# A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL

Report by the Majority Staff of the Subcommittee on Investigations and Oversight of the Committee on Science and Technology,
U.S. House of Representatives to
Subcommittee Chairman Brad Miller

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# **INDEX**

	Page
Findings	1.
Introduction and Executive Summary	4.
A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL	13.
1. CDC Lead Programs and the Known Effects of Lead in Water	. 13.
2. Origins of the Lead-in-Water Crisis in the District of Columbia	17.
3. CDC's Involvement in the District's Lead-in-Water Crisis and the MMWR Dispatch	24.
4. CDC to Washington, D.C.: There is No Public Health Crisis	33.
5. Efforts by CDC, DC and the Subcommittee to Identify Missing Blood Lead Level Data	38.
6. Dr. Edwards' Investigation: The Missing Cross-Sectional Data	43.
7. CDC's Response to Criticisms and a New Analysis	48.
8. Dr. Edwards' Peer-Reviewed Research: Elevated Water Lead Levels Endangered District's Children	54.
9. Conclusion	58.

#### STAFF FINDINGS

The staff findings represent the essential elements of what could be proven based on the records provided to the Subcommittee and the information gathered in dozens of interviews with both former and current officials from the Centers for Disease Control and Prevention (CDC), the Public Health Service (PHS), and the District of Columbia. A fuller accounting of the results of the staff's work can be found in the Summary and body of the report.

In the Subcommittee's attempt to fully investigate many of the allegations surrounding the publication of the March 30, 2004 *Morbidity and Mortality Weekly Report Dispatch (MMWR)* and the CDC's overall response to the DC lead-in-water crisis, it has been very difficult to obtain all relevant records regarding the issue from either the CDC or the District of Columbia government, and there are key documents that have been referred to by persons interviewed that have never been located. In other instances, records obtained by the Subcommittee from non-CDC sources completely contradict allegations made by CDC officials. Some assertions made by CDC staff remain completely unsubstantiated by documentation or by outside participants who should have knowledge of the events.

Despite the gaps in some of the Subcommittee's information, it is clear that the CDC's March 30, 2004 *MMWR* was marred by many problems that have yet to be corrected. Among the Subcommittee's primary findings:

- CDC Has Yet to Inform Public Health Community of Its Faulty Analysis. Since 2004, lead experts, including some at CDC, have done significant research that negates most of the conclusions of the 2004 MMWR article about the lack of a correlation between exposure to elevated water lead levels [WLLs] and the public's health. These include determining that elevated WLLs can cause lead poisoning in children and did so in the District of Columbia; that the substitution of chloramine for chlorine as a water disinfectant causes lead corrosion and elevated WLLs and BLLs; and that "partial" lead line replacements can elevate, instead of reduce, WLLs and result in increased BLLs. CDC has failed its public health responsibilities by refusing to withdraw its 2004 MMWR article or to alert the public health community at large of this new information.
- CDC Has Failed to Publish Its Own Subsequent Research Showing that Elevated WLLs Increase BLLs. In 2007, CDC researchers presented a paper at a public health conference showing that elevated WLLs can cause lead poisoning in children and did so in the District of Columbia; that the substitution of chloramine for chlorine as a water disinfectant causes lead corrosion and elevated WLLs and BLLs; and that "partial" lead line replacements can elevate, instead of reduce, WLLs with an accompanying four-fold risk for elevated BLLs. CDC has only informed DC officials of these results recently and has failed to inform public health and water utility officials elsewhere of these results. These findings are important since many cities and states across the country have engaged in changing disinfectants and partial lead line replacements. The DC government alone spent nearly \$100 million replacing lead service lines as a response to

the DC lead-in-water crisis before the program was halted because of concerns it was actually increasing, at least in the near term, not decreasing the water lead levels.

Because the *MMWR* is not a peer-reviewed publication, but is heavily relied on by public health offices, CDC should publish its key findings expeditiously in the *MMWR* as it does other public health alerts.

- CDC Failed to Include Key Data When It Published the Results of a "Cross-Sectional Study" in the MMWR. The cross-sectional study looked at BLL test results for residents of homes with over 300 parts per billion (ppb) of lead in their drinking water, and did not find a single person with an elevated blood lead level. It was the most-cited part of the MMWR and used as evidence that elevated WLLs did not affect BLLs. But the study failed to mention that many residents had stopped drinking their tap water months earlier, although three co-authors suggested raising this issue in the MMWR.
- CDC Failed to Include Residences with WLLs between 100 and 300 ppbs in Its Cross-Sectional Study Even Though It had Evidence that the BLLs of Children in Those Homes Would Actually Be Higher than Those in Homes with WLLs over 300 ppb. CDC staff knew that a higher proportion of children in homes with WLLs between 100 and 300 ppbs had tested with BLLs  $\geq 10 \,\mu\text{g/dL}$  than in homes with WLL greater than 300 ppb. None of the authors of the study can explain why they did not expand the study to include these homes.
- CDC Cannot Produce the Raw Data Used in the Cross-Sectional Study. Both CDC and the District government claim they have no records containing the raw scientific data to substantiate the basis for this study. The only raw data available, a single spreadsheet provided to Dr. Marc Edwards in a FOIA request in 2006, points to grave problems in the scientific integrity of this study, including individuals who were "tested" after the MMWR article was published and the fact that more than half of those surveyed said they drank bottled water, a key detail never mentioned in the MMWR article. In addition, according to this spreadsheet only 13 individuals in the study drank tap water exclusively and did not use a water filter or drink bottled water. This key fact was also omitted from the MMWR article.
- The MMWR Eliminated One Child with an Elevated BLL. Dr. Lynette Stokes, the first author of the MMWR article, a former CDC official and chief of the Bureau of Hazardous and Toxic Substances at the D.C. Department of Health, who oversaw the DC lead program, admitted in an interview that one child who lived in a home with 300 ppb of lead in the water and no other known source of lead in the child's home, was identified in February 2004 as having an elevated BLL. Dr. Stokes said she excluded this child from the cross-sectional study because the child had only lived in the house a short time. Excluding this child permitted CDC to conclude that even among homes with the highest water lead levels not a single person was found with an elevated blood lead level. No records concerning this case can be located, or have been produced by either the District or the CDC.

- In Its Hurry to Release "Good News," CDC Ignored Decades of Its Own Research and That of the Scientific Community When It Claimed That Elevated Water Lead Levels in the District of Columbia Did Not Significantly Impact the Blood Lead Levels of Children. Humans have known since at least the time of the Roman Empire that ingestion of lead in water leads to lead poisoning and negative cognitive and health impacts particularly in children. CDC publications have warned of the threat posed by lead-contaminated water, and numerous peer-reviewed studies over the years have documented increases in blood lead levels in children consuming water with high lead levels. When CDC's 2004 cross-sectional study concluded that there was no such correlation, it should not have been published without a thorough peer review. Such a review would have resulted in the cancellation of that publication because of the major short-comings of the study.
- CDC Failed to Provide Reliable Public Health Guidance When It Published an *Emergency* Dispatch Based on Known Missing Data. Before publishing the *MMWR Dispatch*, Dr. Mary Jean Brown, the principal author of the longitudinal study who is also the chief of the CDC's Childhood Lead Poisoning Prevention Branch (CLPPB), knew that thousands of blood lead level test results were missing, and that the District's Department of Health had had major problems with entering this data into its computer system. She chose not to inform her editors, superiors, co-authors or the public about these problems. As a result, the *MMWR* article included incomplete blood lead level test data for the years 2002 and 2003. The Subcommittee's investigation has found that the number of DC children with elevated blood lead levels in 2002 and 2003 was at least three times greater than the CDC claimed in 2004.
- In its Public Messaging about Health Effects of Blood Lead Levels, CDC Officials Focused on Levels Greater than 10 μg/dL. The public statements of CDC after the issuance of the MMWR Dispatch focused on its conclusion that there was no increase in children with blood lead levels (BLLs) over 10 μg/dL. However, there was an increase in children with blood lead levels over 5 μg/dL, which CDC acknowledged but did not consider significant. On February 23, 2004, CDC's own Advisory Committee on Childhood Lead Poisoning Prevention issued a review of the evidence of health effects of BLLs under 10 μg/dL in children and concluded that lower BLLs had a negative impact, even in children with BLLs less than 5 μg/dL. CDC chose not to provide this critical information to public health officials and District residents. The crisis in Washington D.C. turned on whether large numbers of children with blood lead levels greater than 10 μg/dL would be found or not, even though CDC officials were well aware significant harm could occur to the development of young children even at much lower levels.

#### INTRODUCTION AND EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC), a division of the U.S. Department of Health and Human Services (HHS), is the nation's premier public health agency. Since its establishment in 1946, the CDC has played a leading role in eradicating smallpox, identifying the cause of Legionnaires' disease and investigating the first known cases of acquired immunodeficiency syndrome (AIDS). The "CDC protects the health of Americans on many levels and in many arenas," the agency states. "We conduct surveillance on a wide range of health threats—from infectious diseases to bioterrorism to environmental hazards. When diseases break out around the globe, CDC responds at a moment's notice, lending its expertise and resources to conduct outbreak investigations and provide technical assistance."

The Lead Contamination Control Act of 1988, an amendment to the Safe Drinking Water Act, authorized the Centers for Disease Control and Prevention (CDC) to initiate program efforts to eliminate childhood lead poisoning in the United States.<sup>3</sup> A major aspect of that program was to provide blood lead level screening grants to state and local jurisdictions. In 2000, a federal interagency work group was established to develop recommendations to eliminate childhood lead poisoning as a major public health problem in the United States by 2010. The work group produced a "coordinated federal program" to eliminate childhood lead poisoning. Its focus was on eliminating the hazards of lead paint.<sup>4</sup> This focus would have significant implications for the federal response to the lead-in-water crisis in the District of Columbia.

### Public Health Implications of Exposure to Lead

The fact that lead in water can cause poisoning of humans has been known for centuries, and the adverse health effects of lead poisoning, which include death, insanity, nervous system damage and sterility, have been known since the second century BCE. For decades, the CDC has warned of the dangers, especially to children, of elevated levels of lead in drinking water. Numerous peer-reviewed studies done in the 1980s documented the increases in blood lead levels (BLL) in young children who were consuming lead-contaminated water in their formulas and prepared foods. In 1989, Dr. Mary Jean Brown, currently head of CDC's childhood lead poisoning prevention branch,

<sup>&</sup>quot;Historical Perspectives History of CDC," *Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, June 28, 1996, accessed at: <a href="http://www.cdc.gov/mmwr/preview/mmwr/tmth/00042732.htm">http://www.cdc.gov/mmwr/preview/mmwr/tmth/00042732.htm</a>.

<sup>&</sup>lt;sup>2</sup> "State of CDC 2008: Partnering for a Healthy World," Centers for Disease Control and Prevention, p. 4, accessed at: <a href="http://www.cdc.gov/about/stateofcdc/pdf/SOCDC2008.pdf">http://www.cdc.gov/about/stateofcdc/pdf/SOCDC2008.pdf</a>.

<sup>&</sup>lt;sup>3</sup> P.L. 100-572,

<sup>&</sup>lt;sup>4</sup> President's Task Force on Environmental Health Risks and Safety Risks to Children, "Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards," February 2000, p.1 accessed at: <a href="http://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf">http://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf</a>

<sup>&</sup>lt;sup>5</sup> Major, RH, Classic Descriptions of Disease, 3rd ed. Springfield, Illinois: Charles C. Thomas Publishing, 1945.
<sup>6</sup> See, e.g., Ryn, J.E.; Ziegler, E.E., Nelson, S.E., Formon, S.J., "Dietary intake of lead and blood lead concentration in early infancy," American Journal of Disabled Children, 137, 886-91 (1983); Bonnefoy., X, Huel, G., Gueguen, R., "Variation of the Blood Lead Level as a Result of Lead Contamination of the Subjects Drinking Water," Water Res. 19, 1299-1303 (1985; Sherlock, J.C., Quinn, M.J., "Relationships between blood lead concentrations and dietary lead intake in infants: the Glasgow duplicate diet study 1979-1980," Food Additives and. Contaminants. 3, 167-176 (1986).

co-authored an article in the Journal of Environmental Health that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," the paper stated. It concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water."<sup>7</sup>

The BLL in children that CDC has used to mandate action has dropped from  $40 \mu g/dL$ [40 micrograms of lead per deciliter of blood] in 1970 to 10  $\mu$ g/dL in 1991. In the publication announcing that change, CDC warned of the danger of lead in drinking water, stating that it was "probably absorbed more completely than lead in food", and that for babies consuming formula made with hot tap water the "lead exposures from water are unusually high."8

In 1991, the Environmental Protection Agency (EPA) set an action level for lead in drinking water of 15 parts per billion (ppb). Both of these limits are still in place today, despite the fact that lead experts have known since the 1980s that BLLs less than 10  $\mu$ g/dL also are linked to decreased IQ and cognition in children from 1-5 years of age. In a study funded by the National Institute of Environmental Health Sciences of the National Institutes of Health, children with BLLs less than 10  $\mu$ g/dL scored an average of 11.1 points lower on the Stanford-Binet IO test. 10 Although it was expected that CDC would reduce its action level as a result of this study, that never occurred. However, in February of 2004, a working group of the advisory committee for CDC's Childhood Lead Poisoning Program reviewed the literature on the cognitive effects of BLLs < 10  $\mu$ g/dL and found numerous negative impacts on children that did not become weaker at lower mean BLLs.<sup>11</sup> Dr. David Jacobs, an expert in lead poisoning, told a Senate committee in 2007 that the CDC "level of concern" was neither "safe" nor "normal." 12

In the 1980s, EPA began developing its Integrated Exposure Uptake Biokinetic (IEUBK) model, which indicated that the BLLs of infants drinking formula containing lead in water would be expected to rise by as much as 11 ug/dL for each increase of 100 ppb of lead in water. 13

http://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp 

9 Levin R., Brown, MJ. et al., "Lead Exposures in U.S. Children, 2008: Implications for Prevention," Environmental Health Perspectives, October 2008, p. 1285

<sup>11</sup> CDC/NCEH, "A Review of Evidence of Health Effects of Blood Lead Levels <10 μg/dL in Children Reported by a Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention," Feb. 23, 2004. 12 "Statement of David E. Jacobs" before the Environment and Public Works Committee, Oct. 18, 2007.

<sup>&</sup>lt;sup>7</sup> E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water,"

Journal of Environmental Health, Volume 52, Number 1, July/August 1989, pp. 346-349.

8 "Preventing Lead Poisoning in Young Children: 1991," U.S. Department of Health and Human Services, Centers for Disease Control, Oct. 1, 1991, p. 15, accessed at

<sup>&</sup>lt;sup>10</sup> AP, "Study: Lead Affects Child IQ," April 30, 2001. The study was subsequently published in the New England Journal of Medicine (NEJM). See, Canfield, Henderson, Cory-Slechta, Cox, Jusko and Lanphear, "Intellectual Impairment in Children with Blood Lead Concentrations below 10 µg per Deciliter," NEJM, April 17, 2003.

<sup>&</sup>lt;sup>13</sup> Memorandum from Paul White, Chief, Quantitative Risk Methods Group, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency to David A. Bussard, Director, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency, "SUBJECT: Risks of elevated blood lead for infants drinking formula prepared with tap water," March 3, 2004; and White, Van Leeuwen et al., "The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children," Environmental Health Perspectives, December

#### Origins of the Lead-in-Water Crisis in the District of Columbia

In 1998, EPA published its "Stage 1 Disinfection Byproduct Rule," which mandated that water treatment systems reduce the production of carcinogenic disinfection byproducts that resulted from the use of chlorine. The Army Corps of Engineers, which control the Washington Aqueduct used by the District of Columbia's Water and Sewer Authority (WASA), began to use chloramine in November of 2000. This change increased lead corrosion inside the D.C. drinking water system and resulted in elevated water lead levels (WLLs). WASA did not notify the public until 2003, but the notices were unclear and announced meetings to "discuss and solicit public comments on WASA's Safe Drinking Water Act projects." As a result, thousands of unwitting D.C. residents and their children were exposed for two years to harmful levels of lead from the water they were drinking and using for cooking and infant formulas.

#### Public Knowledge of Excessive Lead in Water

On Saturday, January 31, 2004, a front-page story in *The Washington Post* told the public for the first time that water tests conducted the previous summer by WASA found that thousands of D.C. homes – two-thirds of those tested – had tap water lead levels above the EPA limit of 15 ppb. Approximately 2,300 of the homes tested had results over 50 ppb, and 157 were higher than 300 ppb. <sup>18</sup>

The District fell into a crisis mode as the media revealed that WASA and EPA officials had been aware of the problem since 2002 but never informed the public. <sup>19</sup> Residents inundated WASA's water hotline with calls and overwhelmed water testing laboratories. District officials called for public meetings and established an inter-agency task force to investigate. <sup>20</sup> There were questions about what D.C. officials knew, when they knew it and whether they took the issue seriously. At a Congressional hearing, EPA officials described the levels of lead contamination as the worst they had ever seen and threatened to take over the system.

<sup>&</sup>lt;sup>14</sup> "Disinfectants and Disinfection Byproducts Notice of Availability," 63 Fed. Reg. 15673-692, March 31, 1998.

<sup>&</sup>lt;sup>15</sup> Edwards, M., Dudi, A., "Role of chlorine and chloramines in corrosion of lead-bearing plumbing materials," *Journal of American Water Works Association* 96, 69-81 (2004).

<sup>&</sup>lt;sup>16</sup> "Changes in Lead Levels during Annual Switch to Free Chlorine, Lead in DC Drinking Water," undated, Environmental Protection Agency, accessed at: <a href="http://www.epa.gov/dclead/chlorine.htm">http://www.epa.gov/dclead/chlorine.htm</a>

<sup>&</sup>lt;sup>17</sup>"Water in D.C. Exceeds EPA Lead Limit: Random Tests Last Summer Found High Levels in 4,000 Homes throughout City," *Washington Post*, Jan. 31, 2004, A1. See also, "Audit of Elevated Levels of Lead in the District's Drinking Water," Office of the Inspector District of Columbia, pp. 39-45; "Summary of Investigation Reported to the Board of Directors of the District of Columbia Water and Sewer Authority," WASA, July 16, 2004, pp. 7-8 and 77-91.

<sup>&</sup>lt;sup>18</sup> 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*, January 31, 2004, p.A1.

<sup>&</sup>lt;sup>19</sup> EPA had initially said that WASA's actions had followed "the letter of the law," but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post*, March 7, 2004, C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No SDWA-03-2004-0259DS," USEPA Region III, June 2004.

<sup>&</sup>lt;sup>20</sup> "D.C. to Create WASA Task Force; Water Agency Accused of Not Revealing Data on High Lead Levels," *Washington Post*, B1, Feb. 5, 2004.

Even then the city's reaction was slow and inadequate. The D.C. Department of Health did not issue an advisory to warn pregnant women and children under six to stop drinking unfiltered tap water and have their blood tested until a month after the story broke and described it only as a "cautionary" measure until they determined what was causing the elevated WLLs.<sup>21</sup>

In an attempt to respond to the public outcry and to get a quick answer about the potential human health impact, Dr. Daniel Lucey, the District's new interim medical director, sought the assistance of CDC two weeks after the news of the lead-in-water crisis first broke. The CDC responded within a week by providing expert technical assistance and sending Dr. Brown, the head of its childhood lead poisoning prevention branch. On March 10, 2004, the Surgeon General also dispatched U.S. Public Health Service (PHS) officers to help locate affected residents and test their blood.<sup>22</sup>

# CDC to Washington, D.C.: There is No Public Health Crisis

Based on this effort, on March 30, 2004, the CDC published an emergency "dispatch" in its Mortality and Morbidity Weekly Report (MMWR) titled: "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004" that summarized the results of "preliminary investigations." The purpose of the unusually rapid publication was to let the public know that CDC — "working as quickly as we could" and "under some constraints" — had not found any evidence of a public health crisis. This conclusion was counter to all previous peer-reviewed research on the impact of the ingestion of elevated WLLs on children.

In fact, according to CDC, based on a longitudinal study of the four-year period from 2000-2003, elevated BLLs  $\geq 10~\mu g/dL$  in the District's children had actually declined from 9.8 percent to 7.6 percent for children living in homes with lead service lines. This trend, however, did not hold true for children with BLLs between 5 and  $10~\mu g/dL$ . CDC conveniently ignored all the scientific evidence and its own advisory group in not warning D.C. residents that these children could also be severely and negatively affected.

The results of a separate study, known as the "cross-sectional study," and included in the *MMWR*, were even more compelling to the press and the general public. This study targeted homes in the District with water lead levels at or above 300 ppb to see if there was a correlation with elevated BLLs among residents in those homes. Surprisingly, not a single child or adult was found with a BLL above the action level. The *MMWR Dispatch* thus concluded, although

<sup>&</sup>lt;sup>21</sup> "District to Issue Warning on Lead; Health Advisory on Water to Target Pregnant Women, Small Children," *Washington Post*, Feb. 25, 2004; "D.C. Assailed for 25-Day Delay in Acting; Former Health Directors, Others Chide City, Saying Warnings Were Long Overdue," *Washington Post*, Feb. 26, 2004.

<sup>22</sup> Subcommittee staff interview of Dr. Tim Cote, Sept. 8, 2009.

<sup>&</sup>lt;sup>23</sup> "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Dispatch*, Vol. 53, March 30, 2004, available here: <a href="http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf">http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf</a>. Three days later it was re-published in the regular *MMWR Weekly*. "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Weekly*, Vol. 53, No. 12, April 2, 2004, available here: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm</a>.

<sup>&</sup>lt;sup>24</sup> "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," quoting Dr. Mary Jean Brown, Washington Post, Jan. 27, 2009, Met 2 edition.

with many qualifications, that the CDC's longitudinal analysis of blood tests of the city's children "suggest[ed]" that excessive lead in water might increase blood lead levels slightly but not raise it to harmful levels, which it inexplicably defined as  $\geq 10 \,\mu\text{g/dL}$  – once again in opposition to the conclusions of its own advisory group. The report stated unequivocally that "although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs ≥10 µg/dL, even in homes with the highest water lead levels." (emphasis added)<sup>25</sup> In other words, not a single child in the entire District required follow-up action because of lead in their drinking water.

