risk Assessments For Selected Case Studies (July 30, 2007), Section 4, pages 4-1 to 4-42; *see also, e.g.*, Appendix Sections G, H, J, L, M (citing Lanphear, et al. 2005 study throughout). It is apparent that EPA, in conjunction with ICF, utilized the data gathered by Lanphear et al. to provide its risk assessment model found in the EPA report. We note that EPA published a correction to Lanphear's study based upon its own review of the data on January 26, 2007. In addition, the underlying study was funded in part by the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention and the United States Environmental Protection Agency. As such, the data are available for public receipt.

2. A copy of the data collection forms and any software programs required to access and analyze the data identified in paragraph 1 in its computerized form, and

3. The data dictionaries for the raw data identified in paragraph 1.

The above-listed data and information should be provided in electronic, machine readable format, if available. It is our belief that the data should be readily accessible, easy to download on to storage media such as a CD or DVD and would be neither difficult nor time consuming to obtain. To the extent that the data contains subject names or other identifying information, we are willing to receive the data in a format without subject identifiers. Further, we are willing to pay a reasonable fee to obtain and/or produce the data requested. Please contact me with an estimate of the fee for this FOIA request.

We have copied Dr. Zachary Pekar, EPA Office of Air Quality Planning and Standards, on this FOIA letter, as Dr. Pekar is identified in the above-cited report as the contact person for questions and comments to the report. Dr. Pekar is likely to have access to the information requested in this FOIA letter, or information to permit the EPA to access the data requested from ICF International. The Lanphear, et al. data is addressed in the EPA's report, and it is apparent

that the EPA authors and/or ICF International had access to some or all of the raw data from the Lauphear, *et al.* 2005 study. Further, in his letter dated January 26, 2007 (copy attached for convenience and also available at *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html*), Dr. Pekar referenced corrections in the 2005 Lauphear, et al. data, which further indicates that the EPA has access to or has the ability to obtain the raw data from the Lauphear, et al. study requested in this FOIA letter.

In the event you decline to comply with this FOIA request, please issue a written explanation detailing the reasons for your decision.

Please contact me with any questions. My telephone number is 412-394-7263.

Very truly yours,

Amy K. Pohl

cc: Dr. Zachary Pekar
U.S. Environmental Protection Agency
Office of Air Quality Planning & Standards
Mail Drop C504-06
Research Triangle Park, NC 27711
P.I.I. [redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 14 2008

OFFICE OF
GENERAL COUNSEL

Amy K. Pohl
Jones Day
500 Grant Street, Suite 3100
Pittsburgh, PA 15219-2502

Re: Freedom of Information Act Appeal HQ-RIN-01843-07 (HQ-APP-00009-08)

Dear Ms. Pohl:

I am responding to your October 18, 2007 Freedom of Information Act ("FOIA") appeal. You appealed the September 21, 2007 decision of Kelly Rimer for Stephen D. Page, Director, Office of Air Quality Planning and Standards, Office of Air and Radiation ("decision") of the U.S. Environmental Protection Agency ("EPA" or "Agency"), to deny the request you submitted to EPA on August 9, 2007. Your request sought the data underlying the July 2005 federally funded study, "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," reported in Environmental Health Perspectives ("Study"). The decision stated that your request was denied because (1) the Agency does not have the underlying data, and (2) because the draft report, "Lead Human Exposure and Health Risk Assessment for Selected Case Studies" ("Report"), which cites the Study, does not have the "force and effect of law" as required by 40 C.F.R. § 30.36. The decision also indicates that the Report in final form would not satisfy the "force and effect of law" requirement.

I have carefully considered your request, EPA's decision, and your appeal. For the reasons set forth below, I have determined that your appeal should be, and is granted in part and denied in part.

You assert in your appeal that EPA has not conducted a proper search for records responsive to your request. After receiving your appeal, I have confirmed that the Agency conducted a reasonable search for records responsive to your request, and am confident that the Agency does not have the requested data.

You also assert that Office of Management and Budget's ("OMB's") regulation at 2 C.F.R. § 215.36 requires the EPA to obtain a copy of the data and release the data under FOIA.[1] The Agency's regulation at 40 C.F.R. § 30.36(d)(1) states that "in response to a Freedom of Information Act (FOIA) request for research data relating to published

[1] EPA's version of the OMB regulation is found at 40 C.F.R. § 30.36.

research findings produced under an award that were used by the Federal government in developing an agency action that has the force and effect of law, the EPA shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA." "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined in the regulation as "when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law."

The original determination was correct that use of the Study in the Report does not obligate EPA to obtain the data underlying the study pursuant to 40 C.F.R. § 30.36(d)(1). However, since the time of that determination EPA has issued an Advance Notice for Proposed Rulemaking ("ANPR") for the lead National Ambient Air Quality Standards (NAAQS) revision (Federal Register publication December 12, 2007) which cited the Study in presenting and soliciting comment on evidence and risk-based considerations and regulatory options for the Administrator's review of the lead NAAQS. Furthermore, by court order, the Agency must, *inter alia*, issue its Proposed Rule for the lead NAAQS revision by May 1, 2008. In light of all of these facts and circumstances, I have determined that your request satisfies the requirement of 40 C.F.R. §30.36 and therefore, your appeal is granted on this ground.

In accordance with EPA's regulations, EPA will proceed to process your request in accordance with 40 C.F.R. § 30.36(d)(1), contact the grant recipient, and will request an estimate of fees for responding to your request. Per your original request, EPA will contact you with an estimate of fees before proceeding further.

This letter constitutes EPA's final determination on your appeal. In accordance with 5 U.S.C. § 552(a)(4)(B), you have the right to seek judicial review of this determination by instituting an action in the district court of the United States in the district in which you reside, or have your principal place of business, or in which the Agency records are situated, or in the District of Columbia.

Should you have any questions concerning this matter, please call Sara E. McGraw, at (202) 564-2565.

Sincerely,

Kevin M. Miller
Assistant General Counsel
General Law Office

cc: HQ FOI Office

EXHIBIT

R

Wigington Declaration EXHIBIT R

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Baghurst, Peter (CYWHS) [redacted]
Sent: Monday, November 03, 2008 6:39 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Cc: [redacted]
Subject: FOIA Request for data

Dear Ms Wigington,

I have received your request dated October 24, 2008 for the release of data which we contributed to a pooled analysis undertaken by Dr Bruce Lanphear.

Please note

(a) the data you were seeking were not obtained using CDC funds and therefore your assertion that our data are subject to OMB Circular A-110 and 45 C.F.R. section 74.36(d) is incorrect
(b) the data we supplied to Dr Lanphear, completely free of charge, was given to him expressly for the purpose of an agreed pooled analysis – and for no other purpose.

I therefore do not give permission for CDC or any other person or agency to access our data.

Yours sincerely,
Peter Baghurst

Assoc Prof Peter Baghurst
Head, Public Health Research Unit
Women's and Children's Hospital
Children Youth and Women's Health Service
72 King William Road
North Adelaide
South Australia 5006
[redacted]

EXHIBIT S

Wigington Declaration **EXHIBIT S**

UNIVERSITY OF Cincinnati

Department of Environmental Health
University of Cincinnati College of Medicine
Kettering Lab Complex
3223 Eden Ave.
PO Box 670565
Cincinnati, OH 45267-0565
Phone 513-558-6701

To: Paula S. Wigington From: Kim N. Dietrich

Fax: 770-784-4820 Pages: 4

Phone: Date:

Re: Cc:

[ ] Urgent [ ] For Review [ ] Please Comment [ ] Please Reply

Comments:

Data Request

Wigington Declaration **EXHIBIT S**

FREUND, FREEZE & ARNOLD

July 19, 2005

Via Facsimile 1-412-394-7959

Thomas S. Jones, Esq.
Jones Day
500 Grant Street
Suite 3100
Pittsburgh, PA 15219-2502

RE: State of Rhode Island v. Lead Industries Assoc./Dietrich Subpoena

Dear Mr. Jones:

This is to confirm that we have resolved all issues with regard to the subpoena served July 13 on Dr. Kim Dietrich. In exchange for withdrawing the subpoena, we have agreed to produce to you the raw data provided to Dr. Bruce Lanphear which provided the basis for his recent article contained in Environmental Health Perspectives, Vol. 113, No. 7. This data will be sent to you via overnight mail on a CD. I anticipate that I will be able to mail the data to you by tomorrow, July 20, 2005. Additionally, sometime next week we will supply you with a data dictionary sufficient to allow you to identify each of the 183 variables contained in the data set. Finally, we will provide you with an affidavit signed by Dr. Dietrich indicating that the data provided to you is identical to that produced to Dr. Lanphear and that it was maintained in the ordinary course of business.

Should my agreement of our understanding be in any way incorrect, please let me know as soon as possible. As always, should you have any or concerns about this case whatsoever, please do not hesitate to contact me.

Very truly yours,

FREUND, FREEZE & ARNOLD

David A. Shearer

cahp

Wigington Declaration EXHIBIT S

FREUND FREEZE & ARNOLD
A LEGAL PROFESSIONAL ASSOCIATION

David A. Shearer, Jr., Esq.

