EXHIBIT 3

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 STEPHEN D. PAGE

I, Stephen D. Page, hereby declare and state as follows:

1. I am the Director, Office of Air Quality Planning and Standards Organization ("OAQPS") U.S. Environmental Protection Agency ("EPA" or "Agency"). I have held this position since 2002. Through the exercise of my official duties I am familiar with this civil action and I submit this declaration in conjunction with EPA's filing of Defendants' Opposition to Plaintiff's Motion for Attorneys' Fees and Costs in the above-captioned case. I declare that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge and on information supplied to me in my official capacity by employees under my supervision and other EPA employees.
2. I am the Director of OAQPS, which is part of the EPA Office of Air and Radiation ("OAR") and is located at Research Triangle Park, North Carolina. OAQPS is responsible for protecting human health and the environment by preserving and improving air quality in the United States. It was this office that handled the processing of Plaintiff's Freedom of Information Act (FOIA) request.

Pohl's FOIA Request

3. Through the exercise of my official duties, I have become familiar with the August 9, 2007, request for records from Amy K. Pohl under the FOIA, 5 U.S.C. § 552, which resulted in this civil action. Plaintiff's FOIA request, assigned tracking number HQ-RIN-01843-07, specified the following:

> 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 an Children's Intellectual Function: An International Pooled Analysis," *Environmental Health Perspectives*, 113(7) (2005) [("the Study")]. . . . 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. . . .
>
> 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.

According to Plaintiff's request, if "the EPA does not possess the data requested in this FOIA letter, then the EPA is required to obtain all the requested data" pursuant to "2 C.F.R. Part 215.36(d)." A true and correct copy of this document is attached as Exhibit A. To my knowledge, this was the first time that the Agency received a FOIA request pursuant to 2 C.F.R. Part 215.36(d).

4. EPA had communications with the authors of the Study prior to receiving Plaintiff's FOIA request. For example, EPA noted possible typographical errors in a table in the Study. As a result, EPA received from the authors and made publically available a corrected version of that table in the Study. However, EPA had not received the data underlying the Study.

5. Even though OAQPS employees were aware that EPA had never received the data, in response to Plaintiff's FOIA request, EPA checked with all the Agency scientists involved in the health aspects of the lead NAAQS review—as they would have been the only individuals likely to have had the data in their possession—and confirmed that no one had received data underlying the Study, with or without the data collection forms, software programs, or data dictionaries for the Study.

6. More specifically, Dr. Zachary Pekar, an employee in the Ambient Standards Group in OAQPS who was working with the published results of the Study and had docketed the corrected table for the Study, led the search for responsive documents. Dr. Pekar searched his e-mail and determined that he did not have any Study data and sent an e-mail to employees within EPA's Office of Research and Development (ORD) to confirm that EPA never received underlying Study data. None of the e-mail recipients indicated that they had received any raw data. One ORD employee indicated that he had obtained from the authors descriptive information about the Study data but that he had not received any data for the Study.

7. In an e-mail sent to Plaintiff by Sherry Russell dated September 21, 2007, which came from Kelly Rimer on my behalf, EPA explained that employees "within EPA's Office of Air Quality Planning and Standards conducted a search that was reasonably calculated to uncover records in the Agency's possession and control that were responsive to your request, and have not located any documents response to your request." A true and correct copy of this document is attached as Exhibit B.

8. The September 21, 2007, e-mail also explained that the Study was not subject to 2 C.F.R. § 215.37 [sic] because it was used in support of a draft report that did not have the force and effect of law.

9. On October 18, 2007, Plaintiff filed an administrative appeal. A true and correct copy of this document is attached as Exhibit C.

10. On February 14, 2008, Kevin M. Miller, Assistant General Counsel, General Law Office, in EPA's Office of General Counsel denied in part and granted in part Plaintiff's appeal. First, Mr. Miller denied the appeal on the ground that EPA had conducted a reasonable search for responsive records, and the Agency did not have the requested data. Second, Mr. Miller determined that, after the September 21, 2007, determination, the Study had been cited in an Advance Notice for Proposed Rulemaking for the lead National Ambient Air Quality Standards (NAAQS) revision and that the Agency was required by court order to issue its Proposed Rule for the lead NAAQS by May 1, 2008. Due to this change in circumstances, EPA's action now had "the force and effect of law" and thus Plaintiff's request now satisfied the requirements of EPA's regulations, 40 C.F.R. § 30.36. Mr. Miller determined that Plaintiff's request should be "process[ed]" in accordance with the regulation and stated that EPA would contact the grant recipient and request an estimate of fees for responding to Plaintiff's request. A true and correct copy of this document is attached as Exhibit D.

11. By letter dated May 29, 2008, which was signed by Jenny Noonan Edmonds on my behalf, EPA referred Plaintiff's FOIA request to HHS. Pursuant to statutory and regulatory authority, 5 U.S.C. § 552(a)(6)(B)(iii)(III); 40 C.F.R. 2.103(d), EPA can refer FOIA requests to other federal agencies when the records at issue originated with another

agency or another agency has a substantial interest in the determination of the request. EPA believed that, under this authority, it was appropriate for the granting agency to be the point of contact with the grantee and to coordinate the response to the request. Because HHS appeared to have been the primary source of federal funding for the Study, EPA referred the request to HHS. Ms. Edmonds's letter further explained that EPA had determined that the request satisfied the criteria under EPA's regulations that correspond to 2 C.F.R. § 215.36. A true and correct copy of this document is attached as Exhibit E.

12. To my knowledge, Plaintiff never contacted EPA to challenge EPA's decision to refer the request to HHS.

13. EPA had no further involvement with the processing of Plaintiff's FOIA request.

Steinwurtzel's FOIA Request

14. Almost two years after receiving Plaintiff's request, EPA received another request for the same information from an unrelated party.

15. On July 22, 2009, EPA received a FOIA request from Robert N. Steinwurtzel, on behalf of the Association of Battery Recyclers, Inc., "for information related to B.P., et. al., Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894-899 (2005) ('Lanphear (2005)'.)." The request sought, among other things, "the research data used in connection with the findings of the Lanphear (2005) study pursuant to FOIA, 2 C.F.R. § 215.3(d), and 40 C.F.R. § 30.36(d)." A true and correct copy of this document is attached as Exhibit F.

16. The Steinwurtzel request took note of EPA's referral of Plaintiff's request, addressing at length why EPA should not refer his request to HHS. In response to this argument, EPA examined its records, determined that both EPA and HHS had provided funding that supported Lanphear's published findings, and determined that either EPA or HHS could be proper agencies for processing FOIA requests for the study data under 2 C.F.R. § 215.36(d), 40 C.F.R. § 30.36. EPA did not refer Steinwurtzel's request, as it had Pohl's request. Steinwurtzel's request was assigned tracking number HQ-RIN-01677-09.
17. EPA first contacted Dr. Bruce Lanphear, the first author of the published study, with regard to the Steinwurtzel request for the data.
18. By letter dated April 8, 2010, Dr. Lanphear stated that he was declining to provide copies of raw "research data" because of the existence of confidentiality agreements. A true and correct copy of this document is attached as Exhibit G.
19. After receiving Dr. Lanphear's response, EPA's Office of Administration and Resources Management next contacted the Cincinnati Children's Hospital Medical Center (CCHMC) to request the data. On April 13, 2010, Jeff Meetre, Chief of EPA's Grants Management Branch A, sent a letter to CCHMC requesting that CCHMC provide EPA with a cost estimate for providing research data underlying the Lanphear study. A true and correct copy of this document is attached as Exhibit H.
20. On May 12, 2010, CCHMC responded by letter and informed EPA that CCHMC has an obligation to keep the data confidential and asserted that it was not required to provide a cost estimate for data. A true and correct copy of this document is attached as Exhibit I.
21. In subsequent communication, Denise Benjamin Sirmons, Director of EPA's Grants and Interagency Management division, asked to review the confidentiality agreements. In

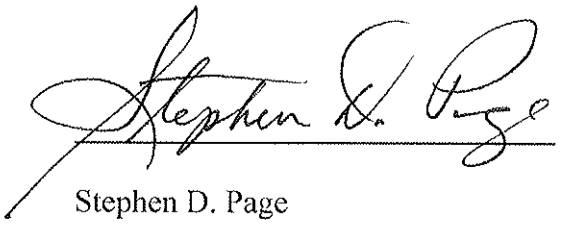
response, by letter dated on September 2, 2010, CCHMC indicated that Dr. Lanphear located two e-mails evidencing an agreement. In addition, CCHMC informed EPA that it "does not own a majority of the data being requested[;]" that "the underlying cohort data provided by the co-authors and used to create the pooled analysis was collected prior to 2000, before the effective date of the Shelby Act[;]" and that "some of the cohort data used to create the pooled analysis utilized no government funding." A true and correct copy of this document is attached as Exhibit J.

On November 22, 2010, Denise Benjamin Sirmons, Director of EPA's Grants and Interagency Management Division sent a letter to CCHMC that constituted the EPA's decision regarding this matter. EPA concluded that "CCHMC must provide the research data to EPA" under 40 C.F.R. § 30.36(d). A true and correct copy of this document is attached as Exhibit K.

22. It is my understanding that EPA did eventually receive the data from counsel at the Department of Justice as part of this litigation.

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

Executed on November 28, 2011.



Stephen D. Page
Director
Office of Air Quality Planning and Standards Organization
Office of Air and Radiation
U.S. Environmental Protection Agency

Page Declaration

EXHIBIT A

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.

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 [redacted]; Fax [redacted]

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 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 [redacted] *and email* [redacted] P.I.I. [redacted] *)*

Page Declaration

EXHIBIT B

Page Declaration **EXHIBIT B**

EPA_Office_of_Air_Quality_Planning_and_Standards@epamail.epa.gov

Sent by: [redacted] P.I.I.

09/21/2007 12:48 PM

To akpohl@jonesday.com

cc

bcc

Subject Your Freedom of Information Request - RIN-01843-07

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

Re: Freedom of Information Act Request RIN-01843-07

Dear Ms. Pohl:

This is in response to your Freedom of Information Act (FOIA) request of August 9, 2007, pursuant to 5 U.S.C. § 552 et seq. and 2 C.F.R. § 215.37 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").

Employees within EPA's Office of Air Quality Planning and Standards conducted a search that was reasonably calculated to uncover records in the Agency's possession and control that were responsive to your request, and have not located any documents responsive to your request.

Although Dr. Zachary Pekar did issue a correction notice regarding this study, EPA identified that error without having reviewed the data underlying the Study. Likewise, although EPA received, and made publicly available, a corrected table for the Study, EPA did not receive data underlying the study along with the correction table.

You also requested that EPA make the data available under 2 C.F.R. § 215.37. This regulation provides that, in certain circumstances, a Federal agency shall request research data from a researcher in response to a FOIA request. However, this provision only applies where published research findings produced under an award "was used by the Federal Government in developing an agency action that has the force and effect of law." 2 C.F.R. § 215.37(d)(1); see also § 215.37 (d)(2)(iii) (defining "used by the Federal Government in developing an agency action that has the force and effect of law").

