

# **EXHIBIT 4**



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892  
[www.nih.gov](http://www.nih.gov)

December 18, 2008

Ms. Amy K. Pohl, J.D.  
Jones Day  
Suite 3100  
500 Grant Street  
Pittsburgh, PA 15219-7959

RE: FOI Case No. 35135

Dear Ms. Pohl:

This is the final response to your August 9, 2007, Freedom of Information Act (FOIA) request addressed to the Environmental Protection Agency (EPA). Your request was referred to the National Institutes of Health (NIH) via the Department of Health and Human Services (DHHS) because of our responsibilities under the FOIA, and was received in this office on June 9, 2008. Pursuant to the FOIA and the provisions of Office of Management and Budget (OMB) Revised Circular A110, you requested a copy of the data related to an EPA Report: "Lead Human Exposure and Health Risk Assessments for Selected Case Studies (July 30, 2007)." According to your request, the data relied upon in the EPA report were produced under grants awarded by the National Institute of Environmental Health Sciences (NIEHS), which is part of the NIH, and the Centers for Disease Control (CDC), specifically the research results published by Bruce Lanphear, *et al.*, "Low-Level Environmental Lead Exposure and Children's Intellectual Functions: An International Pooled Analysis," *EHP* 116(7): July 2007.

We searched the files of the NIEHS to determine if the data relied upon by EPA were produced under an award that satisfies the criteria for processing your request under OMB Revised Circular A110. Our search indicates that the grant referenced by Dr. Lanphear in his article, IR13ES10868-01, is a Conference grant. Conference grants support recipient sponsored and directed international, national or regional meetings, conferences and workshops. The funds awarded under the subject NIEHS grant were used to fund travel expenses for Dr. Lanphear to a workshop where the groundwork for the pooled analysis was established. However, no data were produced or analyzed at the workshop. It is our understanding that subsequent to the workshop, the relevant data were turned over to Dr. Lanphear for the pooled analysis but NIEHS did not fund or financially support that analysis. Therefore, Revised Circular A110 does not apply to the NIEHS grant.

You have the right to appeal this determination that the provisions of OMB Revised Circular A110 do not apply to your request for data produced under an award made by NIEHS. Should you wish to do so, you must send your appeal within thirty (30) days of receipt of this letter to

Page 2 - Ms. Pohl (35135)

the Deputy Assistant Secretary for Public Affairs (Media), United States Department of Health and Human Services, Parklawn Building, Room 17A-46, 5600 Fishers Lane, Rockville, MD 20857, following the procedures outlined in Subpart C of the enclosed DHHS FOIA Regulations. Please mark both the envelope and the appeal letter "FOIA Appeal."

Provisions of the FOIA allow us to recover part of the cost of complying with your request. In this case, the cost fell below the \$25 minimum fee so there is no charge associated with our response.

Sincerely,



Susan R. Cornell, J.D.  
FOIA Officer, NIH

P.I.I.

9000 Rockville Pike  
Bethesda, MD 20892

Enclosure: DHHS FOIA Regulations

## **EXHIBIT 5**

**Dinsmore & Shohl** LLP  
ATTORNEYS

Matthew D. Shuler  
513-977-8560  
matthew.shuler@dinslaw.com

Admitted in Ohio and Kentucky

November 29, 2010

**Via Federal Express**

Karen P. Seifert, Esq.  
United States Department of Justice  
Civil Division, Federal Programs Branch  
20 Massachusetts Avenue, N.W.  
Washington, D.C. 20001  
(202) 305-0891

Re: *Amy K. Pohl v. United States Environmental Protection Agency, et al.*  
United States District Court for the Western District of Pennsylvania  
Civil Action No. 2:09-cv-01480-WLS

Dear Ms. Seifert:

As you know, I represent Cincinnati Children's Hospital Medical Center ("CCHMC") and Dr. Bruce Lanphear in the above-referenced litigation. On November 22, 2010, Cincinnati Children's Hospital Medical Center received a letter (a copy of which is enclosed herewith) from Denise Benjamin-Sirmons, the Director of the Grant and Interagency Agreements Management Division for the United States Environmental Protection Agency. In her capacity as the Disputes Decision Official, Ms. Sirmons concluded that CCHMC was obligated to provide the data relating to "Low Level Environmental Lead Exposure in Children's Intellectual Function: An International Pooled Analysis," authored by Dr. Bruce Lanphear and others and published in *Environmental Health Perspectives* (2005 Jul; 113 (7): 894-899).

Prior to receipt of Ms. Sirmons' letter, CCHMC had objected to production of the research data surrounding Dr. Lanphear's study for a variety of reasons, including that the information was not "research data" under certain provisions of federal law and that confidentiality agreements with other parties prevented disclosure of the information. Clearly, interpretation of the provisions of the Shelby Act and the Freedom of Information Act is an evolving area of law and CCHMC sought guidance from the EPA as to whether it would mandate production of the data. In her letter dated November 22, 2010, Ms. Benjamin-Sirmons made the EPA's position clear: the information constituted research data and the confidentiality agreements in place did not preclude production of the research data. My clients have opted not to further contest the decision of Ms. Benjamin-Sirmons.

