

***The Agency for Toxic Substances and Disease Registry (ATSDR):
Problems in the Past,
Potential for the Future?***

**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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Introduction

Last April the Subcommittee on Investigations and Oversight held a hearing on the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of the Centers for Disease Control and Prevention (CDC). The hearing looked at how the agency produced a scientifically flawed and misleading health consultation on the health hazards of potential formaldehyde exposures by survivors of Hurricanes Katrina and Rita living in travel trailers provided by the Federal Emergency Management Agency (FEMA).¹ Last September the Subcommittee issued a detailed staff report on our investigation which found that: “The leadership of ATSDR obfuscated their role in reviewing and approving the February 2007 health consultation and attempted to abdicate their own responsibility for the agency’s fundamental failure to protect the public’s health. Most disturbingly, as the agency’s troubled response to the formaldehyde fiasco unraveled, the leadership of ATSDR attempted to shift blame for the inappropriate handling of the incident to others, primarily [whistleblower Dr. Chris] De Rosa and his staff.”² Unfortunately, the poor scientific integrity of ATSDR’s formaldehyde health consultation and the weak leadership at the agency that permitted the production of this misleading report which went uncorrected for so long – keeping the public in harm’s way for a year longer than necessary – was not an isolated incident.

The agency’s mission “is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances.”³ On paper, according to ATSDR, the agency is deeply involved with the local communities it is intended to help protect, it makes independent, objective health decisions based on the best science available, it conducts exposure investigations to assess health impacts of environmental toxins and it provides and explains the results of their evaluations, medical consultations and investigations to local communities and tribes.⁴ In reality, across the nation local community groups believe that ATSDR has failed to protect them from toxic exposures and independent scientists are often aghast at the lack of scientific rigor in its health consultations and assessments. The studies lack the ability to properly attribute illness to toxic exposures and the methodologies used by the agency to identify suspected environmental exposures to hazardous chemicals are doomed from the start.

¹ “Toxic Trailers: Have the Centers for Disease Control Failed to Protect Public Health?,” Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, April 1, 2008, available here:

http://science.house.gov/publications/hearings_markup_details.aspx?NewsID=2133.

² “Toxic Trailers - Toxic Lethargy: How the Centers for Disease Control and Prevention Has Failed to Protect the Public Health,” Majority Staff Report, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, September 2008, available here: http://democrats.science.house.gov/Media/File/CommDocs/ATSDR_Staff_Report_9.22.08.pdf.

³ “Statement of Mission,” Agency for Toxic Substances and Disease Registry, undated, available here: <http://www.atsdr.cdc.gov/about/mission.html>.

⁴ “What You Can Expect From ATSDR,” Agency for Toxic Substances and Disease Registry, May 2002, available here: <http://www.atsdr.cdc.gov/COM/expect.pdf>.

The Subcommittee staff is not suggesting that ATSDR find problems where none exist or that ATSDR should or can identify the sources of a possible cancer cluster, disease or other health hazard in every instance or where the potential source of toxic exposures are ambiguous or elusive. Yet time and time again ATSDR appears to avoid clearly and directly confronting the most obvious toxic culprits that harm the health of local communities throughout the nation. Instead, they deny, delay, minimize, trivialize or ignore legitimate concerns and health considerations of local communities and well respected scientists and medical professionals.

Many independent scientists, medical professionals, local environmental groups and public health advocates believe that rather than objectively and aggressively trying to identify the source of reported health problems, ATSDR often seeks ways to avoid linking local health problems to specific sources of hazardous chemicals. Instead, says one current ATSDR scientist who spoke to the Committee on the condition of anonymity: “It seems like the goal is to disprove the communities’ concerns rather than actually trying to prove exposures.” None of these problems are new to ATSDR but it will require a new will and desire to fix them on the part of ATSDR’s leadership.

Background

In 1980 Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) through the enactment of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (Public Law 96-510) commonly referred to as “Superfund.” CERCLA authorized the Environmental Protection Agency (EPA) to clean up nationally identified toxic waste (Superfund) sites and Section 104(i) required the Department of Health and Human Services’ (HHS) Public Health Service to establish a new agency to carry out health-related activities at these waste sites.⁵ Thus, ATSDR was created to help determine the potential human health consequences of releases of toxic chemicals at these sites.

Although ATSDR was created with the best of intentions, it had an extremely difficult birth and has struggled ever since. The EPA and HHS provided it with little support and at times tried to subvert it. It took three years after enactment of the law that authorized the creation of ATSDR for the agency to actually emerge. By June 1983 the HHS’ Public Health Service “had developed few detailed procedures concerning the new agency and how the Superfund responsibilities would be carried out,” according to a report from Congress’s investigative arm, the U.S. General Accounting Office (GAO).⁶ “HHS objected to establishing a separate agency to carry out its Superfund responsibilities, contending it was not necessary.”⁷ In fact, HHS never wanted ATSDR

⁵ “Interim Report on Establishment of the Agency for Toxic Substances and Disease Registry and the Adequacy of Superfund Staff Resources,” U.S. General Accounting Office, GAO/HRD-83-81, August 10, 1983, p. 1, available here: <http://archive.gao.gov/f0302/122111.pdf>.

⁶ *Ibid*, p. 3, available here: <http://archive.gao.gov/f0302/122111.pdf>. The name of the General Accounting Office was changed in 2004 to the Government Accountability Office (GAO).