As of the date of your request, EPA had cited the Study in support of its draft report, released July 30, 2007, Lead Human Exposure and Health Risk Assessment for Selected Case Studies (as well as an earlier draft report on a pilot version of the lead risk assessment, released December 15, 2006). This draft report does not have the force and effect of law. Indeed, the final version of this report will not have the force and effect of law when it is issued. Rather, it will represent an effort by agency staff to provide relevant

information to the Administrator for his use in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS) for lead. See 42 U.S.C. § 7409 (requirements for establishing and reviewing NAAQS); §7601(a)(1) (prohibiting Administrator from delegating the authority to promulgate or revise NAAQS). Accordingly, EPA is not required to obtain data underlying the Study pursuant to 2 C.F.R. § 215.37 and has not done so.

You may appeal this response to the National Freedom of Information Officer U.S. EPA, Records, FOIA and Privacy Branch 1200 Pennsylvania Avenue, NW (2822T) Washington, DC 20460, Fax: P.I.I. P.I.I., E-mail: P.I.I. The appeal must be made in writing and it must be submitted no later than 30 calendar days from the date of this letter. The Agency will not consider appeals received after the 30 calendar day limit. The appeal letter should include the RIN number listed above. For quickest possible handling, the appeal letter and its envelope should be marked "Freedom of Information Act Appeal."

Sincerely,

Kelly Rimer (for)

Stephen D. Page
Director
Office of Air Quality Planning

(Note: This mailbox does not accept reply messages.)

Page Declaration

EXHIBIT C

JONES DAY

500 GRANT STREET • SUITE 3100 • PITTSBURGH, PENNSYLVANIA 15219-2502
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akpohl@jonesday.com

JP420391/1164752v1
589170-096075

October 18, 2007

Appeal
OGC => Action
OAR => FYI
HQ-APP-000

VIA FACSIMILE P.I.I.
AND E-MAIL P.I.I.

National Freedom of Information Officer
U.S. Environmental Protection Agency
Records
FOIA and Privacy Branch
1200 Pennsylvania Avenue, N.W.
2822T
Washington, DC 20460

(ref. HQ-RIN-01843-07)

RECEIVED
OCT 18 2007

Re: Freedom of Information Act Appeal; RIN-01843-07

Dear Sir or Madam:

Please accept this appeal letter in connection with Freedom of Information Act ("FOIA") Request RIN-01843-07.

I. Summary of Freedom of Information Act Request RIN-01843-07

On August 9, 2007, our firm submitted a FOIA request to the Environmental Protection Agency ("EPA"). A copy of the August 9, 2007 FOIA request is attached to this appeal letter as Exhibit 1. The EPA acknowledged receipt of the FOIA request in a letter from EPA headquarters dated August 16, 2007. A copy of the EPA's August 16, 2007 acknowledgement letter is attached as Exhibit 2.

The August 9, 2007 FOIA letter requested data from a study cited in the following EPA report: "Lead Human Exposure And Health Risk Assessments for Selected Case Studies" (July 30, 2007) (hereinafter, "EPA Report" or "July 30, 2007 EPA Report"). The EPA Report was drafted by EPA in conjunction with ICF International, a recipient of federal funding under EPA

contract. The EPA Report was prepared as part of the EPA's larger agency action to review and potentially revise the National Ambient Air Quality Standards ("NAAQS") for lead, which are codified in the Code of Federal Regulations, 40 C.F.R. Part 50.12. The EPA Report contains a description of the results and methodologies of human exposure and health risk assessments relating to lead. *See* EPA Report Fact Sheet, attached as Exhibit 4. Information from the EPA Report will be considered along with other EPA reports and initiatives as the agency completes its review of the current lead standards and revises the lead standard in new regulations. *See id.*

Among other things, the EPA Report evaluates several research studies relating to lead exposure and risk assessment. In particular, the following peer-reviewed, published scientific study is referenced in the EPA Report: Bruce Lanphear, *et al.*, "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," *Environmental Health Perspectives*, 113(7) (2005) (hereinafter referred to as the "Lanphear Study"). The Lanphear Study was a federally funded study, funded by grants from the EPA and the National Institute of Environmental Health Sciences. The Lanphear Study consisted of an analysis of blood lead and lead exposure data relating to a group of children. The EPA and/or ICF International clearly relied on the Lanphear Study in preparing the July 30, 2007 EPA Report. The EPA Report makes extensive reference to the Lanphear Study, and the risk assessment analysis and conclusions set forth in the EPA Report are largely dependent on information from the Lanphear Study.

Notably, the EPA also previously considered and relied on the Lanphear Study in connection with its October 2006 "Air Quality Criteria Document" for Lead. *See, e.g.*, U.S.

Environmental Protection Agency, Air Quality Criteria Document for Lead, *available at* http://www.epa.gov/tnn/naaqs/standards/pb/s_pv_cr_cd.html, at p. 8-28. The Air Quality Criteria Document is another EPA Report prepared as part of the EPA's regulatory activities regarding federal air quality standards for lead. Significantly, the primary author of the Lanphear Study – Dr. Bruce Lanphear – is a member of the EPA's own Clean Air Scientific Advisory Committee. The Clean Air Scientific Advisory Committee is charged with reviewing both the October 2006 Air Quality Criteria Document, as well as the July 30, 2007 EPA Report. The EPA's reliance on the Lanphear Study as part of both the October 2006 Air Quality Criteria Document and the July 30, 2007 EPA Report, along with Dr. Lanphear's membership on the EPA Clean Air Scientific Advisory Committee, strongly suggest that the EPA has access, control and/or possession of the underlying data from the Lanphear Study.

In our August 9, 2007 FOIA letter, we requested a copy of all underlying data from the Lanphear Study. As stated in our August 9 letter, we believe that the data from the Lanphear Study is subject to disclosure. To the extent the EPA has possession of the Lanphear Study data, we requested a copy of the data from the EPA, as required under FOIA. *See* Ex. 1 (citing FOIA, 5 U.S.C. §552). To the extent EPA does not have possession of the data, we requested that EPA obtain a copy of the data from ICF International and/or Dr. Lanphear, as required under OMB Regulations permitting public access to data from federally-funded scientific studies. *See* Ex. 1 (citing OMB Regulations at 2 C.F.R. Part 215.36).

II. EPA's September 21, 2007 Determination of FOIA Request

Mr. Stephen Page, from EPA's Office of Air Quality, sent EPA's written response to the FOIA request on September 21, 2007, via electronic mail. A copy of the EPA's September 21 written response is attached to this appeal letter as Exhibit 3. In its September 21 response, EPA denied the FOIA request on two grounds.

First, EPA stated that it was unable to produce the data requested under FOIA because EPA did not have possession of the data.

Second, EPA denied its responsibility to obtain a copy of the requested data from ICF International or Dr. Lanphear under OMB Regulations at 2 C.F.R. Part 215.36. In its September 21 response, EPA claimed that the July 30, 2007 EPA Report in which the Lanphear Study was referenced is not an agency action having the "force and effect of law." EPA maintained that it is not required to obtain data from federally-funded research studies under 2 C.F.R. Part 215.36 where the studies are not cited in support of an agency action that has the effect and force of law, and, thus, EPA took the position that it was not required to obtain the Lanphear data for production in response to our FOIA request. *See* Ex. 3.

We disagree with the EPA's September 21 letter denying our FOIA request. We submit this administrative appeal of the determination within the time required by FOIA and applicable EPA regulations.

III. Grounds for Appeal

The EPA's decision to deny the August 9, 2007 FOIA request should be revisited and reversed, on two grounds. First, the EPA should search its own files again for the data requested

and produce any data in its possession under FOIA. Second, EPA must obtain a copy of the data from ICF International and/or Dr. Lanphear under 2 C.F.R. Part 215.36.

A. ***EPA must produce the data under FOIA if it is within the EPA's possession.***

There is no dispute that EPA is required to produce the data from the Lanphear Study under FOIA if EPA has possession of the data. *See* 5 U.S.C. §552. In its September 21, 2007 letter, EPA claimed that it searched, but located no documents responsive to our FOIA letter within the EPA's possession or control. *See* Ex 3.

It is very difficult to believe that EPA does not possess the requested data. EPA could not have prepared its July 30, 2007 EPA Report without at least some review or analysis of the data from the Lanphear Study. The Report was "part of the Environmental Protections [sic] Agency's (EPA's) review of the National Ambient Air Quality Standards (NAAQS) for lead (Pb)." Exhibit 5, EPA Report – Preface. It was "reviewed by the Office of Air Quality Planning and Standards, [USEPA], and approved for publication." *Id.* The Report was "prepared by staff of the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency." *Id.* "Volume I of this document has been drafted by EPA staff, and the appendices (contained in Volume II) have been drafted by EPA staff, in conjunction with ICF international (through Contract No. EP-D-06-115)." *Id.* Thus, it is clear that EPA staff are the principal drafters of the Report, in conjunction with ICF International under a government contract.

The EPA Report purports to describe "quantitative human exposure and health risk assessments being conducted" in support of the NAAQS review. *See* Exhibit 6, EPA Report – Introduction, at p. 1-1. To quantify risk, the EPA Report "focuses on IQ loss in children."

Exhibit 7, EPA Report – Section 4.1, at p. 4-1. "IQ loss is derived using a set of concentration-response functions *developed* based on results from a pooled analysis of epidemiology studies (Lanphear *et al.*, 2005)." *Id.* This is the data which is requested in our August 9, 2007 FOIA request. Throughout the Report, EPA indicates that it has developed risk assessment models based upon the Lanphear Study data:

- "[L]og-linear concentration-response functions for IQ loss for the concurrent and lifetime average blood PB metrics were obtained from a large pooled study (Lanphear et al., 2005) and used as the basis for estimating IQ changed in children in this analysis." *Id.*
- "Plots of the three types of IQ-loss functions *developed for this assessment* are presented in Figure 4-1 for the concurrent blood PB metric." *Id.*

Indeed, specific comments in the EPA Report certainly suggest review of the data from the Lanphear Study. For example, the EPA Report states "[t]his concentration-response function is the log-linear function for IQ change form Lanphear et al. (2005), with incorporation of a cutpoint at the blood Pb level *corresponding to the lowest levels represented by measurements in the underlying pooled analysis*." Exhibit 7, EPA Report – Section 4.1.1.1, at p. 4-3 (emphasis added). This comment directly references the underlying data in the Lanphear Study. It seems unlikely that EPA could have made such a reference without EPA review of the actual "measurements in the underlying pooled analysis."

In the part of the EPA Report regarding analysis of the Two-piece Linear Function, the EPA describes its procedure as follows: "[t]he procedure involved first generating blood Pb values for each of the two blood Pb metrics, concurrent and lifetime average, for a set of N =

1,333 simulated children representative of those included in the pooled analysis (Lanphear et al., 2005)." Exhibit 7, EPA Report – Section 4.1.1.3, at p. 4-4. Again, it appears that the EPA modeling exercise involved comparison to the children included in the Lanphear Study, a difficult task if the EPA never actually saw the Lanphear Study data representing such children.