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Karen P. Seifert, Esq.  
November 29, 2010  
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As a result, and due to the pending litigation, CCHMC and Dr. Lanphear are producing the research data for his publication to you as counsel for the EPA. Enclosed is a CD bearing the research data in the format maintained by CCHMC. While CCHMC asserted a number of objections to production of the research data (as set forth in the enclosure), CCHMC is producing the data without "confidential business information" designation in reliance upon the guidance and authority set forth in Ms. Benjamin-Sirmons' letter and consistent with the final determination of the EPA.

Please do not hesitate to contact me should you have any questions.

Very truly yours,



Matthew D. Shuler

MDS\lkh  
Enclosure



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

November 22, 2010

OFFICE OF  
ADMINISTRATION  
AND RESOURCES  
MANAGEMENT

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.<sup>1</sup> 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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<sup>1</sup> 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."<sup>2</sup> September 2 CCHMC letter at 1-2.

On October 20, 2010, I held an informal conference with Dr. Lanphear and CCHMC's Counsel, **P.I.I.** 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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<sup>2</sup> 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[er] 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 [oboyle.ellen@epa.gov](mailto:oboyle.ellen@epa.gov). 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.

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.

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

"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,

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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.

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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://efpub.epa.gov/ncsr\\_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770/report/2003](http://efpub.epa.gov/ncsr_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." 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

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

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(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).

EPA FOIA  
July 22, 2009  
Page 5

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

## **EXHIBIT 6**

**From:** [Anthony J Bellino](#)  
**To:** [Seifert, Karen P. \(CIV\)](#)  
**Cc:** [Laura E. Ellsworth](#); [Thomas S Jones](#)  
**Subject:** Re: Pohl v. EPA  
**Date:** Tuesday, November 30, 2010 6:19:03 PM

---

Karen,

To follow up on our earlier phone call, we want to keep the status conference as scheduled at this time because the data is not currently in our possession. If we receive the data in a reasonable time before the scheduled status conference, we will then contact the court to ask to continue, pending our review of the data.

Please feel free to follow up with any additional questions or updates on the status of the data production.

Kind Regards,  
Tony Bellino

Anthony J. Bellino  
JONES DAY

-----  
500 Grant Street, Suite 4500, Pittsburgh PA 15219-2514  
Direct: 412.394.7242 / Fax: 412.394.7959  
abellino@jonesday.com

**From:** "Seifert, Karen P. (CIV)" <Karen.P.Seifert@usdoj.gov>  
**To:** <abellino@jonesday.com>  
**Date:** 11/30/2010 05:12 PM  
**Subject:** Pohl v. EPA

---

Hi Tony –

Thanks for speaking with me this afternoon. Please let me know your desired course of action as soon as possible, as I would need to file something with the court tomorrow, if desired.

Thank you,  
Karen Seifert

Karen P. Seifert  
Trial Attorney  
United States Department of Justice  
Civil Division, Federal Programs Branch  
20 Massachusetts Ave. NW  
Washington, D.C. 20530  
(202) 305-0891

[karen.p.seifert@usdoj.gov](mailto:karen.p.seifert@usdoj.gov)

=====

This e-mail (including any attachments) may contain information that is private, confidential, or protected by attorney-client or other privilege. If you received this e-mail in error, please delete it from your system without copying it and notify sender by reply e-mail, so that our records can be corrected.

=====

## **EXHIBIT 7**



## U.S. Department of Justice

Civil Division

Karen P. Seifert  
Trial Attorney

Washington, D.C. 20530

January 28, 2011

Laura E. Ellsworth  
Thomas S. Jones  
Anthony J. Bellino  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh, PA 15219-2514

RE: Pohl v. Environmental Protection Agency, *et al.*

Counsel:

Enclosed please find a compact disc containing files responsive to Ms. Pohl's August 9, 2007 Freedom of Information Act ("FOIA") request. Cincinnati Children's Hospital Medical Center and Dr. Lanphear sent these files to the government and stated that they contain the data underlying Dr. Lanphear's article *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An international Pooled Analysis*, ENVIRONMENTAL HEALTH PERSPECTIVES 133(7) (2005). This production contains the data files and data dictionaries in the agencies' possession that are responsive to your request.

Ms. Pohl also requested "[a] copy of the data collection forms and any software programs required to access and analyze the data . . . in its computerized form." The agencies do not possess any data collection forms related to this data. The agencies will not provide "software programs" as computer software is not an "agency record" subject to production under FOIA, 5 U.S.C. § 552(a)(4)(B), and the agencies' ownership and distribution of such software is subject to licensing agreements.

Under 5 U.S.C. § 552(a)(4)(A) and 40 C.F.R. § 30.36(d)(1), you are responsible for fees related to this production. The Environmental Protection Agency will bill you for these fees directly.

The production of these documents moots your legal claims against the agencies. I propose that we jointly stipulate to dismiss the case with prejudice, with each party to bear their own costs and fees. Please inform me by February 22, 2011 whether you agree to this proposal.

Sincerely,

A handwritten signature in black ink that reads "Karen Seifert". The signature is written in a cursive, flowing style.