⁷ *Ibid*, p. 2, available here: <http://archive.gao.gov/f0302/122111.pdf>.

to have its own staff and tried to reign in the new agency's independence by detailing CDC staff to ATSDR and forcing it to use CDC's administrative and support structure.⁸

In addition, because the Office of Management and Budget (OMB) reduced the number of HHS requested staffing positions in 1984 to ATSDR, CDC officials told GAO's investigators that because of limited staff "they expected to eliminate virtually all [of ATSDR's planned] long-term health studies, [health] registries, and laboratory projects."⁹ During this same time-frame both EPA and OMB consistently reduced ATSDR's annual budget.¹⁰ Three years after ATSDR was physically established, a new law was passed, the Superfund Amendments and Reauthorization Act of 1986 (SARA) that set an arbitrary deadline of December 1988 for the agency to conduct health assessments at 951 Superfund sites. The law was necessary at the time, many believed, because ATSDR had made zero headway in accomplishing these tasks. As a result of the new law ATSDR developed "initial mandate assessments" at 950 sites within a little over two years. The agency achieved a quantitative victory in producing so many assessments in so little time.

But Congress's desire to force the new understaffed agency to become more effective, efficient and responsive to fulfilling its initial mandate had unintended qualitative consequences. In order to prepare health assessments on 951 Superfund sites within this time period ATSDR wrote 785 assessments in 15 months and "labeled 165 previously prepared documents in its files as health assessments" even though some were several years old, according to GAO. To accomplish this massive effort, ATSDR ignored "its own guidance requiring visits to sites" and instead conducted "desk" assessments, GAO found. The agency, for instance, labeled previously produced documents not intended to be full health assessments as "assessments." "In the rush to complete these assessments, ATSDR dropped plans to do full internal quality checks on its assessments, and no review was made by outside experts," according to GAO.¹¹

When GAO reviewed the quality and usefulness of ATSDR's health assessments in 1991 they hired five independent experts to evaluate 15 of the agency's assessments. What they found was that the initial mandate assessments "were seriously deficient overall." Although follow up assessments were improved over the earlier assessments GAO's expert reviewers "continued to find deficiencies in evidence or analysis, such as unsupported conclusions."

GAO concluded that ATSDR needed to improve its quality controls and to establish "some independent peer review." It found that ATSDR should involve local communities more in developing assessments. The GAO panel also found the reports it reviewed contained "(1) inadequate descriptions or analyses of health risks, (2) failures to

⁸ *Ibid*, p. 3, available here: <http://archive.gao.gov/f0302/122111.pdf>.

⁹ *Ibid*, p. 7, available here: <http://archive.gao.gov/f0302/122111.pdf>.

¹⁰ "SUPERFUND: Funding for the Agency for Toxic Substances and Disease Registry," U.S. General Accounting Office, GAO/RCED-87-112BR, March 1987, p. 2. available here: <http://archive.gao.gov/t2pbat22/132595.pdf>.

¹¹ "Superfund: Public Health Assessments Incomplete and of Questionable Value," General Accounting Office, RCED-91-178, August 1, 1991, p. 13, available here: <http://archive.gao.gov/t2pbat7/144755.pdf>.

indicate whether communities had been exposed to contaminants, (3) overly general recommendations, and (4) inattention to the sufficiency of data.”¹² One of the GAO panel members said that “regardless of the wide diversity of sites that we studied [the assessments] come up with the same conclusion: that there is a potential problem.” Incredibly out of the 951 initial assessments ATSDR conducted it found just 13 sites as posing a “significant health risk.”¹³

In the rush to push out nearly 1,000 health assessments in two years time the agency developed a check-box mentality that helped to undermine virtually everything the agency did. Quality became an after-thought to the ability to produce public health documents quickly. The integrity of the data, assessment of the public health risks and credibility of the conclusions all suffered deeply as a result.

Unfortunately, the past problems identified by GAO have not disappeared. Reviews of the FEMA trailer health consultation on formaldehyde, as well as other health reports from ATSDR, appears to suggest the agency has never recovered from the initial problems that overshadowed its birth. Internally, many ATSDR employees have told the Subcommittee over the past year that the agency lacks appropriate quality controls, it conducts inadequate analyses of health risks to local communities and they often do not collect and analyze the most relevant and revealing data about potential environmental health hazards. Externally, the local communities that ATSDR was created to help protect often believe the agency does more harm than good by offering them reassuring but unfounded and unsound advice and analysis which simply creates an artificial perception of safety to the public that is not supported by scientific inquiry or independent examination.

Investigating environmental public health issues is a difficult and daunting task. Local communities *expect* state or federal public health agencies to identify the cause of their specific health concerns, provide medical or other support and eradicate the environmental hazard. In some cases it is exceedingly difficult to establish a definitive link between specific toxic exposures and health problems. In other cases it may be difficult to quantify an actual health problem and in some instances the scientific evidence may not identify *any* problem let alone the specific *cause* of a health problem. But in many, many cases ATSDR seems to get the science wrong, ignores community complaints or both.

Midlothian, Texas – Cement Kilns

Mr. Sal Mier is a local resident of Midlothian, Texas and former official at the Centers for Disease Control and Prevention (CDC). Midlothian is known as the cement capital of the world and is home to three cement plants and one steel mill. These plants have released nearly one billion pounds of toxic chemicals into the local environment since 1990. The Texas Commission on Environmental Quality (TCEQ) began environmental monitoring in Midlothian in 1991. In June 2005, the Texas Department of

¹² *Ibid*, p. 18, available here: <http://archive.gao.gov/t2pbat7/144755.pdf>.

¹³ *Ibid*, p. 28, available here: <http://archive.gao.gov/t2pbat7/144755.pdf>.