July 19, 2005

Via Facsimile: 1-412-394-7959

Thomas S. Jones, Esq.
Jones Day
500 Grant Street
Suite 3100
Pittsburgh, PA 15219-2502

RE: State of Rhode Island v. Lead Industries Assoc./Dietrich Subpoena

Dear Mr. Jones:

This is to confirm that we have resolved all issues with regard to the subpoena served on Dr. Kim Dietrich. As such we have vacated the hearing date set for July 20 on our motion to quash the subpoena. As always, if you have any questions or concerns, please do not hesitate to contact me.

Very truly yours,

FREUND, FREEZE & ARNOLD

David A. Shearer

cmp

cc Attorney General Patrick C. Lynch (via facsimile)
John J. McConnell, Jr., Esq. (via facsimile)
Neil T. Leifer, Esq. (via facsimile)

Wigington Declaration **EXHIBIT S**

Gerald J. Petros, Esq. (via facsimile)
Richard W. Mark, Esq. (via facsimile)
John A. Turantino, Esq. (via facsimile)
Philip H. Curtis, Esq. (via facsimile)
Joseph A. Kelly, Esq. (via facsimile)
Timothy S. Hardy, Esq. (via U.S. Mail)
Donald R. Scott, Esq./Andre M. Panka, Esq. (via facsimile)
Gerald C. DeMaria, Esq. (via facsimile)
Michael T. Nilan, Esq. (via facsimile)
Joseph J. McClair, Esq. (via facsimile)
James J. Fitzgerald, Esq. (via facsimile)
Melissa M. Horne, Esq. (via facsimile)

EXHIBIT

T

Wigington Declaration EXHIBIT T

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Richard L. Canfield [redacted]
Sent: Monday, November 10, 2008 12:35 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FOIA

Dear Ms. Wigington,

After speaking with Bruce Lanphear I learned that the data set requested of me (R01/CC521049-01) has already been provided by him. How shall I proceed?

Best regards,

Richard Canfield

Richard L. Canfield, PhD
Division of Nutritional Sciences
B09 Savage Hall
Cornell University
Ithaca, NY 14853

[redacted]

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Monday, November 10, 2008 12:40 PM
To: P.I.I.
Subject: RE: FOIA

Dear Dr. Canfield,

Dr. Lanphear has not provided us with any data. All he provided to us was the agreement not to share the data.

Can you send me an e-mail or letter saying that you give your permission for him to provide your data to CDC?

Thanks!

Pam Wigington
Health Communications Specialist
Division of Emergency and Environmental Health Services
CDC/National Center for Environmental Health
Chamblee 106, room 6008
MS F-60
Phone: P.I.I.
Fax: P.I.I.
E-mail: P.I.I.
Cell: P.I.I.

From: Richard L. Canfield P.I.I.
Sent: Monday, November 10, 2008 12:35 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Subject: FOIA

Dear Ms. Wigington,

After speaking with Bruce Lanphear I learned that the data set requested of me (R01/CC521049-01) has already been provided by him. How shall I proceed?

Best regards,

Richard Canfield

Richard L. Canfield, PhD
Division of Nutritional Sciences
B09 Savage Hall
Cornell University
Ithaca, NY 14853

P.I.I.

EXHIBIT

U

Wigington Declaration EXHIBIT U

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Thursday, November 13, 2008 7:26 AM
To: P.I.I.
Cc: Armstrong, Lynn (CDC/OD/OCS); Ford, Kenya S. (CDC/OCOO/OD); Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR); Millette, Deborah (Deb) (CDC/CCEHIP/NCEH); Dowling, Audrey (ATSDR/OPPE)
Subject: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Dr. Lanphear,

Please confirm whether you are contending that the exclusion below, found at 45 CFR 74.36(d)(2)(i)(A), applies to the data that CDC has requested from you.*

45 CFR 74.36(d)(2)(i)(A) states that "research data" ***does not*** include:

- Trade secrets,
- Commercial information,
- Materials necessary to be held confidential by a researcher until they are published, or
- Similar information which is protected under law.

The link to the complete section (45 CFR 74.36) is http://www.peo7.com/CFRFiles/PEOusCFR_45PUBLICWELFARE_119259.htm.

Thank you for your help!

*FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health
Division of Emergency and Environmental Health Services
Chamblee 106, room 6008
office phone: P.I.I.
e-mail: P.I.I.
cell: P.I.I.

EXHIBIT

V

Wigington Declaration EXHIBIT V

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Thursday, December 11, 2008 10:51 AM
To: P.I.I.
Cc: Armstrong, Lynn (CDC/OD/OCS); Ford, Kenya S. (CDC/OCOO/OD); Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR); Millette, Deborah (Deb) (CDC/CCEHIP/NCEH); Dowling, Audrey (ATSDR/OPPE)
Subject: RE: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Hi, Dr. Lanphear,

We discussed this last month so I'm aware that you are contending that the data we are requesting are excluded per the third and fourth bullets in the list below. However, I need your response in an e-mail.

Can you please reply to this message with that information? Thanks so much!

Pam Wigington
Health Communications Specialist
CDC/National Center for Environmental Health
Division of Emergency and Environmental Health Services
Chamblee 106, room 6008
office phone: P.I.I.
e-mail: P.I.I.
cell: P.I.I.

From: Wigington, Pamela S. (CDC/CCEHIP/NCEH)
Sent: Thursday, November 13, 2008 7:26 AM
To: P.I.I.
Cc: Armstrong, Lynn (CDC/OD/OCS); Ford, Kenya S. (CDC/OCOO/OD); Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR); Millette, Deborah (Deb) (CDC/CCEHIP/NCEH); Dowling, Audrey (ATSDR/OPPE)
Subject: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Dr. Lanphear,

Please confirm whether you are contending that the exclusion below, found at 45 CFR 74.36(d)(2)(i)(A), applies to the data that CDC has requested from you.*

45 CFR 74.36(d)(2)(i)(A) states that "research data" ***does not*** include:

- Trade secrets,
- Commercial information,
- **Materials necessary to be held confidential by a researcher until they are published, or**
- **Similar information which is protected under law.**

The link to the complete section (45 CFR 74.36) is http://www.peo7.com/CFRFiles/PEOusCFR_45PUBLICWELFARE_119259.htm.

Thank you for your help!

*FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

EXHIBIT

W

Wigington, Pamela S. (CDC/ONDIEH/NCEH)

From: Bruce Lanphear [P.I.I.]
Sent: Thursday, December 11, 2008 1:52 PM
To: Wigington, Pamela S. (CDC/CCEHIP/NCEH); blanphear@sfu.ca
Cc: Dowling, Audrey (ATSDR/OPPE); Ford, Kenya S. (CDC/OCOO/OD); Armstrong, Lynn (CDC/OD/OCS); Millette, Deborah (Deb) (CDC/CCEHIP/NCEH); Harrykissoon, Samantha (CDC/CCEHIP/NCEH) (CTR)
Subject: Re: FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Ms. Wigington:

Thank you for your letter dated November 13th, 2008.

On behalf of the investigators who were involved with the international pooled analysis of lead-exposed cohorts, I am contending that a stipulation of the agreement to use these data was that they would be treated as confidential and would not be used or shared for any other purpose. This is consistent with the exclusion, "the research data includes similar information which is protected under the law" by a prior agreement.

Moreover, although many of the investigators were comfortable making their raw data available, our international colleagues were not willing to release their data. As such, it would not be possible to release the pooled data set.

Best regards,

Bruce Lanphear

>>> "Wigington, Pamela S. (CDC/CCEHIP/NCEH)" P.I.I. 11/13/08
>>> 7:25 AM >>>
Dr. Lanphear,

Please confirm whether you are contending that the exclusion below, found at 45 CFR 74.36(d)(2)(i)(A), applies to the data that CDC has requested from you.*

45 CFR 74.36(d)(2)(i)(A) states that "research data" does not include:
* Trade secrets,
* Commercial information,
* Materials necessary to be held confidential by a researcher until they are published, or
* Similar information which is protected under law.

The link to the complete section (45 CFR 74.36) is http://www.peo7.com/CFRFiles/PEOusCFR_45PUBLICWELFARE_119259.htm.

Thank you for your help!

*FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Pam Wigington

Health Communications Specialist
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>>> "Wigington, Pamela S. (CDC/CCEHIP/NCEH)" P.I.I. 11/13/08
>>> 7:25 AM >>>
Dr. Lanphear,

Please confirm whether you are contending that the exclusion below, found at 45 CFR 74.36(d)(2)(i)(A), applies to the data that CDC has requested from you.*

45 CFR 74.36(d)(2)(i)(A) states that "research data" does not include:
* Trade secrets,
* Commercial information,
* Materials necessary to be held confidential by a researcher until they are published, or
* Similar information which is protected under law.

The link to the complete section (45 CFR 74.36) is http://www.peo7.com/CFRFiles/PEOusCFR_45PUBLICWELFARE_119259.htm.