Karen P. Seifert

## **EXHIBIT 8**

## JONES DAY

500 GRANT STREET • SUITE 4500 • PITTSBURGH, PENNSYLVANIA 15219-2514  
TELEPHONE: 412-391-3939 • FACSIMILE: 412-394-7959

Direct Number: (412) 394-7242  
ajbellino@jonesday.com

JP011654/1228279v2  
589170-096077

February 18, 2011

### VIA E-MAIL AND U.S. MAIL

Karen P. Seifert, Esq.  
United States Department of Justice  
Civil Division, Federal Programs Branch  
20 Massachusetts Ave. NW  
Washington, D.C. 20530

Re: Amy K. Pohl v. United States Environmental Protection Agency, et al.,  
No. 2:09-01480-WLS

Dear Karen:

Thank you for your January 28, 2011 letter and compact disk containing files responsive to Ms. Pohl's August 9, 2009 Freedom of Information Act ("FOIA") request. These files contain a large amount of the data requested. Unfortunately, several files necessary to make the FOIA request complete are missing. These missing files are primarily data dictionaries containing the definitions of the variables referenced in the data files. Without the variable definitions provided in these missing dictionaries, the data cannot be interpreted. Described below, and summarized in Exhibits 1 and 2, is the outstanding data we require before entertaining the possibility of dismissing our case.<sup>1</sup>

1. Boston: Complete, no additional data needed.
2. Cincinnati:
  - (a) Please provide the data dictionary for *Cincinnati wiscr67.sd2*.
3. Cleveland:
  - (a) Please provide the data dictionaries for *Cleveland clairebpb.sas7bdat*, *Cleveland Martier.xls*, and *Cleveland martier1.sd2*.
  - (b) Please define, explain, and provide raw data for the variables "Momiq" and "marital", which appear in the pooled dataset, *Cleveland.sas7bdat*, but not in the raw data, *Cleveland clairebpb.sas7bdat*, *Cleveland Martier.xls*, and *Cleveland martier1.sd2*.

---

<sup>1</sup> Electronic file names are italicized.

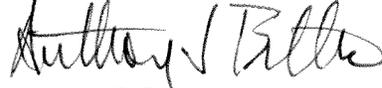
Karen P. Seifert, Esq.  
February 18, 2011  
Page 2

4. Mexico: Complete, no additional data needed.
5. Port Pirie:
  - (a) Please provide the data dictionary for *portpiriea.sas7bdat*.
  - (b) Please provide a complete cross reference data dictionary for *portpirie.sas7bdat*.
    - (i) Included in the material provided was *Port Pirie.xls*, which appears to be a cross reference data dictionary. This file is incomplete. Although it contains references to variables from the pooled analysis, it lacks references to the raw data. Differences exist in the values of similarly named variables, e.g., *cordpb* and *pbcord*, indicating some pooled data variables may contain a mix of raw data variables.
  - (c) Please define, explain, and provide raw data for the variable “Maxaclday”, which appears in the pooled data set, *portpirie.sas7bdat*, but not in the raw data, *portpiriea.sas7bdat*.
6. Rochester:
  - (a) Please provide the data dictionary for *Rochester pooled\_analysis\_1.sas7bdat*.
  - (b) Please provide a cross reference dictionary for *Rochester2.sas7bdat*.
    - (i) Included in the material provided were *Rochester PooledVbls.xls* and *RochesterPooledVbls.xls* (note: space between Rochester and Pooled in the titles is intentional and distinguishes the two files). Both files are incomplete.
7. Yugoslavia: Complete, no additional data needed.
8. Pooled Analysis:
  - (a) Please provide definitions for the variables found in Exhibit 2. These variables are used in the pooled analysis of all cohorts, e.g., *leadpooled1003.sas7bdat*, but are not defined in any of the individual cross reference dictionaries. For example, the variable “Newpeak” is referenced in the pooled analysis of all cohorts but is not defined in any individual cross reference dictionaries.

Karen P. Seifert, Esq.  
February 18, 2011  
Page 3

Once we have received this information to make the production complete, we will consider your request regarding the future of this matter.

Very truly yours,



Anthony J. Bellino

cc: Matthew D. Shuler, Esq.  
John J. Richardson, Esq.  
Laura E. Ellsworth, Esq.  
Thomas S. Jones, Esq.

**Exhibit 1****POHL v. EPA****SUMMARY OF MATERIALS PROVIDED AND STILL NEEDED**

<b>Study</b>	<b>Data Dictionary (Code Book) for Cohort-Specific Raw Data</b>	<b>Data Dictionary for Pooled Analysis Variables - Cross Reference Between Raw and Pooled Codes</b>
<b>Boston</b>	<i>Boston chpool.doc</i>	<i>Boston.xls</i>
<b>Cincinnati</b>	<b>NEED</b>	<i>Cincinnati.xls</i>
<b>Cleveland</b>	<b>NEED</b>	<i>Cleveland.xls</i>
<b>Mexico</b>	<i>Mexico variable definition.doc</i>	<i>Mexico.xls</i>
<b>Port Pirie</b>	<b>NEED</b>	<b>NEED</b>
<b>Rochester</b>	<b>NEED</b>	<b>NEED</b>
<b>Yugoslavia</b>	<i>Yugoslavia Environmental Lead data dictionary for pooled ana.doc</i>	<i>Yugoslavia.xls</i>
<b>Pooled</b>	<b>NEED PARTIAL</b> <i>see Pooled Analysis Tables (Ex. 2)</i>	N/A