State Health Services (DSHS) completed a review of the Texas Birth Defects registry and found that one type of birth defect related to urinary tract development (hypospadias or epispadias) was statistically elevated. The previous month DSHS completed a cancer cluster investigation that found no elevation in cancers when it examined residents in three zip codes in Midlothian and two other towns.¹⁴ But by expanding the pool of individuals in this investigation to those outside of Midlothian, critics say the study diminished the ability to specifically identify increased rates of cancers among Midlothian residents.

In 2005, Mr. Mier petitioned ATSDR to look into health issues in Midlothian. In August 2005, ATSDR agreed to conduct a health assessment on the potential health effects of toxic substances released from Midlothian's cement kilns. Under a cooperative agreement with ATSDR, DSHS would conduct the health investigation along with some support, review and final concurrence by ATSDR. In December 2005, DSHS said that the health consultation would be completed and reviewed by ATSDR and released for public comment by "the first part of February 2006."¹⁵ In February 2006 the document's release date was pushed back to March 2006 "due to the large volume of information to be reviewed."¹⁶

In December 2007, 27 months after ATSDR began their investigation, the agency finally released a "draft" health consultation for "public comment." The report found that for the vast majority of chemicals they examined there was no public health hazard. They concluded, for instance, that there was "no evidence to suggest that adverse health effects would be anticipated as a result of any of the short-term or peak exposures to VOCs [Volatile Organic Compounds] or Metals" being emitted from the plants in Midlothian. The agency's overall conclusion was that the air in Midlothian posed an "Indeterminate Public Health Hazard."¹⁷ A "final" version of that study is planned to be released in the next couple of months – more than three and one half years after the investigation began.

Mr. Mier received comments on this document from several independent scientists who concluded it was deeply flawed. Dr. Stuart Batterman, Associate Chairman of the Department of Environmental Health Sciences, School of Public Health at the University of Michigan, wrote: "The Health Consultation is biased. It contains overarching statements that discount all indications that emissions from local industry and environmental conditions might or do pose a health concern in the community." Dr. Peter L. deFur, a Research Associate Professor in the Center for Environmental Studies at Virginia Commonwealth University agreed.

¹⁴ "Birth Defects Monitoring 2005 Report Summary," Texas Department of State Health Services and "Cancer Registry 2005 Report Summary," Texas Department of State Health Services both available here: <http://www.dshs.state.tx.us/epitox/midlothian/reports.shtml>.

¹⁵ "Midlothian Petition Community Site Update, Texas Department of State Health Services, December 2005, available here: http://www.dshs.state.tx.us/epitox/midlothian/december_update.pdf.

¹⁶ "Midlothian Petition Community Site Update, Texas Department of State Health Services, February 2006, available here: <http://www.dshs.state.tx.us/epitox/midlothian/update206.pdf>.

¹⁷ "Health Consultation: Public Comment Release, Midlothian Area Air Quality Part 1: Volatile Organic Compounds & Metals, Midlothian, Ellis County, Texas, December 11, 2007, available here: <http://www.dshs.state.tx.us/epitox/midlothian/updates.shtm>.

“Throughout the document, ATSDR attempts to marginalize or disregard data that indicate that compounds produce human health risks. ATSDR has more than enough data to classify the site as a “Public Health Hazard.” For the past fifteen months ATSDR has been reviewing these and many other public comments they received on their draft health consultation and intend to release the final version of their report in the next couple of months.

It is clear that the release of toxic material from the three cement plants and steel mill in Midlothian has been enormous over the years. Using state and federal records from the Environmental Protection Agency’s (EPA) Toxics Release Inventory (TRI) and TCEQ’s Emission Inventory two graduate students at the University of North Texas, Amanda Caldwell and Susan Waskey, conducted a study of the local emissions from Midlothian for the local environmental non-profit group Downwinders At Risk. The study found that between 1990 and 2006 these four industrial plants released more than **one billion pounds** of toxic emissions to the environment. The emissions were a brew of toxic substances, including millions of pounds of manganese, lead and sulfuric acid, as well as hundreds of thousands of pounds of trichloroethylene, zinc compounds, mercury, benzene, hydrochloric acid, formaldehyde, toluene and other hazardous chemicals.¹⁸ Tying down specific health effects to individual industrial plants in Midlothian would be a difficult undertaking. But Midlothian residents are frustrated that ATSDR has ignored critical signs of potential health problems in the community and has essentially given the community a clean bill of health despite many indications that the community may be suffering from health problems due to exposures to industrial pollutants.

Sue Pope, a Midlothian resident and one of the creators of Downwinders At Risk, had hair samples of 55 people living in or near Midlothian, many of them infants and young children, analyzed for toxic substances between 1988 and 1993. What the tests revealed was that many of the residents had high levels of aluminum, lead, cadmium and nickel. She turned over copies of these documents to Texas state authorities who were investigating health issues in Midlothian, but she says nothing ever came of it.

Other residents and independent scientists have chronicled health problems in Midlothian too. In 1998, scientists led by Dr. Marvin Legator at the University of Texas Medical Branch, Division of Environmental Toxicology published a peer-reviewed paper in the journal *Toxicology and Industrial Health* titled: “The Health Effects of Living Near Cement Kilns; A Symptom Survey in Midlothian, Texas.” The study found that respiratory illnesses in Midlothian were three times more common than in neighboring Waxahatchie.¹⁹

Two years earlier, Legator published an editorial in the *Archives of Environmental Health*, titled: “A Deliberate Smokescreen,” which criticized the scientific integrity of ATSDR’s studies and the methods ATSDR uses in an attempt to investigate potential environmental exposures. In the article Legator and a colleague recommended “that

¹⁸ Amanda Caldwell and Susan Waskey, “Midlothian Industrial Plant: Emission Data,” Geography Special Problems, University of North Texas, July 25, 2008.

