

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY

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August 3, 2009

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Sebelius:

The Subcommittee on Investigations and Oversight is investigating several issues related to the 2003-2004 lead in water crisis in Washington, D.C. We have been particularly interested in the role played by the Centers for Disease Control and Prevention (CDC). I previously sent letters requesting documents to Dr. Richard Besser, then-CDC's acting director, in March and April of this year.

You may recall that *The Washington Post* broke a story in January 2004 revealing that D.C. and federal authorities knew that houses serviced by lead lines were carrying water into homes with lead levels as much as 20 times above that allowed under the Safe Drinking Water Act.¹ The CDC joined other Federal agencies in responding to this public health crisis and published a paper in March 2004, coauthored by CDC officials, which suggested there was no danger to children or the public from the elevated lead levels in water.² With that CDC publication, the public's concern for this issue died down.

During the course of our preliminary investigation, the Subcommittee has discovered that the District of Columbia government and the CDC failed to collect or analyze all data from 2003 that would have shed light on the public health risks associated with lead in D.C.'s water. In fact, CDC knew of serious questions regarding a major gap in the blood lead level (BLL) test data even before they published the March 2004 paper. Further, the Subcommittee has been told by CDC officials of problems in the management of the D.C. lead reporting system. This should

¹ David Nakamura, "Water in D.C. Exceeds EPA Lead Limit; Random Tests Last Summer Found High Levels in 4,000 Homes Throughout City," *The Washington Post*, p. A1, January 31, 2004.

² "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004," *Morbidity and Mortality Weekly Report (MMWR) Dispatch*, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Vol. 53 / March 30, 2004. Co-authors of this report came from CDC, the U.S. Public Health Service and the D.C. Department of Health.

have set off warning bells that the CDC could not rely on the numbers being provided for public health statements.

It has long been a puzzle why the District reported a significant drop in the number of BLL tests for children younger than 72 months (six years) of age. In 2002, almost 16,000 children were tested for lead exposure; in 2003, the number dropped to just a little over 9,000.³ The Subcommittee wrote to each of the labs that analyzed BLL tests for the District in 2003 and has a new and more complete number. According to the reports provided to the Subcommittee, those labs reported to DC at the time that they tested a total of 13,758 individual children in 2003 not the 9,229 reported by the District of Columbia and CDC. Further, the labs provided test results to the DC DOH in 2003 indicating that at least 486 children – not the 193 reported by DOH in 2003 and publicly listed by the CDC today – had elevated blood lead levels.⁴ Blood lead levels in children are considered “elevated” if they are at or above the CDC’s “level of concern” of 10 micrograms of lead per deciliter of blood (10 mg/dL). Under the new data provided to the Subcommittee, the ratio of DC children suffering from lead poisoning in 2003 was actually 3.5-percent, not the 2.1-percent listed by the CDC.⁵

The numbers reported to the Subcommittee are significantly greater than those used by the CDC and District officials to write an article in March 2004 in the CDC’s “Morbidity and Mortality Weekly Report (MMWR)”. That article downplayed the relationship between lead in the water and elevated lead levels in both children and adults. The article also included the results of a study that tested the blood lead levels of 201 residents in 98 homes with extremely high levels of lead in their water lines, but the CDC and DOH did not mention in their report that the residents of these homes had been told months earlier to stop using tap water. They also failed to disclose in the MMWR report that the majority of the residents in the study had been drinking bottled water.⁶ Yet, the MMWR suggested that increases in lead in D.C. tap water of almost 20 times the limit set by the Safe Water Drinking Act did not result in elevated BLLs for

³ The inconsistencies in the 2003 blood lead level numbers were plainly obvious to anyone that looked at them. Dr. Marc Edwards, a civil and environmental engineering professor at Virginia Tech and recent MacArthur Fellow, first wrote to CDC about concerns with the data relied upon in the March 2004 MMWR in January 2007 and again in September 2007. In those letters, Dr. Edwards alleged potential “scientific misconduct.”

⁴ The numbers of total and “elevated” BLL tests mentioned by the Subcommittee above is an underestimate of the numbers actually reported to the DC Department of Health. One of the labs reporting data to the Subcommittee, for instance, no longer had BLL test data that they reported to DC for January, February and March 2003. In other cases labs reported to the Subcommittee that they had similar names of children for multiple “elevated” BLL tests and counted these as belonging to one child rather than two. In addition, the Subcommittee erred on the side of caution and did not count one “elevated” BLL test because the lab said it did not arrive in a lead-free tube and may have resulted in falsely elevated results. On top of the 13,758 individual DC children who had BLL tests in 2003 reported to the DC DOH, the Subcommittee was also told of another approximately 6,000 BLL tests which did not reveal elevated blood lead levels that were never reported to D.C. by one lab, although this was required under D.C. law at the time.