**Exhibit 2****POOLED ANALYSIS – ALL COHORTS**

<b>POOLED ANALYSIS FILES OF ALL COHORTS</b> <i>e.g., leadpooled1003.sas7bdat</i>
<b>Undefined Variables In Pooled Data Sets<sup>2</sup></b>
<b>Newpeak</b>
<b>Mthrunit</b>
<b>Fas</b>
<b>Pbch18m</b>
<b>G_Alc1</b>
<b>G_Alc2</b>
<b>Maxalcday</b>
<b>Momhigrade</b>
<b>Del</b>
<b>Iq</b>
<b>Iqv</b>
<b>Iqp</b>
<b>Lead</b>
<b>Deliq</b>
<b>Delconcurrent</b>
<b>Dellead6m</b>
<b>Home</b>
<b>Peaklead</b>
<b>Meanlead6m_24m</b>
<b>Meanlead6m_Concurrent</b>
<b>Meanlead6m_Concurrent1</b>
<b>Meanlead6m_24m1</b>
<b>Lead1</b>
<b>Peaklead1</b>
<b>Addlast</b>
<b>Add1</b>

<sup>2</sup> A data dictionary for the Pooled Analysis was not provided but many of the variable names and descriptions are identified in the cross reference dictionaries for specific cohorts. However, the variables listed here are not defined.

<b>Auc</b>
<b>Auc1</b>
<b>Lead_G10</b>
<b>Lead_Le10</b>
<b>Meanlead6m_Concurrent_G10</b>
<b>Meanlead6m_Concurrent_Le10</b>
<b>Peaklead_G10</b>
<b>Peaklead_Le10</b>
<b>Meanlead6m_24m_G10</b>
<b>Meanlead6m_24m_Le10</b>
<b>Momiqj</b>
<b>Dale_Waisiq</b>
<b>Agecat</b>
<b>Momigraven</b>
<b>Percentile</b>
<b>Auc624</b>
<b>Auc6241</b>
<b>Meanauc624</b>
<b>Meanauc6241</b>
<b>Meanauc</b>
<b>Meanauc1</b>
<b>Rawhome</b>
<b>Rawmomiq</b>
<b>Rawmomeduc</b>
<b>Rawbirthwt</b>
<b>Intplace</b>

## **EXHIBIT 9**

**Seifert, Karen P. (CIV)**

---

**From:** [REDACTED] **P.I.I.**  
**Sent:** Monday, February 21, 2011 8:48 AM  
**To:** Seifert, Karen P. (CIV)  
**Subject:** Re: Data Production: Pohl v. EPA, et al.

Karen,

I received your voicemail and I am heading off to a meetings so I will not be in my office to discuss. I will forward to the researchers and get back to you.

Best regards,

**P.I.I.**

>>> "Seifert, Karen P. (CIV)" <[Karen.P.Seifert@usdoj.gov](mailto:Karen.P.Seifert@usdoj.gov)> 2/18/2011 6:01 PM >>>

**P.I.I.**

I received this letter today from Jones Day. I am unable to evaluate whether the claims that data dictionaries are missing are accurate. I produced to Jones Day all of the data files and data dictionaries you sent.

Could you please have your researchers review the letter as quickly as possible and give me a call to discuss?

My cell is [REDACTED] **P.I.I.** I will be traveling next week and the best time to reach me will be 10-11 am (EST).

Thank you - Karen Seifert

From: Anthony J Bellino [<mailto:abellino@jonesday.com>]  
Sent: Friday, February 18, 2011 5:32 PM  
To: Seifert, Karen P. (CIV)  
Cc: Laura E. Ellsworth; Thomas S Jones; [matthew.shuler@dinslaw.com](mailto:matthew.shuler@dinslaw.com); [John.richardson@dinslaw.com](mailto:John.richardson@dinslaw.com)  
Subject: Data Production: Pohl v. EPA, et al.

Karen,

Please see the attached letter regarding the materials produced by the government on January 28, 2010.

Best,  
Tony

Anthony J. Bellino  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh PA 15219-2514  
Direct: 412.394.7242  
Fax: 412.394.7959  
[abellino@jonesday.com](mailto:abellino@jonesday.com)

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## **EXHIBIT 10**

**Seifert, Karen P. (CIV)**

---

**From:** Shuler, Matthew <MSHULER@DINSLAW.com>  
**Sent:** Wednesday, March 02, 2011 3:44 PM  
**To:** Seifert, Karen P. (CIV)  
**Subject:** Pohl v. EPA  
**Attachments:** clmomiq.sd2; clmommar.sd2; Raven Correction.xls; Analysis 12-01.sas; Raven IQ for paper.doc; Data Dictionary Cincinnati wisr67 sd2.xlsx; Data Dictionary for Cleveland.xlsx; PortPirie conversion.xls; Data Dictionary for Portpiriea.xlsx; PooledVbls checklist all sites.xls; Rochester PooledVbls conversion.xls; Data Dictionary for Rochester.xlsx; Exhibit 2.xlsx

Karen,

Attached please find Cincinnati Children's Hospital Medical Center's supplemental data production related to the the study "Low Level Environmental Lead Exposure in Children's Intellectual Function: An International Pooled Analysis," authored by Dr. Bruce Lanphear and others and published in Environmental Health Perspectives (2005 Jul; 113 (7): 894-899). CCHMC is producing the attached data files for the reasons outlined in my November 29, 2010 letter which contained the initial responsive data that were in our files.