Thank you for your help!

*FOIA Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CC521049-01 (International Pooled Analysis of Lead-Exposed Cohorts)

Pam Wigington
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EXHIBIT

X

Wigington Declaration **EXHIBIT X**

JONES DAY

[redacted]

Direct Number: (412) 394-7938
[redacted]

[redacted]
[redacted]

December 2, 2008

VIA CERTIFIED MAIL

Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of the Chief Information Officer
FOIA Office, MS-D54
1600 Clifton Road, N.E.
Atlanta, GA 30333

Re: FOIA Case No. 08-01169-FOIA

Dear Ms. Armstrong:

By letter dated June 30, 2008 (copy attached), you informed Ms. Amy K. Pohl that the Centers for Disease Control and Prevention ("CDC") was processing the above captioned FOIA request originally submitted to EPA on August 9, 2007 and granted February 14, 2008. I am following up on that letter as five months have passed without any further communication, determination, or information in regard to this file.

In addition, it has come to our attention that the primary investigator of the study from which we requested data has moved out of the country. Specifically, Bruce Lanphear has moved to Vancouver, British Columbia, Canada. It is our hope that this will not delay our efforts to obtain the data we have requested and are entitled to.

Please produce the information requested in the August 9, 2007, FOIA letter as soon as possible, and/or please contact me with information on the status of CDC's processing of this FOIA request. Thank you for your prompt attention to this matter.

Very truly yours,

Matthew A. Meyers

Enclosure

EXHIBIT

Y

Wigington Declaration EXHIBIT Y

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

December 16, 2008

Amy K. Pohl
Jones Day
500 Grant Street, Suite 3100
Pittsburgh, Pennsylvania 15219-2502

Dear Ms. Pohl:

This letter is the final response from the Centers for Disease Control and Prevention (CDC) to your Freedom of Information Act (FOIA) request of August 9, 2007, addressed to the U.S. Environmental Protection Agency (EPA) and your subsequent follow-up letters of December 2 and December 8. The original request was forwarded to the CDC/ATSDR FOIA Office in June of this year and logged in on June 12, 2008. It was given CDC FOIA #08-01169.

You requested grantee-held data under the provisions of OMB Circular A-110. The data at issue is a pooled dataset from a number of contributors for the purpose of using the lead coefficients from the pooled analysis in a manuscript and for a newly constructed model using a linear lead term. Program staff contacted the grantee regarding the availability of the data. The grantee's response is a claim of exclusion for the compiled dataset pursuant to 45 CFR 74.36(d)(2)(i)(A). This is based on a private agreement among the co-authors reached at the outset of the collaboration.

Specifically, 45 CFR 74.36(d)(2)(i)(A) states that "research data" ***does not*** include:

- Trade secrets,
- Commercial information,
- Materials necessary to be held confidential by a researcher until they are published, or
- Similar information which is protected under law.

The link to the complete section (45 CFR 74.36) is http://www.pco7.com/CFRFiles/PUOusCFR_45PUBLICWELFARE_119259.htm.

Wigington Declaration EXHIBIT Y

Therefore, based on the grantee's claim of exclusion, we are informing you that the requested data is not "research data" subject to the provisions of OMB Circular A-110, section __.36(d) and the Department's implementing regulation at 45 CFR 74.36(d).

You have the right to appeal this decision to deny you full access to agency records. Send your appeal, within 30 days from the date you receive this letter, to the Deputy Assistant Secretary for Public Affairs (Media), U.S. Department of Health and Human Services, Room 17A-46, 5600 Fishers Lane, Rockville, Maryland 20857. Please mark both your appeal letter and envelope "FOIA Appeal."

Sincerely yours,

Lynn Armstrong

Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of the Chief Information Officer
P.I.I.
P.I.I.

EXHIBIT

Z

Wigington Declaration EXHIBIT Z

JONES DAY

500 GRANT STREET • SUITE 4900 • PITTSBURGH, PENNSYLVANIA 15219-2514
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Direct Number: (412) 394-7924
tsjones@jonesday.com

JP003924:589170-096077
Your Ref.: CDC FOIA #08-01169
NIH FOIA #35135

January 9, 2009

2009 JAN 12 AM 10:35
RECEIVED BY
FOIA/PA STAFF OFFICE

VIA OVERNIGHT MAIL

Ms. Carol Maloney (or appropriate officer)
Deputy Assistant Secretary for Public Affairs (Media)
U.S. Department of Health and Human Services, Room 17A-46
5600 Fishers Lane
Rockville, MD 20857

Re: FOIA Appeal (CDC FOIA #08-01169 and NIH FOIA #35135)

Dear Ms. Maloney:

We are in receipt of the Department of Health and Human Services' December 16, 2008 letter in which CDC/ATSDR FOIA officer Lynn Armstrong determined that FOIA request #08-01169 should be denied. (*See* Exhibit 1 attached). The denial, addressed to my colleague Amy Pohl, was forwarded to my attention as Ms. Pohl is currently on maternity leave. On Ms. Pohl's behalf, we appeal that adverse determination pursuant to 45 C.F.R. § 5.34 and expect a prompt review and decision on this appeal within the statutory time period.

In addition, we are in receipt of the Department of Health Human Services' December 18, 2008 letter to Ms. Pohl in which NIH FOIA officer Susan Cornell purportedly denied a request for the same information on behalf of the National Institute of Health, Case No. 35135. (*See* Exhibit 2 attached). Again, on Ms. Pohl's behalf, we appeal this decision pursuant to 45 C.F.R. § 5.34.

I. Background of Request and Appeal.

A. The United States Environmental Protection Agency Adopts A Regulation With the Force And Effect of Law Based Upon Federally-Funded Research And Analysis.

On October 15, 2008, the United States Environmental Protection Agency ("EPA") signed into effect the National Ambient Air Quality Standards for Lead, codified in the Code of Federal Regulations under Chapter 40 in parts 50, 51, 53 and 58, Fed. Reg., Vol. 73, No. 219, pp. 66963-67062 (Nov. 12, 2008) ("Final Rule") (Exhibit 3). Adopted pursuant to the Clean Air Act, 42 U.S.C. § 7408 and 7409, this regulation lowered a pre-existing regulatory standard which had established the permitted air lead level at 1.5 $\mu g/m^3$ to a new standard of 0.15 $\mu g/m^3$. *See*

Final Rule at 66965. It was the culmination of a four-year process that began on November 9, 2004, with a general call for information, 69 Fed. Reg. 64926, an air criteria document released in December 2005, a second draft of the document released in May of 2006, comments of the Clean Air Scientific Advisory Committee's review, and multiple draft risk assessment reports. *See* Final Rule at 66965-66968. EPA published a draft rule on December 12, 2007, received public comments and held public meetings. *Id.* A proposed decision was signed on May 1, 2008, and the final rule was published on October 15, 2008. *Id.*

In reaching the conclusion that the air lead standard should be reduced by 90%, the Final Rule relied heavily on a study published by Bruce Lanphear, *et al., Low Level environmental lead exposure and children's intellectual function: an international pooled analysis*, Envt'l Health Persp., Vol. 113:894-899 (2005) ("Lanphear Study") (Exhibit 4). As the associated criteria document and public docket demonstrate, the Lanphear Study provided the foundation for the evaluation of the risk of lead in the air, in particular the claim that very low levels of lead in children's blood can cause a decrement in IQ at blood lead levels under 10 µg/dL or even 7.5 µg/dL. *See, e.g.*, Final Rule at 66978-66979 (Table 1). The administrative record is replete with correspondence between Dr. Lanphear, his researchers and the EPA with questions and corrections regarding his data. (*See* Exhibit 5 (correspondence and corrections to data)). In reaching its decision to set a lower air lead standard, the EPA credited Dr. Lanphear's conclusion that IQ decrements may occur at low blood lead levels, Final Rule at 67005 (referencing "air-related IQ loss of 2 points" as the standard for the new rule), and this supported EPA's decision to adopt its final rule and lower the existing air lead standard. *Id.* at 67006 ("The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral effects and neurocognitive effect, in children. A standard set at this level provides a very significant increase in protection compared to the current standard."). There can be no dispute that the EPA reviewed and relied upon the Lanphear Study and the underlying data in reaching its conclusion. (*See generally* Final Rule at 66977 (terming the Lanphear Study "the most compelling evidence for Pb effects at blood levels < 10 µg/dL . . . .")).

B. Procedural History.

1. Initial Request And Denial.

On August 9, 2007, Ms. Pohl made her initial request for the data that Dr. Lanphear used in his study and analysis and which was relied upon by the EPA in publishing the air criteria document, the risk assessment, the draft rule and the Final Rule. (Exhibit 6) Citing FOIA and OMB Circular A-110, Ms. Pohl explained that the data sought were compiled during the rule making procedure, that the data in possession of the EPA were required to be produced under FOIA and that any data in the hands of grantees assisting in the rulemaking procedure were

required to be obtained by EPA and produced under OMB Circular A-110. In particular, the request sought:

- "A copy of all data related to the [Lanphear Study]"
- "A copy of the data collecting forms and any software programs required to access and analyze the data . . . " and
- "The data dictionaries for the raw data identified in paragraph 1."