⁵ See the “CDC’s National Surveillance Data” collected from state and local health departments from 1997 to 2006, the most recent year available. The data is available here:

http://www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls

⁶ The allegations of major omissions in the 300 ppb “Cross Sectional Analysis” that looked at extremely high lead levels in DC drinking water and increased BLLs in DC residents, which was part of the MMWR report, are supported by documentation provided by Professor Marc Edwards in the two letters regarding “scientific misconduct” that he sent to the CDC’s Associate Director for Science in 2007.

affected D.C. residents. The claim by the MMWR seemed to contradict numerous previous studies—including one done by the same leading author—that found that excessive lead in water resulted in dangerous BLLs.⁷

However, we now know that the analysis D.C. and CDC officials did for the MMWR was based on wildly incomplete data from 2003. We also know that the CDC has done a still unpublished reassessment of data from 2001-2006—still using incomplete data for 2003—that shows a significant correlation between elevated BLLs in children and lead service lines. This unpublished study falls more in line with all previous work by CDC and other public health officials on the effects of lead in water. The March 2004 MMWR acknowledged the health hazards of lead in children, but concluded that District of Columbia residents had not been harmed by drinking lead-contaminated water. It also led local school officials in other cities, including in New York and Seattle, to downplay the potential health consequences of exposure to high levels of lead in their own public water supplies.

The 2004 MMWR relied on data that CDC officials had ample reason to question. First, the CDC was aware of the dramatic and unexplained drop in the number of DC children reportedly being tested for blood lead levels in 2003 compared to the previous year. The number of DC children younger than 72 months who had BLL test data reported to the DC Department of Health (DOH) reportedly declined by 6,526 children, from 15,755 children in 2002 to 9,229 children in 2003.

The CDC was reportedly told by the database coordinator of the Washington, D.C. Childhood Lead Poisoning Prevention Program (CLPPP) that the drop in the data was the result of one lab failing to report all BLLs to DC in 2003. CDC officials interviewed by the Subcommittee staff say they were told by that DC official that the lab only reported “elevated” BLLs in 2003, thus explaining the decline in reporting data.⁸

However, the Subcommittee contacted that lab and they report that the lab had continuously reported only elevated BLLs from 1999 until April of 2004, so there was no change in their reporting practice that could account for an overall drop in numbers. The CDC was aware of this drop-off in thousands of DC children being tested for lead exposures by

⁷ A CDC co-author of the MMWR indicated that this was definitely a “counter-intuitive” result, but the previous research on lead in water was not mentioned in the MMRW report. See, for instance: E. Cosgrove, MJ Brown, et al. al, “Childhood lead poisoning; Case study traces source to drinking water,” *Journal of Environmental Health*, Vol. 52 / Issue 1, July 1, 1989; Michael Shannon and John W. Graef, “Lead intoxication from lead-contaminated water used to reconstitute infant formula,” *Clinical Pediatrics*, Vol. 28, No. 8, pp. 380-382 August 1989; and “Lead-contaminated drinking water in bulk-water storage tanks – Arizona and California, 1993,” *Morbidity and Mortality Weekly Review*, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, October 21, 1994.

⁸ Over the past several months the Subcommittee has repeatedly attempted to contact two key individuals who were in the Washington, D.C. Childhood Lead Poisoning Prevention Program (CLPPP) in 2003/2004 responsible for overseeing the collection of blood lead test data from the laboratories and providing it to the CDC in order to interview them about these and related issues. One of those officials, speaking through his attorney, says several labs were not reporting all data to DC. However, both of these officials still refuse to be interviewed by the Subcommittee.

approximately February of 2004, but never verified the claim that only one lab had stopped reporting non-elevated results.

At that same time, CDC officials learned that the same individual in the DC DOH lead program also admitted to CDC officials that he had “forged” the numbers in the 2003 quarterly administrative reports regarding the BLL data provided to CDC in order to cover up the thousands of missing tests. Three different CDC staff acknowledged to Subcommittee staff of knowing of this fabrication. However, the individual, speaking through his attorney, denied to the Subcommittee that he fabricated any reports or data regarding blood lead tests. According to CDC officials, the allegedly “forged” numbers in the quarterly report were not used for data analysis in the MMWR nor posted on the web.