Matt

Matthew D. Shuler, Esq.

Partner

Dinsmore & Shohl, LLP

1900 Chemed Center, 255 East 5th Street

Cincinnati, Ohio 45202

(513) 977-8560

[matthew.shuler@dinslaw.com](mailto:matthew.shuler@dinslaw.com)

**NOTICE:** This electronic mail transmission from the law firm of Dinsmore & Shohl may constitute an attorney-client communication that is privileged at law. It is not intended for transmission to, or receipt by, any unauthorized persons. If you have received this electronic mail transmission in error, please delete it from your system without copying it, and notify the sender by reply e-mail, so that our address record can be corrected.

## **EXHIBIT 11**

**Seifert, Karen P. (CIV)**

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

From: Seifert, Karen P. (CIV)

Sent: Friday, March 04, 2011 4:35 AM

To: 'abellino@jonesday.com'

Cc: 'matthew.shuler@dinslaw.com'; 'leellsworth@jonesday.com'; 'tsjones@jonesday.com'

Subject: Pohl v. EPA et al. - second production of data

Counsel:

Please find attached to this email files responsive to Ms. Pohl's August 9, 2007 Freedom of Information Act ("FOIA") request. In response to your letter of February 18, 2011, counsel for Cincinnati Children's Hospital Medical Center and Dr. Lanphear produced these additional files to the government and stated that they are related to Dr. Lanphear's article Low-Level Environmental Lead Exposure and Children's Intellectual Function: An international Pooled Analysis, Environmental Health Perspectives 133(7) (2005). This production contains the remaining data files and data dictionaries in the agencies' possession that are responsive to your request.

The production of these documents moots your claims against the agency defendants. I propose that we jointly stipulate to dismiss the case with prejudice, with each party to bear their own costs and fees. Please inform me by March 18, 2011 whether you agree to this proposal.

Sincerely,

Karen P. Seifert

Karen P. Seifert

Trial Attorney

United States Department of Justice

Civil Division, Federal Programs Branch

20 Massachusetts Ave. NW

Washington, D.C. 20530

(202) 305-0891

[karen.p.seifert@usdoj.gov](mailto:karen.p.seifert@usdoj.gov)

## **EXHIBIT 12**

**Seifert, Karen P. (CIV)**

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**From:** Seifert, Karen P. (CIV)  
**Sent:** Wednesday, April 06, 2011 12:39 PM  
**To:** Anthony J Bellino  
**Subject:** RE: Pohl - FOIA Request

Dear Tony,

Thank you for the email below. I believe that the record which you are seeking may be responsive to the language stated below. I must inform you, however, that EPA considers this a new FOIA request. The agencies' position is that the past two production have mooted your claims in the present case.

Your prior request sought only data, data collection forms, and data dictionaries related to the Lanphear study. EPA does not consider software code or analysis as included in terms of that request. Furthermore, EPA is unclear that the researcher is required to produce such code or analysis under the terms of the 2 C.F.R. § 215.36(d)(1), which requires only a production of "research data." The Shelby Amendment itself, authorizing the regulation, envisions only production of "data produced under an award." Omnibus Consolidated & Emergency Supplemental Appropriations Act, 1999, PL 105-277, 2 1998 HR 4328, 112 Stat 2681, 2681-495.

However, to the extent that the record has now become an "agency record" within the meaning of FOIA, the EPA will review your FOIA request for that record in due course. The agency may have to consider any claim by the researcher that this record is proprietary and exempt from production under 5 U.S.C. § 552(b)(4). As I am sure you can understand, the agency is in the position to both ensure compliance with FOIA and also protect the researchers to the extent required by the law. EPA contends that it should fully review any production in this instance, especially given the possibility of setting precedent in this unique area.

I realize that this process may take some time. I believe EPA would consider reviewing this new FOIA request in an expedited manner as part of this litigation, contingent on a settlement agreement between the parties.

Sincerely,

Karen Seifert

Karen P. Seifert  
Trial Attorney  
United States Department of Justice  
Civil Division, Federal Programs Branch  
20 Massachusetts Ave. NW  
Washington, D.C. 20530  
(202) 305-0891  
[karen.p.seifert@usdoj.gov](mailto:karen.p.seifert@usdoj.gov)

---

**From:** Anthony J Bellino [<mailto:abellino@jonesday.com>]  
**Sent:** Monday, April 04, 2011 5:27 PM  
**To:** Seifert, Karen P. (CIV)  
**Subject:** Pohl - FOIA Request

Karen,

With regard to amending the FOIA request, please advise if you find the following language a sufficient description of the file most recently released to you by the hospital: "Statistical Analysis Software ("SAS") code used in the Lanphear Study." If this is satisfactory, I will draft an amendment letter for all the parties review.

I am happy to discuss further by phone to reach language that is satisfactory.