For D.C. residents, that was CDC's take-away message. It was clearly spelled out in the "talking points" written by Dr. Mary Jean Brown, the MMWR's primary author and the head of the CDC's childhood lead poisoning prevention branch:

> Main message: There is no indication that DC residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults as a result of lead in water (emphasis in original).<sup>26</sup>

There were many problems with both the longitudinal and cross-sectional studies. For children living in homes with lead service lines, the decrease in children testing over 10 µg/dL was less than the national decline. And there was no decrease from 2000 to 2003 of children with BLLs  $\geq 5 \mu g/dL$  with lead service lines, who would also be affected negatively by lead exposure. Nor was anyone able to tell Subcommittee staff why only residents of homes with WLLs of 300 ppb were chosen for the cross-sectional study when much lower WLLs were known to be harmful. Most importantly, the cross-sectional study did not include any information about whether the residents were actually drinking tap water or not.

There were other problems. There was a mysterious drop of almost 6,000 in the number of children tested in 2003 compared to 2000, and no one could explain the discrepancy. Longstanding data entry problems in the District's lead program made reliance on its data highly questionable.

Some of the co-authors were surprised by the results of the studies, particularly the crosssectional study, and described them as "counter-intuitive." That, however, did not stop CDC from issuing its emergency Dispatch before determining how such "counter-intuitive" results were obtained. And it was the results of that study that caught everyone's attention, not the fact that those studied might not have been actually drinking the water. The public message was that if children drinking water with 300 ppb of lead weren't affected, everyone else could relax.

When asked why the results of these "preliminary investigations" were not held up until they could be verified, Dr. Brown stated that there was pressure from the city, EPA and CDC to get something out quickly on the public health effects of elevated WLLs.<sup>27</sup>

<sup>&</sup>lt;sup>25</sup> MMWR Dispatch,: supra, p. 2.

<sup>&</sup>lt;sup>26</sup> Dr. Mary Jean Brown's "Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)." <sup>27</sup> Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

Dr. Bruce Lanphear, one of the leading experts on lead poisoning of children, later described the report as "a quick and sloppy study to address public health concerns." If the article had been "submitted to a journal to 'prove' that lead in water wasn't an important source, it would have been rejected."<sup>28</sup>

But for public health officials, CDC's "main message" of no harm brought a rapid end to the public's concern about the elevated drinking WLLs. Many local and federal officials and the residents of DC breathed a collective sigh of relief. As reported in the *Washington Post*, "In other words, lead in water seems likely to raise children's blood lead levels past 5 micrograms but not past 10 micrograms." The issue soon faded from the headlines. Two days after publication of the *MMWR Dispatch*, Dr. Brown reported to Dr. Falk, that for the first day in over a month there wasn't a story on lead in water in the *Washington Post*. "I guess that means it worked!" <sup>29</sup>

Three months later, District health officials were telling the public that lead paint was actually the cause of all unsafe blood lead levels in their children. According to those officials, "every single one" of the homes where children had elevated blood levels that the Health Department had assessed between February and May of 2004 had "increased amounts of lead paint in the home, lead in the soil and lead in other areas of the home." That conclusion was reiterated in Congressional testimony<sup>30</sup> and in a fact sheet the department issued. The message to the public, as recalled by a local environmentalist, was that city and WASA officials said that concerns about the impact of lead in drinking water were "a scare and that there wasn't any health impact at all – there weren't any cases found of health impact." EPA issued a fact sheet based on the report that stated unequivocally: "Residents with high lead levels in their tap water did not have elevated blood lead levels." "31"

The MMWR's impact went far beyond the District of Columbia. Despite the years of research indicating that for fetuses and very young children, particularly those drinking formula constituted with tap water, there is no safe lead level, and despite evidence that BLLs under 10  $\mu$ g/dL also d permanent damage, CDC's work was used in other cities with elevated water lead levels to dampen citizen concerns about the public health risk of consuming lead-contaminated water.<sup>32</sup>

#### The CDC Study Begins to Unravel

Dr. Marc Edwards, an award-winning professor of civil engineering at Virginia Tech who had been studying corrosion in water utility systems for several years, could not believe

<sup>&</sup>lt;sup>28</sup> Rebecca Renner, "Lead on Tap: An alarming return of lead in drinking water is being ignored by the EPA and municipal officials," *salon.com*, Nov. 27, 2006, accessed at <a href="http://www.salon.com/news/feature/2006/11/27/lead">http://www.salon.com/news/feature/2006/11/27/lead</a> <sup>29</sup> E-mail entitled "RE: MMWR Vol. 53/No. 12" from Mary Jean Brown to Henry Falk, April 1, 2004.

<sup>&</sup>lt;sup>30</sup> Testimony of Jerry N. Johnson, WASA general manager, before the House Committee on Government Reform, May 21, 2004.

<sup>&</sup>lt;sup>31</sup> "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," Washington Post, Jan. 27, 2009, Met 2 Edition

<sup>&</sup>lt;sup>32</sup> There were also elevated WLLs in Maine, Rhode Island, Connecticut, Boston and Portland, Oregon. Renner, "Lead on Tap," *supra*.

CDC's conclusion that elevated WLLs did not have harmful health effects. He looked at the home risk assessments that D.C. DOH had done in early 2004 where children with elevated BLLs lived. In 2006, he told the local public radio station that some of the city's assessments pointed to water as the key source of lead in the home, and that the message that very high levels of lead in water did not cause "measurable public harm" was false.<sup>33</sup>

In early 2007, researchers at Duke University, who had studied a similar lead-in-water spike in a North Carolina town and the resulting lead poisoning of a child after the switch by the water system from chlorine to chloramine, warned that lead poisoning programs needed to be aware of the potential increase in children's BLLs because of the use of chloramines and to take preventive steps in advance.<sup>34</sup> Very little attention was paid in the District to this research.

But in 2009, Virginia Tech's Edwards released another analysis of the blood lead level tests done on District children from 2000 to 2004, which came to a shockingly different conclusion from that in the 2004 MMWR and reopened the debate. Dr. Edwards reviewed thousands of BLL test results, for children under six from the Children's National Medical Center (CNMC), one of the largest service providers for children in the District. He determined that for the most vulnerable population of children -- those under 1.3 years - the incidence of elevated blood levels over  $10\mu g/dL$  "abruptly" increased by 9.6 times in the second half of 2001 over the first half of the year. However, when he attempted to compare the CNMC data, which should have been a subset of the larger dataset used in 2004 by CDC, he found an error rate in the data of over 50 percent and could not analyze the full data set.  $^{35}$ 

Dr. Edwards also found correlations between BLLs and WLLs for children older than 30 months who lived in neighborhoods at high risk for having lead water lines. He concluded that the experience in Washington, D.C., was consistent with the "decades of research linking elevated WLLs to higher BLL and EBL [elevated blood level]."

#### CDC Finally Finds a Negative Health Impact, but Refuses to Publish It

Four days after the 2006 radio report on Dr. Edwards' review of D.C.'s risk assessment reports, CDC announced that it would conduct a new study to determine whether its original finding was correct. Dr. Brown, the primary author of the original study, said she had not known about the home assessments done by the D.C. DOH. CDC would reanalyze the data and look at the assessments with the new study to be complete in "several months."<sup>37</sup>

The new study has never been published, but a preliminary abstract released at the annual meeting of the American Public Health Association in 2007 indicated that the conclusions in the

<sup>&</sup>lt;sup>33</sup> WAMU 88.5FM, "Transcript of "Questions over Harm Caused by Lead in the Water," Sept. 21, 2006, accessed at http://wamu.org/news/06/09/lead\_questions.php

http://wamu.org/news/06/09/lead\_questions.php

34 Miranda, Kim, Hull, Paul and Galeano, "Changes in Blood Lead Levels Associated with Use of Chloramines in Water Treatment Systems," *Environmental Health Perspectives*, February 2007, pp. 221-25.

<sup>&</sup>lt;sup>35</sup> Edwards, Triantafyllidou and Best, "Elevated Blood Lead in Young Children due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," *Environmental Science Technology*, March 1, 2009, pp. 1618-23.

<sup>36</sup> *Ihid* 

<sup>&</sup>lt;sup>37</sup> WAMU 88.5FM, Transcript of "CDC Lead Study," Sept. 25, 2006, accessed at <a href="http://wamu.org/news/06/09/lead questions.php">http://wamu.org/news/06/09/lead questions.php</a>

new research matched those of Dr. Edwards. The abstract stated that CDC had found that children with BLLs over 5 or  $10 \,\mu\text{g/dL}$  were "significantly more likely" to have lived in a home with a lead service line, even after adjusting for the "confounders," such as the age of the housing unit with its presumed lead-based paint.<sup>38</sup>

None of the results of CDC's new work was provided to the EPA, the District of Columbia, WASA or the public. No new "emergency dispatch" was published in the *MMWR*, and many public health experts continue to rely on the discredited 2004 article when dealing with elevated WLLs.

#### The Subcommittee's Investigation

Since March 2009, the Subcommittee staff has been investigating these serious questions about the reliability, accuracy and scientific integrity of the 2004 *MMWR* and the process used by the CDC to produce it. Numerous interviews by Subcommittee staff of CDC and District personnel and the listed authors on the study made it clear that the data reporting by the District was seriously flawed, with large amounts of data apparently never entered into the system. As a result, the Subcommittee obtained the raw test results for 2002 and 2003 from the laboratories that performed the tests.

From that data, Subcommittee staff determined that the number of children with elevated BLLs in 2002-03 was at least *three times* greater than reported by the CDC in the *MMWR*. Specifically, the CDC found a little over 300 children with elevated BLLs in 2002 and 2003. In reality, based on the actual lab reports obtained by Subcommittee, *nearly 1,000 District children had elevated BLLs during that same time frame*.

The responsibility for collecting and maintaining accurate BLL test data is with the local or state agency tasked – in this case, the District of Columbia. Subcommittee staff found massive problems, both technological and human, with the District's efforts to maintain this database. A computer system put in place in 1999 at the behest of CDC never worked properly, requiring a laborious and error-prone manual entry process. CDC was well aware of these problems. In 2002, the CDC data manager ran the District's 2001 annual submission and found so many errors that the data could not be loaded. To compound the problems, the data entry employees responsible for taking lab results and putting them manually into the District's system were laid off in 2003, causing massive delays in entering BLL test results. There were allegations of forgery of reports and test results that were never entered or thrown away before entry. A properly functioning computer system was not installed until after the CDC report was published.

<sup>&</sup>lt;sup>38</sup> "Association between Lead Poisoning among Children less than Six Yeard Old and Lead Service Pipes in Washington DC," APHA, Abstract # 166176, Nov. 7, 2007, accessed at <a href="http://apha.confex.com/apha/135am/techprogram/paper\_166176.htm">http://apha.confex.com/apha/135am/techprogram/paper\_166176.htm</a> Nonetheless, Dr. Tee Guidotti, then WASA's public health consultant, told the WASA board in both 2007 and 2008 that "the lead in DC water did not appear to be associated with elevated BLL on a population or on an individual basis." Minutes of the Ad-hoc Committee on Drinking Water Quality, WASA Board of Directors, June 30, 2008. See also, Minutes of Meeting of WASA Board of Directors, July 26, 2007.

<sup>&</sup>lt;sup>39</sup> E-mail from Jaime Raymond [nee Schoonover] to Obiora Offor, entitled: "Subject: DC's 2001 Submission," February 18, 2003.

The Subcommittee also asked for the original data used in CDC's cross-sectional study. Neither the District nor CDC could produce it. Furthermore, even the single spreadsheet provided by the District to Dr. Edwards pointed to grave problems in the scientific integrity of this study. For example, it listed individuals who appeared to have been tested *after* the *MMWR* was published.

All of these problems made it clear that any reliance by CDC on the 2003 data from the District's reporting system and the hastily collected BLL tests for the cross-sectional study as the basis for an emergency "Dispatch" advising parents and public health officials that the children of the District were in no danger from drinking lead-laced water was highly questionable. When new data came out in 2006, 2007 and 2009 which contradicted the CDC's initial work, CDC should have withdrawn the 2004 report and done a more thorough study based on accurate data. It never did so.

It is inexplicable that the CDC – the nation's premier public health agency – promoted as credible a report that countered every single piece of research that outside scientists, the agency and its own advisory committee had previously issued on the dangers of elevated lead levels in drinking water and the permanent damage to children from blood lead levels less than  $10 \,\mu\text{g}/\text{dL}$ . CDC's actions in publishing – and continuing to stand by – the *MMWR* article made the problem go away for the agency and the politicians, but not for the parents and the children throughout the nation who will suffer life-time consequences from this misguided document.

# A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL

#### 1. CDC Lead Programs and the Known Effects of Lead in Water

The Lead Contamination Control Act of 1988, an amendment to the Safe Drinking Water Act, authorized the Centers for Disease Control and Prevention (CDC) to initiate program efforts to eliminate childhood lead poisoning in the United States. In 2000, after significant funding increases had been proposed for the program, a federal interagency work group was established to develop recommendations to eliminate childhood lead poisoning as a major public health problem in the United States by 2010. The work group produced a "coordinated federal program" to eliminate childhood lead poisoning by focusing on eliminating the hazards of lead paint. This focus would have significant implications for the federal response to the lead-inwater crisis in the District of Columbia (D.C.) as eliminating lead paint, not lead-contaminated water, was the primary goal of public health officials.

The CDC provides grants for blood lead screening programs to many local and state lead programs. In 2003, the CDC awarded \$31.7 million to 42 state and local health departments to develop and implement comprehensive lead poisoning prevention efforts of which \$500,000 went to the District. Over the years, the CDC has provided the District with more than \$12 million in lead grants. At the time of the lead-in-water crisis, the Bureau of Hazardous Materials and Toxic Substances in the District's Department of Health (D.C. DOH) ran the Childhood Lead Poisoning Prevention Program (CLPPP) which collected blood lead level (BLL) test data for children under six years old, did follow-up home risk assessments where children with high BLLs lived, and provided general public education on lead poisoning. In 2004, Dr. Lynette Stokes, a former CDC official, was the Chief of the Bureau of Hazardous Materials and Toxic Substances. The CDC's Lead Poisoning Prevention Branch (LPPB) was (and still is) headed by Dr. Mary Jean Brown.

As part of their agreements with the CDC, the recipients of these grants were required to provide summary data on the total number of BLL tests they conducted and the number of elevated BLLs in quarterly reports provided to the CDC's LPPB. They were also required to submit copies of their annual surveillance testing "raw data" by the end of April of the following year.

<sup>&</sup>lt;sup>40</sup> "Lead Contamination Control Act of 1988," Public Law 100-572, October 31, 1988, accessed at: <a href="http://www.epa.gov/history/topics/sdwa/06.htm">http://www.epa.gov/history/topics/sdwa/06.htm</a>.

President's Task Force on Environmental Health Risks and Safety Risks to Children, "Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards," February 2000, p.1 accessed at: http://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf

<sup>&</sup>lt;sup>42</sup> "Cooperative Agreement Funding," Childhood Lead Poisoning Prevention Branch, Centers for Disease Control and Prevention, available here: <a href="http://www.cdc.gov/nceh/lead/funding.htm#CooperativeAgreement">http://www.cdc.gov/nceh/lead/funding.htm#CooperativeAgreement</a>

<sup>&</sup>lt;sup>43</sup> History of CDC lead grant funding to the District of Columbia from 1992-to-2009 provided in a spreadsheet e-mailed to the Subcommittee from the CDC on July 2, 2009.

#### Public Health Implications of Exposure to Lead

The fact that lead in water can cause poisoning of humans has been known for centuries, and the adverse health effects of lead poisoning, which include death, insanity, nervous system damage and sterility, have been known since the second century BCE. <sup>44</sup> During the Roman Empire, lead plumbing systems supplying water to cities around Rome are believed to have caused widespread lead poisonings. <sup>45</sup> In 1893, the *Washington Post* ran a story warning of the health hazards of lead exposures from lead-based pipes being placed in the city to carry public drinking water. The newspaper called the installation of lead pipes "a menace to the health of the people." <sup>46</sup> An article in the 1923 edition of the *American Journal of Public Health* noted that in 1901 physicians in New Hampshire were well aware of "lead poisoning from drinking water." In 1936, an article in the same journal said: "In some instances the occurrence of lead poisoning from water has been so extensive as to be spoken of as an epidemic."

Children are especially susceptible to ingesting large amounts of lead from drinking water. They drink more water per pound of body weight per day than adults do and absorb it more easily. The greatest potential for harm from lead is in the immature brain where loss of IQ is sustained from lead exposure. In addition, children with elevated BLLs develop attention deficits, language problems, reading difficulties and other learning problems.<sup>49</sup>

In the 1980s, EPA also had developed its Integrated Exposure Uptake Biokinetic (IEUBK) model to predict the impact of lead exposures on the BLLs in infants and young children. That model indicated that the BLLs of infants drinking formula containing lead in water would be expected to rise by as much as 11 ug/dL for each increase of 100 ppb of lead in water. A National Academy of Sciences report on lead exposures in children in 1993 said: "Lead in tap water-consumed in the home, offices, other worksites, and public buildings-can be a particularly important source of lead exposure of young children, pregnant women, and other

Major, RH, Classic Descriptions of Disease, 3rd ed. Springfield, Illinois: Charles C. Thomas Publishing, 1945.
 Jack Lewis, "Lead Poisoning: A Historical Perspective," EPA Journal, Environmental Protection Agency, May

<sup>1985,</sup> accessed at: <a href="http://www.epa.gov/history/topics/perspect/lead.htm">http://www.epa.gov/history/topics/perspect/lead.htm</a>.

46 "Lead Pipes Unsatisfactory: Looking for a Good Sanitary Pipe For Supplying Water," The Washington Post, June 0, 1803

<sup>9, 1893.

47 &</sup>quot;Charles D. Howard, "Lead in Drinking Water," *American Journal of Public Health*, Volume 13, Issue 3, March 1, 1923.

<sup>&</sup>lt;sup>48</sup> G. N. Quam and Arthur Klein, "Lead Pipes as a Source of Lead in Drinking Water," American *Journal of Public Health*, Volume 26, August 1936.

Memorandum from Paul White, Chief, Quantitative Risk Methods Group, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency to David A. Bussard, Director, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency, "SUBJECT: Risks of elevated blood lead for infants drinking formula prepared with tap water," March 3, 2004; and White, Van Leeuwen et al., "The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children," *Environmental Health Perspectives*, December 1998, pp. 1513-30, accessed at <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533456/pdf/envhper00541-0248.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533456/pdf/envhper00541-0248.pdf</a>

people."<sup>51°</sup> In the mid-1980s elevated water lead levels in the Palisades neighborhood of Washington, D.C. were believed to have led to elevated blood lead levels in some children.<sup>52</sup>

For decades, the CDC has warned of the dangers, especially to children, of elevated levels of lead in drinking water. In 1997, in a public health assessment of contamination resulting from various chemicals, volatile organics and lead at Camp LeJeune, the Agency for Toxic Substances and Disease Registry (ATSDR), an office within CDC, stated that

[P]eople drinking water containing lead at levels above 50 ppb [parts per billion] could absorb enough lead to experience long-term health consequences. Moreover, people highly sensitive to the effects of lead, particularly children, infants and fetuses, could experience irreversible adverse health effects such as decreased IQ and compromised mental development. . . .

It is the total body burden of lead that is related to the risk of adverse health effects. Because the body accumulates lead over a lifetime and releases it slowly, even small doses of lead over time can cause lead poisoning. Further, relatively low blood lead levels can cause adverse health effects, some of which, like decreased IQ or mild behavioral disorders, may not produce noticeable signs or symptoms. <sup>53</sup>

Numerous peer-reviewed studies done in the 1980s documented the increases in blood lead levels (BLL) in young children who were consuming lead-contaminated water in their formulas and prepared foods. <sup>54</sup> In 1989, Dr. Mary Jean Brown, currently head of CDC's childhood lead poisoning prevention branch, co-authored an article in the *Journal of Environmental Health* that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," the paper stated. As the "only identified source of lead" was solder from newly installed water pipes, the paper concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water."

<sup>&</sup>lt;sup>51</sup> "Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations," Committee on Measuring Lead in Critical Populations, National Research Council, National Academy of Sciences, 1993.

Margaret Engel, "City Officials Say Lead in Water Poses Problem in Palisades Section of NW," *The Washington Post*, November 3, 1986, p. D1.

ATSDR, "Public Health Assessment," U.S. Marine Corps Camp LeJeune Military Reservation, Camp LeJeune, Onslow County, North Carolina, CERCLIS No. NC6170022580, January 1997, pp. 16-17, citing ATSDR, "Case studies in environmental medicine: lead toxicity," 1992, and CDC, "Preventing Lead Poisoning, in Young Children," October 1991.

Children," October 1991.

54 See, e.g., Ryn, J.E.; Ziegler, E.E., Nelson, S.E., Formon, S.J., "Dietary intake of lead and blood lead concentration in early infancy," *American Journal of Disabled Children*, 137, 886-91 (1983); Bonnefoy., X, Huel, G., Gueguen, R., "Variation of the Blood Lead Level as a Result of Lead Contamination of the Subjects Drinking Water," *Water Res.* 19, 1299-1303 (1985; Sherlock, J.C., Quinn, M.J., "Relationships between blood lead concentrations and dietary lead intake in infants: the Glasgow duplicate diet study 1979-1980," *Food Additives and. Contaminants.* 3, 167-176 (1986).

<sup>&</sup>lt;sup>55</sup> E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water," *Journal of Environmental Health*, Volume 52, Number 1, July/August 1989, pp. 346-349.

The BLL in children that CDC has set to mandate action has dropped from  $40 \mu g/dL$  [40 micrograms of lead per deciliter of blood] in 1970 to  $10 \mu g/dL$  in 1991. In the publication announcing that change, CDC made the following statement about the danger of lead in drinking water:

Lead in drinking water is probably absorbed more completely than lead in food. Adults absorb 35-50% of the lead they drink, and the absorption rate for children may be greater than 60% [citation omitted]. In general, lead in drinking water is not the predominant source for poisoned children. In some circumstances, however, lead exposures from water are unusually high . . . . Several babies have been poisoned when hot tap water, which was then boiled (resulting in concentrating the lead), was used to make baby formula. <sup>56</sup>

In 1991, the Environmental Protection Agency (EPA) set an action level for lead in drinking water of 15 parts per billion (ppb). Both of these limits are still in place today.

#### Are the Action Levels "Safe"?

Public health experts have known since the 1980s that BLLs lower than CDC's action level of  $10~\mu g/dL$  are linked to decreased IQ and cognition in children from 1-5 years of age. <sup>57</sup> In a study funded by the National Institute of Environmental Health Sciences of the National Institutes of Health, children with BLLs less than  $10~\mu g/dL$  scored an average of 11.1~points lower on the Stanford-Binet IQ test. "There is no safe level of blood lead," Dr. Bruce Lanphear, one of the researchers and a childhood lead expert, declared, a conclusion that has been espoused by the CDC and other national and international health organizations. <sup>58</sup> It was expected that CDC would reduce its action level as a result of this study, but that never occurred.