¹⁹ Marvin Legator, et al., “The Health Effects of Living Near Cement Kilns; A Symptom Survey in Midlothian, Texas,” *Toxicology and Industrial Health*, Vol. 14, No. 6, 1998.

careful evaluation be made of a significant number of ATSDR or ATSDR-sponsored studies to determine how well the victims of chemical exposure and our taxpayers have been served by this agency.”²⁰

Last December *USA Today* ran an in-depth special report titled “The Smokestack Effect: Toxic Air and America’s Schools,” that used the same EPA data as the report on Midlothian’s toxic emissions by Caldwell and Waskey to track the path of industrial pollution and then mapped the locations of almost 128,000 schools to determine the levels of toxic chemicals in their path. The *USA Today* report’s interactive map of the United States shows that of the nine schools located in Midlothian, Texas, two of them were ranked in the 1st percentile of the schools exposed to the most toxic chemicals in the nation, three of the schools were ranked in the 3rd percentile and each of the others were ranked in the 6th, 14th, 21st and 32nd percentiles. According to the *USA Today* report only 174 of the nation’s 127,809 schools they ranked had worse toxic air exposures than the Mt. Peak Elementary School in Midlothian, for instance.²¹

Anecdotally, many Midlothian children apparently have severe cases of asthma, cancer cases are wide-ranging among the population and there has been a history of poor health problems among cattle, horses and other animals in the area. Debra Markwardt, a local Midlothian dog breeder, recently suggested to ATSDR’s director, Dr. Howard Frumkin, that his agency examine her dogs as an indicator of what is happening to the human population in Midlothian. Markwardt moved to Midlothian in 1988. Her dogs soon started experiencing a wide-range of disturbing health problems. The photos of her dogs are troubling. Some were born with missing limbs, many had skin problems, and others were born with organs outside of their bodies and entire litters died shortly after birth. Most surprisingly, dogs that were sold and moved off of her property with severe skin problems began to regain their health within months but those that stayed continued to suffer from ill-health effects. (*See photos of Markwardt’s dogs in attachment*).

Recently, Markwardt had herself and some of her dogs tested for heavy metals. Over the past few years, veterinarians have found high levels of aluminum in her animals, she says. In May 2007, Ms. Markwardt’s own doctor wrote: “She has lived in a home that has very high levels of aluminum in the soil and in the dust that is found in the home. She has had a urinalysis that shows her aluminum level to be markedly elevated and it should be zero,” wrote her doctor. Last July, her veterinarian wrote: “It is my opinion that these dogs need to be moved off of the property. Since nothing medical has helped, it is highly probable that this is an environmental problem.”

On December 19, 2008, Dr. William Cibulas, the Director of ATSDR’s Division of Health Assessment & Consultation (DHAC) wrote to Ms. Markwardt on behalf of Dr. Frumkin. “ATSDR is sympathetic toward the plight of your animals, however,

²⁰ Marvin S. Legator and Amanda M. Howells-Daniel, “A Deliberate Smokescreen,” Archives of Environmental Health, Vol. 49 (No. 3), May/June 1994.

²¹ USA Today Special Report, “The Smokestack Effect: Toxic Air and America’s Schools,” December 8, 2008, <http://content.usatoday.com/news/nation/environment/smokestack/index?loc=interstitialskip>.

veterinary and animal issues are outside of our mandated domain,” he wrote. Clearly frustrated by this response Ms. Markwardt exchanged some more e-mails with ATSDR.

On January 22, 2009, Markwardt wrote back to ATSDR and copied Dr. Frumkin on the e-mail. “Please do not tell me again that veterinary and animal issues are outside of [your] mandated domain. You know full well (or should) that the potential impact on people is the issue that I raised,” wrote Markwardt. “All that we have asked you to do is to provide trusted health information. Do you feel that an honest conclusion in the Midlothian Public Health Consultation can be reached by pretending what is happening to these animals is not happening; therefore, it cannot be an indicator of what is happening to human health?”

The next day, on January 23, 2009, a technical officer in DHAC, Alan Yarbrough, responded. “Again, ATSDR is sympathetic to the plight of your animals,” he wrote, “but studies involving animals, even as sentinels for human health issues, are not activities engaged in or funded by our agency.”

In 1991, however, the National Academies of Sciences’ Committee on Animals as Monitors of Environmental Hazards was *charged by ATSDR* “to review and evaluate the usefulness of animal epidemiologic studies for human risk assessment and to recommend types of data that should be collected to perform risk assessments for human populations.” In their final 176-page report for ATSDR, the academy wrote that animals can be “used to monitor concentrations of pollutants” and “can yield a better evaluation of hazard to humans” than “mechanical devices can.” In fact, the academy concluded: “An investigator planning an environmental assessment should always consider using an animal sentinel system, when it is practicable, as an adjunct to conventional assessment procedures. Animal sentinel data are likely to be especially useful in circumstances where the conventional procedures are most prone to uncertainty, including assessing accumulated chemicals, complex mixtures, complex exposures, uncertain bioavailability, and poorly characterized agents.”²²

Since then ATSDR has published numerous health consultations involving animals. In April 2003 under a cooperative agreement with the California Department of Health Services, ATSDR released a health consultation regarding contamination in the private water wells of residents near the Pacific Gas and Electric Facility in Hinkley, California, made famous by environmental investigator and activist Erin Brockovich. In that instance, the health consultation did examine the potential health impact on horses, cows, dogs and cats from the exposures to Nitrate, Lead, Thallium and Chromium.²³ In

²² “Animals as Sentinels of Environmental Health Hazards,” Committee on Animals as Monitors of Environmental Hazards, National Research Council, National Academy Press, Washington, D.C., 1991, available here: http://www.nap.edu/catalog.php?record_id=1351.