In December, 2006, the EPA published a Technical Report titled: "*Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas – Pilot Phase – External Review Draft Technical Report*" (Dec. 15, 2006), *available at* http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html ("Technical Report" or "December 2006 Technical Report"). The December 2006 Technical Report, which formed the foundation of the July 30, 2007 EPA Report, further supports the conclusion that the EPA or its staff had access to the Lanphear Study data at issue. That Technical Report, prepared by ICF in conjunction with the EPA staff, also stated that "the blood Pb-IQ relationships are derived from the results of a recent analysis of pooled epidemiological data by Lanphear et al. (2005)." Exhibit 8, Technical Report – Section 6.1.1, at p. 6-1. Although not entirely clear, the following paragraph suggests that ICF and/or EPA reviewed and manipulated the Lanphear Study data:

> As noted above, the blood Pb-IQ models were derived from the results of a large epidemiological analysis by Lanphear et al. (2005), in which the relationships between blood Pb concentrations and IQ test results in seven populations were analyzed. The 1,333 subjects in the study population included subjects of four studies in the Untied States, and one each from Mexico, Australia, and Kosovo. A number of statistical techniques were used to characterize the relationships between several blood Pb metrics and test results for individual cohorts and for the pooled study population For the pilot phase assessment, model forms were selected that related to IQ change to two blood pb metrics, lifetime

> average and concurrent. . . . The log-linear model for IQ loss derived from the Lanphear et al. pooled analysis was adapted for use in the pilot phase assessment.

Exhibit 8, Technical Report – Section 6.1.2, at p. 6-1-6-2. The authors go on to discuss the distribution of data in the Lanphear Study data set: "[B]ecause of the log linear form of the models, they predict very large changes in IQ for small changes in blood Pb at low concentrations. *Thus, it is important to stay within the range of the exposure data used in fitting the functions when predicting IQ loss for hypothetical exposed* populations." *Id.* at p. 6-2.

The core of the on going risk assessment in the EPA Report is the assessment of various lead levels on IQ. It seems highly unlikely that EPA would take at face value Dr. Lanphear's work which was conducted pursuant to a federal grant. The various comments, model construction and error recognition contained in the EPA Report all suggest that EPA staff have had access to materials and data that underlie Dr. Lanphear's published study.

The conclusion that the EPA must have possession or control of the Lanphear Study data is further supported by the fact that the Lanphear Study was relied on in the EPA's Air Quality Criteria Document published in October, 2006. *See, e.g.,* U.S. Environmental Protection Agency, Air Quality Criteria Document for Lead, *available at* http: // www.epa.gov /tnn/ naaqs/standards/pb/s_pv_cr_cd.html, at p. 8-28. Indeed, Dr. Lanphear himself is a member of the EPA's Clean Air Scientific Advisory Committee – the very Committee responsible for reviewing and evaluating the scientific data and research supporting the EPA's review of NAAQS Lead regulations. *See* Exhibit 9 (Advisory Committee member list). It is very unlikely that, in assessing the scientific bases for the Air Quality Criteria Document, the EPA's own

Scientific Advisory Board would not have obtained copies of the scientific data cited by the agency. Surely the agency or the agency's Clean Air Scientific Advisory Committee reviewed the Lanphear Study data before relying on the Study in the Air Quality Criteria Document. Further, the EPA has access to or control of Dr. Lanphear's data due to his participation as a member of an agency committee.

We respectfully request that EPA conduct another search of its records for the data requested in our August 9 FOIA letter. If EPA has possession of the data, then we request that the data be produced to us immediately.

B. EPA must obtain a copy of the data from ICF International and/or Dr. Lanphear.

To the extent EPA does not have possession of the data requested, the EPA is obligated to request and obtain a copy of the data from either ICF International or Dr. Lanphear under OMB Regulations permitting public access to federally funded research data, codified at 2 C.F.R. Part 215.36.

1. *Background on 2 C.F.R. Part 215.36:*

By way of background, in 1998 the Shelby Amendment was added to an appropriations act, requiring federal agencies such as the EPA to make available to the public research data produced by federal funding grantees. The Shelby Amendment was intended to allow public access to data in order to secure public confidence in government spending:

> Transparency and accountability in government are two principles crucial to securing the public trust. Americans have a right to know how their tax dollars are spent and whether they are spent wisely, as well as the underlying scientific basis for many of our federal policies and rules.

Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 Harv. J. on Leg. 369, 370.

The Shelby Amendment required the Office of Management and Budget ("OMB") to devise a policy and regulations that would provide public access to data from federally-funded research projects. Accordingly, the OMB issued a revised Circular A-110 in 1999, which provided for public access of federal grantee data in certain situations. The final revisions of OMB Circular A-110 were published on October 9, 1999, and the regulation became effective April 17, 2000. *See* 64 Fed. Reg. 54926 (Oct. 8, 1999); 65 Fed. Reg. 14406 (Mar. 16, 2000). At the time it published the Circular in October 1999, the OMB also published comments which aid in interpreting the meaning of the data access policy. *See* 64 Fed. Reg. 54926 (Oct. 8, 1999).

The final revision of OMB Circular A-110 was eventually codified in the Code of Federal Regulations (C.F.R.) in 2004. The current regulation regarding access to data from federally-funded grants is now contained in 2 C.F.R. Part 215.0-215.73 ("OMB Regulation").

2. *Text of 2 C.F.R Part 215.36:*

The relevant text of the OMB Regulation states as follows:

> **(d)(1)** [I]n response to a Freedom of information Act (FOIA) request for research data relating to published research findings produced under an award that was 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 the FOIA. If the Federal 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 the costs incurred by the agency, the recipient, and the

applicable sub recipients. This fee is in addition to any fees the agency may assess under the FOIA.

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

(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) Personal and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy . . .

(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.

2 C.F.R. Part 215.36(d)(1).

3. *The EPA incorrectly denied the FOIA request for data*

In its September 21 response letter, EPA stated that it was not required to obtain the data requested because the OMB Regulations only require production of data cited in support of agency actions having the "force and effect of law." *See* Ex. 3. The EPA claims that the EPA's

July 30, 2007 Report does not have the "force and effect of law," and therefore EPA will not obtain the requested data cited in the Report. *See* Ex. 3.

EPA's September 21 decision is incorrect, for two reasons.

First, the general spirit and underlying purpose of the OMB Regulation is frustrated by the EPA's refusal to permit public access to data from federally-funded research studies such as the Lanphear Study. The OMB Regulation seeks to implement a balanced approach that "(1) furthers the interest of the public in obtaining the information needed to validate Federally-funded research findings, (2) ensures that research can continue to be conducted in accordance with the traditional scientific process, and (3) implements a public access process that will be workable in practice." 64 Fed. Reg. 54926 (Oct. 8, 1999). The primary stated purpose of the OMB Regulation -- to "further the interest of the public in obtaining the information needed to validate federally-funded research findings" -- is not satisfied when agencies such as EPA deny FOIA requests for research data from published, federally-funded studies. The purpose of the Shelby Amendment and the OMB Regulation is to provide taxpayers (those who pay for the research studies) the ability to access and review the underlying data through the procedures in FOIA. This purpose is not served when agencies such as the EPA here limit or refuse public access to data from published federally-funded research studies.

Second, contrary to the EPA's September 21 letter, the EPA Report ***is*** part of an agency action that will have the force and effect of law. The EPA is in the process of reviewing the agency's national ambient air quality standards ("NAAQS"). NAAQS are standards mandated by federal regulation, and have the force and effect of law. *See* 40 C.F.R. Part 50.2. The

NAAQS for lead is codified in the Code of Federal Regulations, 40 C.F.R. Part 50.12. The EPA is in the process of determining whether and how to revise the NAAQS for lead. The EPA's decision to revise (or to retain) NAAQS for lead will ultimately be subject to formal notice, rulemaking, and regulation that will have the force and effect of law.

The EPA Report was produced to support the agency's regulatory action to review and potentially revise of NAAQS for lead. *See* EPA Report Fact Sheet, attached as Exhibit 4. The EPA Report will become part of the EPA's determination in revising or retaining the regulatory air quality standards:

> These documents were developed under our historic approach for reviewing NAAQS, which has included completion of a policy assessment, in the form of a Staff Paper, and of any related risk and exposure assessments (risk/exposure reports) prior to the development of *notices of proposed and final rulemakings*. The policy assessment is intended to "bridge the gap" between the scientific assessment contained in the CD [Air Quality Criteria Document for Lead] and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

See Preface to EPA Report (July 30, 2007), attached as Exhibit 5 (emphasis added).

Significantly, the EPA Report was open to public review and comment. Public comment and review is required for agency actions that will amount to rulemaking and binding regulations having the force and effect of law. The EPA Report was subjected to such public comment and review. *See* 73 Fed. Reg. 41325-41326.[1] In the Federal Register Notice of public review and

[1] In fact, the OMB Comments to the OMB Regulation suggest that data should be made available to the public whenever agency actions or activities are in a public comment period. The OMB received numerous comments inquiring about the timing of data access during public comment periods, and the OMB suggested that a "reasonable time" standard was sufficient to ensure that the public could have access to data within the public comment periods:

comment, the EPA even referred to the EPA Report as a "support document" for EPA's regulatory process of reviewing and potentially revising of the NAAQS for lead. *See id.* at 41325. Characterization of the EPA Report as a "support document" for the EPA's regulatory action is strong indication that the EPA Report is part of an agency action having the force and effect of law, which entitles the public to review of research data. The August 9, 2007 FOIA request for research data also advised the EPA that the data was needed "so that we may meaningfully assess the [EPA] report within the applicable comment period set by the EPA." *See* Exhibit 1. When it denied our FOIA request, the EPA denied our right to meaningfully assess the EPA Report within the public comment period established in the Federal Register Notice.

The OMB Regulations state that agencies like EPA must obtain and produce "research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law...." 2 C.F.R. Part 215.36(d)(1). The research findings from the Lanphear Study cited in the EPA Report are clearly being used by the EPA in "developing" an agency action having the force and

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(continued...)

> A number of commenters raised concern about whether requesters would be able to obtain the research data sufficiently in advance of when public comments are due on proposed regulations . . . since OMB and the agencies do not yet have experience with implementing the public access process, we believe the "reasonable time" standard, which allows consideration of the circumstances of a particular case, is appropriate. As OMB and the agencies gain experience with the public access process, we may be able to develop further clarification on this point.

Id. at 54929.

effect of law (*i.e.*, the revision of air quality standards in EPA regulations). Indeed, the Lanphear Study has also been relied upon in the EPA's other, related agency reports regarding Air Quality, which similarly are part of the EPA's regulatory action. *See, e.g.*, U.S. Environmental Protection Agency, Air Quality Criteria Document for Lead, *available at* http:// www.epa.gov /tnn /naaqs/ standards/pb/s_pv_cr_cd.html, at p. 8-28. Accordingly, the EPA's September 21, 2007 denial of the FOIA request for research data should be reversed, and the data should be made available immediately.

For agency convenience, a copy of the Lanphear Study is attached as Exhibit 10.

IV. Conclusion

For all of the reasons stated above, the EPA's denial of our August 9, 2007 FOIA Request was improper, and should be overruled or reversed by the agency. The EPA should grant the August 9, 2007 FOIA request, and obtain and produce the data requested therein.

Consistent with FOIA and applicable EPA regulations, we request a written determination of this administrative appeal within twenty (20) days.

Please contact me if you have any questions.