-Tony

Anthony J. Bellino  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh PA 15219-2514  
Direct: 412.394.7242  
Fax: 412.394.7959  
[abellino@jonesday.com](mailto:abellino@jonesday.com)

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=====

## **EXHIBIT 13**

**Seifert, Karen P. (CIV)**

---

**From:** Anthony J Bellino <[abellino@jonesday.com](mailto:abellino@jonesday.com)>  
**Sent:** Monday, May 02, 2011 4:13 PM  
**To:** Seifert, Karen P. (CIV)  
**Subject:** Pohl v. EPA - Update

Karen,

Unfortunately, I do not have a substantive update for you at this time regarding a possible stipulation for dismissal involving the government defendants. We are still waiting on the Hospital to provide us with the remaining file. I hope to have an update for you between now and the status conference on Thursday.

Regards,  
Tony

Anthony J. Bellino  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh PA 15219-2514  
Direct: 412.394.7242  
Fax: 412.394.7959  
[abellino@jonesday.com](mailto:abellino@jonesday.com)

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=====

## **EXHIBIT 14**

**From:** [Seifert, Karen P. \(CIV\)](#)  
**To:** [Laura E. Ellsworth](#)  
**Cc:** [Thomas S. Jones](#); [Paul J. Jalsevac](#)  
**Subject:** Pohl v. EPA, et al. - Discovery Issues  
**Date:** Tuesday, April 20, 2010 6:42:00 PM

---

Counsel –

Judge Standish’s December 18, 2009 Order stayed discovery in this case “until such time as the neutral has submitted his or her report or as otherwise ordered by the court.”

I am in receipt of Plaintiff’s First Set of Requests for Production. Defendants continue to contend that discovery is inappropriate and unnecessary at this juncture, and should not be permitted. Regarding the Freedom of Information Act claim, Defendants plan to file a dispositive summary judgment motion, accompanied by detailed affidavits providing an adequate basis for decision. *Davin v. U.S. Dept. of Justice*, 60 F.3d 1043, 1050 (3rd Cir. 1995) (summary judgment in FOIA action may be granted on the basis of agency’s affidavits); *Lee v. U.S. Dept. of Justice*, 235 F.R.D. 274, 287 (W.D. Pa. 2006) (In a FOIA action, “discovery relating to the agency’s search and the exemptions it claims for withholding records generally is unnecessary so long as the agency’s submissions [of affidavits] are facially adequate”). To the extent Plaintiff takes issue with Defendants’ affidavits, Plaintiff can then file a Rule 56(f) motion. Regarding the Administrative Procedure Act claim, Defendants plan to file a Motion for Judgment on the Pleadings, and no discovery is necessary to evaluate that question of law. As to the substance of any potential APA claim, discovery is also premature at this time. *Florida Power and Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (“The factfinding capacity of the district court is . . . typically unnecessary to judicial review of agency decisionmaking.”); *see, e.g., McCrary v. Gutierrez*, 495 F.Supp.2d 1038, 1041 (N.D. Cal. 2007).

Please let me know, no later than tomorrow, whether you are willing to withdraw your Requests for Production and stay discovery pending resolution of Defendants’ anticipated Motion for Summary Judgment. I intend to attend Thursday’s meeting with a proposed schedule for that motion. If we do not come to a joint resolution, Defendants will file a Motion for Protective Order seeking the stay of all discovery.

Thank you,

Karen

Karen P. Seifert  
Trial Attorney  
United States Department of Justice  
Civil Division, Federal Programs Branch  
20 Massachusetts Ave. NW  
Washington, D.C. 20530  
(202) 305-0891  
[karen.p.seifert@usdoj.gov](mailto:karen.p.seifert@usdoj.gov)

## **EXHIBIT 15**



## U.S. Department of Justice

Civil Division

Federal Programs Branch  
20 Massachusetts Ave., N.W.  
Washington, D.C. 20001Karen P. Seifert  
Trial AttorneyTel: 202-305-0891  
Email: karen.p.seifert@usdoj.gov

August 4, 2010

Paul J. Jalsevac, Esq.  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh, PA 15219-2514

Dear Paul,

Thank you for your letter of July 29, 2010, renewing your request for your "First Set of Requests for Production." This letter is a follow up to our phone call of August 3, 2010. As stated in the past, the agency defendants do not believe discovery is appropriate in this matter.

Precedent supports that discovery is not appropriate on any of your claims. First, discovery is generally unavailable in Freedom of Information Act ("FOIA") suits. *See Wolf v. CIA*, 569 F. Supp. 2d 1, 9 (D.D.C. 2008).<sup>1</sup> In FOIA cases, discovery occurs, if at all, only after the agency files its motion for summary judgment. *Lawyers' Committee for Civil Rights of San Francisco Bay Area v. U.S. Dept. of the Treasury*, 534 F.Supp.2d 1126, 1131-1132 (N.D. Cal. 2008).<sup>2</sup> Discovery in FOIA cases occurs only after summary judgment because the agency has the burden of proof under FOIA, 5 U.S.C. § 552(a)(4)(B), and the agency submits detailed affidavits describing the validity of its FOIA search. The Third Circuit has noted that the agency's submission of affidavits on summary judgment provides a plaintiff with the necessary information about the processing of her FOIA request, and these submissions establish the "detailed factual basis" for deciding a FOIA action. *Davin v. U.S. Dept. of Justice*, 60 F.3d 1043, 1050 (3d Cir. 1995) (quoting *McDonnell v. United States*, 4 F.3d 1227, 1241 (3d Cir. 1993)).