²³ “HEALTH CONSULTATION: Response to Community Inquires Regarding Nitrate, Lead, Thallium and Chromium Levels in Water from Private Domestic Wells near the Pacific Gas and Electric Facility in Hinkley, California -- Pacific Gas and Electric Facility, Hinkley, San Bernardino County, California,” Prepared By: California Department of Health Services, Under a Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, April 25, 2003, available here: http://www.atsdr.cdc.gov/HAC/pha/pganderesp/pge_toc.html.

March 2005, ATSDR released a health consultation that investigated potential exposures from TCE in private well water of both humans and animals in the City of Cliff Village, Missouri. The investigation began after several residents and domestic animals in the Cliff Village area experienced unusual health problems that resulted in the death of a domestic animal.²⁴ In December, 2005, ATSDR issued a health consultation that investigated the poisoning of a 97-pound Siberian Husky in Des Moines, Iowa.²⁵

The above cases were gleaned from a cursory search of ATSDR's web-page by the Subcommittee. Why ATSDR refused Debra Markwardt's request is unclear, but there is certainly precedent for ATSDR to examine animals, particularly when there health and safety are closely tied to the health and safety of people.

On February 6, 2009, ATSDR's Yarbrough responded again to Ms. Markwardt. But this time, the agency's rationale for refusing to investigate the health of Markwardt's dogs changed slightly. Originally, Markwardt was told "veterinary and animal issues are outside of our mandated domain," wrote ATSDR. This time, Yarbrough wrote: "ATSDR's enabling legislation does not prohibit our conduct of animal studies; however, ATSDR and the Texas Department of State Health Services do not have the expertise to conduct the appropriate animal studies," he wrote. Instead, ATSDR told Markwardt that they referred her case to two veterinarians with Texas A&M. But the researchers do not yet have any funding to support an investigation and they have not yet contacted her.

Polycythemia Vera Cancer Cluster in Eastern Pennsylvania

Dr. Ronald Hoffman, MD is Professor of Medicine, Hematology/Oncology Section, at the Tisch Cancer Institute and Professor of Gene and Cell Medicine at Mt. Sinai School of Medicine in New York. He is also the former President of the American Society of Hematology. Dr. Hoffman is a leading expert on a rare cancer called polycythemia vera (PV). He had never heard of ATSDR before being called by ATSDR staff in 2006 to lend his expertise to an investigation it was conducting in eastern Pennsylvania examining a potential cluster of PV cases.

In October 2006, ATSDR began assisting the Pennsylvania Department of Health in investigating the high number of reported PV cases in three counties in Pennsylvania -- Carbon, Luzerne and Schuylkill counties. The area ATSDR investigated is home to seven Superfund hazardous waste sites that are either closed or in the process of being remediated and seven waste coal burning power plants, which emit polycyclic aromatic hydrocarbons (PAHs). Recent research has suggested PAHs may potentially contribute to polycythemia vera.

²⁴ "HEALTH CONSULTATION: Cliff Village Wells Site, City of Cliff Village, Newton, Missouri, March 21, 2005, Agency for Toxic Substances and Disease Registry, available here: <http://www.atsdr.cdc.gov/HAC/pha/CliffVillageWellsSite/CliffVillageWellsHC.pdf>.

²⁵ "HEALTH CONSULTATION: Pesticide Contamination of Residential Soil -- Des Moines, Polk County, Iowa," December 8, 2005, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, available here: www.atsdr.cdc.gov/HAC/pha/PesticideContamination120805/PesticideContaminationSoilHC120805.pdf.

The local community has suspected that environmental pollution in the area has a contributor to health problems there for a long time. By the fall of 2007, ATSDR had confirmed more than three dozen cases of PV in the area, more than four times the level outside the region. The agency also discovered four cases of PV on one two-mile stretch of road not far from the former McAdoo superfund site. None of the PV patients on Ben Titus Road in Northeast Schuylkill County were blood relatives. Two of them, who both passed away last year, were husband and wife. The environmental significance of this tight grouping of PV cases on a single road and the proximity to a hazardous waste site seemed obvious to many, including Dr. Ronald Hoffman.

But that connection did not appear so obvious to ATSDR. The lead ATSDR official in charge of the investigation, Dr. Steven Dearwent, described it to Subcommittee staff as “compelling” information, but nothing more. On October 24, 2007, ATSDR released a “media announcement” regarding their PV investigation. The agency confirmed more than three dozen cases of PV in Schuylkill, Luzerne and Carbon counties in Pennsylvania but assured the public: “ATSDR found no link between environmental factors and PV in this area.”²⁶ The agency also failed to mention in the media announcement the four PV cases it found along Ben Titus Road near a former Superfund site, although they had already confirmed these cases at the time.

So, when Dr. Hoffman presented an abstract of the PV investigation at the annual meeting of the American Society of Hematology in Atlanta in December 2007 titled: “Evidence for an Environmental Influence Leading to the Development of JAK2V617F-Positive Polycythemia Vera: A Molecular Epidemiological Study,” this apparent contradiction did not sit well with some ATSDR officials. The agency says the paper, which included the names of ATSDR scientists, did not go through ATSDR’s “clearance process.”

In December 2007, the Associated Press reported that ATSDR was distancing itself from Dr. Hoffman and his paper. Dr. Dearwent, the senior ATSDR official in charge of the PV cluster investigation told the AP: “We’re going to have to retract the abstract to correct the record because it is erroneous information.” Dr. Dearwent claimed that the abstract had been written early in the summer and that subsequent analysis of the data did not support the conclusion of an environmental link.²⁷ In fact, it seems nothing had actually changed regarding the data but that ATSDR did not feel comfortable drawing any connection between the PV cluster and potential chemical exposures in the environment. Dr. Dearwent told Subcommittee staff that because Dr. Hoffman is a “clinician” and not an epidemiologist he may have viewed the PV cluster differently than the agency. Dr. Dearwent said that “we had nothing telling us at the time nor do we now” that this cluster is somehow linked to environmental exposures.