CDC did, however, task a working group of its Advisory Committee on Childhood Lead Poisoning Prevention to review the evidence of health effects of blood lead levels less than 10  $\mu$ g/dL in children. Their report, which was issued in February of 2004 – just as the CDC was beginning work in the District of Columbia to determine the health effects on children because of elevated lead levels in drinking water – stated that both longitudinal and cross-sectional studies had consistently found a relationship between lowered cognitive functions and BLLs less than 10  $\mu$ g/dL. <sup>59</sup>

<sup>57</sup> Levin R., Brown, MJ. et al., "Lead Exposures in U.S. Children, 2008: Implications for Prevention," Environmental Health Perspectives, October 2008, p. 1285

<sup>&</sup>lt;sup>56</sup> "Preventing Lead Poisoning in Young Children: 1991," U.S. Department of Health and Human Services, Centers for Disease Control, Oct. 1, 1991, p. 15, accessed at <a href="http://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp">http://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp</a>

<sup>&</sup>lt;sup>58</sup> AP, "Study: Lead Affects Child IQ," April 30, 2001. The study was subsequently published in the *New England Journal of Medicine (NEJM)*. See, Canfield, Henderson, Cory-Slechta, Cox, Jusko and Lanphear, "Intellectual Impairment in Children with Blood Lead Concentrations below 10 μg per Deciliter," *NEJM*, April 17, 2003. <sup>59</sup> CDC/NCEH, "A Review of Evidence of Health Effects of Blood Lead Levels <10 μg/dL in Children Reported by a Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention," Feb. 23, 2004, accessed at: <a href="http://www.cdc.gov/nceh/lead/ACCLPP/meetingMinutes/lessThan10MtgMAR04.pdf">http://www.cdc.gov/nceh/lead/ACCLPP/meetingMinutes/lessThan10MtgMAR04.pdf</a>

As. Dr. David Jacobs testified before the Senate Environment and Public Works Committee in 2007.

Importantly, the CDC level of concern was not established to be a "safe" or "normal" level, although some have used it in this fashion. As early as 1991, CDC reported that adverse health effects could be seen at blood lead levels below  $10 \,\mu\text{g/dL}$  [footnote omitted]. More recent evidence from multiple studies, reviewed by CDC itself, has confirmed the 1991 CDC Statement that no safe level of lead exposure has been found [footnote omitted].

Dr. Jacobs further stated instead of using the nation's children as "detectors of lead problems" and to "avoid the perception that a blood lead level of  $10 \mu g/dL$  or  $5 \mu g/dL$  is 'normal' or 'safe,' CDC and other medical authorities might consider labeling blood lead levels between 2 and 10  $\mu g/dL$  what they really are: 'above average." "61

#### 2. Origins of the Lead-in-Water Crisis in the District of Columbia

In 1998, EPA published its "Stage 1 Disinfection Byproduct Rule, which mandated that water treatment systems to reduce the production of disinfection byproducts that resulted from the use of chlorine. Those byproducts, known as trihalomethanes, were recognized carcinogens. The Army Corps of Engineers, which control the Washington Aqueduct used by the District of Columbia's Water and Sewer Authority (WASA) began to use chloramine, a compound composed of chlorine and ammonia, in November of 2000. This change increased lead corrosion inside the D.C. drinking water system and resulted in elevated water lead levels (WLLs). By late 2001, WASA knew that the levels of lead in the District's drinking water were above EPA's limit. One reporter later described it as one of the worst lead contaminations of city water on record. WASA notified EPA in August of 2002. Although WASA was also required to notify customers of the elevated WLLs within 60 days, it did not do so until 2003. Subsequent investigations found that WASA's notices lacked both clarity and a sense of urgency. Advertisements for public meetings did not reveal the lead problem, but stated the meetings would "discuss and solicit public comments on WASA's Safe Drinking Water Act projects." As a result, thousands of unwitting D.C. residents and their children were exposed

62 "Disinfectants and Disinfection Byproducts Notice of Availability," 63 Fed. Reg. 15673-692, March 31, 1998. 63 Edwards, M., Dudi, A., "Role of chlorine and chloramines in corrosion of lead-bearing plumbing materials," Journal of American Water Works Association 96, 69-81 (2004).

<sup>65</sup> Rebecca Renner, "Health agency covered up lead harm," *salon.com*, April 10, 2009, accessed at <a href="http://www.salon.com/env/feature/2009/04/10/cdc">http://www.salon.com/env/feature/2009/04/10/cdc</a> lead report

<sup>&</sup>lt;sup>60</sup> "Written Statement of David E. Jacobs, Ph.D., CIH," U.S. Senate Environment and Public Works Committee, Oct. 18, 2007, p. 12.

<sup>&</sup>lt;sup>61</sup> Jacobs Statement, supra, p. 13.

<sup>&</sup>lt;sup>64</sup> "Changes in Lead Levels during Annual Switch to Free Chlorine, Lead in DC Drinking Water," undated, Environmental Protection Agency, accessed at: <a href="http://www.epa.gov/dclead/chlorine.htm">http://www.epa.gov/dclead/chlorine.htm</a>

<sup>&</sup>lt;sup>66</sup> Water in D.C. Exceeds EPA Lead Limit: Random Tests Last Summer Found High Levels in 4,000 Homes throughout City," *Washington Post*, Jan. 31, 2004, A1. See also, "Audit of Elevated Levels of Lead in the District's Drinking Water," Office of the Inspector District of Columbia, pp. 39-45; "Summary of Investigation Reported to the Board of Directors of the District of Columbia Water and Sewer Authority," WASA, July 16, 2004, pp. 7-8 and 77-91.

for two years to harmful levels of lead from the water they were drinking and using for cooking and infant formulas.

#### Public Knowledge of Excessive Lead in Water

On Saturday, January 31, 2004, a front-page story in *The Washington Post* told the public for the first time that water tests conducted the previous summer by WASA found that thousands of DC homes – two-thirds of those tested – had tap water lead levels above the EPA limit of 15 ppb. Approximately 2,300 of the homes tested had results over 50 ppb, and 157 were higher than 300 ppb.<sup>67</sup>

The District fell into a crisis mode as the media revealed that WASA and EPA officials had been aware of the problem since 2002 but never informed the public. 68 Residents inundated WASA's water hotline with calls and overwhelmed water testing laboratories. District officials called for public meetings and established an inter-agency task force to investigate. <sup>69</sup> High lead levels were found in the fountains at nine District schools.<sup>70</sup> The District Health Department's director was ousted after it was found that he did not respond to a call for help in December of 2003 from WASA because lead in water was a WASA, not a city, problem. A few days later, it was determined that District health officials actually had known about the lead problem since October of 2002 and even assisted WASA in drafting an education brochure, but did not believe it was a "major" health concern. 71 At a Congressional hearing, EPA officials described the levels of lead contamination as the worst they had ever seen and threatened to take over the system. 72 Earlier statements that the contamination was confined to houses with lead service lines were questioned when it was found that houses with copper service lines also had elevated WLLs. But WASA often didn't know the actual composition of the service lines.<sup>73</sup> WASA's directives to about where to expect lead, how to flush it away and when not to drink the water often were based on false assumptions and had to be withdrawn.<sup>74</sup>

<sup>67</sup> 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*, January 31, 2004, p.A1.

<sup>&</sup>lt;sup>68</sup> EPA had initially said that WASA's actions had followed "the letter of the law, but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post*, March 7, 2004, C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No SDWA-03-2004-0259DS," USEPA Region III, June 2004.

<sup>&</sup>lt;sup>69</sup> "D.C. to Create WASA Task Force; Water Agency Accused of Not Revealing Data on High Lead Levels," *Washington Post*, B1, Feb. 5, 2004.

<sup>&</sup>lt;sup>70</sup> "High Lead Levels Found in Water at 9 D.C. Schools; Untested Fountains, Sinks Still in Use," Washington Post, Feb. 25, 2004, B1.

<sup>&</sup>lt;sup>71</sup> "D.C. to Oust Health Chief over Response to Lead Problems," *Washington Post*, March 26, 2004, B8 "D.C. Knew of Lead Problems in 2002; Timing of E-mails Contradicts Claims," *Washington Post*, March 29, 2004, A1 <sup>72</sup> EPA had initially said that WASA's actions had followed "the letter of the law, but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post,i March 7, 2004*, C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No. SWDA-03-2004-259DS," USEPA Region III, June 2004.

<sup>73 &</sup>quot;Homes with Copper Lines not Immune to High Lead," Washington Pos,t March 13, 2004, B1.

<sup>&</sup>lt;sup>74</sup> "WASA Backpedaling Prompts Confusion; D.C. Agency Changed Advice on Flushing Taps, Replacing Pipes, Health Risks," *Washington Post*, March 14, 2004, A16.

There also was evidence that city health officials – who had decided in 2002 that lead in water was not really a serious problem - had not really changed their views. The Department of Health did not issue an advisory warning pregnant women and children under six to stop drinking unfiltered tap water and have their blood tested until a month after the story broke. Even then, they described it as a "cautionary" measure until they determined what was causing the elevated WLLs.<sup>75</sup>

In an attempt to respond to the public outcry and to get a quick answer about the potential human health impact, Dr. Daniel Lucey, the District's new interim medical director, sought the assistance of CDC, the federal agency which issued the grants for childhood blood lead screening and provided public education, two weeks after the news of the lead-in-water crisis first broke. 76 CDC Director Julie Gerberding quickly directed top staff members to "help Dan. He is the new Acting DC health director. He is terrific!!!"<sup>77</sup> The CDC responded within a week by providing expert technical assistance and sending Dr. Brown, the head of its childhood lead poisoning prevention branch. On March 10, 2004, the Surgeon General also dispatched U.S. Public Health Service (PHS) officers to help locate affected residents and test their blood.<sup>78</sup>

#### Problems with the District's Lead Tracking System

Both the quarterly reports and the raw surveillance data submissions from the D.C. CLPPP to the CDC would play important roles in the scientific integrity issues that arose regarding the credibility of the underlying raw data used in the March 30, 2004 Morbidity and Mortality Weekly Report (MMWR) Dispatch to evaluate the public health impact of lead in water in Washington, D.C. The conduct by D.C. offices is not the focus of this report, but it is impossible to fully appreciate the data integrity problems associated with the CDC's lead analysis at the time of the 2004 lead-in-water public health crisis without an appreciation of the source of the data used by CDC. Further, an appreciation of how much was and is known by CDC officials regarding problems with the management of data by city offices helps clarify questions about those officials commitment to transparency and integrity.

Prior to 1999, the District's lead program maintained a manual system to track lead test data results and individual childhood lead case files. In 1999, the D.C. CLPPP implemented a CDCdeveloped, software program that the CDC provided free of charge to state and local CLPPPs to track medical and environmental activities and to maintain BLL test data. The software, called STELLAR (Systematic Tracking of Elevated Lead Levels & Remediation), was meant to replace the functions of a paper tracking system with a computerized one, provide easier and quicker access to data and automate routine program tasks. The laboratories that reported BLL test

<sup>75 &</sup>quot;District to Issue Warning on Lead; Health Advisory on Water to Target Pregnant Women, Small Children," Washington Post, Feb. 25, 2004; "D.C. Assailed for 25-Day Delay in Acting; Former Health Directors, Others Chide City, Saying Warnings Were Long Overdue," *Washington Post*, Feb. 26, 2004.

76 E-mail from Daniel Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water

from Dan Lucey," Feb. 16, 2004.

<sup>&</sup>lt;sup>77</sup> E-mail entitled "FW: A washington post.com article on lead in the DC water from Dan Lucey," from Julie Gerberding to Henry Falk, Patrick Meehan, Richard Jackson and Tom Sinks, Feb. 16, 2004. <sup>78</sup> Subcommittee staff interview of Dr. Tim Cote, Sept. 8, 2009.

<sup>79 &</sup>quot;STELLAR: Systematic Tracking of Elevated Lead Levels & Remediation" & Remediation" web-page, Childhood Lead Poisoning Prevention Program (CLPPP), The National Center for Environmental Health (NCEH),

data results to D.C. would simply send the data on a computer disk that could be easily uploaded to STELLAR and be retrieved by D.C. CLPPP staff. Accuracy would be improved because of the elimination of the manual entry of laboratory results by data entry clerks.

However, the STELLAR database had problems from the start in both the District and in other jurisdictions. In 1999, the District database crashed, and it is unclear if all the data was ever recovered. "I was looking back over my notes about your 99 data submission and noticed our discussion about trying to identify how much data you recovered after your crash," wrote Wendy Blumenthal, then the head of CDC's lead database reporting program, to Obiora Offor, database manager of the D.C. lead program. 1919

The electronic data often could not be uploaded into STELLAR, so the data entry clerks in the D.C. CLPPP office had to manually input the data from paper copies. As before, the process was time consuming and prone to human errors. In addition, in 2002 the District began to lay off the estimated one dozen data entry clerks then working in the D.C. CLPPP office, leading to a significant data entry backlog. By May 2002, Offor realized that the lead program's data entry of test results was far behind. The target was to enter 22,000 BLL test records into STELLAR in FY2002. But in the first seven months, from October 1, 2001 through May 2, 2002, only 4,856 test results had been entered. 82

In the 2002 timeframe, Offor wrote several undated memos to Christine Onwuche, the D.C. lead program manager, highlighting his concerns about the STELLAR database and the ability of the D.C. lead program to accurately and efficiently track its childhood lead cases. He requested a new computer system to help eliminate these issues. By May, only two data entry clerks were entering BLL test results into STELLAR. In a memo that month, labeled "Data Concern," Offor pleaded with some of the lead program's investigators to volunteer to enter blood lead test results into the lead database. Offor and four other lead program employees volunteered to meet a quota each week entering a specific number of blood test results into STELLAR. Offor pledged to enter 150 BLL tests himself each week, and the other volunteers committed to entering 600 BLL test results. "While I see this as a temporary solution to this data problem," wrote Offor, "I look forward to the approval of the funding for the new web-based system to [sic] that will eliminate the need to seek so many people to enter data." Offor proposed that the District scrap STELLAR and acquire a new lead tracking database by Welligent LLC called LeadTrax "to facilitate data sharing, improve communication and enable

Centers for Disease Control and Prevention (CDC), Page last updated: June 1, 2009, accessed at: <a href="http://www.cdc.gov/nceh/lead/data/stellar.htm">http://www.cdc.gov/nceh/lead/data/stellar.htm</a>.

<sup>&</sup>lt;sup>80</sup> Barry Brooks, the CDC's health advisor to the District of Columbia and the CDC project manager for CDC's lead grants to D.C. told the Subcommittee staff that STELLAR was never intended to be a surveillance system, but was a case management system. Subcommittee staff interview with Barry Brooks, July 14, 2009.

<sup>&</sup>lt;sup>81</sup> E-mail from Wendy J. Blumenthal to Obiora Offor, cc'd to Jaime Schoonover, entitled "DC data," Oct. 10, 2001. <sup>82</sup> Undated Memo titled "Data Concern" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

<sup>&</sup>lt;sup>83</sup> Undated Memo titled "Data Concern" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

us to better serve the citizens of the District of Columbia."<sup>84</sup> According to Offor, by the end of 2002, all the data entry clerks had been laid off.<sup>85</sup>

There were also major accuracy problems in the data that was entered. In February 2003, the CDC's new LPPB data manager, Jaime Raymond, told Offor that she had run D.C.'s 2001 annual submission and found "there were so many errors, that you hit the >10% error, so I was not able to load any of your data." By 2003, critical problems with data collection still paralyzed the D.C. lead program. In August 2003, Offor faxed a letter to Bobby Dixon of the Laboratory Corporation of America (LABCORP), one of seven laboratories reporting blood lead level screening data to CLPPP, asking for all lead screening data processed between September 1st 2002 and July 31st, 2003. The reason was that "on close examination of the District Lead database, it was discovered that not all lead result [sic] were . . . entered into the database." (emphasis added)

#### CDC's Knowledge of Data Gaps and Inconsistent Reports

In November of 2003, Barry Brooks, the CDC's new project manager in charge of the CDC lead grant funding for the District's (as well as several other states') CLPPP program, visited the D.C. CLPPP offices for the first time. His trip report said that he became aware during that visit that the D.C. CLPPP was "manually entering" data into STELLAR because of technical issues uploading the electronic data from the laboratories into the database. <sup>89</sup>

However, according to Subcommittee staff interviews with CDC officials, including Brooks, Dr. Brown, and Raymond, the CDC's lead program database manager, none of them were aware of the D.C. CLPPP's STELLAR blood lead test data "backlog." Dr. Brown said she was aware that there was a "lag" of several weeks in the labs reporting their BLL test data to the D.C. lead program, but that she was not aware of the backlog in entering data. <sup>90</sup>

According to Offor, because there was a growing backlog of BLL test results that had not been entered into STELLAR in 2003, every month the D.C. CLPPP program staff was adding

<sup>86</sup> E-mail from Jaime Raymond [nee Schoonover] to Obiora Offor, entitled: "Subject: DC's 2001 Submission," February 18, 2003.

<sup>&</sup>lt;sup>84</sup> Undated Memo titled "Request For A New Database" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

<sup>85</sup> Subcommittee staff interview with Obiora Offor, Sept. 1, 2009.

In 2003 the following laboratories were reporting blood lead level test results to the DC Department of Health: 1) The Laboratory Corporation of America (LABCORP), Herndon, Virginia; 2) Quest Diagnostics, Chantilly, Virginia; 3) Quest Diagnostics, Baltimore, Maryland; 4) Children's National Medical Center; Washington, D.C.; 5) DC Public Health Laboratory, Washington, D.C.; 6) MedTox Laboratories, St. Paul, Minnesota; 7) Mayo Labs, Rochester, Minnesota.

<sup>&</sup>lt;sup>88</sup> "Data Request" faxed from Mr. Obiora Offor, Computer Specialist, Government of the District of Columbia, Department of Health, Childhood Lead Poisoning Screening & Education Program to the Laboratory Corporation of America (LABCORP), August 5, 2003.

<sup>&</sup>lt;sup>89</sup> Subcommittee staff interviews of Barry Brooks, July 13, 2009 and October 22, 2009; also see "Draft Timeline of CDC Activities related to Lead in Water in the District of Columbia," prepared by Barry Brooks and Mary Jean Brown, June 1, 2009, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

<sup>&</sup>lt;sup>90</sup> Subcommittee staff interview with Mary Jean Brown, October 22, 2009.

the number of BLL test results received, but *not* yet entered into STELLAR, into monthly "Performance Measures Reports" used internally by the D.C. lead program. The report for September 2003, for example, showed that the D.C. CLPPP had 5,324 blood lead test results that had *not* been entered into STELLAR. 91 Offor said these monthly reports were provided to both Onwuche and Dr. Stokes on a routine basis, and he assumed that Onwuche was providing them to the CDC. But in October 2009, when the Subcommittee showed Dr. Brown and Brooks copies of this September 2003 report during separate interviews with them, both said they had never seen these reports before and were unfamiliar with them.

The LeadTrax database was finally installed in April 2004, a month after the *MMWR* article was published. But the problems regarding the "data entry" issues in the D.C. CLPPP program played a key role in undermining the scientific integrity of the raw data the *MMWR* relied upon to base its analysis of the D.C. lead-in-water crisis and the article's ultimate conclusions. Based on the subsequent research done by Dr. Marc Edwards, as well as work done by the Subcommittee staff, it is clear that the data used in the longitudinal study published in the March 2004 *MMWR* was significantly incomplete, inaccurate and undermined any reliable conclusions about the health effects of elevated WLLs that were made in that report.

# Data Problems: A Blood Lead Level Test "Data Gap"

Barry Brooks told the Subcommittee that when the lead-in-water crisis broke publicly in January 2004, he immediately went to look at the District's quarterly reports to get a quick handle on what their elevated blood lead tests showed.<sup>93</sup>

According to the CDC, in 2001, 16,042 children in D.C. under six years old were screened for elevated BLLs; 156 had elevated BLLs. In 2002, 15,755 children were screened; 122 had elevated BLLs. <sup>94</sup> When Brooks looked at the D.C. lead program's quarterly reports for 2003 that were filed with CDC, he claims, they showed that approximately 15,000 D.C. children had been screened for lead in 2003, roughly the same as the year before, although he does not recall the exact numbers with elevated BLLs. <sup>95</sup>

(DCDOH), Environmental Health Administration, September 30<sup>th</sup> FY 2003.

Subcommittee staff interview with Dr. Mary Jean Brown, October 22, 2009; Subcommittee staff interview with Mr. Barry Brooks, October 22, 2009.

"Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: <a href="http://www.cdc.gov/nceh/lead/data/State">http://www.cdc.gov/nceh/lead/data/State</a> Confirmed by Year 1997 to 2006.xls

<sup>&</sup>lt;sup>91</sup> "Performance Measures Report," Childhood Lead Poisoning, Screening, and Education Program (CLPSEP), Bureau of Hazardous Materials and Toxic Substances (BHMTS), District of Columbia Department of Health (DCDOH), Environmental Health Administration, September 30<sup>th</sup> FY 2003.

<sup>&</sup>lt;sup>93</sup> The quarterly reports are short 2-page summary documents that provide a snapshot of the numbers of blood lead tests conducted, children identified with elevated BLLs and related statistical information. The "raw data" in the blood lead screening test results received from the laboratories actually performing the blood lead tests include information related to each actual blood lead screening test result, not simply summarized statistical data. The CDC requires that it is provided with a copy of this raw surveillance data by all of its lead grant recipients annually.

<sup>&</sup>lt;sup>95</sup> The Subcommittee staff conducted three interviews with Barry Brooks, the CDC's health advisor to the District of Columbia and the CDC's project manager in charge of the CDC lead grants to DC. The first interview with Mr. Brooks via telephone was conducted on March 23, 2009 the other two interviews were conducted in the Subcommittee offices in Washington, D.C. and occurred on July 13, 2009 and October 22, 2009. Brooks reiterated

However, on Feb 28, 2004, as part of the CDC's review, the D.C. lead program's raw surveillance data maintained in STELLAR for the years from 1998 through 2003 was brought to the CDC in Atlanta for analysis. This data – the source for the longitudinal study in the *MMWR* article – included records for the screening of only 9,229 children in 2003, an astounding drop of 6,526 children from the previous year. The dramatic decline was unprecedented and unexplained. It should have raised red flags at CDC about the completeness and reliability of the District's data for use in the *MMWR* report. It did not.