(*See* Exhibit 6).

On September 21, 2007, EPA responded by e-mail denying the request. (Exhibit 7) Despite having issued a draft air quality criteria for lead based, in part, on the Lanphear Study and even publishing a correction to the tables contained in the study, EPA maintained that it never had "possession and control" of the data which were required under the general provisions of FOIA. (*Id.*). With respect to disclosure under OMB Circular A-110, EPA determined that although the data at issued had been included and relied upon in the draft lead risk assessment, the tentative nature of the document kept it from having "the force and effect of law," thus making OMB Circular A-110 inapplicable. (*Id.*).

2. **EPA Grants Appeal.**

Ms. Pohl timely appealed this determined on October 18, 2007. (Exhibit 8) In that appeal, Ms. Pohl challenged the assertion by the EPA that it did not have possession and control of the data given the references made in EPA documents. She further explained why the use of the data in the draft risk assessment met the requirement of OMB Circular A-110. (*Id.*).

On November 20, 2007, Ms. Pohl inquired as to the status of her appeal, in particular why EPA had not met the statutorily-mandated 20 days to render a decision on her appeal. (Exhibit 9).

On February 14, 2008, EPA resolved the appeal through a "final" decision. (Exhibit 10). Although EPA maintained that the initial basis for denial was correct, it determined that the data at issue were included in Advance Notice for Proposed Rulemaking for the National Ambient Air Quality Standards (published December 12, 2007). As a result, EPA "determined that your requests satisfied the requirement of 40 C.F.R. § 30.36 and therefore, your appeal is granted on this ground." (*Id.* at 2). EPA indicated that it would contact the grantee, Dr. Lanphear, obtain an estimate of production costs and proceed in obtaining the data. (*Id.*)

On March 17, 2008, Ms. Pohl contacted EPA and indicated that EPA had never responded with the costs of production or a schedule under which the data would be produced. (Exhibit 11).

3. **EPA Transfers Responsibility For Producing Data To HHS.**

On May 29, 2008, EPA responded and, citing no authority that would permit transfer of the obligation to obtain and produce the data, advised Ms. Pohl that because certain of the grants at issue where issued by HHS, it would assign the processing of the production to HHS. (Exhibit 12). On June 2, 2008, Ms. Pohl, having not yet received EPA's letter, again inquired as to the status of her request. (Exhibit 13).

On June 17, HHS, through the CDC FOIA office, acknowledged the determination by EPA that the data should be produced and advised Ms. Pohl that it would process her request. (Exhibit 14) It made no mention that it would reconsider the basis of her request. (*Id.*). Shortly thereafter, on June 30, 2008, the CDC FOIA officer advised Ms. Pohl that it would not expedite her request. Again, HHS made no mention that it would reevaluate the basis of her request or that it would seek to refuse to comply with the appeal decision made by EPA. (Exhibit 15).

On July 1, 2008, Ms. Pohl received a letter from a different individual at HHS, this time the NIH FOIA officer, who indicated that HHS would evaluate whether the data at issue was obtained or analyzed pursuant to an NIEHS grant (the very basis on which EPA transferred the matter to HHS for processing in the first place). (Exhibit 16)

On October 6, 2008, the CDC FOIA officer advised Ms. Pohl that "Program staff are negotiating the availability of the data and the cost of providing it with the grantee." (Exhibit 17). Again, the CDC FOIA officer did not suggest that Ms. Pohl's entitlement to the data, already finally resolved by the EPA, was being reconsidered by the CDC FOIA staff. On December 2, 2008, Mr. Matthew Meyers, on behalf of Ms. Pohl, inquired of both the CDC FOIA officer and the NIH FOIA officer as to the status of the requests and further advised both that in the sixteen months since her initial request, the principal investigator, Dr. Lanphear, had moved out of the country. (Exhibits 18 and 19).

4. **HHS, *Sua Sponte*, Reconsiders EPA's Decision To Grant Request.**

Nothing further occurred under December 16, 2008 at which time HHS, through the FOIA officer at CDC, advised Ms. Pohl that the data sought did not, in fact, constitute data obtainable under OMB Circular A-110 – effectively reversing the determination made ten months ago on appeal by the EPA. (Exhibit 1) In particular, the CDC FOIA officer determined that the data at issue were exempt from disclosure under 45 C.F.R. § 74.36(d)(2)(i)(A) based upon an assertion by the grantee of entitlement to that exemption. (*Id.*).

Two days later, Ms. Pohl received a second letter from HHS, this time from the FOIA officer at NIH, which purported to deny her request for the separate reason that NIEHS grants at issue were not sufficiently related to the Lanphear Study or data analysis to render OMB Circular A-110 applicable. (Exhibit 2). In particular, NIH stated that it "understood" that NIEHS money was not used in the analysis of the data although it did not disclose how it arrived at this

"understanding" or on what documents or evidence it reached this conclusion. (*Id.*). Notably, the NIH FOIA officer did not cite the exemption relied upon by the CDC FOIA officer.

These appeals followed in a timely fashion.

C. **Relevant Legal Authority.**

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.*, the United States government and its agencies must make available to the public upon request certain information gathered on behalf of the public. *See* 5 U.S.C. § 552(a)(3). Congress enacted FOIA "to facilitate public access to Government documents." *United States Department of State v. Ray*, 502 U.S. 164, 173 (1991). It is premised on the belief that "an informed electorate is vital to the proper operation of a democracy." S. Rep. No. 813, 89th Cong, 1st Sess. 3 (1965). As a result, FOIA creates a strong presumption in favor of disclosure. *Department of Air Force v. Rose*, 425 U.S. 352, 361 (1976). Such concerns are heightened when the agency at issue imposes new obligations on the citizens. Recognizing that "sunlight is the best disinfectant," disclosure of the federally-funded foundation of federal regulations furthers the purpose of FOIA and related regulations. Although each agency is empowered to adopt regulations pertaining to the disclosure of its records, both EPA and HHS have adopted regulations that implement FOIA. See 45 C.F.R. § Part 5, *et seq.* (HHS); 40 C.F.R. Part 2, *et seq.* (EPA).

Of particular relevance to this appeal, the Office of Management and Budget adopted OMB Circular A-110 which it subsequently revised in 1993 and 1999. Entitled the Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations ("Circular A-110"), it directs the heads of all executive departments, including EPA and HHS, to adhere to "standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations." 2 C.F.R. § 215.1. Circular A-110 applies not only to grantees but to "subrecipients performing substantive work under grants and agreements that are passed through or awarded by the primary recipient . . ." *Id.* § 215.3.

Under Circular A-110, the Federal Government has the right to receive and publish data that are gathered under an agency award. *Id.* § 215.36(c). "In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public *through the procedures established under FOIA*." *Id.* § 215.37(d)(1) (emphasis added). Thus, under Circular A-110, additional information not in the possession of the government agency is subject to disclosure as if the government possessed it under FOIA.

Certain limitations, however, apply. Circular A-110 does not reach "preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues." *Id.* § 215.37(d)(2)(i). Nor does it include "trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law" or information that "would constitute a clearly unwarranted invasion of personal privacy." *Id.* The circular goes on to define publication as occurring when "research findings are published in a peer-reviewed scientific or technical journal; or [a] Federal agency publicly and official cites the research findings in support of an agency action that has the force and effect of law." *Id.*

Both EPA and HHS have adopted Circular A-110 and it is applicable to both agencies. *See* 40 C.F.R. § 30.36; 45 C.F.R. § 74.36.

D. **The Lanphear Study Was Produced Using Federal Grant Monies And Supports A Federal Regulation With The Force Of Law.**

As discussed above and in the attachments to this appeal, EPA undoubtedly "used" the Lanphear Study "in developing an agency action that has the force and effect of law." Thus, in order for the data that support the study to be subject to disclosure upon request, it need only be established (a) that the data "relat[e] to published research findings" and (b) that such findings were "produced under an award." 45 C.F.R. § 74.36(d)(1). The burden would then shift to the agency to identify some exemption from disclosure.

The Lanphear Study involved a new analysis of disparate data collected in seven studies regarding the effects of lead on IQ in children. Lanphear Study at 894. According to both grant applications related to this work and the article itself, *see infra*, Dr. Lanphear and his co-authors believed that the individual studies themselves failed to provide a sufficient sample size to draw conclusions about low level lead effects on the intellectual attainment of children.[1] A new analysis was needed. As a result, Dr. Lanphear arranged for the authors of the various studies to come together at a conference, requested that those authors submit their datasets to him for a new analysis, and produced a new piece of analysis looking particularly at subjects whose blood lead levels were under 10 µg/dL and 7.5 µg/dL under a number of various measures (the "Pooled Analysis"). This study included data published for the first time. Lanphear Study at 895.