²⁶ “Federal Agency Releases Results of Polycythemia Vera Investigation,” ATSDR Media Announcement, Agency for Toxic Substances and Disease Registry, October 24, 2007, available here: <http://www.atsdr.cdc.gov/NEWS/schuylkillpa102407.html>.

²⁷ Mike Stobbe and Michael Rubinkam, “Feds hedge on environmental link to Pennsylvania illnesses,” Associated Press (AP), December 7, 2007, available here: <http://www1.phillyburbs.com/pb-dyn/articlePrint.cfm?id=1452897>.

To his credit, Dr. Hoffman presented his abstract at the American Society of Hematology conference despite efforts by ATSDR to interfere with his presentation. Last year, ATSDR posted an oddly worded statement about the abstract on its website. The agency said that the conclusions in the abstract differed from what ATSDR told the public in October 2007 and that it “prematurely” inferred certain conclusions about the PV cluster. Yet, it concluded: “The presentation made at the American Hematology Society meeting accurately reflected ATSDR’s current assessment of the data.”²⁸

In January 2008 Dr. Hoffman e-mailed Dr. Howard Frumkin, the director of ATSDR, about his experience with the PV investigation. “I believe that some members of your staff are unable, incapable or unwilling to objectively looking [sic] at this data,” wrote Hoffman. “This nonscientific approach has led to a state of denial and paralysis in you [sic] organization which has resulted in the present confusion about this matter in the community and the press. There are important issues here and objectivity is required,” wrote Hoffman. “I hope that the cynical and nihilistic behavior of some of your staff is not a reflection of the scientific veracity of the Agency[.]”

In this case, ATSDR finally acknowledged that a cancer cluster existed in the area of Eastern Pennsylvania they investigated. The agency released the final results of their investigation last August and found residents in the three counties in Pennsylvania that they assessed were more than four times more likely to develop polycythemia vera than people living outside those counties. And while ATSDR said “There were potential environmental exposure sources common to some of the high-rate areas,” they concluded that: “It is not known whether a relationship exists between any of these sources and the PV cases.”²⁹ The agency said future studies may attempt to investigate the environmental connection further. Dr. Hoffman says that ATSDR continually sought to downplay and minimize any links between the PV cases and the environment suggesting it was just an unusual circumstance. He described their behavior as “very odd and counter-intuitive.”

Interestingly, in 1993 ATSDR conducted a public health assessment on the McAdoo Associates Superfund site. That site had ceased operations in 1979, was remediated and taken off of the Superfund list in 2001. The 1993 ATSDR public health assessment of the site found: “Site-related contamination poses no public health hazard because there is no evidence of current or past exposures, and future exposures to contaminants at levels of public health concern are unlikely.”³⁰ Ben Titus Road where ATSDR investigators discovered four unrelated PV cases is close to this site. But conceding that there may be an environmental health hazard present in this community

²⁸ “Response to the American Hematology Society Abstract,” Agency for Toxic Substances and Disease Registry, available here: http://www.atsdr.cdc.gov/sites/polycythemia_vera/abstract.html.

²⁹ Polycythemia Vera Investigation, Agency for Toxic Substances and Disease Registry, http://www.atsdr.cdc.gov/sites/polycythemia_vera/.

³⁰ “Public Health Assessment, McAdoo Associates, McAdoo, Schuylkill County, Pennsylvania,” Prepared By: Pennsylvania Department of Health Under Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, September 29, 1993, available here: http://www.atsdr.cdc.gov/HAC/pha/mcadoo/mca_p1.html#SUMMARY.

today could put ATSDR in the awkward position of acknowledging mistakes with their past public health conclusions.

In the wake of internal disagreements between Dr. Hoffman and ATSDR regarding the potential link between environmental contamination and the PV cluster, Dr. Hoffman says he pushed to publish a peer-reviewed article of the PV investigation's findings, fearing that ATSDR was not willing or able to acknowledge the significance of the PV cluster in Pennsylvania. Last month the work of Dr. Hoffman, ATSDR scientists and other colleagues at the University of Illinois College of Medicine, published their findings in the journal *Cancer, Epidemiology, Biomarkers and Prevention*. The paper reported that the risk of developing PV was 4.3 times greater for the residents living inside the three Pennsylvania counties they examined than for those living outside the area. The article concluded: "The close proximity of this cluster to known areas of hazardous material exposure raises concern that such environmental factors might play a role in the origin of polycythemia vera."³¹ Dr. Dearwent, who was not an author on the paper, contends that "some of the language in the manuscript that we opposed made it back in to the paper." Dr. Hoffman and other authors of the paper deny that.

Asbestos Beach - Illinois State Beach Park in Chicago

Mr. Jeffery Camplin is President of Camplin Environmental Services and technical consultant to the Dunesland Preservation Society in Illinois. Since 2003 he has been investigating asbestos contamination on the Illinois shoreline of Lake Michigan and has filed several complaints with ATSDR regarding the inadequacies of their studies of asbestos contamination at the Illinois State Beach Park in Chicago. He is a certified safety professional (C.S.P.), certified professional environmental auditor (C.P.E.A.) and has been an accredited instructor in asbestos abatement by the Environmental Protection Agency (EPA) for more than 20 years. In 2006 he was named Environmental Safety Professional of the year by the American Society of Safety Engineers (ASSE). He is also the lead safety volunteer for the Illinois Medical Emergency Response Team (IMERT).