#### **Allegations of Forgery**

What is even more astounding was the unquestioned use of this data based on the knowledge that CDC had about the problems with the District's data prior to the *MMWR*'s publication. Not only was D.C. having trouble with its blood lead database and significant backlogs in entering test results into the database, but CDC also received an allegation of forgery of the administrative quarterly reports submitted by the District. According to Brooks, in February or March of 2004, he telephoned the D.C. CLPPP program and asked about the 6,500 discrepancy in the numbers between the 2003 quarterly reports submitted to CDC and the "raw data" in the STELLAR database.

Brooks claims that during that telephone call, a CLPPP program official admitted to "forging" the quarterly CDC reports. According to Brooks, the official claimed they did this because of the huge disparity between the screening numbers for 2003 as compared to those provided from D.C. to the CDC in previous years. Although Brooks claims that the CDC had three separate copies of the allegedly "forged" quarterly reports, the CDC has been unable to locate any of them for the Subcommittee and claims they were all lost during an office move. In addition, none of the 2003 quarterly reports obtained by the Subcommittee from the District of Columbia government support the allegations of forgery made by Brooks and repeated by Dr. Brown. It is unclear when Dr. Brown learned of this claim of "forgery." In staff interviews, she suggested she knew before the MMWR was published, but an "official" internal CDC chronology prepared by Brown and Brooks for senior CDC officials indicates that she was told by Brooks in the first week of April-right after the MMWR was released. 99

this description of what he found in February 2004 when he reviewed DC's 2003 quarterly reports submitted to CDC during each of these interviews.

<sup>&</sup>lt;sup>96</sup> "Draft Timeline of CDC Activities related to Lead in Water in the District of Columbia," included in "Office of the Director Briefing Memo: Lead in Water," Monday, June 1, 2009, 1:00 – 2:00 p.m., Roybal Campus, Bldg. 21, Conference Room 12302, For Internal Discussion Only, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). The dataset included nearly 85,000 blood lead test results which were used for the longitudinal analysis in the *MMWR* article.

<sup>97 &</sup>quot;Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: <a href="http://www.cdc.gov/nceh/lead/data/State">http://www.cdc.gov/nceh/lead/data/State</a> Confirmed by Year 1997 to 2006.xls

<sup>&</sup>lt;sup>98</sup> In interviews with the Subcommittee, the D.C. official Brooks named adamantly denies these assertions and says such a suggestion was not made. This official could point to some documents in their attorney's possession that seemed to confirm their story.

The Subcommittee has not been provided with any records by CDC to indicate exactly when Barry Brooks informed Dr. Brown about the allegations of "forgery." The CDC apparently has no contemporaneous e-mails,

Furthermore, Brooks claimed that in March 2004 he was told by the same D.C. official that Quest Diagnostics laboratory, one of the seven labs that provided blood lead data to D.C. in 2003, claimed that it had stopped reporting *all* BLLs to D.C. in 2003 and *only* reported elevated results. Dr. Brown confirmed that she was aware of this claim that a lab had not reported all of its results and said she sent an e-mail (no email has ever been provided by CDC or D.C. to confirm this communication) to Dr. Stokes in D.C. asking that the lab be contacted for a full reporting. Both Brooks and Dr. Brown told Subcommittee staff they believed this was a cause of the 2003 "missing" blood lead level test data. Yet, that official has denied that Quest labs ever said any such thing, or that he suggested this to Brooks. The information provided to the Subcommittee from Quest labs, as well as additional information provided by the D.C. government, also contradicts the recollection of events or causes for the drop in 2003 BLL test data from both Brooks and Dr. Brown.

#### 3. CDC's Involvement in the District's Lead-in-Water Crisis and the MMWR Dispatch

Offices of the CDC learned of problems with lead in D.C.'s water even before the Washington Post story broke. According to Dr. Brown, the Environmental Protection Agency (EPA) contacted Dr. Tom Sinks, deputy director at CDC's Agency for Toxic Substances and Disease Registry (ATSDR) sometime in late 2003 or early 2004 and reported that WASA was out of compliance with the lead and copper water rules. Dr. Brown began working with the District's lead office and EPA's water office in early February 2004. Some kind of human testing program may have already been under consideration because CDC had asked for the addresses of persons whose water had elevated lead levels, but there is no evidence of urgency in either Brown's efforts or CDC's response. December 102

Very quickly, CDC's involvement escalated. February 10, 2004, was the first day of Dr. Daniel Lucey's three-month contract to be the District's interim chief medical officer. Dr. Lucey was an infectious disease specialist with no experience in dealing with lead poisoning, no staff or budget and only a temporary office left vacant by an employee on leave. Within three days of

memorandums or other records about this alleged incident. But the Brooks/Brown timeline prepared for senior CDC officials conveniently says Brooks informed Brown of the allegations of "forgery" in the "First week of April 2004," days after the publication of the MMWR article. Regardless of the specific day Dr. Brown became away of the alleged "forgery" she acknowledged to Subcommittee staff that she did not share this information with any other CDC officials, including her superiors, for more than *four years*. In July 2008 she finally informed former NCEH/ATSDR director Dr. Howard Frumkin about these allegations in preparing him for an interview with science reporter Rebecca Renner. Dr. Frumkin in turn failed to inform Renner about this issue until March 2009, eight months after she interviewed him about the "missing" blood lead level test results. Dr. Mark Bashor, the Associate Director for Science (ADS) at NCEH/ATSDR, did not learn about these allegations until March 2009 as well. "I never heard a whisper about it from Mary Jean Brown," Bashor told Subcommittee staff. "I was the ADS for god's sake. It takes a lot to get me mad," said Bashor. "I was totally ticked off."

Subcommittee staff interview of Dr. Brown, July 22, 2009.

<sup>&</sup>lt;sup>101</sup> Subcommittee staff interview of Dr. Brown, July 22, 2009.

<sup>&</sup>lt;sup>102</sup> E-mail from Dan Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water from Dan Lucey," Feb. 16, 2004.

coming on the job, he was told by Mr. James Buford, then the head of the District's Department of Health (DOH) that he was to be "the face of lead in DC." 103

In an e-mail to himself dated February 16, 2004, Dr. Lucey recorded the frustration of the public resulting from the lack of reliable information and skepticism about the ability of the District's task force to address the problem as expressed in a *Washington Post* editorial:

To this day, the public has no idea of the number of District homes that have lead levels in their water that exceed the federal limit of 15 parts per billion. We know that more than 4,000 homes fall into the category based on WASA tests last summer, but we know that only because of media reports two weeks ago . . . But there are . . . as estimated 23,000 lead service lines in the city. The extent to which homes connected to those lines have lead contamination is unknown and will remain unanswered until WASA completes a survey. The first letter targeted to those estimated 23,000 homes or locations likely to have lead lines, we learned yesterday, may be mailed out by WASA sometime next week. This is coming roughly seven months after WASA first learned that lead exceeded federal limits in thousands of District homes. Little wonder WASA had so many anxious and outraged customers on its hands. (emphasis added)<sup>104</sup>

The same day, he forwarded the editorial in an e-mail to Dr. Julie Gerberding, then CDC's director, seeking the agency's expertise and assistance in responding to the D.C. lead-in-water crisis. He informed Dr. Gerberding that a series of public community meetings would begin the next day and asked to talk to a "content expert" and a "risk assessor for lead." He also referred to the previous request from the CDC for the addresses of persons whose water may have elevated levels of lead as District officials had expressed concern about confidentiality. 105

Dr. Gerberding quickly responded and commandeered top CDC staff to help. She forwarded the e-mail to Dr. Henry Falk, then the director of CDC's National Center for Environmental Health (NCEH) and assistant administrator for ATSDR; Tom Sinks, his deputy; Dr. Patrick Meehan, the NCEH deputy director; and Richard Jackson, one of her senior advisors "Please help Dan," she wrote. "He is the new Acting DC health director. He is terrific!!!" Dr. Sinks reported back to Dr. Gerberding that Dr. Brown had been working with the D.C. lead office and EPA's water office for a week, but that he would have her contact Dr. Lucey. "Thanks Tom!" Dr. Gerberding replied. "Dan is just a few days on the job and getting hit with

<sup>&</sup>lt;sup>103</sup> Subcommittee staff interview of Dr. Dan Lucey, Nov. 4, 2009. Buford was fired because of his poor performance responding to the DC lead crisis before the *MMWR* was released at the end of March 2004. See: Avram Goldstein, "D.C. to Oust Health Chief Over Response to Lead Problem," *The Washington Post*, March 26, 2004, B8.

<sup>&</sup>lt;sup>104</sup> E-mail from Dan Lucey to Dan Lucey entitled "A washingtonpost.com article on lead. . ." from Dan Lucey to Dan Lucey, quoting from an editorial entitled "In Deep Water", *Washington Post*, Feb. 14, 2004, A28, Feb. 16, 2004 <sup>105</sup> E-mail from Dan Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water from Dan Lucey" from Dan Lucey to Julie Gerberding. Feb. 16, 2004. Dr. Lucey and Dr. Gerberding had conducted their medical internships and residencies together at the University of California in San Francisco in the early 1980s. <sup>106</sup> E-mail from Julie Gerberding to Henry Falk, Patrick Meehan ,Tom Sinks and Richard Jackson entitled

<sup>&</sup>lt;sup>100</sup> E-mail from Julie Gerberding to Henry Falk, Patrick Meehan, Tom Sinks and Richard Jackson entitled "FW: A washingtonpost.com article on lead . . .", Feb. 16, 2004.

E-mail from Tom Sinks to Julie Gerberding, entitled "Re: A washingtonpost.com article on lead . . .", Feb. 16, 2004.

this mess."<sup>108</sup> Dr. Sinks contacted Dr. Brown and – in an e-mail marked of "high" importance – asked her to get in touch with Dr. Lucey "to see what his needs are," and then provide a one-pager to Dr. Gerberding about their activities. <sup>109</sup>

The next day, Dr. Lucey had a conference call with Dr. Brown, Dr. Falk and Dr. Meehan. "I was asking for help," Dr. Lucey recalled. "The CDC said they were glad to help in any way they could." Dr. Brown offered to come to Washington and arrived on February 24. Dr. Lucey said that, because of their expertise, Dr. Stokes and Dr. Brown became the lead experts he relied upon most often in developing a response to the D.C. lead crisis.

Two days later, on February 26, the District's Department of Health (D.C. DOH), under Dr. Lucey's signature and with the assistance of the CDC, sent a letter to the 23,000 residences that were believed to have lead service lines. It warned them of potential hazards from elevated water lead levels (WLLs), and stated that "Children under six years and women who are pregnant or breastfeeding should not drink unfiltered water, or use it to prepare infant formula or concentrated juice, in any of these 23,000 residences until the concerns regarding the lead levels in the water have been resolved." 112

#### CDC's Studies: The Longitudinal and Cross-Sectional Studies

Two parallel, but separate, data review and collection efforts were quickly spawned after the CDC became involved in the D.C. lead issue. Both became part of the March 2004 MMWR. The first involved looking at the District's historic BLL test data to identify specific trends and anomalies regarding the increases or decreases of elevated BLLs among the city's children. This longitudinal study was led by Dr. Brown. The other effort involved going to the homes with the highest known WLLs and taking BLL samples from those residents in an attempt to correlate the public health impact from exposure to elevated WLLs in the city's drinking water supply. This effort was designed and led by Dr. Tim Cote of the U.S. Public Health Service and was included in the MMWR report as the cross-sectional study.

#### The Longitudinal Study

The longitudinal study was based on public health surveillance data maintained by the D.C. CLPPP. Public health surveillance data can serve as a useful means to identify public health trends over time and to detect potential health perils to the public. Surveillance data, by

<sup>&</sup>lt;sup>108</sup> E-mail from Julie Gerberding to Tom Sinks entitled "Re: A washingtonpost.com article on lead . . . " Feb. 16, 2004.

<sup>&</sup>lt;sup>109</sup> E-mail from Tom Sinks to Mary Jean Brown, Tina Forrester and Christopher DeRosa entitled "Dr. Gerberding was contacted directly about the Pb situation in DC by Dan Lucey," Feb.17, 2004.

E-mail from Henry Falk to Tom Sinks entitled "Re: Dr. Gerberding was contacted directly about the Pb situation in DC by Dan Lucey," Feb. 17, 2004; Subcommittee staff interview of Dr. Lucey, Nov. 4, 2009.

Subcommittee staff interview of Dr. Dan Lucey, supra.

<sup>112 &</sup>quot;Dear Resident" letter, signed by Dr. Daniel R. Lucey, M.D., Interim Chief Medical Officer, Office of the Director, Department of Health, Government of the District of Columbia, available here: <a href="http://www.dewatch.com/wasa/040226.htm">http://www.dewatch.com/wasa/040226.htm</a>.

<sup>&</sup>quot;Welcome to Child Blood Lead Surveillance (CLBS) Orientation," Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), available here: http://www.cdc.gov/nceh/lead/training/surveillance/index.html. The CDC defines public health surveillance data as

definition, is "not perfect," as CDC officials repeatedly told the Subcommittee staff. But, as discussed above, the District's data had such significant omissions and errors that reliance upon it was very questionable. At the time of *MMWR*, it was well-known that there was an unexplained drop of more than 6,500 in the number of children tested in 2003 compared to 2002. Flaws, errors or omissions in public health surveillance data may put the public at risk by failing to identify known health dangers or underestimating the extent of the potential danger. Those shortcomings must be pointed out in any study that purports to provide advice on public health. The authors of the MMWR had a scientific obligation and public health responsibility to clearly identify those shortcomings, but they never did. Six years after the publication of the MMWR they have still not informed the public of the article's many data integrity flaws or their faulty conclusions.

Both Brooks and Dr. Brown made a variety of claims to the Subcommittee staff about why the data for more than 6,500 children was missing, and why CDC continued to use data that was – at a minimum – incomplete. Dr. Brown, the head of the CDC's lead branch and primary author of the *MMWR*, had several explanations. She assumed – based on her previous experience – that any "missing" blood lead tests were non-elevated screening tests not reported by the labs. <sup>114</sup> She claimed that the 2003 data provided for use in the *MMWR* did not include the last quarter as there was often a lag between tests being submitted and labs reporting back. She also claimed that the "Quest Labs" non-reporting story explained some of the gap. Finally, she indicated that whether she had the data or not wouldn't make a difference in the final results. No effort was made to confirm any of these problems by Dr. Brown. She simply assumed away the reasons for the missing 6,500 tests. <sup>115</sup>

In short, Dr. Brown's reasons for ignoring the data gap was questionable. While Dr. Brown did not apprise any of the *MMWR* editors, her co-authors, other CDC officials, or the public of the critical data integrity questions that swirled around the 2003 BLL test data used in the *MMWR*, some of her co-authors were likely to have known of the problems. The lead author of the *MMWR* article was Dr. Lynette Stokes, head of the D.C.CLPPP. Another co-author with direct knowledge of problems was Christine Onwuche, the CLPPP manager.

In training materials, CDC directed state and local public health officials to acknowledge known limitations or potential flaws in public health data. A CDC on-line guide on child BLL surveillance states, "The key to interpreting data is to know the limitations of the data and to keep the limitations in mind when describing the findings. Inaccuracies in the data may preclude more sophisticated analyses," the guide, developed under the leadership of Dr. Brown, states. "Erratically collected or incomplete data cannot be corrected by complex analytic techniques," it warns. The CDC, however, failed to follow its own advice and never offered any warnings

follows: "Ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control." See CLBS Orientation, Module 1 – Child Blood Lead Surveillance, Surveillance in Public Health section, prepared by Dr. Pamela Meyer.

<sup>&</sup>lt;sup>114</sup> Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

<sup>115</sup> Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

<sup>&</sup>quot;Welcome to Child Blood Lead Surveillance (CLBS) Orientation," Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), Module 4 – Analysis, Interpretation and Use of CBLS Data, Data Interpretations and Limitations section, available here:

http://www.cdc.gov/nceh/lead/training/surveillance/Module05/Analysis-Limitations.html.

about the known flaws in the data used to compile the MMWR report or attempted to correct them before publication.

#### CDC'S Cross-Sectional Study: Another Flawed Effort

Fifteen years before she oversaw the publication of the *MMWR* article, Dr. Brown was a co-author of an article in the *Journal of Environmental Health* that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," her article published in 1989 said. "A case of childhood lead poisoning is presented in which the only identified source of lead was lead solder from newly installed water pipes." The paper concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water." <sup>117</sup>

The cross-sectional study was the most significant portion of the MMWR article because it allegedly did not find a correlation between homes that had WLLs  $\geq$ 300 ppb – the "worst" cases – and elevated BLLs of those residents. The study was small, including only 201 residents, just 17 of whom were children under the age of six years old. This is the element of the MMWR that was the most widely cited by the media and local, state and federal health officials. They relied on it to claim that in the D.C. lead-in-water crisis there is no evidence that even these highest WLLs led to human harm. Even though the study lacks statistical power given its small size, the persuasive power of looking at the worst of the worst cases and failing to find a single instance of a person with lead above the level of concern cannot be understated.

In the talking points that Dr. Brown prepared for the release of the *MMWR Dispatch*, she wrote that "all [the participants in the cross-sectional study] had BLLs below the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults." The Subcommittee, however, has identified serious questions with the integrity of the data used in this study.

The study was designed by Dr. Tim Cote, a Public Health Service officer. The explanation offered to Subcommittee staff for choosing homes with 300 ppb or greater of lead in water has been that public health investigators were looking for the "worst case" examples to see what impact, if any, the most extreme levels of lead in water may have had on the blood lead levels of residents drinking the water. Dr. Cote said, "We needed to conduct a rapid assessment." As a result, they focused on the "worst case" homes. <sup>119</sup> The D.C. Water and Sewer Authority (WASA) provided a list of 179 homes that fit the criteria. <sup>120</sup>

E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water," *Journal of Environmental Health*, Volume 52, Number 1, July/August 1989, pp. 346-349.

<sup>&</sup>quot;Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)", prepared by Mary Jean Brown.

Subcommittee staff interview of Dr. Tim Cote, September 8, 2009.

E-mail from Gregory Hope, Chief, D.C. Water Quality Control Branch, to Nkechi (Christine) Onwuche and Obiora Offor, cc'd to Lynette Stokes and Jerusalem Bekele, entitled "Updated Lead Replacement Monitoring Data," "Attachments: Combined WASA Lead Monitoring Data Above 300.xls; Partial Lead Replacement GE 300.xls," Feb. 11, 2004.

However, Dr. Brown by mid-March 2004 already had information indicating that the highest BLL results were not found in homes with WLLs over 300 ppb, but in homes with WLLs from 16 to 300 ppb in both the first and second draws of water. This data was included in a series of tables attached to an e-mail sent to Dr. Lucey by Dr. Brown on March 12, 2004, more than two weeks before the *MMWR*'s release. In that e-mail, Dr. Brown told Dr. Lucey the "good news" that BLLs in the District were decreasing, even though they were higher in homes with lead service lines. Without evidence or home risk assessments, Dr. Brown claimed that these results were "confounded by age of housing and presumably lead contaminated house dust and soil in these same homes." But she did not mention the findings in the attached charts for the 852 homes with WLLs of 15 ppb and above, a significantly larger number than the 179 homes that had WLLs over 300 ppb. Those homes had a much higher percentage of children with elevated BLLs than the homes with WLLs over 300 ppb.

In fact, Table 10 in Dr. Brown's e-mail shows that while 34.1 percent of people tested in homes with WLLs between 201 and 300 ppb had elevated BLLs, only 8.1 percent of those in homes with WLLs above 300 ppb had elevated blood lead levels. Given the existence of this data, limiting the cross-sectional study to only those homes with WLLs of 300 ppb or more seriously skewed the results of the study in favor of finding no violations of the CDC levels of concern.

Table 10: Frequency of Elevated Blood Lead Tests in 852 Home by Second Draw Water Lead Level

Load Dov	01						
Blood	0-15	16-50	51-100	101-200	201-300	> 300	TOTAL
Lead	ppb	ppb	ppb	ppb	ppb	ppb	
Levels		,					
<10	577	612	324	183	60	34	1,790
μg/dL	85.7%	84.9%	78.8%	85.5%	65.9	91.9%	83.3%
≥ 10	97	109	87	31	31	3	358
μg/dL	14.4%	15.1%	21.2%	14.5%	34.1%	8.1%	16.7%

Source: Subcommittee on Investigations and Oversight, based on data provided in March 12, 2004 e-mail from Dr. Mary Jean Brown to Dr. Daniel Lucey.

The co-authors of the *MMWR* article interviewed by Subcommittee staff, including Dr. Brown, Dr. Lucey, Dr. Stokes and Dr. Cote all agreed that the fact the Cross-sectional study did not identify a single individual with an elevated BLL was "counterintuitive." "It doesn't make a lot of intuitive sense, does it," Dr. Cote said. But that was what the data showed, they argued. "We are interested in finding relationships," said Dr. Cote. "But we take the facts as they come." <sup>123</sup>

In fact, one resident in those homes was found to exceed the level of concern. In a radio interview on February 27, 2004 Dr. Stokes said: "One child had a 14 microgram per deciliter blood lead level from that 175 homes with addresses above 300 parts per billion." That child

<sup>&</sup>lt;sup>121</sup> E-mail from Mary Jean Brown to Dan Lucey, March 12, 2004, Tables 9 and 10.

E-mail from Mary Jean Brown to Dan Lucey, March 12, 2004, Tables 9 and 10.

Subcommittee staff interview of Dr. Tim Cote, Sept. 6, 2009.

Lisa Nurnberger, "Lead Crisis in DC," Metro Connection, WAMU 88.5 American University Radio, Feb. 27, 2004, audio available here: http://wamu.org/programs/mc/04/02/27.php.

was dropped from the study, allowing the authors to make the false claim that "The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs > 10  $\mu$ g/dL, even in homes with the highest water lead levels."125

When the Subcommittee first interviewed Dr. Stokes on May 1, 2009, and asked her about her statement, she said it must have been taken out of context, and that she must have been talking about a child exposed to lead paint. 126 However, when a Subcommittee staff member sat in on another interview of Dr. Stokes by D.C. Office of Inspector General (OIG) investigators in September 2009, her recollection changed dramatically. When asked about the radio interview, Dr. Stokes said that when D.C. investigators examined the home of the child, they found no signs of lead in the paint, dust or soil. 127 Although this was one of the 175 homes with a WLL of at least 300 ppb, Dr. Stokes said the child was excluded from the Cross-sectional study because the child had only lived in the home for a short time, a matter of "weeks or days." Lead, however, remains in the blood stream for a relatively short period of time, normally around 30 days. 128 It is therefore an indicator only of recent lead exposure. Even if a child had been in a home for a few weeks but had been drinking tap water with elevated levels of lead, the result could have been an elevated BLL. Dr. Stokes, who was hired in the D.C. Department of Health because of her lead expertise and is both an epidemiologist and toxicologist, said she was unfamiliar with how long lead stays in the bloodstream. 129

Instead of following up on the one case that clearly showed a child living in a home with a WLL above 300 ppb, who also had an elevated BLL, Dr. Stokes simply excluded this child from the MMWR study. Several of Dr. Stokes' MMWR co-authors, including Dr. Brown, said they were unaware of anyone being dropped from the study. 130

Not only was at least one participant excluded from the cross-sectional study by Dr. Stokes, some individuals were included despite the fact that they had either only lived in the targeted homes infrequently or had stopped drinking the water long before they had their blood tested. One of the few children included in the study appears to have been Charles Eason's grandson who only stayed at Mr. Eason's home on the weekends. Mr. Eason had been informed of his elevated WLLs in the fall of 2003. He had stopped consuming any tap water in November of 2003 and made sure his grandson only drank bottled water while at his home. 131

Subcommittee staff interview of Dr. Lynette Stokes, May 1, 2009.