The "pooling" portion of the analysis was critical because although the whole dataset contained 1,333, only 244 had a peak blood lead concentration of less than 10 µg/dL and only 103 had a peak blood lead of less than 7.5 µg/dL. In order for the authors to obtain a sufficient sample size, most of the individual studies contributed some members to the under 10 and under

[1] (*See* Exhibit 20 (United States Department of Health and Human Services Grant Application No: 1 R13 ES10868-01, dated January 31, 2000, at 2 ("Each of the prospective studies have included too few children to examine any adverse effects of blood lead concentration < 10mcg/dl.").

7.5 cohorts.[2] The characteristics of the combined dataset as a whole and the subsamples used for the "under 10" and "under 7.5" analysis are set forth in Tables 1 and 2 of the Lanphear Study.

Having obtained the data, Dr. Lanphear then analyzed the combined dataset to determine whether IQ scores decreased with changing lead levels. *Id.* He purportedly determined that IQ did, indeed, decrease as lead levels increased and reached the surprising conclusion that IQ decreased much more rapidly at lower levels of lead exposure than at higher levels. *Id.* at 898. Dr. Lanphear published his results in the July 2005 edition of Environmental Health Perspectives, Volume 113, Number 5. Thus, there can be no dispute that Dr. Lanphear's conclusions constitute "published research findings" nor that the data at issue "relat[e]" to these findings, as required under Circular A-110.

Nor can there be any dispute that the data and conclusions found in Dr. Lanphear's study "were used by the Federal Government in developing an agency action that has the force and effect of law." EPA calculated a hypothesized effect of lower blood lead levels on the IQ of children in reaching its Final Rule be relying on the Lanphear data. Final Rule at 66978-66979, Table 1. In fact, its reliance was so substantial that EPA corresponded directly with Dr. Lanphear and his colleagues during the rule making process and actually issued multiple corrections of the tables in the Lanphear Study after discovering material errors. (Exhibit 5)

Finally, there can be no doubt that the Lanphear Study constitutes "research findings produced under an award." The Study itself states that "[t]his study was funded, in part, by the National Institution of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency." Lanphear Study at 894.

Review of relevant grant applications confirms that the Lanphear Study was the product of no fewer than three federal grants – two HHS grants and one from EPA. More specifically, the funding came from HHS grants ES 010868 and ES 011261, both provided by the National Institute of Environmental Health Science ("NIEHS"), and EPA grant R829389. These grants covered two distinct phases of the project. With funding from ES 010868, Dr. Lanphear, *et al.*, carried out the initial planning, strategy, and analysis work for the project. Then, under the Center for the Study of Prevalent Neurotoxicants in children, a project funded jointly by grants ES 011261 and R829389 as a program of closely related work, the investigators carried out the data analysis and production of the final publication.

Conference Grant ES 010868

In January of 2000, Dr. Bruce Lanphear submitted an application to HHS requesting funding for a workshop to be held in conjunction with the 18th International Neurotoxicity

[2] Although the analysis was on the pooled subsample, certain data sets predominated. For example, the Rochester cohort (another federally-funded Lanphear study group) contributed 103 of the 244 subjects to the under 10 µg/dL dataset and 69 of the 103 subjects in the under 7.5 µg/dL subsample. (*See* Lanphear Study at p. 896 (Tables 1 and 2)).

Conference in Colorado Springs, Colorado on September 23, 2000.[3] The application titled the project *A Workshop: Pooled Analysis of Lead-Exposed Cohorts*.[4] The stated purpose of the workshop was "to convene 16 investigators representing 7 international, prospective lead-exposed cohorts for a meeting … to conduct a pooled analysis and examine lead-associated cognitive deficits below 10 micrograms per deciliter (mcg/dl)." However, the workshop was more than merely a "conference." The objectives of this workshop were to (1) "Review existing scientific literature on the adverse effects of lead exposure below 10 mcg/dl"; (2) "Identify the specific levels of lead exposure that cause adverse cognitive effects in humans"; (3) "Promote collaboration and coordination among researchers to ensure that the human health effects of lead exposure are effectively examined in a pooled analysis"; and (4) "Develop an analytic strategy to conduct a pooled analysis of 7 lead-exposed cohorts from across the globe."[5]

The workshop served as the starting point, and initial planning session, for a project that would last five years under funding from the EPA, NIEHS and Centers for Disease Control and Prevention ("CDC").[6] The workshop sessions, of which there were two, aimed to overcome the hurdles that the group would encounter in conducting the Pooled Analysis, and developing an analytical roadmap for the project. In the first session, the participants discussed the limitations of the current studies and the analytic strategies that they would need to implement in order to address those issues in the pooled analysis to follow. In the second session, the participants sought to define the variables that the analysis would consider, refine the analytic strategy, and arrive at a proposed study design for the new analysis.[7]

The application requested funding of $24,500 for the workshop to cover the transportation expenses of the participants.[8] On June 23, 2000, The NIEHS issued an award of $4,000.[9]

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[3] (*See* Exhibit 20 (United States Department of Health and Human Services Grant Application No: 1 R13 ES10868-01, dated January 31, 2000, at 1, 2, 10)).

[4] (*Id.* at 1, 10).

[5] (*Id.* at 2, 8).

[6] (*See* Exhibit 21 (United States Department of Health and Human Services Grant Progress Report, Grant No. ES 11261-03, dated July 10, 2003, at 20., *see also* United States Environmental Protection Agency, "2003 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2003*); Exhibit 22 (United States Environmental Protection Agency, "2004 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2004*); Exhibit 23, United States Environmental Protection Agency, "2005 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2005*)).

[7] (*See* Exhibit 20 (United States Department of Health and Human Services Grant Application No: 1 R13 ES10868-01, dated January 31, 2000, at 9)).

[8] (*Id.* at 1).

Center Grants ES 011261 and R829389

While the initial planning and development of the Pooled Analysis began with NIEHS grant ES 010868, the bulk of the data analyses and the publication of the paper were carried out under a single project funded equally by NIEHS and EPA.

Effective September 25, 2000, the National Center for Environmental Research ("NCER") posted a request for applications ("RFA").[10] The request sought applications by joint invitation from both EPA and NIEHS for up to four new centers to "conduct multidisciplinary[,] basic[,] and applied research in combination with community-based research projects to support studies on the causes and mechanisms of children's developmental disorders with special emphasis on environmental exposures[,] which may put children at risk of these disorders."[11] The RFA sought centers with at least two research projects covering basic mechanistic research, epidemiology, or exposure assessment and analysis, paired with one community based participatory research project.[12] This RFA represented the continuation of a program begun by NIEHS and EPA in 1998 under which the two agencies had already jointly funded eight universities.[13] Applications were made subject to various regulations, including the HHS incorporation of Circular A-110.[14]

In response to the RFA, Dr, Lanphear submitted a grant application dated January 7, 2001, carrying the title, *Centers For Children's Environmental Health And Disease Prevention Research*. The application proposed the creation of a Center at the Children's Hospital Medical Center in Cincinnati (the "Center").[15]

The grant proposal was accepted and, after review, EPA sought approval of its decision to fund Dr. Lanphear's project from NCER. The terms of the project were provided in a letter dated November 10, 2001, from Acting Director of NCER, Becki M. Clark, to Deputy Director of NCER, John C. Puzak. The letter indicated that the Center would be jointly funded by EPA

(continued...)

[9] (Exhibit 24 (United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Conference Grant, Grant No. 1 R13 ES10868-01, dated June 23, 2000.).

[10] (Exhibit 25 (National Center for Environmental Research, Centers for Children's Environmental Health and Disease Prevention Research, FY 2001 Science to Achieve Results (STAR) Program, available at: http://es.epa.gov/ncer/rfa/ kidscenter01.html (last accessed September 17, 2001) (September 25, 2000), at 1)).

[11] (*Id.* at 1-2, 10).

[12] (*Id.* at 7).

[13] (*Id.* at 3).

[14] (*Id.* at 16).

[15] (Exhibit 26 (United States Department of Health and Human Services Grant Application No. 1 P01 ES011261-01, dated January 7, 2001, at 1-2)).

and NIEHS, each grant representing fifty percent of the Center's funding.[16] Attached to the letter was an accounting summary, dated September 20, 2001, outlining how the requested funding would support the project. According to the accounting, EPA and NIEHS would contribute equal funding to the Center over the five-year period, starting in year one (2002) with $753,911 each, and $746,824, $737,036, $730,349, and $736,385, respectively, in subsequent years.[17]

While EPA records indicate that it issued payments in line with the September 2001, summary,[18] on March 14, 2002, NIEHS issued an award letter to Bruce Lanphear, funding the project *Study of Prevalent Neurotoxicants in Children*, in the amount of $655,619.[19] Subsequent NIEHS awards consistently provided funds that were approximately $100,000 below the initial projections.[20] However, the following terms appeared in the NIEHS award letter:

> This project funded by NIEHS and EPA has been determined to be part of a program of closely related work. As such, the recipient may treat the entire program of related projects as a single cost objective. A cost that is allocable to the program may be charged by the recipient to any one or more of the awards that make up the program, in any proportion.[21]

Therefore, regardless of the amounts actually contributed, the clear and stated intent of the Center grant was to treat all monies received from EPA and NIEHS as one collective pool.