In Illinois there has been a long history of asbestos containing materials and fibers washing up on the shoreline of Lake Michigan for more than one decade. The Johns-Manville Corporation built a large plant on the shore of Lake Michigan that produced insulation products containing asbestos beginning in the 1920s. The plant, which included a 150-acre asbestos disposal area containing approximately 3 million cubic yards of asbestos-containing waste, was declared a Superfund site in 1983 and ceased operations in 1998. The asbestos disposal area was covered with soil to prevent its spread. But since then seven areas containing asbestos-containing material from the plant were discovered off-site.³²

³¹ Dr. Vincent Seaman, et. al., "Use of Molecular Testing to Identify a Cluster of Patients with Polycythemia Vera in Eastern Pennsylvania," *Cancer Epidemiology Biomarkers & Prevention*, 18(2), February 2009, available here, <http://cebp.aacrjournals.org/cgi/content/abstract/18/2/534>.

³² "Region 5 Superfund (SF) National Priorities List Fact Sheet: Johns-Manville Corp.," Environmental Protection Agency, Last Updated: June, 2008, available here: <http://www.epa.gov/region5superfund/npl/illinois/ILD005443544.htm>.

Around the same time as the plant's closure, asbestos debris began washing up along the shoreline at the Illinois Beach State Park, the state's most popular park at two to three million visitors per year.³³ In May 2000, the Illinois Department of Public Health under a cooperative agreement with ATSDR released a public health assessment regarding asbestos contamination at the state park. The report did find that asbestos containing material had been found scattered along the beach at the park and that material containing "low asbestos levels" had been discovered, but not at levels that would be expected to cause adverse health effects in Park workers or visitors," it said. The report concluded: "no apparent public health hazard exists related to asbestos contamination at Illinois Beach State Park."³⁴

But the discovery of asbestos material on the public beach at the state park never ceased. Portions of the state park were cleared of asbestos in March 2006. In the summer of 2006 ATSDR used grading equipment to churn up the sand and air filters to capture and measure any potential asbestos fibers. The tests discovered fibers of amphibole asbestos, the most toxic kind of asbestos.

In 2007 ATSDR wrote a draft health consultation based on their findings which said there was no health hazard from the asbestos. In April 2007, local EPA officials submitted written comments of the report to ATSDR. The letter, written by Brad Bradley, the EPA's Remedial Project Manager in the agency's Region 5 section and the EPA's lead asbestos expert covering Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin, was written to Mark Johnson, ATSDR's regional representative in Chicago, on behalf of the entire EPA Region 5 staff. The letter identified 13 items they believed needed clarification or correction. Many of them were not subtle editorial fixes but significant issues revolving around safety and health issues and the scientific integrity of the ATSDR report. The letter said many of the statements by ATSDR were "misleading," "questionable" and contained "inconsistencies."³⁵

"The paragraph on page 12, which states that "Based on the bulk analysis of sand samples collected, the sand in [and] of itself does not appear to pose a significant source of asbestos fibers" is a little misleading," wrote Bradley. "The air samples near the beach grading equipment were significantly elevated; therefore, this would indicate that there might be a problem with this statement," he wrote. But the final ATSDR health consultation read: "Based on the bulk analysis of sand samples collected, the sand does not appear to pose a significant source of asbestos fibers." The public health agency ignored the EPA's concerns about the public's health.

³³ See: "Asbestos washes up on beach at state's most popular park," Associated Press, February 3, 1998; and Charles Nicodemus, "State moves in on asbestos // 4 agencies study danger to beach," Chicago Sun-Times, February 4, 1998.

³⁴ "Public Health Assessment: Asbestos Contamination at Illinois Beach State Park," Prepared by: Illinois Department of Public Health Under Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, May 23, 2000, available here: http://www.atsdr.cdc.gov/HAC/pha/illinoisbeach/ibp_toc.html.

³⁵ Letter from Brad Bradley, Remedial Project Manager, Environmental Protection Agency, Region 5, to Mark Johnson, Regional Representative, Agency for Toxic Substances and Disease Registry, April 24 2007.

The EPA noted other problems that ATSDR also simply chose to ignore. In his April 2007 letter, Bradley wrote: “13) Regarding the human health safety statements in the Report, the Executive Summary states that it is within the acceptable risk range under certain conditions to use the IBSP [Illinois Beach State Park] beaches for the general public BUT for maintenance activities they should be conducted when sand surface is wet or closed to the public. It is also stated that the IDNR [Illinois Department of Natural Resources] should continue asbestos removal from the beach. These inconsistencies and the actual air monitoring results raise concerns regarding the safety of human use of the beaches. There is ACM [Asbestos Containing Material] on the beach and it should be removed, the maintenance workers should take precautions but it is OK for the public and especially children to play with and on the beach. What is going on here, either the beach is safe or the safety is questionable,” Bradley wrote. But ATSDR cleared up the answer to that question in their final report. “What are the conclusions of the EI [Environmental Exposure Investigation]?” asked ATSDR. “The activities simulated at the beaches at IBSP pose no apparent public health hazard,” they declared.

In an interview with Subcommittee staff ATSDR’s Mark Johnson acknowledged that his agency did not include all of the suggestions submitted by the EPA officials. It is an ATSDR document, he said, and the ultimate decision of what is in the health consultation rests with the Agency for Toxic Substances and Disease Registry. ATSDR is now in the process of reviewing new sampling data of the beaches and expects to release their new health consultation any day, according to ATSDR.