<sup>125</sup> MMWR Dispatch, supra, p. 2.

Joint interview of Dr. Lynette Stokes by Subcommittee staff and DC Office of Inspector General, Sept. 10, 2009. "Toxicological Profile for Lead," Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), August 2007, available here: http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf. While the half-life of lead in blood is about 30 days, it remains in soft tissue for between 30 and 45 days and in bone for between 25-to-30 years.

Joint interview of Dr. Lynette Stokes by Subcommittee staff and DC Office of Inspector General, Sept. 10, 2009. Public Health Service officials who visited DC homes with 300 ppb of lead in the water and collected blood lead samples for the Cross-sectional study say they did not exclude anyone from their survey regardless of how long they lived in these homes. See, e.g., Subcommittee staff phone interview of Capt. Lydia Velazquez, U.S. Public Health Service, Oct. 20, 2009.

Subcommittee staff telephone interview of Charles Eason, Sept. 15, 2009.

In the fall of 2003, as it did for thousands of other District residents with lead service lines, WASA provided Mr. Eason with a free sampling kit and requested that he sample his water and mail it back. In November, WASA sent him a letter stating that the EPA limit for WLLs was 15 ppb and that Eason's water measured 550 ppb. But the letter provided little additional information. Eason began using a filter on his tap water immediately and drinking bottled water. He kept trying to get fuller answers from WASA about his water but had little luck. A few weeks after the WASA letter arrived, Eason saw an announcement for a WASA community meeting at the Martin Luther King Branch Library on Dec. 17, 2003, which he attended According to Eason, there was only one other D.C. resident at the meeting and several WASA officials.

One of the WASA officials at the meeting said that two-thirds of the D.C. homes WASA tested were above the EPA limit of 15 ppb. Eason was surprised that he had not heard this before and wondered if the public was aware of what he believed was an important public health issue. Eason called *The Washington Post* and spoke with Dave Nakamura, the reporter who broke the story on the D.C. lead-in-water crisis on Saturday, January 31, 2004.

Equally important to the credibility of the cross-sectional study was the fact that it did not adequately address whether the residents of the homes were actually drinking unfiltered tap water. The reality was that more than half of them acknowledged drinking bottled water, a fact omitted from the study. Still more were filtering their water. Based on the only data available from the field work (see discussion regarding this issue below), only 13 individuals in the study – from 11 separate residences' -- drank tap water exclusively and did not use a water filter or drink bottled water. This key fact was omitted from the *MMWR* article. <sup>133</sup>

At least three individuals involved in the cross-sectional study – two co-authors and one public health service officer acknowledged for his assistance in the article – raised concerns prior to the publication of the report that many of those included in the study may have been drinking filtered or bottled water prior to having their blood drawn. Obviously, this would undermine the study's conclusion that there was no correlation between elevated WLLs and elevated BLLs.

"Do we want to mention that many of D.C. residents (couldn't give you #'s though) have been drinking bottled water before any of this went public?" asked Lt. Cmdr. Christine Yu, a senior regulatory management and PHS officer at the Food and Drug Administration. "Or does

<sup>&</sup>lt;sup>132</sup> See letter to Mr. Donald S. Welsh, Regional Administrator, Environmental Protection Agency, Region III, Philadelphia, Pennsylvania from Jerry N. Johnson, General Manager, District of Columbia Water and Sewer Authority (DCWASA), Attachment #1, "DCWASA Community and Civic Lead Meetings," December 17, 2003, EPA Grant Meeting, Martin Luther King Branch Library, available here: <a href="http://www.epa.gov/dclead/WASA\_Letter\_3-17-04.pdf">http://www.epa.gov/dclead/WASA\_Letter\_3-17-04.pdf</a>.

The only raw data available on the MMWR's cross sectional study is a single spreadsheet obtained by Dr. Marc Edwards in a Freedom of Information Act (FOIA) request he submitted with the District of Columbia government. The Excel spreadsheet was sent to Dr. Edwards via e-mail from Tom Collier, the D.C. Department of Health FOIA Officer as an attachment on May 31, 2006. In formal requests by the Subcommittee to the D.C. government and various components of the Department of Health and Human Services, including the CDC, requesting all raw data used as a basis for the conclusions and findings in the MMWR's cross sectional study none of those agencies have found a single record responsive to the Subcommittee's request.

that just confound the data some more?" Yu's e-mail was cc'd to both Dr. Cote and Dr. Brown. 134

Another Public Health Service officer, LCDR Anthony Walker, wrote to Mary Jean Brown and asked:

"I am not sure if the bottled water consumption would skew the data, but it does present another peice [sic] that might confuse the reader." 135

On March 23, 2004, PHS Capt. Mark Eberhardt also sent an e-mail to Dr. Brown raising similar concerns.

"6) Do you want to point out that the water sample [sic] that were tested in many of the homes were done last year, but the blood lead measures were determined this month? Between these two time periods, some people stopped drinking water supplied by WASA; some people started using filters, and some people had the lead supply lines to their home replace[d] before blood lead levels were measured. The point is that this may help to explain why currently no persons have blood lead levels above the levels of concern." (emphasis added)<sup>136</sup>

There is no evidence that this obvious and critical concern was ever addressed by the authors prior to publication. The Subcommittee was never provided with a single e-mail response from Dr. Cote or Dr. Brown regarding how to handle this issue in the *MMWR*, nor did they remember anyone raising it when interviewed by staff.

Given the arbitrary selection of those homes with WLLs of over 300 ppb, the very small number of children under six in the study and the failure to determine whether any residents were actually drinking tap water at the time the blood tests were taken made the conclusions scientifically meaningless. It is inconceivable that trained scientists would produce such a study, and expect that it would stand up to any kind of critical review or attempt to use it to reach any sort of valid public health conclusion about the impact of elevated WLLs. Despite the factual and scientific problems with the study, some of the *MMWR* authors remained comforted by its conclusions. "People were relieved there weren't bodies in the street," Dr. Cote told Subcommittee staff.<sup>137</sup>

<sup>134</sup> E-mail from Christine Yu to one dozen Public Health Service colleagues and cc'd to Dr. Tim Cote and Dr. Mary Jean Brown, entitled "Subject: RE: MMWR Lead contamination data analysis," Wed., March 24, 2004 1:17 AM.

135 This e-mail was one of many undated e-mails placed into a word file and provided to the Subcommittee by the Centers for Disease Control and Prevention (CDC) regarding the "clearance" of the cross-sectional study in the MMWR article. The date is unknown because they appear to be deleted from the information provided by the CDC to the Subcommittee.

<sup>&</sup>lt;sup>136</sup> E-mail from Mark Eberhardt to Mary Jean Brown, cc'd to Dr. Cote, "Subject: Comments regarding DC lead MMWR," March 23, 2004. Emblematic of the data integrity problems with the MMWR article is the fact that Eberhardt's name was spelled incorrectly (Eberhart) in the MMWR article which did not address his comments and he was cited as a Medical Doctor (MD), which he is not, according to a Subcommittee staff interview with Mark Eberhardt, September 16, 2009.

<sup>&</sup>lt;sup>137</sup> Subcommittee staff interview of Dr. Cote, Sept. 8, 2009.

#### Rationale for the MMWR and its Consequences

What had started as an effort to offer support to the D.C. public health authorities had morphed into a push to get an article published. As Dr. Brown acknowledged, an article was desired by D.C. officials. Dr. Lucey told staff that he relied on the CDC staff to do public health work and when they told him they were not finding any evidence of a problem due to lead in water, he wanted them to get that out as quickly and authoritatively as possible. Lucey was not a lead expert and was managing the public health response of town hall meetings and blood testing clinics. He relied on Dr. Brown and Dr. Stokes to manage the public health inquiries.

The MMWR was published very rapidly, just six weeks after the first contact with Dr. Gerberding at the CDC. The two studies that form the basis of that article were neither peer reviewed nor subject to elaborate internal review by CDC staff. The article was drafted in a political atmosphere where CDC staff were responding to perceived pressure from the top of their agency—Dr. Gerberding wanted them to help Dr. Lucey—and perceived pressure within the District to calm panic about water quality and health. On top of this, there is an undoubted feeling in the CDC lead program that a fixation on lead in water could derail the progress the program had been making on lead in paint, an issue perceived as being much more dangerous to children across the country. <sup>138</sup>

### 4. CDC to Washington, D.C.: There is No Public Health Crisis

Based on this effort, on March 30, 2004, the CDC published an emergency "dispatch" in its Mortality and Morbidity Weekly Report (MMWR) titled: "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004" that summarized the results of "preliminary investigations." The purpose of the unusually rapid publication, according to a statement made in 2009 by Dr. Brown, its primary author, was to let the public know that CDC – "working as quickly as we could" and "under some constraints" – had not found any evidence of a public health crisis. <sup>140</sup> In fact, according to CDC, based on a longitudinal study of the four-year period from 2000-2003, elevated BLLs  $\geq$  10  $\mu$ g/dL in the District's children had declined from 9.8 percent to 7.6 percent for children living in homes with lead service lines. This trend, however, did not hold true for children with BLLs  $\geq$  5  $\mu$ g/dL.

Despite the well-documented history of the toxic effects of lead in water on human health and her own publications — and perhaps because of the focus of federal programs on eliminating the lead paint hazard — Dr. Brown seemed singularly focused on the hazards of lead paint and dust, even during the height of the District's lead-in-water crisis. On July 16, 2004, four months after the *MMWR* article was released, Brown wrote to Dr. Lynette Stokes, "Now that there is a better understanding of the public health impact of lead in the drinking water in the District, I hope we will be able to focus on the issue of lead-based paint hazards," she wrote. Memo from Mary Jean Brown to Lynette Stokes, entitled "Subject: Environmental Lead Hazards for Young Children Living in Washington DC," July 16, 2004.

<sup>&</sup>quot;Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," MMWR Dispatch, Vol. 53, March 30, 2004, available here: <a href="http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf">http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf</a>. Three days later it was re-published in the regular MMWR Weekly. "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," MMWR Weekly, Vol. 53, No. 12, April 2, 2004, available here: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm</a>.

<sup>&</sup>lt;sup>140</sup> "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," quoting Dr. Mary Jean Brown, *Washington Post*, Jan. 27, 2009, Met 2 edition.

While the integrity of the underlying data and the methodology used in both studies in the *MMWR* were highly questionable, the public health message to the citizens of the District was very clear: there was no public health crisis. While full of the normal warnings about no safe level of lead, and the adverse impacts of lead on children and adults, the one English language sentence most likely to resonate with readers read:

"The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs >10  $\mu$ g/dL, even in homes with the highest water lead levels." <sup>141</sup>

At the same time, her own agency's advisory committee was warning of the health effects of BLLs of less than  $10 \mu g/dL$  on children, Dr. Brown's prepared talking points to be used in response to public, press, congressional and other potential inquiries after the release of the MMWR Dispatch said all was well:

Main message: There is no indication that DC residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults as a result of lead in water (emphasis in original).<sup>142</sup>

As if to reinforce the message of the article, most of the Public Health Service staff packed up and returned to their home agencies by mid-April. The crisis was officially over.

In the wake of the *MMWR* being published, Dr. Falk sent Dr. Brown an e-mail on April 1, 2004 with the *MMWR Dispatch* article attached. "Have you had many calls re this? How is it going?" Falk asked. <sup>143</sup> Dr. Brown's response implied a shared sense of relief that the public interest in the D.C. lead-in-water crisis had finally abated.

"Today has been the first day in over a month that there wasn't a story on lead in water in the Washington Post and also the first that I haven't been interviewed by at least one news outlet. I guess that means it worked!" 144

From January 31, 2004 through March 31, 2004, *The Washington Post* had published 66 individual stories revolving around the D.C. lead-in-water crisis. In an interview with Subcommittee staff, Brown explained her statement by suggesting that she was hoping that the *MMWR Dispatch* would serve as a single source of information for reporters and others

Dr. Mary Jean Brown's "Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)."

E-mail from Mary Jean Brown to Dr. Henry Falk entitled "RE: MMWR Vol. 53 / No. 12," April 1, 2004.

<sup>&</sup>lt;sup>141</sup> MMWR Dispatch, March 30, 2004, page 2.

E-mail from Dr. Henry Falk to Mary Jean Brown, cc'd to Patrick J. Meehan, entitled "FW: MMWR Vol. 53 / No. 12," April 1, 2004, 4:01 pm.

regarding the CDC's analysis and findings. 145 Dr. Falk suggested that his interpretation of Brown's response was the same. 146

Indeed, the MMWR article was very effective in informing the public that the CDC didn't think there was a public health crisis. On April 6, 2004, a week after publication, a commentary titled: "EPA's lead heads," in The Washington Times, read, "The ongoing hysteria about lead in D.C.'s drinking water is much ado about nothing, according to a new report from the Centers for Disease Control and Prevention." Based on the MMWR article, the commentary continued: "No health effects whatsoever have been attributed to the lead in D.C.'s water. This is hardly a surprise since the already very low blood lead levels among D.C. residents overall have dropped steadily for years, according to the CDC." (emphasis added)<sup>147</sup>

The District of Columbia government was also quick to seize on the report's findings. On April 9, 2004, the D.C. Interagency Task Force on Lead in Drinking Water, chaired by D.C. Mayor Anthony Williams and Councilmember Carol Schwartz, issued their interim report, which was followed by a final report on April 22, 2004. Both reports cited the basic conclusions of the MMWR Dispatch that there was no problem. 148

When asked why the results of these "preliminary investigations" were not held up until they could be verified, Dr. Brown stated, "The city certainly wanted a document out there. . . . EPA Region 3 wanted it; CDC wanted it.... Lots of people wanted to push it forward." But. five-years later, Dr. Brown told the Subcommittee staff that she didn't have "a lot of confidence" in the 300 ppb, cross-sectional study data. "There were lots of people not drinking the water." she said. 150

Dr. Bruce Lanphear, one of the leading experts on lead poisoning of children, later described the report as "a quick and sloppy study to address public health concerns." If the article had been "submitted to a journal to 'prove' that lead in water wasn't an important source, it would have been rejected."151

According to Dr. Falk, Dr. Gerberding, CDC's director, proclaimed herself "very pleased" with the results. 152

<sup>&</sup>lt;sup>145</sup> Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

<sup>&</sup>lt;sup>146</sup> Subcommittee staff interview of Dr. Henry Falk, Sept. 2, 2009.

Steve Milloy, "EPA's lead heads," Special to The Washington Times, April 6, 2004, p. A14.

<sup>148 &</sup>quot;Final Report of the Interagency Task Force on Lead in Drinking Water and Recommendations of the Co-Chairs," Government of the District of Columbia, April 22, 2004, p. 10: Available here:

http://www.dc.gov/mayor/news/2004/lead task force report 4.23.04.pdf.

The interim report released on April 9, 2004, is available here:

http://www.dc.gov/mayor/pdf/Task\_Force\_Report040904.pdf. 

149 Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

<sup>150</sup> Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

Rebecca Renner, "Lead on Tap: An alarming return of lead in drinking water is being ignored by the EPA and municipal officials," salon.com, Nov. 27, 2006, accessed at http://www.salon.com/news/feature/2006/11/27/lead 152 Subcommittee staff interview of Henry Falk, Sep. 2, 2009.

#### The Broader Impact of the MMWR

In a March 21, 2004, e-mail exchange between Dr. Cote and Dr. Brown regarding draft comments on the *MMWR* paper, the two appear to realize the importance of the paper that they were about to publish and its broader public health implications. "Something happened to the water [in D.C.], and this could happen elsewhere," wrote Brown, "so the recommendation for caution is important." "Hey, I'm all for caution," Dr. Cote wrote. "I agree that this paper will be important for many municipalities outside DC," he wrote. 153

In fact, at the same time that CDC officials were completing their work on the *MMWR* article, Pitt County health workers in Greenville, North Carolina, detected elevated BLLs in two young children at the same time the local water utility discovered elevated WLLs in several of the city's homes, including the homes of those children. As in the District, the cause of the high WLLs was also attributed to the addition of chloramines into the city's drinking water supply. By November 2004, the Greenville water utility mailed notices to 27,000 customers warning them that the city had exceeded the EPA's standards for lead levels in water. <sup>154</sup>

But county health officials did not connect the elevated WLLs and the lead poisoned children because they had never seen a case of lead poisoning attributed to elevated WLLs before. In addition, Dr. John Morrow, the Pitt County health director, said in a phone interview with Subcommittee staff that he had read the CDC's *MMWR* article and spoken briefly with Dr. Brown via telephone about the article and therefore kept looking for non-water sources of lead exposures in Greenville. It was not until March 2005 – a year after the children's elevated BLLs were discovered – that the North Carolina health workers finally made a connection between the elevated BLLs and elevated WLLs. Dr. Edwards blames that year-long delay on the *MMWR*'s influence on local and state public health workers.

On May 8, 2004, writing in *The Seattle Times*, William O. Robertson, medical director of the Washington Poison Center, cited the CDC's *MMWR* in his efforts to downplay fears about lead-in-water issues that had emerged in some of Seattle's schools. On July 16, 2004, a story in *The Seattle Times* regarding elevated WLLs in Seattle's schools again cited the CDC's *MMWR* article. "Parents should not be overly concerned about lead in Seattle schools' drinking water because it is unlikely any child has been harmed," the paper wrote. It quoted Dr. Brown cautioning parents from thinking their children were brain-damaged because they drank from the school's water fountains. The conclusions of the *MMWR*'s cross-sectional study was prominently

E-mail from Tm Cote to Mary Jean Brown, cc'd to Daniel R. Lucey, "Subject: RE: MMWR draft2 comments," Sunday, March 21, 2004, 11:51 pm.

See for instance: Pat Stith, Catherine Clabby and David Raynor, "Silence, flawed test data hide lead contamination: Water systems muddy their results by testing homes least likely to have lead," *The News & Observer*, March 28, 2006; "NC Lead Poisoning: Pitt County issues advisory after lead discovered in children," *Associated Press*, May 3, 2005; "Tapping into Greenville's Lead and Water Issues," *The Experience*, Department of Environment and Natural Resources, North Carolina Division of Environmental Health, Vol. 1, July 2005.

Subcommittee staff telephone interview with Dr. John Morrow, August 28, 2009.

William O. Robertson, Medical Director, Washington Poison Center, Seattle, Opinion, Northwest Voices; "A sampling of readers' letters, faxes and e-mails," *The Seattle Times*, May 8, 2004, p. B7.

featured, and an inaccurate claim made that most of the people in the study reported drinking tap water – something the study never claimed. 157

On May 21, 2004, Angela Logomasini, director of risk and environmental policy at the Competitive Enterprise Institute, told the House Government Reform Committee that lead in D.C.'s drinking water did not "warrant a panicked response" or the "frenzied reaction we've seen in D.C." The CDC's *MMWR* "study reinforces these findings," she wrote in her testimony. "It found that the elevated lead levels in D.C. water did not raise the level of lead in anyone's blood to a level of concern." She also drew the inaccurate conclusion that the CDC had found that every child with an elevated BLL lived in a home with peeling lead paint and/or lead-containing dust from renovations. 158

On September 5, 2004, Dr. Dean Sienko, then the acting chief medical executive of the Michigan Department of Community Health and the Ingham County medical director, wrote an article in the *Lansing City Pulse* downplaying concerns about elevated WLLs in Lansing, Michigan. He cited the cross-sectional study in the *MMWR* article as a reason not to worry. <sup>159</sup>

Even Congress relied on the *MMWR* to evaluate the potential human health harm caused by the D.C. lead-in-water crisis. The Government Accountability Office (GAO), Congress's investigative arm, cited – without additional analysis – the conclusions of the two studies in its report on the District's attempt to reduce WLLs. <sup>160</sup>

EPA also relied upon the CDC's *MMWR* article. In July 2005, the agency posted a fact-sheet that summarized the findings. It referred to the cross-sectional study and said: "Residents with high lead levels in their tap water did not have elevated blood lead levels" and told readers that "blood lead levels in District residents have been decreasing steadily." <sup>161</sup>

In 2007, in an article in the Montreal paper *The Suburban*, Dr. Joe Schwarcz, the director of McGill University's Office for Science and Society, said: "I have scoured the literature for studies that link levels in the water with levels in the blood. The best studies I have come across which have surveyed really large numbers of homes was in Washington, D.C., where there is a huge problem with lead pipes in underprivileged areas. ... [T]hey found that although the water

Sanjay Bhatt and Warren King, "Schools' lead danger disputed; Experts: water risk "extremely low" / Neurological problems unlikely to stem from exposure to drinking fountains," *The Seattle Times,* July 16, 2004, p. A1.

Angela Logomasini, Director of Risk and Environmental Policy, Competitive Enterprise Institute, prepared testimony before House Government Reform Committee hearing titled: "Thirsty for Results: Lessons Learned from the District of Columbia's Lead Contamination Experience," May 21, 2004.

Dr. Dean Sienko, Acting Chief Medical Executive of the Michigan Department of Community Health and the Ingham County Medical Director and Chief Medical Examiner, Editorial in the *Lansing City Pulse*, September 5, 2004 (the link to this article is no longer available), but the paper can be found here: <a href="http://www.lansingcitypulse.com/lansing">http://www.lansingcitypulse.com/lansing</a>.

<sup>160 &</sup>quot;District of Columbia's Drinking Water: Agencies Have Improved Coordination, but Key Challenges Remain in Protecting the Public from Elevated Lead Levels, Government Accountability Office (GAO), GAO-05-344, March 2005, available here: http://www.gao.gov/new.items/d05344.pdf.