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[16] (Exhibit 27 (Letter, Becki M. Clark Acting Director, NCER to John C. Puzak, Deputy Director, NCER, dated November 10, 2001, at 1, see also attachment, "Programmatic Terms and Conditions for Children's Health Research Centers," dated October 11, 2001, at 1)).

[17] (Exhibit 28 ("FY 2001 Kids Centers Funding Summary," Grant No. R82939-01-0, Bruce Lanphear, Primary Investigator, dated September 20, 2001)).

[18] (Exhibit 29 (United States Environmental Protection Agency, "Final Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/F*); Exhibit 27 (Letter, Becki M. Clark Acting Director, NCER to John C. Puzak, Deputy Director, NCER, dated November 10, 2001, at 5))

[19] (Exhibit 30 (United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 1 P01 ES11261-01 (Revised), dated March 14, 2002, at 7)). The lower NIEHS contributions may have resulted from the fact that an additional $880,000 was received pursuant to an award issued on September 23, 2002, as well as an additional $813,869 on May 3, 2004. That money came from the Department of Housing and Urban Development, and was restricted for use in conjunction with project 3 only.

[20] (*Id.*, *see also* United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 5 P01 ES11261-02, dated September 9, 2002, at 7-8, and United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 5 P01 ES11261-03, dated August 29, 2003, at 6.)).

[21] (Exhibit 30 (United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 1 P01 ES11261-01 (Revised), dated March 14, 2002, at 6)).

Not only were the investigators to treat the money funding this Center as the same collective pool, but the grants also allowed for a single form of progress reporting. By the terms of the agreement, NIEHS protocols were to govern the reporting requirements for the grant. In order to fulfill EPA requirements on Center reporting, the investigators needed only forward a copy of NIEHS-required Applications for Continuation Grant to EPA. For each individual project, EPA only required that an annual report for each project accompany the NIEHS Application for Continuation Grant.[22]

Although EPA and NIEHS did not formally award funding until March 2002,[23] Dr. Lanphear submitted his first Application for Continuation Grant for ES 11261 to NIEHS in August of 2002. Due to the late funding, there was little progress reported.[24] The first substantial progress report came in July of 2003. By that time, each project was underway. This was also the first year for which EPA posted a progress report. As per the terms of the funding as outlined in the letter of November 10, 2001, it appears that EPA received a copy of the same materials submitted to NIEHS. The language carried in the EPA progress report matches, verbatim, the language of the July 2003 Grant Progress Report and outlines, for the first time, the follow-up work conducted on the Pooled Analysis.[25]

In 2003, work continued on the Pooled Analysis as part of the Center with a second meeting of the investigators from the lead-exposed cohorts. The following language appears in both the Overview of Center Activities portion of the Grant Progress Report submitted by Dr. Lanphear to NIEHS in July 2003, and the Progress Summary section of the 2003 EPA Progress Report:

> The Center hosted an international pooled analysis for lead-exposed cohorts to study intellectual impairments at blood lead levels below 10 µg/dL. The findings of our National Institute of Environmental Health Sciences (NIEHS)-funded Rochester Longitudinal Study found substantial lead-associated intellectual

[22] (Exhibit 27 ("Programmatic Terms and Conditions for Children's Health Research Centers," dated October 11, 2001, at 2, as attached to Letter, Becki M. Clark Acting Director, NCER to John C. Puzak, Deputy Director, NCER, dated November 10, 2001); Exhibit 30 (United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 1 P01 ES11261-01 (Revised), dated March 14, 2002, at 2-3.)).

[23] (Exhibit 30 (United States Department of Health and Human Services, National Institute of Health, Notice of Grant Award, Research Program Project, Grant No. 1 P01 ES11261-01 (Revised), dated March 14, 2002, at 1.)).

[24] (Exhibit 31 (United States Department of Health and Human Services, Application for Continuation Grant, Grant No. ES 11261-03, dated August 5, 2002)).

[25] (Exhibit 21 (United States Department of Health and Human Services, Grant Progress Report, Grant No. ES 11261-03, dated July 10, 2003, at 20; *see also* United States Environmental Protection Agency, "2003 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2003*)),

> impairments at blood lead levels below 10 µg/dL (Canfield, *et al.*, 2003). To test these surprising findings in a larger cohort, we convened this international collaboration, which is funded by the Centers for Disease Control and Prevention, the U.S. Environmental Protection Agency, and NIEHS. The collaboration involves more than 1,300 children enrolled in 7 prospective longitudinal cohort investigations from 4 continents. We are pooling the raw data to test whether there are adverse consequences of lead exposure on intellectual abilities at blood lead levels below 10 µg/dL. Further, we are testing whether the relationship is nonlinear and if there are greater impairments at blood lead levels below 10 µg/dL compared with higher blood lead levels. Our analyses are nearing completion, and we anticipate that we will have results in the next 12 months.[26]

These records reflect without equivocation that the Pooled Analysis was not simply a conference held on an isolated day in 2000, but an ongoing project carried out as part of the ongoing work of the EPA and NIEHS-funded Center.

Pursuant to the Center's work on the Pooled Analysis, in 2004 and 2005, Dr. Lanphear continued to update NIEHS and EPA as to the Center's progress on the analysis.[27] Between 2003 and 2004, the Center completed all of the data analysis necessary to draft a manuscript for what would eventually become the Lanphear Study. In 2004, the EPA Progress Report section entitled "Progress Summary" read:

> In our last progress report, we described a meeting, held in Cincinnati in May 2003, of principal investigators representing longitudinal lead-exposed cohorts from the United States, Australia, and Mexico. This meeting was arranged to study the results of the analyses of pooled data from more than 1,300 children and the findings of intellectual impairments at blood lead levels below 10 µg/dL, compared with higher blood lead levels. Our analyses have been completed, and a manuscript was submitted recently to the *Journal of the American Medical Association*. The title of the paper is "Low-Level Environmental

[26] (*Id.*) We have been unable to uncover any information on funding provided by CDC, except that CDC absorbed some of the cost of tests that were run pursuant to the Center's research.

[27] We are still awaiting the results of FOIA requests submitted to NIEHS for Grant Progress Reports and/or Applications for Grant Continuation for fiscal years 2004 through the present pertaining to Grant ES 011261.

Lead Exposure and Children's Intellectual Function: An International Pooled Analysis.[28]

Thus, Dr. Lanphear justified the federal funding of the Center by reference to the Pooled Analysis. According to EPA progress reports, work on the Pooled Analysis continued at the Center through 2005. Although the *Journal of the American Medical Association* did not accept the manuscript for publication, the article was completed in 2005 and appeared in *Environmental Health Perspectives*. Each of these steps was detailed in the progress reports.[29]

From these progress reports on the Center, it is abundantly clear that the Center, as funded jointly and indiscriminately by both EPA and NIEHS, was responsible for performing the data analysis that eventually lead to the publication of the 2005 article reporting on the Pooled Analysis.[30] In fact, EPA maintains records reflecting each and every publication produced under its grants. On the EPA website, the Lanphear Study appears under publications funded by grant R829389: Center for the Study of Prevalent Neurotoxicants in Children.[31]

With all relevant criteria met, the data must be disclosed absent demonstration by the agency that an exception applies.

E. The HHS Determination That The Data Are Not Subject To Disclosure Is Erroneous.

As a factual and legal matter, both the CDC FOIA Officer and NIH FOIA Officer erred in concluding that the data and analysis on which the Final Rule is based are not subject to disclosure. However, as a preliminary matter, this was not a decision for either CDC or NIH to make

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[28] (Exhibit 22 (United States Environmental Protection Agency, "2004 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2004*)).

[29] (Exhibit 23 (United States Environmental Protection Agency, "2005 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2005*)).

[30] A graphic detailing the interrelationship of the grants, projects and funding sources for the Pooled Analysis is attached hereto as Exhibit 32.

[31] http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/0; (Exhibit 22 (United States Environmental Protection Agency, "2004 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2004*); Exhibit 23 (United States Environmental Protection Agency, "2005 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2005*); Exhibit 29 (United States Environmental Protection Agency, "Final Report: Center for the Study of Prevalent Neurotoxicants in Children," Grant No. R829389, *available at http://cfpub.epa.gov/ncer_abstracts/ index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/F*))

1. **Both The CDC and NIH FOIA Officers Erred In Reconsidering The Appellate Decision Of The EPA.**

FOIA has an established process by which requests are made and evaluated. *See* 5 U.S.C. § 552(a)(3). The statute and implementing regulations also set forth the process by which appeals are considered and *finally* determined. By reevaluating Ms. Pohl's request and effectively overturning the EPA decision (without prior notice to Ms. Pohl), HHS overstepped its legitimate authority.