Very truly yours,

Amy K. Pohl

Enclosures

cc: Stephen D. Page (w/encs.)
Director
Office of Air Quality Planning

Page Declaration

EXHIBIT D

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

Page Declaration

EXHIBIT E

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 [redacted]

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

Page Declaration

EXHIBIT F

Page Declaration **EXHIBIT F**

BINGHAM

Robert N. Steinwurtzel
Direct Phone: 202.373.6030
Direct Fax: 202.373.6001
robert.steinwurtzel@bingham.com

JUL 23 2009

July 22, 2009

Via Electronic Mail

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
P.I.I.

Re: Freedom of Information Request - Lanphear (2005)

Dear FOIA Officer:

On behalf of the Association of Battery Recyclers, Inc. ("ABR"), I am submitting this Freedom of Information Act ("FOIA") request for information related to Lanphear, B.P., *et al.*, Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894–899 (2005) ("Lanphear (2005)"). The U.S. Environmental Protection Agency ("EPA") provided a grant toward the publication of this study and the study was relied on by EPA in promulgating the National Ambient Air Quality Standards for Lead, Final Rule, published at 73 Fed. Reg. 66,964 (Nov. 12, 2008) ("Lead NAAQS Rule"). Therefore, ABR requests the research data used in connection with the findings of the Lanphear (2005) study pursuant to FOIA, 2 C.F.R. § 215.36(d), and 40 C.F.R. § 30.36(d). ABR also requests any EPA records related to the Lanphear (2005) study, including, but not limited to, records related to the EPA grant, records related to other FOIA requests for the research data, EPA's review of the Lanphear (2005) study with respect to the Lead NAAQS Rule, and EPA's review of the Lanphear (2005) study with respect to the Information Quality Act.

"Research data" is defined as: "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings," excluding preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. 40 C.F.R. § 30.36(d)(2)(i). Such research data, and this request, include:

1. A copy of all data related to the Lanphear (2005) study, including copies of the data sets used, such as the data from the Boston,

Boston
Hartford
Hong Kong
London
Los Angeles
New York
Orange County
San Francisco
Santa Monica
Silicon Valley
Tokyo
Walnut Creek

Bingham McCutchen LLP
2020 K Street NW
Washington, DC
20006-1806

202.373.6000
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Cincinnati, Cleveland, Port Pirie, Rochester, Mexico City and Yugoslavia prospective child development studies.

2. Any data and materials required to access and analyze the data, including any documents explaining the multi-step process employed by Lanphear (2005) in which the data from individual studies was first fitted to simple unadjusted models and then combined into a linear model adjusted for the seven study sites. In particular, details of the methods used for "adjustment for study site" are requested as well as all methods used in the generation of the single linear model subsequently generated and subjected to analysis using a restricted cubic spline function.

3. All data pertaining to the derivation of the single linear model referred to in paragraph 2. above, inclusive of identifiers for individual data points, their associated blood lead measures and all confounder data associated with each data point.

4. Any documents showing calculations pertaining to the "final model" developed in the pooled analysis, inclusive of details defining the seven separate adjusted models developed for each of the cohorts, and the impact of omitting individual data sets upon overall model characteristics and descriptive parameters.

In February of 2008, EPA determined that it is obligated to obtain research data relating to the Lanphear (2005) study pursuant to 2 C.F.R. § 215.36 and 40 C.F.R. § 30.36, because of its use in the notice of proposed rulemaking for the Lead NAAQS Rule. In a letter from Kevin M. Miller, Assistant General Counsel, to Ms. Amy Pohl, Jones Day (Exhibit 1), EPA indicated that it would "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." Ex. 1 at 2. Although there are some exceptions to what constitutes "research data," EPA did not find any of these exceptions applied to the requested data. Similarly, none of these exceptions apply to the information being requested in this letter.

It was not until May 1, 2009, that EPA first indicated to ABR that EPA had referred the FOIA request at issue in the February 2008 letter to the Department of Health and Human Services ("HHS") (Exhibit 2). To our knowledge, HHS has declined to obtain the data and, thus, has not made it publicly available.

EPA cites to no authority in the May 1, 2009 letter for its referral of the FOIA response to HHS, noting only that HHS "appeared to have been the primary source of federal funds for the study." Ex. 2 at 2. Congress directed the Office of Management and Budget ("OMB") to revise its circular, upon which EPA's regulations are based, "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Pub. L. No. 105-277. *See also* 64 Fed. Reg. 54,926, 54,926 (Oct. 8, 1999). OMB recognized that Congress intended the requirement to apply to all agencies that provide federal funds, regardless of whether the agency is the "primary" source of funds:

> As noted in the proposed revision, the legislative history to the provision contained in Public Law 105–277 indicates that "the amended Circular shall apply to all Federally-funded research, *regardless of the level of funding* or whether the award recipient is also using non-Federal funds." 144 Cong. Rec. S12134 (October 9, 1998) (Statement of Sen. Campbell).

64 Fed. Reg. at 54,929 (emphasis added). Neither 2 C.F.R. § 215.36 nor 40 C.F.R. § 30.36 is limited to the "primary" source of federal funds, but requires all awarding agencies to obtain the data in response to a FOIA request.

EPA provided funds used for the Lanphear (2005) study through EPA Grant R829389. *See* EPA, 2003 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children, *available at* http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2003. *See also* Lanphear (2005) at 894. OMB regulations refer to the "Federal awarding agency." 2 C.F.R. § 215.36(d)(1). "Federal awarding agency means the Federal agency that provides *an award* to the recipient."[1] 2 C.F.R. § 215.2(o) (emphasis added). Section 30.36(d)(1) of EPA's regulations requires *EPA* to request the research data in response to a FOIA request and requires the recipient to 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." 40 C.F.R. § 30.36(d)(1). Further, OMB determined that Congress was concerned with giving the public access to the data that is being used in support of agency action. 64 Fed. Reg. at 54,928. Here, it is EPA, not HHS, that is relying on the Lanphear

[1] "Award means financial assistance that provides support or stimulation to accomplish a public purpose." 2 C.F.R. § 215.2(e).

(2005) study in support of the Lead NAAQS Rule. EPA cannot, therefore, avoid its FOIA obligations or to further unreasonably delay obtaining the requested information by referring the request to HHS.

Moreover, EPA regulations only provide for a "referral" of a FOIA request when the documents requested "originated with another Federal agency." 40 C.F.R. § 2.103(d). Such is not the case here, as the data did not originate with HHS. Even if this regulation gave EPA authority to "refer" the request to HHS, courts have made clear that this does not relieve EPA of the duty to comply with its FOIA obligations. *See In the Matter of Wade*, 969 F.2d 241, 248 (7th Cir. 1992) ("The agency cannot avoid the request or withhold the documents by referring them back to the agency where they originated.") (citing *McGehee v. CIA*, 697 F.2d 1095, 1110 (D.C. Cir. 1983)).

Finally, this Administration has stated a renewed commitment to science and transparency. Among President Obama's first acts as President was to issue several memoranda to federal agency heads expressing a commitment to openness in government. *See* Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Freedom of Information Act, Jan. 21, 2009, 74 Fed. Reg. 4683 (Jan. 26, 2009); Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Transparency and Open Government, Jan. 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009). President Obama stated: "The presumption of disclosure also means that agencies should take affirmative steps to make information public. They should not wait for specific requests from the public. . . . Disclosure should be timely." 74 Fed. Reg. at 4863. Administrator Jackson echoed this commitment to openness. EPA, Mem. to EPA Employees, Jan. 23, 2009, http://www.epa.gov/administrator/memotoemployees.html (last visited July 16, 2009). *See also* EPA, Administrator Lisa Jackson, http://www.epa.gov/administrator/ (last visited July 16, 2009) ("As Administrator, I will ensure EPA's efforts to address the environmental crises of today are rooted in three fundamental values: science-based policies and programs, adherence to the rule of law, and *overwhelming transparency*.") (emphasis added).

EPA has already agreed it has an obligation to provide the data pursuant to FOIA and its regulations and has had, at least, since February 2008, to obtain and make the requested research data available to the public. Due to EPA's long delay in making the information available to the public, we request that such records be made available immediately. In addition, FOIA prescribes a limit of twenty working days for compliance with requests for agency records. 5 U.S.C. § 552(a)(6)(A)(i).

Please contact me if there are any questions concerning this request. I agree in advance to pay reasonable costs of searching for, obtaining and copying the requested research data and records; however, please notify me if the costs are likely to exceed $100.00.

Thank you for your prompt attention to this matter.

Sincerely yours,

Robert N. Steinwurtzel

Robert N. Steinwurtzel

Attachments

cc: Gina McCarthy, Assistant Administrator, Office of Air and Radiation
Linda A. Travers, Acting Chief Information Officer

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

MAY - 1 2009

OFFICE OF
AIR AND RADIATION

Mr. Robert Steinwurtzel
Bingham McCutchen, LLP
2020 K Street, N.W.
Washington, D.C. 20006-1806

Dear Mr. Steinwurtzel:

Thank you for your letter dated March 18, 2009, on behalf of the Association of Battery Recyclers (ABR). In this letter, you express concerns about the March 6, 2009, U.S. Environmental Protection Agency (EPA) decision to defer consideration of the ABR Request for Correction (RFC) dated October 14, 2008, due to pending litigation related to the revised National Ambient Air Quality Standards (NAAQS) for lead. You also request that EPA provide the underlying data and an explanation of methodology and calculations for the Lanphear study[1] that was referenced in the ABR RFC because this information was requested in a 2007 Freedom of Information (FOIA) request.

The *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA IQG) are not intended to impose legally binding requirements or obligations on EPA or the public or to contravene any other legal requirements that may apply to particular agency determinations or other actions.[2] When EPA issued the January 8, 2009, interim response,[3] an internal review of the draft response was being conducted. Shortly thereafter, we were informed that the ABR had filed a petition for review of the Lead NAAQS rule.[4] Consistent with the approach the Agency has taken in its response to other IQG requests when the issues raised in the request may be related to open litigation, EPA made the decision to defer consideration of the ABR IQG request until the conclusion of this litigation.

On August 9, 2007, a requester submitted a FOIA request to EPA seeking the underlying data for the Lanphear study pursuant to 2 C.F.R. § 215.36. After granting the

[1] Lanphear, B.L., Hornung, R., Khoury, J., Yolton, K., Baghurst, P., Bellinger, D.C., Canfield, R.L., Dietrich, K.N., Bornschein, R., Greene, T. Rothenberg, S.J., Needleman, H.L., Schnaas, L., Wasserman, G., Graziano, J., Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: An international pooled analysis. Environ Health Persp 113(7): 894-899.
[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA, 2002. (67 FR 63657), pg 4
[3] http://www.epa.gov/quality/informationguidelines/documents/09001-interim.pdf
[4] *Coalition of Battery Recyclers Association v. EPA*, No. 09-1011 (D.C. Cir., filed Jan. 12, 2009)

requester's appeal, EPA referred her request to the Department of Health and Human Services for further processing, as that agency appeared to have been the primary source of federal funds for the study. If you are interested in reviewing the underlying data for this study, you may wish to submit a similar request to the Department of Health and Human Services.

If you have additional questions or require further information on the EPA IQG administrative mechanism, please contact Reggie Cheatham at [redacted] P.I.I.