Despite the admission of “forgery” by the D.C. employee and the inexplicable gap in the 2003 BLL data provided to CDC, the primary CDC author of the 2004 MMWR never informed any of the MMWR’s co-authors of these problems. Nor did the MMWR mention these issues, which strike at the heart of the reliability of the data for analytical purposes. Finally, the CDC took no direct steps to determine the true cause of the data gap. Instead, the CDC continued to rely on the same official who admitted forging data to try to track down more complete data.⁹

The disparity in the numbers reported by the CDC and the data obtained by the Subcommittee is extraordinarily disturbing. The numbers actually reported by the laboratories to the DC Department of Health show that the number of DC children suffering from lead poisoning in 2003 was more than *twice* as high as the CDC has previously assumed or the DC Department of Health has acknowledged. CDC’s inability or unwillingness to validate and verify the data it was being provided raises serious questions about the ability of the CDC’s lead program to ensure the integrity of the data provided to it for other years by DC as well as from other CDC cooperating states and cities.

At least one of the co-authors on the CDC’s MMWR study was a Public Health Service official assigned to the Food and Drug Administration (FDA). Please ensure that a search of relevant documents requested below is conducted at the CDC, FDA and U.S. Public Health Service. Accordingly, Pursuant to Rules X and XI of the United States House of Representatives and Rule 3 (a) (5) of the Committee on Science and Technology, please provide two sets of copies (one for the minority) of all of the records (see attached definition) and documents listed below:

1. All records, including all communications with, to, between and among officials of the District of Columbia and/or the CDC, FDA and U.S. Public Health Service, as well as internal communications between and among CDC, FDA and/or Public Health Service employees or any other government agencies regarding the DC lead-in-water crisis in 2003/2004. This should include all drafts of the report titled: “Blood Lead Levels in

⁹ The DC employee allegedly involved in the fabrication of quarterly reports apparently asked the labs to resubmit their data to DC in late 2004. He told the CDC that the data he received once again totaled the approximately 9,000 children tested in 2003 that DC had originally reported, say CDC officials.

Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004,” published in Morbidity and Mortality Weekly Report (MMWR) Dispatch, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Vol. 53 / March 30, 2004, and all comments and corrections from co-authors and others involved in the review and publication of that report. These should include all relevant records from January 1, 2003 to present. Because the Subcommittee’s previous request does not appear to have resulted in the production of all of these records, the department’s search should include, but not be limited to, the e-mail correspondence of each of the co-authors of the CDC MMWR study or any other person involved in the review that is or was employed for any agency or division of the Department of Health and Human Services (HHS).

2. Copies of all drafts and the final version of an article by Mary Jean Brown, Jamie Raymond, Tom Sinks and others addressing the association between lead poisoning among children less than six years old and lead service pipes in Washington D.C. that was recently submitted for publication in a scientific peer review journal.
3. All records regarding Battelle Labs’ and any other person’s or organization’s review of the study underlying the article referred to in Question 2. This should include, but not be limited to, draft comments, memoranda, correspondence and recommendations.
4. Copies of all trip reports, technical reviews or corrective action plans regarding the Washington, D.C. Childhood Lead Poisoning Prevention Program (CLPPP) by the CDC from January 1, 2002 to the present.
5. All records and data regarding the “Cross Sectional Analysis” study reported in the CDC MMWR and apparently produced by U.S. Public Health Service employees, including Tim Cote. This should include records relating to the study design, organization, scope and/or purpose and should include all drafts, edits and final versions of the study. Please also include the raw dataset, any summary data, copies of the surveys of the 201 residents in this study, and the specific dataset used for the CDC MMWR publication of March 30, 2004. Please clearly identify this dataset as the data used for the MMWR publication. E-mails, draft comments and all other records regarding this study should be included as well.

It has become apparent from Subcommittee staff interviews with CDC officials over the past several weeks, and staff reviews of the records provided, that the CDC has failed to provide all of the documents requested in prior letters. I note that those requests remain open until completely responded to and I would ask that you direct your staff to collect and deliver copies of those documents immediately. In at least two interviews, CDC staff made specific reference to materials they had copied for provision to the Subcommittee and the Subcommittee has not received those materials.

Please ensure that *all* attachments to e-mails or other communications responsive to this document request are provided to the Subcommittee. In addition, please provide all records on

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single-sided paper so they can be clearly identified. If the Department believes there is a legitimate basis for withholding records from the Subcommittee, please provide us with a list of the specific records withheld and the basis for not providing them.

Please provide the requested records to the Subcommittee offices in Room 2321 of the Rayburn House Office Building by 5 p.m. on Monday, August 17, 2009. If you have any questions or need additional information, please have your staff contact Douglas Pasternak, Investigations and Oversight Subcommittee professional staff member, at (202) 226-8892, or Dr. Dan Pearson, Investigations and Oversight Subcommittee staff director, at (202) 225-4494.

Your assistance in this matter is greatly appreciated.

Sincerely,



BRAD MILLER
Chairman
Subcommittee on
Investigations & Oversight

cc: DR. PAUL C. BROUN
Ranking Member
Subcommittee on Investigations & Oversight

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.