Therefore, numerous court's have found that "[d]iscovery is only proper in a [FOIA] case after the defendant has had an opportunity to submit its justification for withholding documents responsive to a FOIA request by a dispositive motion." *Bay Area Lawyers Alliance for Arms*

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<sup>1</sup>See also *Wheeler v. CIA*, 271 F. Supp. 2d 132, 139 (D.D.C. 2003); *Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp. 2d 19, 25 (D.D.C. 2000); *Schiller v. I.N.S.*, 205 F.Supp.2d 648, 654 (W.D. Tex. 2002).

<sup>2</sup>See also *Miscavige v. I.R.S.*, 2 F.3d 366, 369 (11th Cir. 1993); *Simmons v. Department of Justice*, 796 F.2d 709, 711-12 (4th Cir. 1986); *Florida Immigrant Advocacy Center v. National Security Agency*, 380 F.Supp.2d 1332, 1341 n. 6 (S.D. Fla. 2005); *Murphy v. F.B.I.*, 490 F.Supp. 1134, 1136-38 (D.D.C. 1980).

*Control v. Dep't of State*, 818 F. Supp. 1291, 1294 (N.D. Cal. 1992). The government must “first ha[ve] a chance to provide the court with the information necessary to make a decision.” *Miscavige v. IRS*, 2 F.3d 366, 369 (11th Cir. 1993).<sup>3</sup> Agency defendants ask that you provide them with this chance, as they intend to file for summary judgment upon resolution of the pending Partial Motion to Dismiss.

Should you believe that the agency defendants’ submissions on summary judgment are incomplete, you will have an opportunity to seek additional discovery at that time. *Commonwealth Dept. of Public Welfare v. United States*, No. Civ-A 99-175, 1999 WL 1051963, at \*3 (W.D. Pa. Oct. 12, 1999) (permitting “limited discovery” on “the material produced by [the agency]”). Fed. R. Civ. P. 56(f) allows a plaintiff to assert that she “cannot present facts essential to justify [her] opposition” to summary judgment, and ask the court for discovery. However, in FOIA suits, discovery is permitted only where there is a genuine issue as to the adequacy of the agency’s search, its identification and retrieval procedures, or its good faith. See *Commonwealth Dept. of Public Welfare*, 1999 WL 1051963, at \*3.<sup>4</sup>

I urge you to withdraw your requests because they are “unreasonably cumulative or duplicative” of the agency defendants’ submissions at summary judgment, and production will only delay resolution of your claims. Fed. R. Civ. P. 26(b)(2)(C). Furthermore, your broad requests mainly seek documents protected by the deliberative process privilege, which are exempt from production. 5 U.S.C. § 552(b)(5); *Ajluni v. FBI*, 947 F. Supp. 599, 608 (N.D.N.Y. 1996). Agency defendants will not produce “inter-agency or intra-agency memorandums or letters,” § 552(b)(5), the “disclosure of which would be injurious to the consultative functions of government.” *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 149 (1975) (internal quotation and citation omitted); see also *Abdelfattah v. U.S. Dept. of Homeland Sec.*, 488 F.3d 178, 183 (3d Cir. 2007). Compliance with your request will be timely, and in the end, will result in little information besides a log of privileged documents.

Second, to the extent your discovery relates to your other newly-asserted claims, the agency defendants moved to dismiss your Administrative Procedure Act (“APA”) and Mandamus claims on July 30, 2010. Courts have consistently exercised their discretion to order a stay of all discovery pending a dispositive motion. *Mann v. Brenner*, No. 09-2461, 2010 WL

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<sup>3</sup> See also *Jones v. FBI*, 41 F.3d 238, 241 (6th Cir. 1994); *Founding Church of Scientology v. U.S. Marshals Serv.*, 516 F. Supp. 151, 156 (D.D.C. 1980).

<sup>4</sup> See also, e.g., *Safecard Servs. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991); *Simmons v. U.S. Dep't of Justice*, 796 F.2d 709, 711-12 (4th Cir. 1986). This showing must be significant: a “speculative criticism” of the agency’s submissions is not enough. *Accuracy in Media, Inc. v. Nat'l Park Serv.*, 194 F.3d 120, 124 (D.C. Cir. 1999) (citation omitted); *Kucernak v. FBI*, No. 96-17143, 1997 WL 697377, \* 1 (9th Cir. Nov. 4, 1997); see also *Military Audit Project v. Casey*, 656 F.2d 724, 751-52 (D.C. Cir. 1981); *Broadrick v. Executive Office of President*, 139 F.Supp.2d 55, 63-64 (D.D.C. 2001).