Sincerely,

Elizabeth Craig

Elizabeth Craig
Acting Assistant Administrator

cc: Linda Travers, Acting Assistant Administrator
and Chief Information Officer, OEI
Robert Eckert, FOIA Officer, HHS

Page Declaration **EXHIBIT F**

FOIA Request
Franco, Sandra to: FOIA HQ 07/22/2009 05:04 PM
Cc: Linda Travers, Shela Poke-Williams, "Steinwurtzel, Robert N."

Please find attached a FOIA request being submitted on behalf of the Association of Battery Recyclers.

Thank you in advance for your attention to this matter.

Regards,
Sandra Franco

Print Less --> Go Green

Counsel
202.373.6019
202.373.6001
[illegible]@bingham.com

Bingham McCutchen LLP
2020 K Street NW
Washington, DC 20006-1806

 FOIA Request.pdf FOIA Request Ex. 1.pdf FOIA Request Ex. 2.pdf

EXHIBIT G

SFU

April 8th, 2010

Steve Page, PhD
Director, Office of Air Quality Planning and Standards
US Environmental Protection Agency
Research Triangle Park, NC 27711

Steve:

This letter, which is in response to your letter dated January 29th, 2010, is to confirm that I am declining to provide copies of raw "research data" for the article titled, "Low-level environmental lead exposure and children's intellectual function: an international pooled analysis", published in Environmental Health Perspectives 2005;113:894-899".

The reason I am declining to provide these data is because of the existence of confidentiality agreements, which precludes the release of further sharing of data. As you noted in your letter, I was unsuccessful in requesting a waiver of the confidentiality agreement from more than one of the co-authors of the pooled analysis study.

I would certainly be willing to talk with you more about the possibility of establishing an independent re-analysis of the data, but it would need to conform to existing standards of independent review.

Best regards,

Bruce Lanphear, MD, MPH
Senior Scientist, Child & Family Research Institute
Professor, Simon Fraser University
Vancouver, BC

Page Declaration

EXHIBIT H

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

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

April 13, 2010

Peter C. Koch
Assistant Vice President, Sponsored Programs
Office of Sponsored Programs
Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, OH 45229

Re: EPA Grant Number R-82938901-0; "Study of Prevalent Neurotoxicants in Children"; EPA Freedom of Information Act Request No. HQ-RIN-01677-09.

Dear Mr. Koch:

I am writing pursuant to 40 CFR § 30.36(d) to request that the Children's Hospital Medical Center (CHMC) provide EPA with a cost estimate for providing research data that relate to published findings that appear to have been produced in part under Grant Number R-82938901-0 that are subject to a Freedom of Information Act (FOIA) request. These regulations provide that, in response to a FOIA request, when published research findings produced under an award are used by the Federal Government in developing an agency action that has the force and effect of law, EPA shall request and the award recipient shall provide the research data through the procedures established by FOIA within a reasonable period of time.

A copy of the FOIA request is enclosed. (Enclosure 1). It covers research data relating to Lanphear, B. P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D. C.; Canfield, R. L.; Dietrich, K. N.; Bornschein, R.; Greene, T.; Rothenberg, S. J.; Needleman, H. L.; Schnaas, L.; Wasserman, G.; Graziano, J.; Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894-899 ("the article"). The article was listed in CHMC's final report for Grant Number R-82938901-0. The article also contains an acknowledgement that the study was funded in part by EPA. EPA used and cited this study in its recent review and revision of the National Ambient Air Quality Standards for lead, which was an agency action that had the force and effect of law within the meaning of 40 CFR 30.36(d)(1) and 40 CFR 30.36(d)(2)(iii).

For these purposes, EPA's regulations define "research data" 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.

40 CFR 30.36(d)(2)(i). EPA is authorized to 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." 40 CFR 30.36(d)(1).

EPA has estimated that the cost of responding to the pending FOIA request (which includes requests for EPA records as well as the instant request for research data) is greater than the costs which have been authorized by the requester. As the first step in this process, EPA is requesting only that you provide an estimate of the cost to you (and others) of providing the research data for this study, in order to determine whether the requester wishes to pay the necessary fees. Such costs would include the cost of producing a copy of the research data and providing it to EPA. If you wish to identify certain data that are provided as medical information or confidential business information, then you should also estimate the cost of identifying such information (and of segregating or masking the data as appropriate).

By letter dated September 23, 2009, EPA informed Dr. Bruce Lanphear, CHMC's project manager for Grant Number R-82938901-0, of the FOIA request for research data relating to the article and that EPA was initiating a request for a copy of the research data. EPA also requested that he provide a cost estimate for responding. (Enclosure 2). EPA sent Dr. Lanphear another letter on January 29, 2010. (Enclosure 3). Dr. Lanphear declined to provide the research data on grounds of confidentiality. (Enclosure 4). Since CHMC was the recipient of Grant Number R-82938901-0 (and we understand Dr. Lanphear is no longer employed by CHMC), EPA is requesting the research data from CHMC. See 40 C.F.R. 30.36(d)(1).

Please provide a written response to EPA's request for a cost estimate for providing EPA with the research data relating to the article within 30 days of the date of this letter. CHMC may dispute EPA's decision that CHMC is obligated to provide the Agency with a cost estimate for research data relating to the article in accordance with the dispute procedures at 40 C.F.R. § 30.63(b). The Dispute Decision Official for this matter is Ms. Denise Benjamin-Sirmons, the Director of EPA's Grants and Interagency Agreement Management Division.

If CHMC decides to dispute this decision, CHMC must file an initial request to dispute within 30 calendar days of the date of this decision by sending a concise letter of your objections to the decision and a description of the issues involved. CHMC's request to dispute must be sent to Ms. Benjamin-Sirmons' attention at the Grants and Interagency Agreements Management

Division, 3903R, 1200 Pennsylvania Ave, NW, Washington, DC 20460. I encourage you to submit your request to dispute this decision to Ms. Benjamin-Sirmons electronically at P.I.I. [redacted].

If you have any questions, please contact me on P.I.I. [redacted] or at P.I.I. [redacted]. Thank you in advance for your cooperation in this matter.

Sincerely,

Jeff Meetre

Jeff Meetre
Chief, Grants Management Branch A (3903R)

Enclosures

cc: Connie Hopkins, Compliance Officer CHMC
Dr. Bruce Lanphear
Stephen Page, Director, EPA Office of Air Quality Planning and Standards
Lois Riley, EPA ORD
Abbie Agner, EPA ORD

Page Declaration **EXHIBIT H**

Enclosure 1

BINGHAM

Robert N. Steinwurtzel
Direct Phone: 202.373.6030
Direct Fax: 202.373.6001
robert.steinwurtzel@bingham.com

JUL 23 2009

July 22, 2009

Via Electronic Mail

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
P.I.I.

Re: Freedom of Information Request - Lanphear (2005)

Dear FOIA Officer:

On behalf of the Association of Battery Recyclers, Inc. ("ABR"), I am submitting this Freedom of Information Act ("FOIA") request for information related to Lanphear, B.P., *et al.*, Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894–899 (2005) ("Lanphear (2005)"). The U.S. Environmental Protection Agency ("EPA") provided a grant toward the publication of this study and the study was relied on by EPA in promulgating the National Ambient Air Quality Standards for Lead, Final Rule, published at 73 Fed. Reg. 66,964 (Nov. 12, 2008) ("Lead NAAQS Rule"). Therefore, ABR requests the research data used in connection with the findings of the Lanphear (2005) study pursuant to FOIA, 2 C.F.R. § 215.36(d), and 40 C.F.R. § 30.36(d). ABR also requests any EPA records related to the Lanphear (2005) study, including, but not limited to, records related to the EPA grant, records related to other FOIA requests for the research data, EPA's review of the Lanphear (2005) study with respect to the Lead NAAQS Rule, and EPA's review of the Lanphear (2005) study with respect to the Information Quality Act.

"Research data" is defined as: "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings," excluding preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. 40 C.F.R. § 30.36(d)(2)(i). Such research data, and this request, include:

1. A copy of all data related to the Lanphear (2005) study, including copies of the data sets used, such as the data from the Boston,

Boston
Hartford
Hong Kong
London
Los Angeles
New York
Orange County
San Francisco
Santa Monica
Silicon Valley
Tokyo
Walnut Creek

Bingham McCutchen LLP
2020 K Street NW
Washington, DC
20006-1806

202.373.6000
202.373.6001
bingham.com

Cincinnati, Cleveland, Port Pirie, Rochester, Mexico City and Yugoslavia prospective child development studies.

2. Any data and materials required to access and analyze the data, including any documents explaining the multi-step process employed by Lanphear (2005) in which the data from individual studies was first fitted to simple unadjusted models and then combined into a linear model adjusted for the seven study sites. In particular, details of the methods used for "adjustment for study site" are requested as well as all methods used in the generation of the single linear model subsequently generated and subjected to analysis using a restricted cubic spline function.

3. All data pertaining to the derivation of the single linear model referred to in paragraph 2. above, inclusive of identifiers for individual data points, their associated blood lead measures and all confounder data associated with each data point.

4. Any documents showing calculations pertaining to the "final model" developed in the pooled analysis, inclusive of details defining the seven separate adjusted models developed for each of the cohorts, and the impact of omitting individual data sets upon overall model characteristics and descriptive parameters.

In February of 2008, EPA determined that it is obligated to obtain research data relating to the Lanphear (2005) study pursuant to 2 C.F.R. § 215.36 and 40 C.F.R. § 30.36, because of its use in the notice of proposed rulemaking for the Lead NAAQS Rule. In a letter from Kevin M. Miller, Assistant General Counsel, to Ms. Amy Pohl, Jones Day (Exhibit 1), EPA indicated that it would "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." Ex. 1 at 2. Although there are some exceptions to what constitutes "research data," EPA did not find any of these exceptions applied to the requested data. Similarly, none of these exceptions apply to the information being requested in this letter.

It was not until May 1, 2009, that EPA first indicated to ABR that EPA had referred the FOIA request at issue in the February 2008 letter to the Department of Health and Human Services ("HHS") (Exhibit 2). To our knowledge, HHS has declined to obtain the data and, thus, has not made it publicly available.

EPA cites to no authority in the May 1, 2009 letter for its referral of the FOIA response to HHS, noting only that HHS "appeared to have been the primary source of federal funds for the study." Ex. 2 at 2. Congress directed the Office of Management and Budget ("OMB") to revise its circular, upon which EPA's regulations are based, "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Pub. L. No. 105-277. *See also* 64 Fed. Reg. 54,926, 54,926 (Oct. 8, 1999). OMB recognized that Congress intended the requirement to apply to all agencies that provide federal funds, regardless of whether the agency is the "primary" source of funds:

> As noted in the proposed revision, the legislative history to the provision contained in Public Law 105–277 indicates that "the amended Circular shall apply to all Federally-funded research, *regardless of the level of funding* or whether the award recipient is also using non-Federal funds." 144 Cong. Rec. S12134 (October 9, 1998) (Statement of Sen. Campbell).

64 Fed. Reg. at 54,929 (emphasis added). Neither 2 C.F.R. § 215.36 nor 40 C.F.R. § 30.36 is limited to the "primary" source of federal funds, but requires all awarding agencies to obtain the data in response to a FOIA request.