<sup>&</sup>lt;sup>161</sup> "Results of Blood Lead Level Testing of District of Columbia Residents," Environmental Protection Agency (EPA), July 2005, revised October 2006, available here: <a href="http://www.epa.gov/dclead/BloodLevelsFactSheet10">http://www.epa.gov/dclead/BloodLevelsFactSheet10</a> 06 rev.pdf.

level was sometimes as high as 300 parts per billion, which is astounding, it didn't influence the blood levels." <sup>162</sup>

## 5. Efforts by CDC, DC and the Subcommittee to Identify Missing Blood Lead Level Data

Despite the insistence by Dr. Brown that complete data was not needed to understand what had been happening to D.C.'s children, CDC staff did attempt to obtain missing data for 2003. In March 2005 – a full year after the MMWR article was published – the CDC lead program tried to resolve the cause of the drop in 2003 blood lead test results. A chain of e-mails shows that Barry Brooks asked the D.C. CLPPP office to ask the laboratories to resubmit the 2003 BLL data. Brooks also told Subcommittee staff that he emphasized to District officials the importance of determining if there was missing data. Despite this effort, according to Brooks, the re-submitted lab data regarding the number of children tested and the number with elevated blood lead levels did not change significantly from the "raw data" CDC used in the 2004 MMWR analysis. Nothing the Subcommittee found during its investigation supports the view that the labs did not previously submit this information to the District. The problem appears to have been the incomplete recording of the results by the D.C. lead program staff.

This inability of the CDC to gather accurate data is difficult to understand because the CLPPP program had switched over to the LeadTrax system in April 2004, and had systematically entered all blood lead results from the labs into that system. Based on the material provided to the Subcommittee, it appears that thousands of the missing 2003 results should have been available to the CDC by March of 2005. Furthermore, the Subcommittee did its own collection of lab reports for 2002 and 2003 and had no trouble developing figures for those years that erased the "missing" 6,500 children.

#### LeadTrax

In April 2004, just after the *MMWR* was published, the District finally acquired the new LeadTrax database to track children screened for BLLs. Through the spring and summer of 2004, Offor worked closely with the manufacturer's technical support staff to acquire and upload the historical 2002/2003 BLL test data into the new system. In October 2004, the manufacturer ran an "historical analysis" of all existing BLL test data on the new LeadTrax software, although it apparently did not include all the results submitted by the labs. It did, however, point out reporting gaps in the D.C. blood lead test data, particularly for the 2003 period.

In a summary document, the manufacturer pointed out that data was "very likely missing" from the Children's National Medical Center from late 2003 into early 2004; data from the D.C. Public Health Laboratory was "very erratic over the same period," and all of it was "suspect"; there was an "aberration" in the data in early 2004; and that there was a "fairly

Joel Goldenberg, "No Worry on Water," *The Suburban*, March 14, 2007, available here: <a href="http://archive.thesuburban.com/content.jsp?sid=14400449001260020182649221692&ctid=1000000&cnid=1010853">http://archive.thesuburban.com/content.jsp?sid=14400449001260020182649221692&ctid=1000000&cnid=1010853</a> Subcommittee staff interview of Barry Brooks, July 13, 2009.

<sup>&</sup>lt;sup>164</sup> Subcommittee staff interview of Barry Brooks, July 13, 2009.

substantial drop-off in results from all labs combined for 2003." The major labs of LabCorp. and Quest, however, appears to have a "fairly consistent rate of reporting." <sup>165</sup>

By January 2005, as a result of switching from the poorly functioning STELLAR database to LeadTrax, D.C. had a new, more accurate set of blood lead level test numbers for 2002 and 2003. A January 2005 e-mail from an employee of the U.S. Department of Housing and Urban Development (HUD) to the CLPPP program manager included a table of elevated blood lead levels of D.C. children that had previously been provided by the D.C. Department of Health. <sup>166</sup>

The table, which appears to be sorted by the number of BLL tests conducted and not the specific number of children tested, shows that in 2003 D.C. conducted 22,138 blood lead tests and that at least 400 of those tests showed elevated blood lead levels. The numbers reported to HUD from the D.C.'s lead program in 2005 show:

EBL data	(in	uniform	table)	)
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Year	# of Children Screened	# EBLs 10-14 ug/dL	# EBLs 15-19 ug/dL	Source of Data
2004	26,311			D.C. Department of Health
2003	22,138	244	156	D.C. Department of Health
2002	22,839	319	246	D.C. Department of Health
2001	22,218	378	104	D.C. Department of Health

Source: Subcommittee on Investigations and Oversight, based on D.C. Department of Health 2005 data. 168

#### **I&O Subcommittee Effort to Obtain Data**

Initially, the Subcommittee was unable to get cooperation from the District in gathering up-to-date reports on 2002 and 2003 so staff initiated a survey of the labs. When Chairman Miller wrote to each of the seven laboratories providing BLL test data to the District and asked them to provide the number of children they reported to the D.C. CLPPP in 2002 and 2003 with BLLs above the action level of  $\geq 10~\mu g/dL$ , the Subcommittee obtained drastically different numbers.

<sup>&</sup>lt;sup>165</sup> "Historical Analysis" of the DC blood lead reporting database, produced by Welligent LLC and run on the newly installed LeadTrax software, October 29, 2004.

Tia Clark, Office of Healthy Homes and Lead Hazard Control, U.S. Department of Housing and Urban Development, e-mail to Christine Onwuche, the DC CLPPP program manager, Subject: "EBL table per our conversation," January 27, 2005. The accompanying chart was labeled: "EBL data (in uniform table)."

167 Some children may have been tested multiple times so the number of children with elevated blood lead levels may have been lower. But the table also only includes elevated results from 10 ug/dL to 19 ug/dL. Presumably that random cut-off would have also excluded additional test data on children with EBLLs higher than 19 ug/dL.

168 Tia Clark, Office of Healthy Homes and Lead Hazard Control, U.S. Department of Housing and Urban Development, e-mail to Christine Onwuche, the DC CLPPP program manager, Subject: "EBL table per our conversation," January 27, 2005. The accompanying chart was labeled: "EBL data (in uniform table)."

The labs' documentation of test results provided to the D.C. CLPPP showed that at least 949 D.C. children had BLLs  $\geq 10~\mu g/dL$  in the critical years of 2002 and 2003, three times the 315 used in the 2004 MMWR article to tell the citizens of the District that excessive lead in water was not a serious public health issue. As discussed earlier, there was a tremendous backlog of data not entered into STELLAR in early 2004 when the initial set of raw data was submitted to CDC.

The elevated BLL test results that D.C. had in its LeadTrax system by January 2005 are generally in line with data provided to the Subcommittee by the commercial laboratories in 2009. But those are not the final numbers compiled by the D.C. CLPPP. Data for 2002 and 2003 currently available in LeadTrax show even larger discrepancies between the number of elevated BLL tests for the District's children and the number of elevated BLL tests still being reported by the CDC for those years. That data, detailed in the table below, shows that the number of children in D.C. that had elevated blood lead levels in 2002 and 2003 is actually *three times* higher than the CDC had used in the *MMWR* article. 169

Number of D.C. Children Under Six Years Old with Elevated Blood Lead Levels

YEAR	CDC	I&O Subcommittee
2002	122	457
2003	193	492
Total	315	949

Source: Subcommittee on Investigations and Oversight, based on data provided by seven laboratories which conducted BLL tests for the District of Columbia's CLPPP and data maintained on the CDC's Childhood Lead Poisoning Prevention Program web-page. 170

The CDC's 2004 MMWR article used nearly 85,000 blood lead level "tests" to analyze historic lead levels in DC from 1998 to 2003. Separately, the CDC posts the number of individual "children," not tests, that public health surveillance shows have been identified with elevated blood lead levels annually. Those numbers show that 122 DC children had elevated blood lead levels in 2002 and 193 individual children had elevated blood lead levels in 2003. The blood "test" data results upon which those figures were based were used as the foundation for the historic blood lead level trend analysis in the 2004 MMWR article and were woefully incomplete.

The Subcommittee obtained summary data of the number of individual children five years old or younger who had elevated blood lead levels above the CDC "level of concern" of  $>10\mu g/dL$  [10 micrograms of lead per deciliter of blood] in 2002 and 2003 that were reported to the DC Department of Health. The Subcommittee wrote to all seven laboratories providing blood lead test data to DC back in 2002 and 2003, so that we could compare the data CDC

<sup>170</sup> Cities and states that have cooperative agreements with the CDC and obtain CDC grant funds for their lead programs are required to provide CDC with their raw public health surveillance data regarding lead screening tests each year. Since 1992, the District of Columbia has received nearly \$12 million in CDC lead grant funding. Once the CDC receives this raw surveillance data, which is supposed to include *all* blood lead tests performed that year, then CDC publishes a separate list based upon the number of children tested, not the number of tests conducted, on the CDC lead branch web-site. The incomplete raw surveillance data CDC received from DC regarding the city's 2003 blood lead tests in early 2004 were provided to the CDC for use in the March 2004 MMWR report. The numbers posted by CDC on its web-site in March 2005 regarding the number of individual children who had elevated blood lead tests in DC in 2003 was based on this incomplete and flawed data and remain there today, available here: www.cdc.gov/nceh/lead/data/State Confirmed byYear 1997 to 2006.xls.

It is unclear why the CDC has not updated its database to remove its obviously incorrect data. It posts lead poisoning surveillance data from its 42 cooperating lead programs on its Web site, and its database manager is responsible for cleaning up the data by removing duplicate entries and making sure that the number of children tested is accurate. The final numbers are verified with the cooperating programs and posted. This process normally takes about six months. Even if the efforts in 2005 failed to get a clean LeadTrax report to the CDC, the subsequent complaints about data quality in the CDC database, and the availability of up-to-date reports from the D.C. government, should have induced the CDC to update those numbers.

The CDC also relies on the lead data it posts on its web site to evaluate CDC-funded lead programs to identify cities or states that have indications of elevated lead poisonings that might be caused by environmental factors. Local and state public health professionals and academics use the data to assess potential lead problems. "This is our basic data," acknowledges Barry Brooks. "When we judge programs, this is what we use." The fact that the actual numbers of children in D.C. with elevated BLLs in 2002 and 2003 appears to have been *three times* higher than the number on the CDC Web site is significant. As Brooks admitted, "Elevated numbers drive everything."

With the implementation of LeadTrax in 2004, the BLL test data subsequently reported to the CDC by the D.C. CLPPP was much more accurate, reliable and complete than data submitted under the old STELLAR system. What is much less clear is why CDC failed to understand either the cause or the significance of the 2003 "data gap" and acknowledge it in the *MMWR* article. And even when presented with more accurate data from the D.C. CLPPP and the Subcommittee, CDC has still refused to publicly state that the longitudinal study in *MMWR* report was fatally flawed and its conclusions are scientifically invalid.

### 2005: CDC Contractor Identifies Continuing Problem with D.C. CLPPP

Dr. Brown and Barry Brooks both expressed a belief that the "data gap" issues and the reported admission of "forgery" of quarterly reports were simply one-time, isolated instances that had no bearing on the integrity of the data CDC received from D.C., the conclusions of the *MMWR*, or their trust in the ability of the D.C. Childhood Lead Poisoning Prevention Program to effectively manage D.C.'s lead program.<sup>173</sup>

posted on its website with the data the labs reported to DC. Under the CDC's lead grants to the District, copies of the raw public health surveillance data regarding blood lead tests provided to the DC government from these laboratories was supposed to be provided to the CDC.

<sup>&</sup>lt;sup>171</sup> Subcommittee interview with Barry Brooks, Oct. 22, 2009.

Subcommittee interview with Barry Brooks, July 13, 2009.

The Subcommittee staff conducted a total of six interviews with Dr. Mary Jean Brown and Barry Brooks, three interviews with each of them. The first interview with Mr. Brooks via telephone was conducted on March 23, 2009 and the other two interviews were conducted in the Subcommittee offices in Washington, D.C. and occurred on July 13, 2009 and October 22, 2009. The first Subcommittee staff interview with Dr. Brown also occurred via telephone on March 19, 2009, followed by two interviews in Washington, D.C. on July 22, 2009 and October 22, 2009. Both Dr. Brown and Barry Brooks reiterated this position during each of these interviews.

In reality, even though the D.C. lead-in-water crisis had faded from national headlines soon after the *MMWR* article was published, the D.C. lead program continued to suffer from a host of unresolved problems. In October 2005, Dr. Brown's Lead Poisoning Prevention Branch at the CDC issued a sole source, non-competitive contract award to The National Center for Healthy Housing (NCHH) for "Building Capacity in Childhood Lead Poisoning Prevention Programs." The contract required NCHH to provide on-site technical assistance to the D.C. CLPPP office to help evaluate and revitalize the failing D.C. lead program.<sup>174</sup>

In September of 2007, NCHH completed an internal "Preliminary Work Plan" regarding a summary of their findings of the D.C. lead program. Barry Brooks, the CDC's project officer and health advisor in charge of the CDC lead grant to the District was one of the officials involved in the NCHH assessment. The review, which has never been publicly released, was damning. 175

## Among the report's findings:

- In many cases, children identified as having elevated BLLs in 2004 and 2005 never had risk assessments of their homes completed to identify the actual source of lead exposure. "There is a substantial backlog of EBL [elevated blood lead] cases for which risk assessments have never been performed," the report said, "or for which risk assessments were done too long ago to be valid now." In 2007, the assessment backlog was around 250 cases and growing.
- A review of 41 risk assessment reports found three cases had lead in the water above the EPA limit of 15 ppb with no other lead source identified. In about half of the 41 cases, drinking water had not even been tested for lead.
- There was a continuing mismatch between BLL data collected by the D.C. lead program and BLL test data reported by the CDC. The D.C. lead program "reports that in recent years 16,200 to 18,400 children in D.C. received blood lead tests per year, but CDC figures are substantially lower (12,300 to 14,500)." The report found that CDC reported only around 200 elevated BLL cases annually while D.C. reported 300 to 430 per year. The reason or reasons for this wide discrepancy, however, remained unclear.

A week after NCHH finished its "Preliminary Work Plan," Pierre Erville, the new chief of the District's Bureau of Environmental Hazards and Injury Prevention, wrote to Brooks. Erville, who now oversees the D.C. lead program, said he was writing to let Brooks know he was "concerned about what to me appears to be poor performance by our program," and that he was

<sup>&</sup>quot;Building Capacity in Childhood Lead Poisoning Prevention Programs," Solicitation Notice, Oct. 27, 2005, available here: <a href="http://fedbizopps.info/archive/2005/10-October/29-Oct-2005/FBO-00922487.htm">http://fedbizopps.info/archive/2005/10-October/29-Oct-2005/FBO-00922487.htm</a>.

<sup>&</sup>lt;sup>175</sup> "Preliminary Work Plan - Building Capacity in Childhood Lead Prevention Programs: Technical Assistance and Training to Support the Washington, DC Childhood Lead Poisoning Screening and Education Program's Case Management of Children with Elevated Blood Lead Levels," The National Center for Healthy Housing, September 20, 2007.

"dismayed" by the work of the CLPPP program manager. He assured Brooks that he planned to put "the District of Columbia on the right track to effectively prevent lead poisoning." <sup>176</sup>

Erville noted that he recently hired an epidemiologist for the lead program, that the various D.C. agencies working on lead issues were moving forward as a coordinated group, and that he had re-written the District's risk assessment protocols. "I plan to work closely with [the new epidemiologist] and to achieve long-needed data reliability and analysis," he wrote. "I am also working very closely with the IT folks to ensure Lead Trax is a smooth-functioning program component and putting pressure on supervisory staff to ensure case management follow-up work occurs consistently and in a timely manner," he emphasized. Erville's frank assessment of the D.C. lead program's troubles came more than three years *after* the CDC published the *MMWR* article and the CDC lead program became keenly aware of these systemic problems.

### 6. Dr. Edwards' Investigation: The Missing Cross-Sectional Data

While the vast majority of those reading the *MMWR* article were reassured that District residents had suffered little, if any, harm from the elevated WLLs, a few were troubled by its conclusions. Dr. Marc Edwards, a civil engineering professor and water corrosion expert, who was named a MacArthur Fellow in 2007 with an accompanying \$500,000 grant (often called a "genius grant")<sup>178</sup> to study drinking water safety issues, was more surprised by the findings than almost anyone else. Dr. Edwards, the Charles P. Lunsford Professor in the Civil and Environmental Engineering Department at Virginia Polytechnic Institute and State University, was investigating pinhole leaks in residential water lines in Washington, D.C. in the spring of 2003 when he discovered exorbitantly high levels of lead in the drinking water supply. He determined that chloramines, a chemical used as a disinfectant which had been added to the District's water supply in November 2000 by WASA, was causing lead to leach from household plumbing systems. Edwards soon realized that traditional testing protocols were failing to identify the high lead levels in many homes with lead pipes. He also discovered that children in District homes with elevated water lead levels had elevated blood lead levels too.

Based on his research, Dr. Edwards believed that the MMWR's conclusions of no public harm contradicted the vast majority of published scientific findings regarding the effects of elevated WLLs on children's BLLs and their health. But after hearing it repeatedly cited by scientists and public health officials across the country and even internationally, Dr. Edwards sought to acquire the underlying data used for the MMWR article to do his own analysis.

In 2005, Dr. Edwards filed Freedom of Information Act (FOIA) requests with both the District of Columbia and the CDC for the raw data underlying the *MMWR* article. <sup>180</sup> He was

<sup>176</sup> E-mail from Pierre Erville to Barry Brooks, entitled "DC grant reports," Sept. 27, 2007.

<sup>&</sup>lt;sup>177</sup> Ibid.

<sup>&</sup>quot;MacArthur Fellows 2007: Marc Edwards," John D. and Catherine T. MacArthur Foundation, September 2007, available here: <a href="www.macfound.org/site/apps/nlnet/content2.aspx?c=lkLXJ8MQKrH&b=2913825&ct=4074601">www.macfound.org/site/apps/nlnet/content2.aspx?c=lkLXJ8MQKrH&b=2913825&ct=4074601</a>. Testimony of Marc Edwards, "Public Confidence Down the Drain: the Federal Role in Ensuring Safe Drinking Water in the District of Columbia," Committee on Government Reform, U.S. House of Representatives, March 5, 2004, accessed at <a href="http://www.dcwatch.com/wasa/040305h.htm">http://www.dcwatch.com/wasa/040305h.htm</a>

For information on federal laws related to the Freedom of Information Act (FOIA) see U.S. Department of Justice's FOIA web-page, available here: <a href="http://www.justice.gov/oip/">http://www.justice.gov/oip/</a>; For D.C. specific laws governing public

bounced between the D.C. Department of Health (D.C. DOH) and CDC and back again. "Trying to find the data was like a shell-game," Edwards said. "I went through about 1.5 years with DC DOH with hundreds of pages of FOIA letters, appeals, etc., before the mayors [sic] office ordered them to produce some of the data." <sup>181</sup>

Finally, at the end of May 2006, the District's general counsel ordered the D.C. DOH director to provide the data. 182 Dr. Edwards received a single Excel spread sheet that was apparently the only data that the Department had regarding the 300-ppb Cross-sectional study cited in the MMWR publication. 183

As part of its investigation, the Subcommittee requested all available documents, including the raw data, survey questionnaires and related records, underlying the Cross-sectional study from the U.S. Department of Health and Human Services and its components, including the CDC, the Food and Drug Administration (FDA), and the PHS, and from the District of Columbia and its agencies None of these agencies have provided the Subcommittee with any records directly related to the collection of the raw data for that study or its results. 185

CDC, Dr. Cote and the other co-authors all told Subcommittee staff that they had no raw data or survey instruments used in the study. The MMWR editorial office also did not possess any of the raw data records. They only maintain "clearance sheets" for their articles for six months. But, Dr. Ward, the MMWR editor at the time the DC lead-in-water article was published, said: "I would expect the authors to maintain a copy of the data." <sup>186</sup>

In a letter from Chip Richardson, General Counsel to the Mayor of the District of the Columbia, responding to the Subcommittee on Investigations and Oversight Chairman Brad Miller's request for all records related to the cross sectional study, Mr. Richardson wrote that "No documents responsive to this request have been found." When provided with a copy of the e-mail that the D.C. FOIA officer e-mailed to Dr. Edwards in 2006 which contained the Excel spreadsheet with the "raw data" purportedly used in the study, an official from D.C.'s

access to District government records see: Council of the District of Columbia, Freedom of Information Act (FOIA) web-page, available here: http://www.dccouncil.washington.dc.us/foia

E-mail from Dr. Marc Edward to Subcommittee on Investigations and Oversight staff, "Subject: Re: 300 ppb study," September 3, 2009.

Leonard H. Becker, General Counsel, Government of the District of Columbia, letter to Dr. Gregg Pane, Director, District of Columbia Department of Health, "Re: Freedom of Information Act Appeal," May 31, 2006. E-mail from Tom Collier to Marc Edwards with Excel spreadsheet attached, May 31, 2006. In an earlier e-mail to Dr. Edwards, from Tom Collier on April 12, 2006, Collier had described the information as follows: "I will be mailing you spreadsheets showing blood level screening results for the period from February 3, 2004, to March 22, 2004, and February 3, 2004, to September 21, 2004, by first class mail tomorrow. I will also be getting the raw data for the March, 2004, article and will be forwarding that to you tomorrow. It should be in an electronic format. The other materials you have requested will be forthcoming, to the extent DOH has them (emphasis added)."

Letter from Chairman Brad Miller, Investigations and Oversight Subcommittee, to Health and Human Services (HHS) Secretary Katherine Sebelius, Aug. 3, 2009; letter from Chairman Brad Miller to District of Columbia Mayor Adrian Fenty, Aug. 3 2009.

185 Some records were received from CDC related to comments on the MMWR draft report.

<sup>&</sup>lt;sup>186</sup> Subcommittee staff telephone interview with Dr. John Ward, former Editor of the MMWR Series and Director, Office of Scientific and Health Communications, Centers for Disease Control and Prevention, September 28, 2009. Letter from Chip Richardson, General Counsel to the Mayor of the District of the Columbia, to Brad Miller, Chairman, Subcommittee on Investigations and Oversight, September 3, 2009.

Office of Policy and Legislative Affairs, Executive Office of the Mayor responded that "there is no evidence that a document was attached to the e-mail you've referenced." 188

Regardless of this incomprehensible explanation by the District government, it appears that the spreadsheet received by Dr. Edwards is both authentic and the only available record regarding the 300 ppb Cross-sectional study based on the correspondence between Tom Collier, the D.C. FOIA officer and Dr. Edwards in 2006.