Ms. Pohl sought disclosure of data and information relating to actions taken by the EPA and from a grantee that was the recipient of an EPA grant (among others). EPA considered Ms. Pohl's request and granted it. Upon that decision, EPA "shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A). Instead, EPA transferred the logistics of production to HHS. (*See* Exhibit 12) While under certain circumstances, referral of a FOIA request to another agency is permissible, "when an agency receives a FOIA request for 'agency records,' in its possession, it must take responsibility for processing that request. It cannot simply refuse to act on the ground that the documents originated elsewhere." *McGehee v. CIA*, 697 F.2d 1095, 1100 (D.C. Cir. 1983). Thus, if documents are within the control of the agency to whom the request is made, that agency cannot simply "pass the buck" to another. *See In re Wade*, 969 F.2d 241, 248 (7th Cir. 1992) ("The United States Attorney is obligated to produce nonexempted documents pursuant to the Act. The agency cannot avoid the request or withhold the documents by referring them back to the agency where they originated."). Although a request under Circular A-110 is a bit different in that the material to be produced is in the hands of a third party, once the agency, here EPA, determines that it must be produced, then the procedures under FOIA apply and EPA, as one funding source, was obligated to obtain the requested material.

Under Circular A-110, any "awarding agency" may consider and grant a request under Circular A-110. *See* 2 C.F.R. § 215.36(d)(1). The authors of the Lanphear Study clearly state in the article itself that "[t]his study was funded, in part, by . . . the U.S. Environmental Protection Agency." Lanphear Study at 894. Public documents confirm that many of the researchers on the Lanphear Study were the recipients of EPA money to fund the Center. Subsequent "progress reports" of the EPA-funded Center refer to the Lanphear Study as a product of the participants of the Center. Given that EPA was also the agency that adopted the regulation that had the "force and effect" of law as well as the agency that utilized the data and study at issue, EPA became the agency "primarily qualified" to determine the question of accessibility of the data. And it did when EPA granted Ms. Pohl's appeal on February 14, 2008. (*See* Exhibit 10).

All of the requisite elements for production under Circular A-110 were before EPA at the time it granted Ms. Pohl's appeal. EPA was the agency that had enacted the regulation with the force and effect of law, it had funded, at least in part, the study and analysis on which it relied, and it had full jurisdiction to consider and the grant the appeal taken from the initial denial by the

EPA FOIA officer. *See* 5 U.S.C. § 552(a)(6)(A)(i). Once EPA finally determined that the data fell under Circular A-110, the government was estopped from re-examining that determination. Certainly EPA could not evade the government's responsibility to obtain and produce the data by simply transferring the matter to two other agencies to see if they could mint new reasons to deny the requests.

Were the procedure observed by EPA and the NIH and CDC FOIA officers correct, a FOIA request would simply initiate a never-ending loop of requests and referrals no matter how meritorious the request was. If a staff or appeals officer simply did not want to be bothered with producing the information, the request could be ruled on and passed along to other staff officers for further review.

This matter proved even more egregious in that it was a *staff* FOIA officer that overruled the determination of the EPA *appeals* process. What good is an appeals process if the staff officer at another agency can simply overrule that decision?

Ms. Pohl's appeal may be resolved without resort to any analysis of the disparate reasons selected by the CDC and NIH FOIA officers. The appeal should be granted in recognition of the fact that it has already been resolved in Ms. Pohl's favor and the grantee should be required to produce the data forthwith.

2. **CDC and NIH Have Provided No Foundation For Their Conclusion That The Data At Issue Are Exempt From Disclosure Under Circular A-110.**

Two different HHS agencies have now issued two separate arguments for denying Ms. Pohl's FOIA request. Neither has merit.

a. **The CDC FOIA Officer Erroneously Determined That The Data Which Formed The Analytic Foundation Of The Final Rule Was Exempt From Disclosure.**

Citing a single section of the regulation, the CDC FOIA officer determined that the data described in Table 2 of the Lanphear Study did not constitute "research data" under Circular A-110. (Exhibit 1). In particular, the CDC FOIA officer referred to a "private agreement among the co-authors reached at the outset of the collaboration." (*Id.*) The question becomes quite simple: can researchers eviscerate Circular A-110 by simply agreeing, among themselves, that it doesn't apply?

The analysis should begin by reviewing the text of the agreement between the authors to determine what the authors did, and did not, agree to regarding confidentiality. However, the CDC FOIA officer did not produce the alleged "agreement" nor detail what it said. Rather, the CDC FOIA officer simply indicated that "program staff" contacted "the grantee" and obtained

this explanation. (*Id.*) Is this alleged agreement in writing? What is it's scope? It is based solely on the self-serving recollection of the grantee? Was its existence confirmed by contacting other parties? The CDC FOIA officer does not say.

Parties to FOIA requests have certain procedural rights. For example, the FOIA officer's decision may ultimately be reviewed under Section 706 of the APA which prohibits agencies from "unlawfully withf holding]" action. *See* 5 U.S.C. § 706(1). In addition, the actions of the FOIA officer cannot be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A). An insufficient record as to the basis of a denial of a FOIA request makes the decision essentially unreviewable. Courts have required that the basis for denial give "the FOIA requester a meaningful opportunity to contest, and the district court an adequate foundation to review, the soundness of the withholding." *King v. Department of Justice*, 830 F.2d 210, 217-18 (D.C. Cir. 1987)). To keep the FOIA process from becoming "a potentially ineffective, inquisitorial proceeding against an agency that controls information into a meaningful adversarial process," *Coastal States Gas. Corp. v. Department of Energy*, 644 F.2d 969, 984 (3d Cir. 1981), courts require FOIA decisions to include a "relatively detailed justification" of the basis for the denial. *McDonnell v. United States*, 4 F.3d 1227, 1241 (3d Cir. 1993). In the case where the agency relies upon an alleged "agreement" to keep data private, the first step should be either production of that agreement or sufficient information about that agreement to understand whether it is, in fact, binding. In failing to detail with any specificity the nature of this agreement, the CDC FOIA officer erred.

Next, the analysis must turn to the regulation at issue. The regulation cited by the CDC FOIA officer, subsection 36(d)(2)(i)(A), is designed not to protect that which a researcher does not want others to see but to protect trade and commercial secrets that might be exchanged during the course of research. To reveal such information would disincentive commercial parties from participating in research. It is inconceivable that data at issue analyzed by the Center could constitute either a "trade secret" or "commercial information." Those terms closely mirror FOIA's fourth exemption which is designed to protect confidential commercial information. *See* 5 U.S.C. § 552(b)(4). As used in that section, "trade secret" refers to "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1208, 1288 (D.C. Cir. 1983). Similarly, "commercial information" refers to information that causes, in part, "substantial harm to the competitive position of the person from whom the information was obtained." *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). The concern protected in the FOIA exemption and the parallel provision in Circular A-110 is that individuals engaged in for-profit research (for example, technology development or bio-engineering) might lose intellectual property protection if the government utilizes or relies upon the research in passing a rule or regulation. *See, e.g., Pioneer Hi-bred Int'l v. Holden Found. Seed*, 35 F.3d 1226 (8th Cir. 1994) (holding trade secret protections for corn seed genetic

messages).[32] None of those concerns are present here. Rather, the information at issue are data analyzed under a federal grant and utilized by a federal agency to set a federal rule. There is no suggestion that Dr. Lanphear or any of his co-authors are commercially exploiting the data or using it in a for-profit manner. Thus, those portions of the exemption are inapplicable.

The other sections of the exemption relate to "materials necessary to be held confidential by a researcher *until they are published*" or "similar information which is protected under law." 45 C.F.R. § 74.36(d)(2)(i)(A) (emphasis added). These portions of the subsection include a catch all to protect information otherwise deemed confidential under federal law or materials the researcher must hold in confidence pending publication. Beginning with the concept of legal impediments, the CDC FOIA officer cited no law or regulation that would *require* the data at issue to be held in confidence. Thus, the only portion of the regulation left would be a claim that the grantee is "necessarily required" to hold the information in confidence. Yet, the CDC FOIA officer apparently neglected to refer to the second portion of that requirement, namely "until they are published." The section is not a complete bar to disclosure, rather it is an effort to restrain disgorgement of data *until publication occurs*. Reasonably, scientists that are in the process of conducting federally-funded analysis of data upon which agencies may later rely do not wish to disclose their data prematurely. Yet, that concern is not present here. The data at issue have been "published" in the Lanphear Study in Tables 1 and 2. The entire dataset at issue has been disclosed including some description of the values and categories. There is no concern about premature disclosure because "publication" has occurred. Indeed, under Circular A-110, publication happens whether *either* (a) it appears in a peer-reviewed publication *or* (b) a federal agency relies upon it to enact a rule with the force of law. Here, indisputably, *both* have occurred. Thus, while the investigator can resist disclosure for a time, it is not indefinite.