EPA provided funds used for the Lanphear (2005) study through EPA Grant R829389. *See* EPA, 2003 Progress Report: Center for the Study of Prevalent Neurotoxicants in Children, *available at* http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2003. *See also* Lanphear (2005) at 894. OMB regulations refer to the "Federal awarding agency." 2 C.F.R. § 215.36(d)(1). "Federal awarding agency means the Federal agency that provides *an award* to the recipient."[1] 2 C.F.R. § 215.2(o) (emphasis added). Section 30.36(d)(1) of EPA's regulations requires *EPA* to request the research data in response to a FOIA request and requires the recipient to 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." 40 C.F.R. § 30.36(d)(1). Further, OMB determined that Congress was concerned with giving the public access to the data that is being used in support of agency action. 64 Fed. Reg. at 54,928. Here, it is EPA, not HHS, that is relying on the Lanphear

[1] "Award means financial assistance that provides support or stimulation to accomplish a public purpose." 2 C.F.R. § 215.2(e).

Page Declaration **EXHIBIT H**

(2005) study in support of the Lead NAAQS Rule. EPA cannot, therefore, avoid its FOIA obligations or to further unreasonably delay obtaining the requested information by referring the request to HHS.

Moreover, EPA regulations only provide for a "referral" of a FOIA request when the documents requested "originated with another Federal agency." 40 C.F.R. § 2.103(d). Such is not the case here, as the data did not originate with HHS. Even if this regulation gave EPA authority to "refer" the request to HHS, courts have made clear that this does not relieve EPA of the duty to comply with its FOIA obligations. *See In the Matter of Wade*, 969 F.2d 241, 248 (7th Cir. 1992) ("The agency cannot avoid the request or withhold the documents by referring them back to the agency where they originated.") (citing *McGehee v. CIA*, 697 F.2d 1095, 1110 (D.C. Cir. 1983)).

Finally, this Administration has stated a renewed commitment to science and transparency. Among President Obama's first acts as President was to issue several memoranda to federal agency heads expressing a commitment to openness in government. *See* Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Freedom of Information Act, Jan. 21, 2009, 74 Fed. Reg. 4683 (Jan. 26, 2009); Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Transparency and Open Government, Jan. 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009). President Obama stated: "The presumption of disclosure also means that agencies should take affirmative steps to make information public. They should not wait for specific requests from the public. . . . Disclosure should be timely." 74 Fed. Reg. at 4863. Administrator Jackson echoed this commitment to openness. EPA, Mem. to EPA Employees, Jan. 23, 2009, http://www.epa.gov/administrator/memotoemployees.html (last visited July 16, 2009). *See also* EPA, Administrator Lisa Jackson, http://www.epa.gov/administrator/ (last visited July 16, 2009) ("As Administrator, I will ensure EPA's efforts to address the environmental crises of today are rooted in three fundamental values: science-based policies and programs, adherence to the rule of law, and *overwhelming transparency*.") (emphasis added).

EPA has already agreed it has an obligation to provide the data pursuant to FOIA and its regulations and has had, at least, since February 2008, to obtain and make the requested research data available to the public. Due to EPA's long delay in making the information available to the public, we request that such records be made available immediately. In addition, FOIA prescribes a limit of twenty working days for compliance with requests for agency records. 5 U.S.C. § 552(a)(6)(A)(i).

Page Declaration **EXHIBIT H**

Please contact me if there are any questions concerning this request. I agree in advance to pay reasonable costs of searching for, obtaining and copying the requested research data and records; however, please notify me if the costs are likely to exceed $100.00.

Thank you for your prompt attention to this matter.

Sincerely yours,

Robert N. Steinwurtzel

Robert N. Steinwurtzel

Attachments

cc: Gina McCarthy, Assistant Administrator, Office of Air and Radiation
Linda A. Travers, Acting Chief Information Officer

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

MAY - 1 2009

OFFICE OF
AIR AND RADIATION

Mr. Robert Steinwurtzel
Bingham McCutchen, LLP
2020 K Street, N.W.
Washington, D.C. 20006-1806

Dear Mr. Steinwurtzel:

Thank you for your letter dated March 18, 2009, on behalf of the Association of Battery Recyclers (ABR). In this letter, you express concerns about the March 6, 2009, U.S. Environmental Protection Agency (EPA) decision to defer consideration of the ABR Request for Correction (RFC) dated October 14, 2008, due to pending litigation related to the revised National Ambient Air Quality Standards (NAAQS) for lead. You also request that EPA provide the underlying data and an explanation of methodology and calculations for the Lanphear study[1] that was referenced in the ABR RFC because this information was requested in a 2007 Freedom of Information (FOIA) request.

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On August 9, 2007, a requester submitted a FOIA request to EPA seeking the underlying data for the Lanphear study pursuant to 2 C.F.R. § 215.36. After granting the

[1] Lanphear, B.L., Hornung, R., Khoury, J., Yolton, K., Baghurst, P., Bellinger, D.C., Canfield, R.L., Dietrich, K.N., Bornschein, R., Greene, T. Rothenberg, S.J., Needleman, H.L., Schnaas, L., Wasserman, G., Graziano, J., Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: An international pooled analysis. Environ Health Persp 113(7): 894-899.
[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA, 2002. (67 FR 63657), pg 4
[3] http://www.epa.gov/quality/informationguidelines/documents/0900I-interim.pdf
[4] *Coalition of Battery Recyclers Association v. EPA*, No. 09-1011 (D.C. Cir., filed Jan. 12, 2009)

Page Declaration **EXHIBIT H**

requester's appeal, EPA referred her request to the Department of Health and Human Services for further processing, as that agency appeared to have been the primary source of federal funds for the study. If you are interested in reviewing the underlying data for this study, you may wish to submit a similar request to the Department of Health and Human Services.

If you have additional questions or require further information on the EPA IQG administrative mechanism, please contact Reggie Cheatham at P.I.I.

Sincerely,

Elizabeth Craig

Elizabeth Craig
Acting Assistant Administrator

cc: Linda Travers, Acting Assistant Administrator
and Chief Information Officer, OEI
Robert Eckert, FOIA Officer, HHS

Page Declaration **EXHIBIT H**

FOIA Request
Franco, Sandra to: FOIA HQ
Cc: Linda Travers, Shela Poke-Williams, "Steinwurtzel, Robert N." 07/22/2009 05:04 PM

Please find attached a FOIA request being submitted on behalf of the Association of Battery Recyclers.

Thank you in advance for your attention to this matter.

Regards,
Sandra Franco

Print Less -> Go Green

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

Bingham McCutchen LLP
2020 K Street NW
Washington, DC 20006-1806



FOIA Request.pdf FOIA Request Ex. 1.pdf FOIA Request Ex. 2.pdf

Enclosure 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

SEP 23 2009

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

Bruce Lanphear, M.D.
Faculty of Health Sciences (FHS)
Simon Fraser University
Blusson Hall, Room 11300
8888 University Drive
Burnaby, B.C.
V5A 1S6

Dear Dr. Lanphear:

Enclosed please find a copy of a request the U.S. Environmental Protection Agency (EPA) has received, pursuant to 2 CFR 215.36(d) (section __.36(d) of the attachment to OMB Circular A-110) and 40 CFR 30.36(d) (EPA's corresponding regulations) for a copy of the research data used in connection with Lanphear, B. P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D. C.; Canfield, R. L.; Dietrich, K. N.; Bornschein, R.; Greene, T.; Rothenberg, S. J.; Needleman, H. L.; Schnaas, L.; Wasserman, G.; Graziano, J.; Roberts, R. (2005), Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894-899.

EPA used this study in its recent review and revision of the National Ambient Air Quality Standards for lead, and it appears that this study was produced, at least in part, under an award from EPA. Accordingly, pursuant to EPA's regulations implementing Circular A-110, EPA is initiating a request for a copy of the research data relating to this study.

For these purposes, EPA's regulations define "research data" 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.

40 CFR 30.36(d)(2)(i). EPA is authorized to 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." 40 CFR 30.36(d)(1).

EPA has estimated that the cost of responding to the pending request (which includes requests for EPA records as well as the instant request for research data) is greater than the costs which have been authorized by the requester. As the first step in this process, EPA is requesting only that you provide an estimate of the cost to you (and others) of providing the research data for this study, in order to determine whether the requester wishes to pay the necessary fees. Such costs would include the cost of producing a copy of the research data and providing it to EPA. If you wish to identify certain data that is provided as medical information or confidential business information, then you should also estimate the cost of identifying such information (and of segregating or masking the data as appropriate).

Please provide a response in writing within 30 days of the date of this letter. If you have any questions, please contact David Orlin, in the Office of General Counsel, at P.I.I.

Sincerely,

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

Enclosure

cc: David Orlin
Robert Steinwurtzel

Enclosure 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

JAN 2 9 2010

Bruce Lanphear, M.D.
Faculty of Health Science (FHS)
Simon Fraser University
Blusson Hall, Room 11300
8888 University Drive
Burnaby, B.C.
V5A 1S6

Dear Dr. Lanphear:

On September 23, 2009, I wrote you a letter requesting an estimate of the costs you would incur in providing a copy of "research data," as defined in EPA's regulations at 40 C.F.R. § 30.36(d)(2)(i), used in connection with Lanphear, B. P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D. C.; Canfield, R. L.; Dietrich, K. N.; Bornschein, R.; Greene, T.; Rothenberg, S. J.; Needleman, H. L.; Schnaas, L.; Wasserman, G.; Graziano, J.; Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894-899.

I understand that you have informed David Orlin, of EPA's Office of General Counsel, by phone that you are declining to provide copies of any such "research data" due to the existence of confidentiality agreements signed by you and your co-authors, which preclude the release or further sharing of any data. I further understand you unsuccessfully requested waivers of the confidentiality agreement from one or more of your co-authors.

Please confirm, in writing, that you are declining to provide the requested data due to its confidentiality, and/or, if appropriate, provide any correction or supplementation on these points.

Sincerely,

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

cc: Robert Steinwurtzel

Enclosure 4

SFU

April 8th, 2010

Steve Page, PhD
Director, Office of Air Quality Planning and Standards
US Environmental Protection Agency
Research Triangle Park, NC 27711

Steve:

This letter, which is in response to your letter dated January 29th, 2010, is to confirm that I am declining to provide copies of raw "research data" for the article titled, "Low-level environmental lead exposure and children's intellectual function: an international pooled analysis", published in Environmental Health Perspectives 2005;113:894-899".

The reason I am declining to provide these data is because of the existence of confidentiality agreements, which precludes the release of further sharing of data. As you noted in your letter, I was unsuccessful in requesting a waiver of the confidentiality agreement from more than one of the co-authors of the pooled analysis study.

I would certainly be willing to talk with you more about the possibility of establishing an independent re-analysis of the data, but it would need to conform to existing standards of independent review.

Best regards,

Bruce Lanphear, MD, MPH
Senior Scientist, Child & Family Research Institute
Professor, Simon Fraser University
Vancouver, BC

Page Declaration

EXHIBIT I

Cincinnati Children's

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May 12 2010

VIA: EMAIL & REGULAR U.S. MAIL

Ms. Denise Benjamin-Sirmons, Director
Grants and Interagency Agreement Management Division 3903R
1200 Pennsylvania Avenue, NW
Washington, DC 20460
P.I.I. [redacted]

RE: EPA Grant Number R-82938901-0; "Study of Prevalent Neurotoxicants in Children", EPA Freedom of Information Act Request NO. HQ-RIN-01677-09.