## Dr. Edwards' Analysis: Data in Spread Sheet Doesn't Match Cross-Sectional Study

The MMWR's section on the "Cross-sectional study of Homes with >300 ppb Lead in Water" stated that the D.C. Public Health Laboratory had analyzed the BLL tests on 184 persons in 86 homes with WLLs at or above 300 ppb. In addition, the test results of 17 persons from 12 homes who had blood drawn and analyzed independently and then reported to the D.C. DOH were included for a total of 201 residents from 98 homes. Only 17 of these residents were children under six years of age. The MMWR says a total of 153 residents (76%) reported drinking tap water, but 52 households (53%) reported using a water filter on their taps.

But the numbers in the Excel spreadsheet provided to Dr. Edwards are dramatically inconsistent with the numbers referred to in the *MMWR*. For instance, the Excel spreadsheet lists only 194 residents, not 201. It also shows only 136 residents drank tap water, while the *MMWR* claims 153 residents drank tap water. In addition, the raw data reports that 131 of the 194 residents in the spreadsheet say they drank bottled water. Bottled water is not even mentioned in the *MMWR*, despite suggestions by three co-authors and collaborators that bottled water consumption by those surveyed may confound the results. According to the spreadsheet provided to Dr. Edwards, only 13 individuals in 11 homes did not drink bottled water or use a water filter. In other words, only 13 of the 194 residents in the spreadsheet drank unfiltered tap water, with its highly elevated lead levels, exclusively.

The spreadsheet raised other serious questions about the scientific integrity of the *MMWR* publication. Ninety five people, or nearly half of the 194 participants, have no blood "draw date" listed. This date is important because lead in the bloodstream has a half-life of around 30 days. If survey participants stopped drinking tap water after the D.C. lead-in-water crisis first came to the public's attention at the end of January 2004, there could be a significant difference between those that had their blood drawn in February and those that had their blood drawn in March. From a public health perspective, this is something that the *MMWR* should have addressed. Despite assurances by Dr. Cote that those entering data on the Cross-sectional study used a "double entry" method to help ensure data integrity, the missing "draw dates" and other issues raise troubling questions about the overall quality and integrity of the study's data.

Dr. Regina Tan, a co-author of the *MMWR* article and a PHS officer who volunteered to assist in the D.C. lead-in-water crisis, told the Subcommittee staff that there were significant software and IT-related issues that impacted the entry of the survey data used in the Cross-sectional study. She was deployed for six days from March 15 - 20, 2004, and was in charge of

<sup>&</sup>lt;sup>188</sup> E-mail response to Subcommittee from Jamal H. Anderson, federal affairs advisor, Office of Policy and Legislative Affairs, Executive Office of the Mayor, District of Columbia, Sept. 11, 2009.

overseeing the PHS data entry team. Dr. Tan, who has since left the U.S. Public Health Service, said: "There was a lot of frustration beyond normal data entry, because the system kept crashing and we had to keep re-entering the data. We had to go back to the original data and manually reenter the data," Tan said. "I recall being frustrated because there wasn't a fix. ... We just started again every time the system crashed and hoped we got to the end before it crashed again. We would just enter and enter until it got done." Dr. Tan said that Dr. Cote was well aware of these issues. 189

Once a blood sample is obtained, it normally takes several days for the laboratory to analyze the results in order to determine an individual's blood lead level. According to Subcommittee staff interviews with officials from the D.C. Public Health Laboratory, which analyzed and processed the blood lead samples for the Cross-sectional study, the timeline for those samples was similar. Yet, the raw data spreadsheet provided to Dr. Edwards lists two individuals as having their blood drawn on March 30, 2004, the same day the *MMWR Dispatch* was published. Another individual is listed as having blood drawn on September 30, 1952, almost 52 years prior to the publication of the *MMWR*, and one person is listed as having blood drawn on December 3, 2004, nine months after the MMWR was published.

When asked about these anomalies in the spreadsheet, Dr. Cote, the PHS official who was the lead author on the cross-sectional study, said the data contained in the spreadsheet must have been corrupted "after the fact." It is true that the Subcommittee cannot verify that the table provided Dr. Edwards is accurate or the final basis for the work done in the *MMWR*. However, since the study lead (Dr. Cote) did not retain records, the lead authors (Dr. Stokes and Dr. Brown) did not retain records and neither the District nor the agencies involved retained records, it is hard to give merit to simple assurances that the data was of high quality and the analysis robust.

Despite the data integrity issues raised in the Edwards data file and by the unacknowledged presence of confounding variables that coauthors were aware of at the time of the *MMWR*, Dr. Cote said he believed the data behind the *MMWR* study is still scientifically sound. <sup>190</sup>

Besides the exclusion from the *MMWR* study of the one child who had an elevated blood lead level of 14 ug/dL and lived in a home with more than 300 ppb of lead in the water, there were other significant omissions. On March 25, 2004, Dr. Cote sent an e-mail to Dr. Brown and Dr. Lucey. Dr. Cote said he had taken "a hard look at how BLLs varied by responses to the questionare [sic] on drinking water exposures (among houses with >300ppb lead measured)." Dr. Cote found that those who drank tap water had a 1 microgram per deciliter higher blood lead level than those who said they did not drink tap water at all. "This is exciting and interesting and we'd better be sure about it before we let it out," Dr. Cote wrote. But in the end, this "exciting and interesting" finding was not included.

Subcommittee staff interview with Dr. Regina L. Tan, November 5, 2009.

Subcommittee staff interview with Dr. Cote, September 8, 2009.

E-mail from Dr. Tim Cote to Mary Jean Brown and Dr. Daniel Lucey entitled "Relationship between drinking tapwater and BLLs," March 25, 2004.

One week after this e-mail was sent, however, and the day after the *MMWR* article was released, Dr. Brown was quoted in a story in *The Washington Post* saying: "There is no safe level of lead. Even a small contribution, especially in small children, is not something that we want to happen. . . . We don't want to increase the blood lead levels of those individuals by even 1 microgram if it can be prevented," Dr. Brown said. Yet, a 1 microgram increase in BLLs due to drinking D.C. tap water apparently was not important enough to warrant a mention in the *MMWR* article.

In the end, Dr. Edwards believed the problems in the spreadsheet's data for the cross-sectional study were so egregious, and the resistance from CDC and D.C. DOH to his request for the actual raw data so strong, that he began to believe that it may actually have been fabricated. He also questioned the data used in the *MMWR*'s longitudinal study because of the dramatic and unexplained drop of more than 6,500 in the number of children that were tested in 2003 compared to previous years. <sup>193</sup>

In January of 2007, Dr. Edwards sent a formal complaint to the CDC alleging "possible fabrication and falsification" of the data used in the CDC's March 2004 *MMWR* article. CDC responded that his allegations were directed at District, not CDC, employees. <sup>194</sup> Dr. Edwards then sent a second, more detailed letter to CDC in September 2007 with specific allegations of possible scientific misconduct by CDC scientists.

Dr. James Stephens, CDC's acting associate director for science, was tasked with looking into Dr. Edwards' allegations. But Dr. Stephens never fully investigated Dr. Edwards' allegations because he determined the allegations did not merit an investigation as they did not meet the threshold definition of research misconduct specified in federal regulations. Therefore, an investigation was not required. To qualify as "research misconduct" under the federal

Avram Goldstein, "Water Treatment Affected Levels In Some Children, Study in D.C. Says," *The Washington Post*, March 31, 2004, p. B1.

<sup>&</sup>quot;Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: <a href="http://www.cdc.gov/nceh/lead/data/State">http://www.cdc.gov/nceh/lead/data/State</a> Confirmed by Year 1997 to 2006.xls

Letter from Dr. James W. Stephens, Associate Director for Science, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) to Dr. Marc Edwards, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, September 18, 2007. See also: E-mail from James Stephens to Marc Edwards, "Subject: RE: Outcome of the assessment," October 10, 2007, in which Dr. Stephens wrote: "Per my letter, I would advise raising your concerns with the DC Office of the Inspector General." Some CDC officials did not see how any of the allegations applied to CDC officials because the data that Edwards questioned on both the longitudinal study and the cross-sectional study came from the District government and the U.S. Public Health Service, not the CDC. But others found this a weak position. "We do have some accountability since the data was published in the MMWR and MJB [Mary Jean Brown] is the 1<sup>st</sup> author," wrote Dr. Tom Sinks, deputy director of NCEH/ATSDR. E-mail from Dr. Tom Sinks to Dr. Brown, Dr. Howard Frumkin, cc'd to Dr. James Stephens, entitled "RE: Allegations of possible scientific misconduct," Jan. 18, 2007.

Subcommittee staff interview of Dr. James Stephens, June 30, 2009. During this interview Dr. Stephens acknowledged: "I did not say I did an investigation because that is not what I did." He did not investigate Dr. Edwards' allegations because it did not reach the definition of federal "research misconduct," he said, which can be found here: "Public Health Service Policies on Research Misconduct; Final Rule, 42 CFR Parts 50 and 93," Department of Health and Human Services, printed in the Federal Register, Vol. 70, No. 94, Tuesday, May 17, 2005, available here: <a href="http://ori.dhhs.gov/documents/42\_cfr\_parts\_50">http://ori.dhhs.gov/documents/42\_cfr\_parts\_50</a> and 93 2005.pdf. Other CDC staff apparently

definition, intentional deception must be alleged. Dr. Edwards' allegations may not have been sufficient to charge intentional deception.

But other CDC officials, while agreeing that Dr. Edwards' complaint did not allege research misconduct, thought the issues he raised were troubling and warranted some sort of investigation. "[T]he questioned data were not acquired as a research activity but as surveillance data," wrote Dr. John Dahlberg, director of CDC's Investigative Oversight Division, Office of Research Integrity. As a result, "the research misconduct policy . . . does not apply to the concerns that have been raised." Still, wrote Dahlberg, "The apparent absence of much of the lead data is also troubling. Given the importance of this issue, and the apparently real concerns raised, it would appear that some sort of review should be undertaken. Possibly this could be done by either the DC Inspector General and/or by the HHS IG office." The CDC never informed the D.C. OIG about these allegations. Instead, they suggested to Dr. Edwards that if he had concerns with the data used in the MMWR that he should raise those concerns with the D.C. OIG.

#### 7. CDC Response to Critics and New Unpublished Analysis

### CDC's Notice of Misinterpretation: Resistance and Eventual Publication

One positive result of Dr. Edwards' complaint, however, was that it alerted CDC officials to the fact that the March 30, 2004 *MMWR* was being relied upon by state and local officials to make public health decisions regarding elevated levels of lead in drinking water. Some CDC officials believed that it was being "misinterpreted" to conclude that elevated WLLs were safe.

The result was a decision by CDC in March 2007 to issue a "notice" on the MMWR Web site to address the "misinterpretations." The notice was intended to reiterate what the CDC now claimed were the main conclusions in the 2004 article – that there are no safe levels of lead exposure, and that the *MMWR* never implied that D.C.'s elevated WLLs were safe. But Dr. Brown resisted issuing any sort of "alert" or "notice" for months. In August 2007, she wrote: "Tom Sinks and I had a conversation regarding the misinterpretation of the results published in the MMWR article on lead in water in D.C. We agree that the article is clear that CDC DOES NOT conclude that 300 ppb of lead in water is 'safe.' We also agreed that authors are not responsible for possible misinterpretations of their studies." (emphasis added)<sup>197</sup>

Dr. Brown said she did not want to set an "unwanted precedent" by publishing an alert. "I know CDC data is misunderstood and used inappropriately all of the time," she told Subcommittee staff, "but I did not believe this was a good precedent to set." Brown also said she did not believe the issues raised by Dr. Edwards were "related to science," but rather, there were "people pushing this." She implied that local D.C. activists were somehow behind the allegations

believed Dr. Stephens had done a full investigation and exonerated the agency and its officials. See, *e.g.*, Subcommittee staff interview of Dr. Mark Bashor, Associate Director for Science, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), Centers for Disease Control and Prevention (CDC), Sept. 2, 2009.

E-mail from Dr. John Dahlberg to Dr. James Stephens, entitled "RE: Allegation of misconduct," Feb. 2, 2007.

E-mail from Mary Jean Brown to Jim Rabb and Andrew Dannenberg, cc'd to Sharunda Buchanan, Aug. 3, 2007.

by Dr. Edwards and she suggested that Marc Edwards did not understand the limitations of the *MMWR* or public health surveillance data in general since he was an "engineering professor" and not a public health official. 198

Dr. Mark Bashor, the associate director for science at NCEH/ATSDR, pushed repeatedly to issue a "notice" or "alert" in the spring and summer of 2007 but faced Dr. Brown's resistance. On August 10, 2007, Dr. Bashor, tried to put an end to the continuing delays in posting the "notice:"

To bring closure to the issue that I thought we had closed on earlier (March 26<sup>th</sup>), I met with Dr. Sinks yesterday.

Our decision is that the program should draft a notice to be posted on the web, explaining how the 2004 MMWR article is being misinterpreted/misused, providing appropriate additional information and clarification, and reiterating our position on Pb [lead] in drinking water. 199

Dr. Bashor's e-mail, however, was not sufficient. On August 14, 2007, Dr. Frumkin, NCEH/ATSDR's director, ordered Dr. Brown to write the notice they had discussed.

This will confirm our phone call today in which I directed you to write the short clarifying text on the correct interpretation of our DC water lead data, which has been questioned, for posting on the web site. Please provide it to Mark Bashor by the end of this week. Thank you. 200

Finally, after a five-month delay, the notice was posted on the CDC web-site. The notice was to be the extent of CDC's response to Dr. Edwards' allegations. On September 18, 2007, Dr. Stephens wrote to Dr. Edwards and said he had found no evidence of misconduct by CDC, and that the questions he raised "pertained to data collected by others outside of CDC." Dr. Stephens recommended that Dr. Edwards contact the D.C. Office of Inspector General with his allegations. 202

<sup>&</sup>lt;sup>198</sup> Subcommittee staff interview of Dr. Mary Jean Brown, July 22, 2009.

E-mail from Mark M. Bashor to Sharunda D. Buchanan, cc'd to Tom Sinks, James Stephens and Jana Telfer, entitled "Notice re: 2004 MMWR Pb in D.C. Water paper," Aug. 10, 2007 1:02 pm.

E-mail from Howard Frumkin to Mary Jean Brown, cc'd to Sharunda Buchanan, Mark Bashor and Tom Sinks, entitled "102 paragraphs on correct interpretation of lead data," Aug. 14, 2007, 11:52 a.m.

<sup>&</sup>lt;sup>201</sup> "Addendum: Following the release of the MMWR, "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water -- District of Columbia, 2004", some reports have suggested erroneously that the Centers for Disease Control and Prevention has determined that lead in residential tap water at concentrations as high as 300 parts per billion is 'safe'. CDC would like to reiterate the key message from the 2004 article that because no threshold for adverse health effects in young children has been demonstrated (no safe blood level has been identified), all sources of lead exposure for children should be controlled or eliminated. Lead concentrations in drinking water should be below the U. S. Environmental Protection Agency's action level of 15 parts per billion." The note clarifying the CDC's position on their MMWR article was posted to the CDC web-site on August 17, 2007, available here: http://www.cdc.gov/nceh/lead/tips/water.htm.

Letter from Dr. James W. Stephens to Dr. Marc Edwards, Sept. 18, 2007.

## CDC's Inadequate Review of Dr. Edwards' Allegations

As stated earlier, Dr. Stephens did not conduct a full investigation of the facts underlying Dr. Edwards' allegations. When he wrote his September 2007 letter to Dr. Edwards, Dr. Stephens had not even spoken to Dr. Brown, the primary author of the *MMWR* article. He did not do so until October 2007. During that meeting, Dr. Brown apparently mentioned the "challenges" of relying on public health surveillance data because of missing or incomplete data and the overall problems in obtaining all BLL test data from commercial laboratories in a timely manner. She reiterated the unsubstantiated claim that the Quest lab was to blame for the drop in BLL screening data from 2002 to 2003, and that she was convinced that the CDC was not missing any "elevated" BLL test results. This explanation appeared to have appeased any concerns Dr. Stephens may have had about the integrity of the data underlying the *MMWR*.<sup>203</sup>

Dr. Edwards was not satisfied and sent a follow-up e-mail to Dr. Stephens asking for clarification and then sent a second more detailed letter alleging "Possible Scientific Misconduct by CDC Scientists and Officials." "In this letter," wrote Dr. Edwards, "I allege scientific misconduct by CDC employees, which is something you claim necessary before your office will consider an investigation into this matter."

On October 10, 2007, Dr. Stephens responded in an e-mail: "I was not able to identify any evidence of falsification, fabrication, or plagiarism related to CDC's involvement in the MMWR Dispatch either from the materials you provided or from any internal information," and made it clear that CDC did not believe this issue warranted any further efforts on its part. Once again, he advised Dr. Edwards to go to the District's Office of Inspector General if he still had concerns about the data in the MMWR.<sup>206</sup>

### CDC's New Study on the Impact of Elevated WLLs in D.C.

Dr. Edwards' skepticism about the conclusions of the MMWR also encouraged him to look at the risk assessments that the health department had done of the homes with elevated WLLs and children with elevated BLLs. He found that CDC's and the District's statement that lead paint was the only source of those elevated BLLs was not true. In, 2006, Dr. Edwards told the local public radio station that some of the city's assessments pointed to water as the key source of lead in the home. "The message sent – that very high levels of lead in water did not cause any measurable public harm – is a false message and it has to be retracted," Edwards said. The radio station reviewed department records and confirmed his statement. Four days after that report, CDC announced that it would conduct a new study to determine whether its original finding was correct. Dr. Brown, the primary author of the original study, said she had not known about the home assessments done by the D.C. DOH. "We think everything's safe," she said, but

<sup>&</sup>lt;sup>203</sup> Subcommittee staff interview of Dr. James Stephens, June 30, 2009.

E-mail from Marc Edwards to James Stephens, entitled "Please clarify the meaning of the September 18<sup>th</sup> letter," Sept. 22, 2007. See also, letter from Marc Edwards to James Stephens, Sept. 18, 2007.

Dr. Marc Edwards sent his second letter regarding potential CDC scientific misconduct to Dr. James Stephens on September 18, 2007, with the heading: "Re: Possible Scientific Misconduct by CDC Scientists and Officials."

E-mail from James Stephens to Marc Edwards, entitled "RE: Outcome of the assessment," Oct. 10, 2007.

WAMU 88.5FM, Transcript of "Questions over Harm Caused by Lead in the Water," Sept. 21, 2006, accessed at <a href="http://wamu.org/news/06/09/lead\_questions.php">http://wamu.org/news/06/09/lead\_questions.php</a>

CDC would re-analyze the data and would look at the assessments. That study was supposed to be completed in "several months." 208

Although when CDC published the *MMWR* in 2004, officials stated that it was a "preliminary investigation", and that it was still "ongoing," there was no follow up until Dr. Edwards' radio appearance. Since 2007, Dr. Brown and CDC colleagues had been working on a revised D.C. lead-in-water study based, at least partly, on the same incomplete data used in the March 2004 *MMWR* article. But when the conclusions were released at an American Public Health Association conference in November of 2007 they shattered the finding of the 2004 *MMWR* that the elevated WLLs had no impact on public health. Even when controlling for all the "confounders," such as the age of the housing unit, researcher Jaime Raymond found that "Children who were tested and BLLs  $\geq$ 5  $\mu$ g/dL or  $\geq$ 10  $\mu$ g/dL were significantly more likely to have lived in a HU [Housing Unit] with a LSL [Lead Service Line] compared to children with lower BLLs." In addition, when chloramine was added to the water system as a disinfectant, the CDC found, it may have caused lead service lines to leach lead into the water, contributing to the rise of BLLs in young children. "When chloramine was eliminated as the drinking water disinfectant," Raymond noted, "we saw a dramatic reduction in BLLs in children < 6 years old in Washington DC."  $^{210}$ 

Another key finding of the new study was that the risk of elevated BLLs for children in homes with partial lead line replacements was four times higher than in homes without lead service lines. Despite the significance of these findings both in health and financial terms to the nation's children and the water systems that initially saw partial line replacement as a solution to lead leaching into drinking water, the study has never been published.

In 2004, even before the publication of the *MMWR* article, water experts, including Dr. Marc Edwards, had warned that "partial" lead line replacements would actually increase the water lead levels at least in the short run increasing the potential human health dangers of D.C.'s residents.<sup>212</sup> But in the wake of the D.C. lead-in-water crisis, WASA spent over \$100 million to replace publicly owned lead pipes throughout the city before deciding the program was a waste

<sup>&</sup>lt;sup>208</sup> WAMU 88.5FM, Transcript of "CDC Lead Study," Sept. 25, 2006, accessed at <a href="http://wamu.org/news/06/09/lead\_questions.php">http://wamu.org/news/06/09/lead\_questions.php</a>

<sup>&</sup>lt;sup>209</sup> MMWR Dispatch, supra, p. 1.

<sup>&</sup>quot;Association between lead poisoning among children less than six years old and lead service pipes in Washington DC," Abstract #166176, 135th American Public Health Association (APHA) Annual Meeting, Jaime Raymond, MPH, Chinaro Kennedy, DrPH, MPH, and Mary Jean Brown, ScD, RN, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), Wednesday, November 07, 2007, available here: <a href="http://apha.confex.com/apha/135am/techprogram/paper\_166176.htm">http://apha.confex.com/apha/135am/techprogram/paper\_166176.htm</a>.