Indeed, the rule urged by the grantee in this situation and adopted by the CDC FOIA officer would essentially eviscerate Circular A-110. Under the interpretation adopted by the CDC FOIA officer, researchers could simply enter into a private agreement not to share their data no matter how often papers are published, the federal source of the financing or the fact that it is relied upon to make numerous regulations and laws. Circular A-110 would be rendered makeweight, thrown aside at the unfettered discretion of the researcher who would simply remember to "agree" not to disclose anything. Given the purposes of Circular A-110 and the public interest in seeing the foundation for the laws that govern the people, there can be no legitimate support for this interpretation. Courts and commentators have recognized that even a government promise of confidentiality to supplied information will not shield that information from a properly lodged FOIA request. *See* 37 Am. Jur. 2d § 72, p.122 ("[A]gency promises of confidentiality to those persons supplying it with information cannot in and of itself, defeat the

[32] The apparent redundancy of Section 552(b)(4) and Circular A-110, subsection 36(d)(2)(1)(A) may lie in the need for a record to be in the "control" of the agency for FOIA to apply. Although production of information required to be obtained under Circular A-110 is to be made pursuant to FOIA, it is not clear that the exemptions found in FOIA apply. The subsection at issue may designed simply to ensure that the commercial and trade secret protections found in Section 552(b)(4) extend to the information required to be disclosed under Circular A-110.

disclosure requirements of the Federal [FOIA] and similar state laws.") (citing *Save the Dolphins v. United States Dept. of Commerce*, 404 F. Supp. 407 (N.D. Cal. 1975)). The CDC FOIA officer's decision goes one step further and allows the government funded researcher to unilaterally designate his or her work free from disclosure or review.

The CDC FOIA officer's determination that the researcher's alleged agreement to maintain in confidence the data later disclosed in a peer reviewed publication and relied upon by the EPA in its rulemaking is erroneous and without factual foundation. The determination should be reversed and the grantee ordered to produce the data.

b. **The NIH FOIA Officer Erred In Concluding That The Data And Analysis In The Lanphear Study Are Not Related To NIH Grants.**

The NIH FOIA officer's determination is equally erroneous. She purportedly concluded that the NIH grant at issue simply related to a conference and not to the data analysis on which the EPA relied. (*See* Exhibit 2 ("The funds awarded under the subject NIEHS grant were used to fund travel expenses for Dr. Lanphear to a workshop where the groundwork for the pooled analysis was established. However, no data were produced or analyzed at the workshop.")).

First, this determination lacks factual foundation. How, exactly, did the NIH FOIA Officer determine that "no data were produced or analyzed at the workshop?" The grant application, (Exhibit 20), suggests that data analysis *would* occur at the workshop. Later progress reports detail the analysis that *did* occur. (Exhibits 21-23) Did the NIH FOIA Officer interview workshop participants? Did she review documents or minutes from the meeting? Again, her determination lacks foundation and, therefore, should be overturned on that basis. *See supra.*

Second, the NIH FOIA Officer states that "the grant referenced by Dr. Lanphear in his article, 1R13EDS10868-01, is a Conference grant." (Exhibit 2). But the Lanphear Study references no specific grant. Rather, it simply states that the "study was funded, in part, by the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency." Lanphear Study at 894. How did the NIH FOIA Officer determine which grant Dr. Lanphear meant with the general statement? As discussed above, HHS has provided multiple grants to Dr. Lanphear and his Center and it is HHS grant money that employed Dr. Lanphear's statistics "core" who provided the analysis for the study. (*See* Exhibits 21-23). In fact, the description contained in the Lanphear Study more readily describes the Center funding than the conference grant to which the NIH FOIA officer refers. The NIH FOIA officer erred in concluding, without an adequate factual record, that the *only* NIH grant at issue was a conference grant.

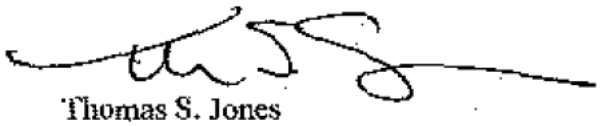
Finally, as the above discussion amply demonstrates, Dr. Lanphear and his statistics team were, indeed, funded by HHS money. As the progress reports submitted to HHS for grant

number ES11261-01 detail, the Pooled Analysis was a project undertaken by the HHS-funded Center and published using HHS and EPA money. (Exhibits 21-23) The NIH FOIA officer erred in her exclusive focus on Grant 1R13EDS10868-01. It is clear from the record that HHS money did, indeed, fund Dr. Lanphear's work and that of his colleagues that gave rise to the Lanphear Study.

II. Conclusion

Both the CDC FOIA officer and the NIH FOIA officer erred in denying Ms. Pohl's request. Neither should have re-examined the final determination of the EPA appeal. Additionally, both had inadequate factual foundations to reach the determinations they made. Finally, both erred, as a matter of fact and law, in their conclusions. The CDC FOIA officer erroneously determined that that grantee was entitled to an exemption designed to keep confidential commercial and trade secret information. The NIH FOIA officer erred in her interpretation of the NIH grants at issue and the funding sources for the Lanphear Study. On behalf of Ms. Pohl, we ask that pursuant to 45 C.F.R. § 5.34 that this appeal be granted within the twenty days set forth in 45 C.F.R. § 5.35(b)(2) and that the grantee be required to produce the data immediately.

Respectfully Submitted,



Thomas S. Jones

cc: Amy Pohl, Esq.

PII-1189491v1

EXHIBIT

AA

February 20, 2009

Dr. Bruce Lanphear
Simon Fraser University
Faculty of Health Sciences
Blusson Hall, Room 11300
8888 University Drive
Burnaby, B.C.
V5A 1S6

Re: FOIA Appeal Request Related to Data Collected Pursuant to CDC Cooperative Agreement Number R01/CCS21049-01

Dear Dr. Lanphear:

I am writing in follow-up to your December 11, 2008 email to Pam Wiggington, a staff member in the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health, (NCEH) Lead Poisoning Prevention Branch (LPPB) claiming the exclusion found at 45 CFR 74.36(d)(2)(i)(A), in relation to a Freedom of Information Act (FOIA) request that CDC received in relation to Cooperative Agreement (CA) number R01/CCS21049-01, awarded to the Children's Hospital Medical Center to fund the project entitled "International Pooled Analysis of Lead-Exposed Cohorts," of which you were the principal investigator. As you know, the initial FOIA request specifically sought data collected pursuant to the above-mentioned CA and subsequently published by the Environmental Protection Agency (EPA) on July 30, 2007 in the report, "Lead Human Exposure and Health Risk Assessment for Selected Case Studies," as well as in the January 26, 2007 EPA letter to Lead NAAQS Docket from Zachary Pekar (EPA OAQPS) regarding "Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implication for Pilot Risk Assessment."

Because the data sought by the FOIA request was collected under a CA funded by CDC, the research data is subject to OMB Circular A-110 and 45 C.F.R. 74.36(d). 45 C.F.R. 74.36(d)(1) states:

> In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under FOIA,...

The data that you collected pursuant to CA R01/CCS21049-01 was published by the EPA in reports placed on its website. More importantly, the research findings were cited in an EPA Advance Notice for Proposed Rulemaking (ANPR) for the lead National Ambient Air Quality Standards revision. The use of the data in this manner satisfies the "published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law" requirement of 45 C.F.R. 74.36(d). Therefore, in accordance with this regulation you are required to provide CDC with the research data so that the agency may be responsive to the FOIA request, unless an exclusion applies.

You claimed the exclusion found at 45 CFR 74.36(d)(2)(i)(A), did apply. That exclusion states that " 'research data' does not include: trade secrets; commercial information; materials necessary to be held confidential by a researcher until they are published; or similar information which is protected under law." CDC understands that you claim this exclusion because of "a stipulation in the confidentiality agreement stating that the data would be treated as confidential and would not be used or shared for any other purpose; [t]his is consistent with the exclusion, "the research data includes similar information which is protected under the law" by a prior agreement." Moreover, you contend that: "although many of the investigators were comfortable making their raw data available, our international colleagues were not willing to release their data. As such, it would not be possible to release the pooled data set."

Based upon your claim of exclusion, CDC denied the initial FOIA request from Jones Day. Jones Day has now filed an appeal of that denial. Jones Day is still seeking the data, and in its appeal (pages 15-19) argues that the confidentiality agreement you entered into does not meet the criteria for the exclusion that you claim. Additionally, Jones Day makes the argument that entering into such confidentiality agreements essentially allows researchers to circumvent the FOIA process.

CDC asks that you please review the enclosed appeal in light of your confidentiality agreement, and provide your thoughts regarding Jones Day's arguments as to applicability of the exclusion and the potential FOIA circumvention. Your response will aid CDC in responding to the FOIA appeal and in further protecting the data from release.

I have enclosed a copy of 45 C.F.R. 74.36(d), the FOIA appeal, your exemption claim and the confidentiality agreement for your review. Please contact the Office of the General Counsel or NCEH/LPPB staff should you have questions or wish to discuss the matter further. Your assistance in this matter is greatly appreciated.

Sincerely,

Kenya S. Ford
Senior Attorney
HHS Office of the General Counsel

Cc: Pamela Wigington, NCEH
Samantha Harrykissoon, NCEH
Lynn Armstrong, CDC FOIA Office
Patricia Mantoan, OGC

Enclosures