Dear Ms. Benjamin-Sirmons,

The following provides Children's Hospital Medical Center's ("CCHMC's") response to EPA's request for a cost estimate pursuant to 40 CFR § 30.36(d) due to a Freedom of Information Act ("FOIA") request. See Attachment 1, EPA FOIA Request. The FOIA request covers underlying data relating to Lanphear, et. al.'s article entitled "Low-level environmental lead exposure and children's intellectual function: an international pooled analysis" published in 2005 ("the article"). As noted in EPA's request, Dr. Lanphear previously declined to provide this data due to confidentiality reasons. See Enclosure 4 of Attachment 1, Lanphear letter.

The article at issue examined data from seven cohorts of children who had participated in separate international population-based longitudinal lead studies. See Lanphear, B.P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D.C.; Canfield, R.L.; Dietrich, K.N.; Bornschein, R.; Greene, T.; Rothenberg, S.J.; Needleman, H.L.; Schnaas, L.; Wasserman, G.; Graziana, J.; Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environ. Health Perspect. 113:894-899. Dr. Lanphear contacted the investigators of these lead cohorts and requested that they release their data sets for purposes of the article. See id. at p. 894-95. This request included a commitment from Dr. Lanphear that the data would be used only for this study and published in the aggregate. See Enclosure 4 of Attachment 1, Lanphear letter.

EPA noted in its request that research data does not include "materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law." 40 CFR 30.36(d)(2)(i)(A). As explained, when the investigators released their data sets to Dr. Lanphear and CCHMC for the article, they did so with the understanding that the data sets would only be used for this limited purpose. As such, CCHMC has an obligation to keep this information confidential as agreed. CCHMC believes that the data would be considered material necessary to be held confidential under these circumstances and not "research data" subject to a FOIA request. Consequently, CCHMC feels it would not be required to provide a cost estimate for data which is not subject to 40 CFR § 30.36(d).

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Please contact me if you would like to discuss further or require additional information.

Best regards,

P.I.I. P.I.I.

P.I.I.
Cincinnati Children's Hospital Medical Center
Phone: P.I.I.
Fax: P.I.I.

cc: Peter C. Koch
Dr. Bruce Lanphear

Page Declaration

EXHIBIT J

Cincinnati Children's

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September 2, 2010

VIA: EMAIL & REGULAR U.S. MAIL

Ms. Denise Benjamin-Sirmons, Director
Grants and Interagency Agreement Management Division 3903R
1200 Pennsylvania Avenue, NW
Washington, DC 20460
P.I.I. [redacted]

RE: EPA Grant Number R-82938901-0; "Study of Prevalent Neurotoxicants in Children", EPA Freedom of Information Act Request NO. HQ-RIN-01677-09.

Dear Ms. Benjamin-Sirmons,

The following provides Children's Hospital Medical Center's ("CCHMC's") response to EPA's letter of August 3, 2010 which requested additional information to evaluate CCHMC's position regarding the referenced Freedom of Information Act ("FOIA") request. See Attachment 1, EPA's August 3, 2010 Letter.

Regarding the terms of the confidentiality agreements, Dr. Lanphear located two emails that confirmed his agreements with his co-authors regarding use of the data provided for the article entitled "Low-level environmental lead exposure and children's intellectual function: an international pooled analysis" ("pooled analysis article"). The first email was sent on May 29, 2000, at the initiation of the collaboration that eventually led to the pooled analysis article. See Attachment 2, Copy of May 29, 2000 Email. When requesting data sets from the co-authors, Dr. Lanphear stated: "…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 (sec) and indicating that the data will not be used for any other purpose without the formal approval of the responsible investigators." See Attachment 2. The second email was sent on May 28, 2004 on behalf of Dr. Lanphear to the "LeadPooledGroup," which included the co-authors from the pooled analysis article. In that email Dr. Lanphear requested permission to release the data for another study and noted: "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** (emphasis added), but only if the co-authors give permission." See Attachment 3, Copy of May 28, 2004 Email. CCHMC believes that these emails evidence the co-authors agreement to only use the pooled data for studies and only with the express permission of the co-authors.

In addition to the concerns related to breaching the agreements between the co-authors to only use the data **with permission for studies**, CCHMC does not own a majority of the data being requested. As such, CCHMC believes that the EPA's request for portions of this data should be directed to the co-authors. Moreover, the underlying cohort data provided by the co-authors and used to create the pooled

Cincinnati Children's

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analysis was collected prior to 2000, before the effective date of the Shelby Act. Finally, it is CCHMC's understanding that some of the cohort data used to create the pooled analysis utilized no government funding.

Although CCHMC would like to provide all data responsive to EPA's FOIA request, CCHMC has concerns of what data it can provide under these circumstances. As such, CCHMC and Dr. Lanphear would like to discuss these issues with the EPA so that a more accurate estimate of the costs to produce the data can be provided. At this point, CCHMC estimates that the costs to produce its data from the study would exceed one hundred dollars. Once CCHMC has clarity of what it can release pursuant to this FOIA request, an improved estimate of cost will be provided. Dr. Lanphear can also provide information regarding whether he was able to obtain waivers from his co-authors to release their data pursuant to this FOIA request during our discussion.

If the EPA would be agreeable to the above, please contact me at your convenience so we can arrange a conference call.

Best regards,

P.I.I.

Cincinnati Children's Hospital Medical Center
Phone: P.I.I.
Fax: P.I.I.

cc: Peter C. Koch
Dr. Bruce Lanphear

ATTACHMENT 1

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

AUG 3 2010

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

[redacted] P.I. [redacted]
Legal Department
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, OH 45229

Re: EPA Grant No. R-82938901-0; "Study of Prevalent Neurotoxicants in Children"
EPA Freedom of Information Act Request No. HQ-RIN-01677-09

Dear **P.I.I.**

This is in response to your letter dated May 12, 2010, in which you advised us that the Cincinnati Children's Hospital Medical Center (CCHMC) disputes EPA's rights under 40 CFR 30.36(d) to obtain "research data" CCHMC produced under Grant Number R-82938901-0 (Grant).

The dispute arises from EPA's letter dated April 13, 2010, requesting that CCHMC provide an estimate of the cost to CCHMC of obtaining the research data so that EPA could respond to a Freedom of Information Act (FOIA) request, pursuant to 40 CFR 30.36(d), for the research data produced under the Grant. The request covers research data related to the study that CCHMC's Principal Investigator for the grant, Dr. Bruce Lanphear, published as Lanphear, B. P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D. C.; Canfield, R. L.; Dietrich, K. N.; Bornschein, R.; Greene, T.; Rothenberg, S. J.; Needleman, H. L.; Schnaas, L.; Wasserman, G.; Graziano, J.; Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environ. Health Perspect 113: 894-899 (Article). Since the Article appears to have been produced with funding from the Grant, and EPA used and cited this study in its recent review and revision of the National Ambient Air Quality Standards for lead, which was an agency action that had the force and effect of law within the meaning of 40 CFR 30.36(d)(1) and 40 CFR 30.36(d)(2)(iii), it appears that the requested information qualifies as "research data" as defined under 40 CFR 30.36(d)(2)(i), and is therefore subject to disclosure under 40 CFR 30.36(d).

CCHMC claims that it has no information that is "research data" under 40 CFR 30.36(d) because as provided in 40 CFR 30.36(d)(2)(i)(A) that term does not include ". . . materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law. . . ." CCHMC advised that "when the investigators released their data sets to Dr. Lanphear and CCHMC for the article, they did so with the understanding that the data sets would only be used for this limited purpose. As such, CCHMC has an obligation to keep this information confidential as agreed."

In support of its position CCHMC points to a letter dated April 8, 2010, from Dr. Lanphear to Steve Page, Director of EPA's Office of Air Quality Planning and Standards in which Dr. Lanphear advised that he declined to provide the raw research data for the article. Dr. Lanphear stated: "The reason I am declining to provide these data is because of the existence of confidentiality agreements, which precludes the release [or] further sharing of data . . . I was unsuccessful in requesting a waiver of the confidentiality agreement from more than one of the co-authors of the pooled analysis study."

In order for us to evaluate your position, we need to review the terms of the confidentiality agreements Dr. Lanphear referenced in his April 8 letter to us. In addition, please inform us whether Dr. Lanphear was able to obtain a waiver of the confidentiality agreement from any of his co-authors, and if so which author(s). Please provide us with the requested information within thirty days of the date of this letter, along with an estimate of the cost for obtaining and providing research data from any such co-authors.

Please direct any questions regarding our request to Dan Schulson P.I.I.

Sincerely,

Denise Benjamin Sirmons, Director
Grants and Interagency Management Division

cc: Bruce Lanphear
Peter Koch
Dan Schulson

Page Declaration **EXHIBIT J**

ATTACHMENT 2

Jane KHOURY - Pooled Analysis

From: Bruce Lanphear
To: Claire Ernhart; David Bellinger; Dietrich, Kim (DIETRIKN); Gail Wasserman; P.I.I. [redacted]; Herbert Needleman; Jane KHOURY; Joe Graziano; Lourdes Schnaas; Peter Baghurst; Rick Canfield; Rick Hornung; Robert Bornschein; Russell Roberts; Stevo 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 wihout the formal approval of the responsible investigators.

Sincerely,

Bruce

Page Declaration **EXHIBIT J**

ATTACHMENT 3

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 Rothenberg, 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] (phone)
P.I.I. [redacted] (fax)
P.I.I. [redacted] (pager)

Page Declaration

EXHIBIT K

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

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

November 22, 2010

CERTIFIED MAIL - RETURN RECEIPT REQUESTED
AND ELECTRONIC TRANSMISSION

Peter C. Koch
Assistant Vice President, Sponsored Programs
Office of Sponsored Programs
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, OH 45229

RE: Environmental Protection Agency Grant Number R82938901-0;
EPA Freedom of Information Act (FOIA) Request No. HQ-RIN-01677- 09

Dear Mr. Koch:

This letter constitutes my decision as the Dispute Decision Official regarding Cincinnati Children's Hospital Medical Center's (CCHMC) dispute of the Environmental Protection Agency's (EPA or "Agency") rights under 40 C.F.R. § 30.36(d) to obtain "research data" that CCHMC produced under Grant Number R82938901-0 ("Grant") relating to published research findings in order for the Agency to respond to a FOIA request. I have determined that data relating to Low-level environmental lead exposure and children's intellectual function: an international pooled analysis (Lanphear et al., Environ Health Perspectives. 2005 Jul;113[7]:894-899) ("Publication"), are research data within the meaning of 40 C.F.R. § 30.36(d)(2). This determination is based on the finding that the Publication was produced, at least in part, with funds EPA provided to CCHMC under the Grant and EPA used the Publication in developing an action that has the force and effect of law. Therefore, CCHMC must provide EPA an estimate of the cost to CCHMC of obtaining and providing a copy of the research data (including the costs of identifying any sensitive medical or personally identifiable data for masking).

Please note, however, that the Agency may charge the FOIA requester for the full incremental cost of obtaining the research data. Research data do not include personnel and medical information the disclosure of which would constitute a clearly unwarranted invasion of privacy. *See* 40 C.F.R. § 30.36(d)(2)(i)(B). Additionally, EPA will only release the research data to the FOIA requestor if they are not exempt from disclosure under FOIA, 5 U.S.C. § 552(b).