Based on his research in 2003, the resulting increase in WLLs caused by chloramines and partial line replacement was identified by Dr. Edwards even before the CDC completed its March 30, 2004 MMWR article. In a Feb. 19, 2004, letter to an expert panel at WASA, Dr. Edwards wrote: "[N]ot does chloramine worsen galvanic corrosion between brass/copper or lead/copper, but it also increases the amount of lead leached to the water when the metals are coupled. . . . replacing a half a lead service with copper is going to dramatically worsen the galvanic corrosion . . . Such partial replacements should be stopped immediately." Dr. Edwards repeated his warning at a Congressional hearing. Testimony of Marc Edwards, "Public Confidence Down the Drain: The Federal Role in Ensuring Safe Drinking Water in the District of Columbia, U.S. House of Representatives, Committee on Government Reform, March 5, 2004.

of money and actually caused a temporary increase in WLLs.<sup>213</sup> Many states, including Michigan, Rhode Island, Wisconsin, New York and Washington have also invested hundreds of millions of dollars in replacing lead service lines.<sup>214</sup> In most cases, however, homeowners responsible for replacing the portion of lead pipe from the street to their home declined to spend the several thousand dollars to do so. By mid-February 2004, for instance, of 526 D.C. residents who had the WASA-owned service lines on their street replaced, only *one* resident chose to pay for the replacement of the line to his home.<sup>215</sup>

In December 2008, the new draft CDC study, co-authored by Raymond, Dr. Brown and other CDC officials was finally submitted for "clearance" at CDC. But the allegations concerning the credibility of the underlying data were raised and have never been resolved. On January 25, 2009 – two days before Dr. Edwards came out with a peer-reviewed article that concluded that very young children in the District were more than four times as likely to have BLLs  $\geq 10~\mu g/dL$  – Dr. Bashor weighed in with his comments. Among his many concerns:

Regarding some big-picture comments based on my reading (NOT clearance review) to date:

- (a) At the center of this paper is the blood lead data from 1998-2006, "...derived from the Washington D.C. Childhood Lead Poisoning Prevention Program...." The strength or weakness of the present draft relies on the accuracy, completeness, and comparability of the blood lead data for each year and across years. The only descriptions I could find regarding the analytical methods and QA/QC methods was a single sentence: "Blood lead tests were analyzed at various laboratories across the United States and were reported as whole numbers to the DC CLPPP." The fact that multiple laboratories over multiple years contribute to the database argues for a more detailed discussion of analytical methods, QA/QC, and implications for the ability to compare with confidence the results from multiple labs across multiple years. The NCEH/DLS could assist in developing this discussion.
- (b) As just noted, the integrity of the blood lead level database is a centerpiece of the entire paper. It appears to be public knowledge (at least reporters' knowledge) that allegations have been made challenging the

E-mail from EPA lead expert Michael Schock to EPA colleague Ronnie Levin and cc'd to nearly three dozen other colleagues including the CDC's Dr. Henry Falk, Subject: "FW: WP 2/11: WASA Avoided Replacing Lead Service Lines," February 18, 2004 7:54 am.

<sup>&</sup>lt;sup>213</sup> Michael Ruane, "WASA Backs off Lead Pipe Program," Washington Post, Sept. 5, 2008.

See: Christian Czerwinski, "Lead line replacement ahead of schedule," Lansing State Journal, May 31, 2006; "Kinetico offers solutions to high lead levels in Ontario water," Canada NewsWire, June 15, 2007; Dean Mosiman, "Mayor: Spend More on Water; Cieslewicz Will Propose a Spending Increase of More Than 50 Percent for Madison Water Utility Infrastructure," The Capital Times & Wisconsin State Journal, August 31, 2006; "Neighbors Syracuse: City to Begin Lead Pipe Replacement in Spring, The Post Standard/Herald-Journal, August 19, 2004; "WASA prioritizing lead line replacement plan," Associated Press, April 15, 2004; "Rhode Island Daybook: Lead Pipe Protest," Associated Press, April 12, 2010; Sanjay Bhatt, "Options presented to clean up water; Estimates vary | Seattle Schools study 3 options to reduce lead," Seattle Times, October 20, 2004.

integrity of this database due to the (alleged?) loss of thousands of data points in a critical year (2003) of this study. ... I am very concerned that we are treating this data as if it were entirely accurate and complete, without having seen anything regarding the District's finding(s) regarding public allegations. Has CDC/NCEH/EEHS/LPPB received assurance(s) regarding the accuracy and completeness of the database? I am especially concerned that we have clarity on this matter, since CDC is using the data, and further, CDC could be perceived as having some responsibility if we fund this data collection program through a Cooperative Agreement (substantial Federal Involvement, by definition).

(c) Given the enormous amount of time that has been consumed addressing controversy regarding the 2004 MMWR paper on this situation, I am surprised that the present draft manuscript—while it cites the subject MMWR—does not include any comparative discussion regarding the findings of that publication, and the present draft manuscript. Is there a reason for this? If not, I think the findings of both should be discussed.<sup>216</sup>

Dr. Bashor returned the paper for revisions. He rejected it a second time on February 27, 2009. But somehow, after the second rejection, the paper went to Dr. Peter Briss, the science officer in the CDC's Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), where Dr. Henry Falk was the director. That was an unusual event. "They had gone over my head and up the chain," said Dr. Bashor in an interview. Asked if that had ever happened before, Bashor said: "I don't think that's *ever* happened, except in this case." <sup>217</sup>

Dr. Tom Sinks, NCEH/ATSDR's deputy director, then spent months revising the paper, and Dr. Briss approved it in CK-May 2009-CK. In fact, because of his substantial involvement in revising the study, Dr. Sinks became a co-author of the new report. But, despite Dr. Bashor's clearly expressed concerns about the use of seriously flawed data in an article to be submitted for peer review, neither Dr. Brown, Dr. Sinks nor any of the other co-authors ever sought to address those criticisms or to obtain the missing blood lead level test data.

The manuscript was sent to the journal *Environmental Health Perspectives* (EHP) last summer which rejected it. It was then submitted to the journal *Environmental Research*, where it underwent peer review. Once again, the issue of the integrity of the underlying data was raised. One reviewer pointed out that the 2003 missing blood lead level data "raises a lot of questions."

First, since the labs are identified did you consider obtaining the unreported data and adding them to the analysis? That would seem

E-mail from Dr. Mark Bashor, Associate Director for Science, NCEH/ATSDR, Centers for Disease Control and Prevention (CDC), to Howard Frumkin, Tom Sinks, James Stephens, Peter Briss, Sharunda Buchanan, Andrew Dannenberg and Mary Jean Brown, "Subject: INITIAL COMMENTS ON BROWN'S DRAFT MS: ASSOICATION BETWEEN CHILDREN'S BLOOD LEAD LEVELS...IN WASHINGTON DC..." Sunday, January 25, 2009, 4:18 pm.

to be the most straightforward way to address the situation. Second, if that is not possible for some reason, it would be preferable for you to provide a quantitative analysis of how the unreported data compare with the results that are reported. Your statement that they were "more likely" to be <10 leaves a lot to be imagined."<sup>218</sup>

A second reviewer identified other problems as well.

There are some biases that are inherent in the analysis, but not identified. For instance, the targeting of children for screening in CLPPPs assumes a principal exposure of dust/paint/soil. The highest risk for elevated exposures due to drinking water is in formula-fed infants. No data for this population were obtained in this study. As such, this analysis likely underestimates the full impact of the elevated lead levels in DC's drinking water. Also, using age of housing to control for lead paint, reduces the significance of the water. <sup>219</sup>

The article has not yet been published.

# 8. Dr. Edwards' Peer-Reviewed Research: Elevated Water Lead Levels Endangered District's Children

At the same time Dr. Bashor was questioning Dr. Brown's reliance on faulty data, Dr. Edwards published a peer-reviewed study in the January 2009 issue of *Environmental Science & Technology* journal that found that in Washington, D.C., the youngest children aged15 months or less were four times more likely to have an elevated BLL from 2001-to-2003 when water lead levels were at their highest compared to 2000 before water lead levels had increased. Along with co-authors Simoni Triantafyllidou and Dr. Dana Best, an epidemiologist and pediatrician at Children's National Medical Center (CNMC) in Washington, D.C., Dr. Edwards had examined 28,000 BLL test results submitted to the D.C. Childhood Lead Poisoning Prevention Program from CNMC between 1997 and 2007. The data showed that hundreds of the youngest D.C. children were exposed to damaging levels of lead in their blood while the District's drinking water supply had high levels of lead – a markedly different conclusion than that of the CDC's 2004 *MMWR* article.

Letter from Ellen Kovner Silbergeld, PhD, Editor-in-Chief, *Environmental Research* to Mary Jean Brown, "Subject: ER-09-0331: Interim Decision," re: Title: Association between Children's Blood Lead Levels, Lead Service Lines, and Chloramines for Water Disinfection, Washington, D.C., 1998-2006, Corresponding Author, Dr. Mary Jean Brown, Authors: Jaime Raymond, MPH; David Homa, PhD, MPH; Chinaro Kennedy, DrPH, MPH; Thomas Sinks, PhD, Aug. 13, 2009.

Marc Edwards, Simoni Triantafyllidou, and Dana Best, "Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," *Environmental Science & Technology*, published by the American Chemical Society, March 1 2009, pp. 1618-1623; published on-line on January 27, 2009, available here: <a href="http://pubs.acs.org/doi/abs/10.1021/es802789w">http://pubs.acs.org/doi/abs/10.1021/es802789w</a>.

Dr. Edwards had obtained a copy, via a FOIA request, of the nearly 85,000 blood lead test results reported to the D.C. lead program from 1998 to 2003 from all laboratories, including CNMC, that were used in the 2004 MMWR article's analysis of historical blood lead tests in Washington, D.C. But when the authors of the Edwards paper tried to compare the CDC records to the CNMC records they found an error rate of more than 50 percent, in five separate domains, including sample data, blood lead level and subject's age. "Because repeated attempts to resolve this and other discrepancies in the CDC data were not successful," the authors wrote, "only the CNMC data were used for analyses and conclusions in this work." 221

In addition, according to the records in the CNMC database, Children's National Medical Center reported 80 elevated blood lead level test results to D.C. in the second half of 2003. However, when Edwards compared this data to the database of BLL tests that CDC used in the *MMWR* study it showed that the database had only 23 elevated BLL test results from D.C. for that same period [CK]. In 2003, CNMC was one of seven labs reporting BLL tests to the D.C. Department of Health. So, the information D.C. reported to CDC should have been a compilation of all of the BLL tests reported to D.C. from all of these labs. Yet, the CDC database contained fewer tests than the CNMC alone. <sup>222</sup> [CK]

The Edwards article sparked widespread media coverage and a hearing by the Council of the District of Columbia. The CDC's response to Dr. Edwards' award-winning research, however, was to downplay the significance of any findings that could be seen as contradicting the basic conclusions from the 2004 *MMWR* article that no one had suffered undue harm from the D.C. lead-in-water crisis. In a follow-up article in *The Washington Post*, Dr. Frumkin – contrary to other lead experts – even implied that the reduction in the IQ of children exposed to elevated water lead levels in D.C. was not a cause for concern. "At these levels, the effects are subtle," said Frumkin. "They are detectable in population studies but generally not in individual

<sup>&</sup>lt;sup>221</sup> Edwards, Triantafyllidou and Best, *supra*, p. 1620. The CDC also provided the Subcommittee with a copy of the underlying raw data of those 85,000 blood lead tests. As Dr. Edwards pointed out, the data includes 9,766 blood test results for 2003, but the vast majority contained no indication of the age of those being tested. Of the 9,766 test results, 8,939 listed the age as zero months. This is indicative of other problems in the underlying data from the DC lead program and CDC.

In an interview with Subcommittee staff in September 2009, Pierre Erville, Associate Director for Lead and Healthy Housing in the DC Department of the Environment which now overseas the District's lead program, said that after the Edwards article came out in January 2009 the District went back to Children's National Medical Center and obtained a copy of the data they used for the Edwards study. Erville admitted that the data contained records that were not available in the District's own blood lead database, but should have been. Eight months after the Edwards paper was published, Erville said DC was still analyzing the CNMC data to see how many records may be missing from the District's blood lead database. 222

See, e.g., Carol Leonnig, "High Lead Levels Found in D.C. Kids," Washington Post, A1; "Lead Probe Sought in D.C.," Washington Post, B1. Dr. Edwards' work was subsequently cited as the best paper of 2009 in the science category by the journal, and he was given the Praxis award for professional ethics by Villanova University in April of 2010 "because of his exemplary dedication to the ethical ideals of his profession as an engineer," said Mark Doorley, director of Villanova's Ethics Program. "Out of a concern for the public welfare, a central value of the engineering profession, Professor Edwards pursued what he thought was a highly dangerous claim about lead in the water of Washington, D.C." Villanova press release, "Dr. Marc Edwards will receive Villanova's 2010 Praxis Award in Professional Ethics," Sept. 28, 2009, accessed at: <a href="http://www.villanova.edu/artsci/ethics/praxisaward/release.htm">http://www.villanova.edu/artsci/ethics/praxisaward/release.htm</a>

children," he said.<sup>224</sup> Once again, the message from the CDC was that there was no reason for D.C. parents to worry. The message was repeated – once again – by WASA officials. In a D.C. Council meeting, WASA General Manager Jerry Johnson said he would allow a child to drink the water, stating that he relied on CDC for information that residents' health had not been harmed. "I'm not a physician; I'm not an epidemiologist. We had to rely on outside services," he said.<sup>225</sup>

Internally the CDC spent significant time and energy strategizing about how to respond to the Edwards paper. Dr. Frumkin proposed a letter to the *The Washington Post*. His draft letter mentioned the new study on the D.C. lead-in-water crisis that Dr. Brown had been working on since 2007. But Glen Nowak, CDC's director of media relations, sent an e-mail to several CDC officials, questioning how CDC could claim to promise the study would provide "critical information the city can use to help vulnerable children," but not release it until later in the year. <sup>226</sup>

Those were reasonable questions that never received clear answers. In the end, officials at the Department of Health and Human Services Department officials (HHS) killed Dr. Frumkin's proposed letter about the new study. The CDC had informed EPA officials about the preliminary conclusions in 2007. But the citizens of the District – those that would benefit most from the CDC's new findings – have never been told of the results of this study. There was no new *MMWR Dispatch* to inform public health officials worldwide that, even when adjusted for the age of the housing unit, children whose water came from lead service lines had a significantly more likely to have an elevated BLL. There was no new *MMWR Dispatch* warning cities that partial lead line replacements or the addition of chloramine would cause a spike in children's BLLs.

In September 2009, after WASA had halted its partial lead line replacement program, Dr. Brown finally informed WASA that CDC's study indicated "that the risk of elevated blood lead levels  $\geq 10$  ug/dL in homes with partial replacements of lead service lines is about 4 times that of the risk for blood lead elevations in homes without lead service lines. We also noted an increase in risk for elevated blood lead levels when homes with partial replacement were compared to homes with full replacement of lead service lines."

In January 2010, a full year after the CDC's Nowak questioned the rationale for sitting on presumably critically important public health information, Dr. Frumkin finally posted a two-paragraph update for lead program managers on the CDC web-site regarding some of the results

E-mail from Glen Nowak (CDC/OD/OEC) to Dr. Mary Jean Brown, Dr. Howard Frumkin, Dr. Tom Sinks, and others on January 28, 2009 12:14 pm.

Letter from Mary Jean Brown to Avis Russell, Interim General Manager, DC WASA, cc'd to District Department of Environment and Environmental Protection Agency's Office of Water, Sept. 4, 2009.

David Brown, "Study Can't Pinpoint Extent of Lead Exposure," *The Washington Post*, January 31, 2009, B1, available here: <a href="http://www.washingtonpost.com/wp-dyn/content/article/2009/01/30/AR2009013003666.html">http://www.washingtonpost.com/wp-dyn/content/article/2009/01/30/AR2009013003666.html</a>.

Post, Feb. 11, 2009, B4.

others on January 28, 2009 12:14 pm.

227 See: E-mail from Edward V. Ohanian, Ph.D., Director, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Environmental Protection Agency to Mary Jean Brown, "Subject: Re: CDC Draft Letter to WASA," August 17, 2009. In the e-mail Ohanian wrote: "Mary Jean: We appreciate the CDC's urgency in providing information to local officials regarding the findings of the draft study currently undergoing peer review. ... We first discussed this study with you in a meeting on December 14, 2007, and our health scientists reviewed a draft of this report in February, 2009."

of Dr. Brown's new paper. "I wanted to bring the preliminary results [of this study] to your attention as they underscore the need to provide health education materials to families that include advice for lead safe water practices following plumbing work in housing with lead water lines or lead solder."<sup>229</sup>

Meanwhile, District of Columbia officials were again quick to rely on the misleading statements made by senior CDC officials about the potential human health dangers of lead in drinking water. On February 10, 2009, in the wake of the release of Dr. Edwards' paper, George Hawkins, then the District Department of Environment director, told a D.C. City Council public hearing on water quality issues that his office was aware of the Edwards' study and had asked CDC to analyze it for them. In the meantime, Hawkins said, he had relied on the "initial analysis" from "experts such as Dr. Howard Frumkin" and quoted Frumkin's remarks to *The Washington Post* that the effects of lead exposure to children was "subtle" and not detectable "in individual children." The take home message nearly five years after the CDC's publication of the *MMWR* was still the same. The lead-in-water crisis in D.C. did not result in any measurable public harm to the Capitol's children.

In April 2009, Rebecca Renner published a story about the CDC's *MMWR* article and the flawed data they relied upon for that study in an article on Salon.com, based partly on her interview with Dr. Frumkin the previous summer. The article focused on the thousands of "missing" blood lead level test results for D.C. children not reported to CDC in 2003. It raised questions regarding why the CDC's 2004 *MMWR* drew such a different conclusion about the public health impact of elevated lead levels in water in D.C. than Marc Edwards' January 2009 paper or the 2007 presentation by the CDC's own Jaime Raymond at the American Public Health Association. "This is a disaster of accountability from the CDC's point of view," John Rosen, a pediatrician and national expert on lead poisoning at Montefiore Medical Center in New York City told Renner. "This raises troubling questions about CDC's complicity in passing on dubious data," Rosen said.<sup>231</sup>

Rather than spending their time, effort and energy trying to finally investigate the cause of the 2003 blood lead level "data gap," the CDC issued a lengthy media statement responding to the Salon.com article defending the scientific merits of the *MMWR* article. "Now, as in 2004, CDC continues to stand by its *MMWR* statement, that, "Because no threshold for adverse health effects in young children has been documented, public health interventions should focus on eliminating all lead exposures in children," the CDC said. Regarding the "missing data," the CDC stuck to the same factually inaccurate claim they had been espousing for half-a-decade regarding the 2003 gap

<sup>&</sup>quot;Important update: lead-based water lines," Howard Frumkin, M.D., Dr.P.H., Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, posted on-line January 2010, available here: <a href="http://www.cdc.gov/nceh/lead/waterlines.htm">http://www.cdc.gov/nceh/lead/waterlines.htm</a>.

Statement by George S. Hawkins, Esq., Director, District Department of Environment, Washington, D.C, Joint Public Hearing on Water Quality in the District of Columbia, Committee on Government Operations and the Environment and Committee on Public Works and Transportation, February 10, 2009, available here:

<a href="http://www.ddoe.dc.gov/ddoe/cwp/view,a,1209,q,499285.asp">http://www.ddoe.dc.gov/ddoe/cwp/view,a,1209,q,499285.asp</a>

Rebecca Renner, "Health agency covered up lead harm: The Centers for Disease Control and Prevention withheld evidence that contaminated tap water caused lead poisoning in kids," Salon.com, April 10, 2009, available here: <a href="http://www.salon.com/env/feature/2009/04/10/cdc">http://www.salon.com/env/feature/2009/04/10/cdc</a> lead report/

in blood lead level reporting data from the District's Childhood Lead Poisoning Prevention Program.

In 2004, a participating commercial laboratory stopped reporting test results that fell below the CDC level of concern of 10 ug/dL. CDC believes this failure of reporting accounts for the missing data because the laboratory continued to report BLLs greater than 10 ug/dL. To the extent "missing" data would have affected overall results, it would have exaggerated the apparent problem, not masked it.<sup>232</sup>

The CDC statement also misconstrued its own "investigation" into Dr. Edwards' scientific misconduct complaint and said the CDC "thoroughly investigated this complaint and found no evidence of scientific misconduct." In fact, CDC had never actually "investigated" Dr. Edwards' allegations. Instead they decided the allegations were not aimed at CDC officials and pointed Dr. Edwards towards the D.C. government.

#### 9. Conclusion

The leaders of CDC's lead program never questioned their fundamental assumptions about the D.C. lead-in-water issue. Rather than attempting to unearth the root scientific explanations for the surprising findings of the 2004 *MMWR* article, or conceding that they may have overlooked, underemphasized or dismissed critical problems in the D.C. lead program their agency continued to fund, the CDC simply refused to acknowledge anything in either the D.C. lead program or their own analysis of the D.C. lead-in-water crisis could potentially be amiss.

The flawed foundation upon which the CDC's *MMWR* article has stood for more than six years has undermined public health efforts to fully and completely investigate lead-in-water issues as a potential public health hazard around the nation. The leadership of CDC's Childhood Lead Poisoning Prevention Program made scientifically unsound assumptions about the data they were analyzing, ignored critically important issues and simply discounted others.

None of the long standing and substantial problems in the D.C. lead program should exonerate the CDC or CDC officials involved in the publication of the *MMWR* lead-in-water article. In fact, given the extent of the problems in the D.C. lead program it is simply astounding that these issues did not receive adequate attention from CDC lead program officials who had been providing the D.C. CLPPP office with millions of dollars in lead grants. The CDC appears to have been blinded to the problems that were brewing in the D.C. lead program. They also failed to take adequate action to either investigate or rectify any of the problems they did become aware of in the D.C. CLPPP. Their lack of action and dismissal of known problems dramatically undercut the scientific integrity of the *MMWR* article on potential human health effects of lead-in-water in Washington, D.C.

<sup>&</sup>lt;sup>232</sup> "CDC Responds to Salon.com Article," Media Statement, Office of Enterprise Communication, Centers for Disease Control and Prevention, April 10, 2009, available here: <a href="http://www.cdc.gov/media/pressrel/2009/s090410.htm">http://www.cdc.gov/media/pressrel/2009/s090410.htm</a>.

The Subcommittee's investigation into the D.C. lead-in-water issues makes it clear that both the 300 ppb cross sectional study and the D.C. lead program's 2002-2003 blood lead test data provided to CDC and used as a foundation for the *MMWR* article were incomplete and untrustworthy. As a result, the full extent and impact this public health crisis had on the city's residents has remained unclear. What is clear is that the public health information the CDC provided in the *MMWR* article, while reassuring, was based upon fundamentally flawed and incomplete data. Rather than immediately and aggressively attempting to address the known questions surrounding the 2003 blood lead level "data gap" and the allegations of forgery, CDC officials cloaked the *MMWR*'s fundamental data integrity failings and the obvious management short-comings in the D.C. Childhood Lead Poisoning Prevention Program from a rigorous, immediate and comprehensive examination.

The nation and the world have relied upon the Centers for Disease Control and Prevention to provide unvarnished scientific facts and forthright analysis regarding critical public health related issues for decades. The imprimatur of the CDC on the MMWR's D.C. lead-in-water article had an impact on local and state public health officials who were investigating lead-in-water health issues of their own. They viewed it as scientifically sound and the public health conclusions it offered as being reliable and responsible. But the main public health messages conveyed to the public in the MMWR article resulted in underestimating the potential public health dangers of lead exposures in drinking water. The faulty assumptions and flawed data used in that article have had a long-lasting and wide-spread impact on objectively, thoroughly and properly confronting the lead-in-water issue in D.C. and in other cities around the country.