1220963 at \*3 (3d Cir. Mar. 30, 2010) (citing *Ashcroft v. Iqbal*, 129 S.Ct.1937, 1954 (2009)).<sup>5</sup> A stay of discovery is particularly appropriate where, as here, the dispositive motion challenges the court's subject matter jurisdiction. *U.S. Catholic Conference v. Abortion Rights Mobilization, Inc.*, 487 U.S. 72, 79-80 (1988). Furthermore, a stay is appropriate when the dispositive motion "pursuant to Rule 12(b)(6) tests the legal sufficiency of a claim, and therefore may be decided on its face without extensive factual development" *Mann*, 2010 WL 1220963 at \*3 (citing *Mitchell v. McNeil*, 487 F.3d 374, 379 (6th Cir. 2007)). "The purpose of F[ed]. R. Civ. P. 12(b)(6) is to enable defendants to challenge the legal sufficiency of complaints **without subjecting themselves to discovery.**" *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987) (emphasis added). You will not be prejudiced by the stay because "discovery is not necessary in ruling on the grounds raised in [agency d]efendants' pending motion to dismiss." *Ball v. Oden*, 2010 WL 598653 (M.D. Pa. Feb. 17, 2010).

Even if a motion to dismiss were not pending, your propounded discovery is not appropriate under the APA. APA claims are judged on the administrative record alone. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985). The district court is not "generally empowered" to compel discovery where the record "adequately explains the agency decision." *Pres. Endangered Areas of Cobb's History, Inc. ("PEACH") v. Army Corps of Engineers*, 87 F.3d 1242, 1246-47 (11th Cir. 1996) (quoting *Lorion*, 470 U.S. at 473). Because agency defendants have not yet had an opportunity to produce the administrative record, there can be no grounds to take issue with the record. Furthermore, many of your requests are not likely to lead to relevant information, because they were not part of the reviewing agencies' decision-making process.

However, once agency defendants file their Motion for Summary Judgment with any supporting materials, you may move under Fed. R. Civ. P. 56(f) for additional discovery. Your claims can be resolved more expeditiously if you provide agency defendants an opportunity to compile an administrative record before submitting discovery requests.

Finally, this discovery is not "relevant" to your Mandamus claim under Fed. R. Civ. P. 26(b). That claim turns entirely on a legal question of the agencies' duty under their regulations. 28 U.S.C. § 1361; *In re Patenaude*, 210 F.3d 135, 141 (3d Cir. 2000). The documents requested seek information about the facts surrounding the processing of your FOIA request and are therefore not relevant.

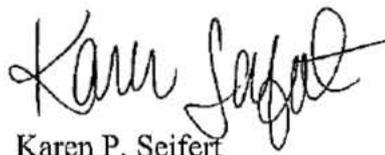
Should you persist in propounding discovery, agency defendants will move for a protective order and to stay discovery until resolution of the pending Partial Motion to Dismiss and anticipated Motion for Summary Judgment. The agency defendants fully intend to provide you as early as possible detailed affidavits and, if necessary, an administrative record. The agency defendants would prefer that the resolution of your case not be derailed by discovery requests that may duplicate these efforts.

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<sup>5</sup>See also, e.g., *In re Orthopedic Bone Screw Product Liability Lit.*, 264 F.3d 344, 365 (3d Cir. 2001); *Hahn v. Star Bank*, 190 F.3d 708, 719 (6th Cir. 1999); *Coastal States Gas Corp. v. Dep't of Energy*, 84 F.R.D. 278, 282 (D. Del.1979).

Please indicate whether you are willing to withdraw your requests for production, or propose a solution to resolve this dispute without court intervention. The courtesy of your response is requested no later than August 5, 2010.

Sincerely,

A handwritten signature in black ink, appearing to read "Karen Seifert", written in a cursive style.

Karen P. Seifert

## **EXHIBIT 16**

EXHIBIT 16  
U.S. Department of Justice

Civil Division

Federal Programs Branch  
20 Massachusetts Ave., N.W.  
Washington, D.C. 20001Karen P. Seifert  
Trial AttorneyTel: 202-305-0891  
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August 6, 2010

Paul J. Jalsevac, Esq.  
Jones Day  
500 Grant Street, Suite 4500  
Pittsburgh, PA 15219-2514

VIA EMAIL

Dear Paul,

I write in response to your letter of August 5, 2010. Agency defendants preferred that this discovery dispute could be resolved without court intervention. Despite that precedent clearly states that plaintiff is not entitled to discovery, agency defendants were willing to entertain a compromise that they would produce a limited amount of readily accessible documents to plaintiff at this time.

Your proposal, however, goes beyond such a limited production and further requests **more** documents. Additionally, plaintiff's Second Set of Requests for Production is not even relevant to her claims against the agencies. In the Second Set, plaintiff seeks documents related to several government research grants provided to Dr. Lanphear and/or the Cincinnati Children's Hospital Medical Center ("CCHMC"). However, agency defendants **do not contest** that Dr. Lanphear's study was funded in part by federal government grants. Because no dispute exists between our parties regarding the funding of this study, plaintiff's requests are not relevant to her claims against the agency defendants. To the extent plaintiff seeks these documents to aid her in her action against Dr. Lanphear and CCHMC, she should direct her requests to those parties.

Furthermore, under your proposal, plaintiff stated she would "reevaluate" the need for a full document production, and that she "reserves" the right for further discovery. Agency defendants are unclear how such a reservation results in an adequate compromise.

Therefore, agency defendants are unable to accept your proposal and will be forced to seek the protection of the court.

Sincerely,

A handwritten signature in black ink, appearing to read "Karen Seifert".

Karen P. Seifert

## **EXHIBIT 17**

**DOCUMENTS FILED UNDER SEAL**