Background

EPA awarded the Grant to CCHMC beginning on October 17, 2001, as part of the National Institute of Environmental Health Sciences/EPA Centers for Children's Environmental Health and Disease Prevention Research program to conduct a "Study of Prevalent Neurotoxins in Children." The initial amount of the Grant was $753,911 with a total amount over five years from EPA of $3,714,505 (with a similar amount provided by the National Institute of Environmental Health Sciences). The Grant had a budget/project period of November 1, 2001, through October 31, 2006. Dr. Bruce Lanphear was CCHMC's Project Manager and Principal Investigator for the Grant.

In July 2005, the scientific journal *Environmental Health Perspectives* published the Publication. Dr. Lanphear was listed as one of the co-authors and a statement in the Publication indicated that the study described in the Publication was funded in part by EPA. CCHMC's progress reports for the Grant also indicated that the Agency at least partly funded the study described in the Publication. EPA cited the Publication in promulgating the final rule for the National Ambient Air Quality Standards for Lead published at 73 Fed. Reg. 66964 (November 12, 2008) (NAAQS Lead Rule). The NAAQS Lead Rule has the force and effect of law.

On July 22, 2009, EPA received a FOIA request for the research data from Robert Steinwurtzel.[1] Pursuant to 40 C.F.R. § 30.36(d)(1), if the Agency receives a 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 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." The Agency may charge the requester the full incremental cost of obtaining the research data. Id.

By letters to Dr. Lanphear dated September 29, 2009, and January 29, 2010, EPA requested cost estimates for providing the research data to EPA. Dr. Lanphear responded by letter dated April 8, 2010, and advised that he declined to provide the research data due to "the existence of confidentiality agreements, which precludes further sharing of data. . . . I was unsuccessful in requesting a waiver of the confidentiality agreement from more than one of the co-authors of the pooled analysis study." By letter dated April 13, 2010, EPA requested that CCHMC provide an estimate of the cost to CCHMC of obtaining the research data so that EPA could respond to the FOIA request. The Agency noted that CCHMC could dispute EPA's initial determination that it possessed research data subject to 40 C.F.R. § 30.36(d) by following the dispute procedures at 40 C.F.R. § 30.63.

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[1] Mr. Steinwurtzel supplemented this FOIA request with a second FOIA request dated July 9, 2010. Prior to this request, by letter dated August 9, 2007, Amy Pohl filed a FOIA request for the research data. That request was referred and forwarded to the Department of Health and Human Services for processing. That FOIA request is the subject of litigation in the Western District of Pennsylvania under the heading of *Pohl v. United States Environmental Protection Agency et al.*, 2:09-cv-01480. CCHMC and Dr. Lanphear are parties to that litigation.

In a letter dated May 12, 2010, CCHMC disputed EPA's decision that CCHMC is obligated to provide EPA with a cost estimate for research data produced under the Grant. CCHMC claimed that it does not have information that is "research data" under 40 C.F.R. § 30.36(d) because that term does not include "materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law." 40 C.F.R. § 30.36(d)(2)(i)(A). CCHMC explained in its May 12 letter that:

> [W]hen the investigators released their data sets to Dr. Lanphear and CCHMC for the article, they did so with the understanding that the data sets would only be used for this limited purpose. As such, CCHMC has an obligation to keep this information confidential as agreed. CCHMC believes that the data would be considered material necessary to be held confidential under these circumstances and not "research data" subject to a FOIA request. Consequently, CCHMC feels it would not be required to provide a cost estimate for data which is not subject to 40 CFR § 30.36(d).

By letter dated August 3, 2010, EPA responded to CCHMC's May 12, 2010, letter. In order to evaluate CCHMC's position, EPA indicated that it wanted to review the terms of the confidentiality agreements Dr. Lanphear referenced in his April 8 letter to EPA. EPA also asked whether Dr. Lanphear was able to obtain a waiver of the confidentiality agreement from any of his co-authors, and if so which author(s).

On September 2, 2010, CCHMC responded to EPA's August 3 letter. CCHMC indicated in its September 2 letter that Dr. Lanphear located two e-mails that "evidence the co-authors agreement to only use the pooled data for the studies and only with the express permission of the co-authors." In addition, CCHMC informed EPA that it "does not own a majority of the data being requested[;]" that "the underlying cohort data provided by the co-authors and used to create the pooled analysis was collected prior to 2000, before the effective date of the Shelby Act[;]" and that "some of the cohort data used to create the pooled analysis utilized no government funding."[2] September 2 CCHMC letter at 1-2.

On October 20, 2010, I held an informal conference with Dr. Lanphear and CCHMC's Counsel, Joan Gates, Esq. During that informal conference they forthrightly acknowledged that CCHMC had possession of the data supporting the findings in the Article. I indicated that if I did not resolve the dispute in CCHMC's favor, and CCHMC provided the research data as EPA requested, EPA would not release data that was exempt from disclosure under FOIA.

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[2] The "Shelby Act" refers to a section of the Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. 105-277, 112 Stat. 2681-495 (October 21, 1998). The provision directs "the Director of OMB [to] amend[] Section --.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Id. OMB promulgated the regulation, 2 C.F.R. § 215.36(d)(1), and EPA implemented OMB's revision to the Circular at 40 C.F.R. § 30.36(d)(1), which is EPA's version of the "common rule" for OMB Circular A-110.

Discussion

EPA's regulations define "research data" as:

> [T]he 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.

40 C.F.R. § 30.36(d)(2)(i).

EPA's regulations define "published" 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.

40 C.F.R. § 30.36(d)(ii).

The Underlying Data are Research Data

CCHMC claimed that the underlying data are not data within the definition of 40 C.F.R. § 30.36(d)(2)(i)(A) because the data are "materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law." CCHMC claimed the data was "confidential" because CCHMC's Principal Investigator for the Grant, Dr. Lanphear, had an agreement, evidenced by two e-mails, to only use the data with co-authors' permission. CCHMC's argument is not persuasive.

Research data is defined "as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings." 40 C.F.R. § 30.36(d)(2)(i). Research data do not include "[t]rade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law." 40 C.F.R. § 30.36(d)(2)(i)(A).

Here, the data underlying the Publication fall within the definition of "research data." The Publication describes research findings from a study that was conducted in part from funding EPA provided under the Grant. The data underlying the Publication are "research data" because they are "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings." 40 CFR 30.36(2)(i). Once the Publication was published in a peer reviewed scientific or technical journal and was cited by EPA in support of the NAAQS Lead Rule, the requirements of 40 C.F.R. § 30.36 are triggered.

The evidence CCHMC provided to support its claim of confidentiality is not sufficient to establish that the data at issue fall within the "materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law" exclusion from the regulatory definition of "research data." 40 C.F.R. § 30.36(d)(2)(i)(A). The two emails provided to support CCHMC's argument state: ". . . I will include a letter stating the purpose of the analyses and indicating that that the data will not be used for any other purpose without the formal approval of the responsible investigators," and "[A]s we agreed at the outset of our collaboration, data from the pooled analysis would be available to other co-authors for other studies, but only if the co-authors give permission." I am not persuaded that these statements are sufficient to either expressly or implicitly establish the existence of an agreement by CCHMC that would overcome the requirement for CCHMC to provide research data under the Grant if EPA requested the data. They offer no indication that the data should be afforded any protections under the applicable regulation or any other applicable law. Consequently, the data is not protected from disclosure under 40 C.F.R. § 30.36(d)(2)(i)(A).

CCHMC also claims that "the underlying cohort data provided by the co-authors and used to create the pooled analysis was collected prior to 2000, before the effective date of the Shelby Act." September 2, CCHMC letter at 1-2. The regulations require the recipient to provide EPA with the "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." 40 C.F.R. § 30.36(d)(ii) (emphasis added). Although the data may have been collected prior to 2000, that data is integral to the published research findings funded, in part, after 2000 by EPA. Therefore, the time at which Dr. Lanphear's co-authors collected the research data does not affect CCHMCs' obligation under 40 C.F.R. § 30.36(d)(1) to provide the research data to EPA.

CCHMC contends that it does not have an obligation to provide the research data to EPA because CCHMC does not "own a majority of the data being requested" and "some of the cohort data used to create the pooled analysis used no government funding." Notwithstanding ownership, Dr. Lanphear used those research data in a study funded, in part, by EPA. CCHMC has possession of those research data. As stated above, the fact that some of the research data described in the Publication were not produced with federal funding is not determinative because all of the data "*relat[e] to* published researched findings produced under [the Grant]. . . ." 40 C.F.R. § 30.36(d)(1) (emphasis added). Therefore, this claim of data ownership does not exempt CCHMC from production.

CCHMC must provide the research data to EPA to materially comply with the terms and conditions of the Grant as stated in a federal regulation – 40 C.F.R. § 30.36 – if the requesters agree to pay the fee authorized under 40 C.F.R. § 30.36(d)(1). CCHMC's concerns regarding disclosure of confidential information that researchers provided to Dr. Lanphear do not provide CCHMC with a basis to decline to provide EPA with research data relating to the Publication. Before turning over the data, CCHMC should identify for masking any data that constitute "medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 40 C.F.R. § 30.36(d)(2)(i)(B). Upon review of the data, EPA will determine the extent to which the data provided contain information excluded from the definition of research data by the terms of the regulation and the extent to which the data is subject to any applicable exemption to the FOIA.

If CCHMC wishes to claim that any of the data are confidential business information (CBI) it should assert such a claim at the time it submits the data, by marking both the outside of its submission and by identifying electronically the specific information claimed as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. If no such claim accompanies the information when it is received by EPA, it may be made available to the requester by EPA without further notice to the CCHMC.

As previously noted, 40 C.F.R. § 30.36(d)(1) allows the Agency to charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. Accordingly, please provide Ellen O'Boyle of my staff with an estimate of those costs. Her email address is P.I.I. [redacted]. EPA will obtain assurance of payment from the FOIA requesters for those costs prior to obtaining the research data from CCHMC. We expect to direct the FOIA requesters to pay CCHMC directly for its costs in providing the research data to EPA.

Conclusion

This Disputes Decision Official (DDO) decision constitutes the final agency action under the Dispute procedures at 40 C.F.R. § 30.63(b). Further requests for review of this action will be handled in accordance with the Dispute procedures at 40 C.F.R. Part 31 Subpart F. Any request for review should be directed to Paul Anastas, Assistant Administrator of the EPA Office of Research and Development, Mail Code 8101R. The request for review, following the procedures at Subpart F, must be sent to his attention at EPA, 1200 Pennsylvania Ave., NW, Washington, DC 20460, within 30 calendar days of the date of this DDO decision. I encourage you to also send a copy of your request to Dr. Anastas to review this DDO decision to me at P.I.I. [redacted].

If you or your staff has any questions about the disputes process or need further assistance, please feel free to contact me or James Drummond of EPA's Office of General Counsel electronically at P.I.I. [redacted] or by phone on P.I.I. [redacted]

Sincerely,

Denise Benjamin Sirmons, Director
Grants & Interagency Agreements Mgmt. Division

cc: James Drummond