Depleted Uranium (DU) Contamination in Colonie, New York

Professor Randall R. Parrish, PhD, is the head of the British Geologic Survey’s Natural Environment Research Council’s (NERC) Isotope Geoscience Laboratories in Nottingham, England and Professor of Isotope Geology at the University of Leicester. In 2007 he was the lead author of a peer-reviewed journal article that investigated depleted uranium (DU) inhalation exposures in Colonie, New York, home to National Lead, Inc., which produced depleted uranium for U.S. military munitions from 1958 to 1984, when the site was closed due to violations of environmental emission standards.³⁶ In 2006, the federal government completed a \$190 million cleanup of the site.

A 2004 ATSDR health consultation found that past emissions from the site “could have increased the risk of health effects—especially kidney disease—for people living near the plant” and found that “the combination of inhaling DU dust and cigarette smoke could have increased the risk of lung cancer.” But because the plant had ceased operating, ATSDR concluded that there was “no apparent public health hazard.” In addition, they rejected a request to conduct a health survey because they said it would not “answer the community’s questions about whether or not the NL plant impacted their

³⁶ Randall R. Parrish, et al, “Depleted uranium contamination by inhalation exposure and its detection after ~20 years: Implications for human health assessment,” Society of the Total Environment, September 2007, available here: http://www.albany.edu/news/pdf_files/Depleted_Uranium_Article.pdf.

health.”³⁷ In 2007, however, professor Parrish and researchers at the University of Albany – using a newly developed method – detected DU exposures in 100% of the former workers at the site they tested and 20% of the residents they tested, in addition to DU in the soil found miles away from the site.

Parrish’s paper said that the “ATSDR Health Consultation concluded that further investigations were unjustified because it would be impossible to determine the incidence of DU contamination after such a long period of time since the inhalation hazard no longer existed.” But Parrish’s paper showed it was possible and the authors recommended that ATSDR do a follow-up study with a larger group of nearby residents to access their “potential health outcomes.” Although ATSDR’s mission statement says it “serves the public by using the best science,” scientists at ATSDR told Subcommittee staff that they are unswayed by Professor Parrish’s findings and say they do not see a need to re-examine the Colonie, New York residents for potential DU exposures. They say that the amount of depleted uranium detected in the residents was so small that it would not result in any health hazard, thereby confirming the conclusions of their earlier health consultation. Professor Parrish says this argument does not take into account what these individuals were exposed to in the past. Parrish says that with further analysis of his work scientists can attempt to calculate the cumulative exposures of individuals to help determine what their exposures were in the past and what the health risk to them might be today.

Vieques Island, Puerto Rico

For years, ATSDR has investigated potential environmental hazards on and off the coast of the island of Vieques in Puerto Rico. The U.S. Navy engaged in live bombing practice activities on and off the coast of Vieques from 1941 to 2003 spreading munitions containing depleted uranium and other toxic chemicals into the sea and local ecosystem. In November 2003, ATSDR issued a summary of its work on the island. “Residents of Vieques have not been exposed to harmful levels of chemicals resulting from Navy training activities at the former Live Impact Area,” ATSDR concluded. “It is safe to eat seafood from the coastal waters and near-shore lands on Vieques,” they said.³⁸

Many independent scientists and health experts question those findings. Most recently, Professor James Porter, Associate Dean at the Odum School of Ecology, University of Georgia, presented findings at a conference last month that found unexploded munitions from the U.S. Navy around the island were, in fact, leaking toxic cancer causing substances into the ocean endangering sea life. Professor Porter found that sea urchins and “feather duster worms” closest to unexploded bombs or bomb fragments off the coast of Vieques had extraordinarily high toxic levels of various

³⁷ “Health Consultation: Colonie Site (Aliases: Colonie Interim Storage Site and Formerly National Lead Industries) Colonie, Albany County, New York, Agency for Toxic Substances and Disease Registry, October 5, 2004, available here: <http://www.atsdr.cdc.gov/HAC/pha/ColonieSite100504-NY/ColonieSite100504HC-NY.pdf>.

³⁸ “A Summary of ATSDR’s Environmental Health Evaluations for the Isla de Vieques Bombing Range, Vieques, Puerto Rico,” Agency for Toxic Substances and Disease Registry (ATSDR), November 2003, available here: http://www.atsdr.cdc.gov/sites/vieques/vieques_profile.pdf.

chemicals. Some of the materials were nearly 100,000 times over established safe limits. Professor Porter cautioned that he performed a “point source study,” meaning he took measurements close to the residual bomb materials and that ATSDR has performed “broad spectrum” tests that measure toxic chemicals in a much wider arena.

That explains the discrepancies in what Professor Porter found and what ATSDR discovered. Although Professor Porter cautioned that it is still unclear what sort of impact these toxins have had on the dinner plate some studies have shown that residents on Vieques Island have a 23% higher cancer rate than those on the main island of Puerto Rico.³⁹ Other studies have found that plants on the island have high concentrations of lead, mercury, cadmium, uranium, cobalt, manganese and aluminum.⁴⁰ Vieques residents question the integrity of the studies conducted by ATSDR, as do many Puerto Rican and other independent scientists.

Kelly Air Force Base, San Antonio, Texas

Issuing public health documents that fail to include relevant information, are based on incomplete or deficient investigations, or omit critical public health data can contribute to the environmental exposure of the public. In 1999 an ATSDR report that examined cancer incidence around the Kelly Air Force Base in San Antonio, Texas, found increased levels of liver and kidney cancer as well as leukemia.⁴¹ But none of ATSDR’s studies on the former Air Force Base linked the illnesses to the toxins from the base that have leached into these neighborhoods.

In a critique of the ATSDR report, Dr. Katherine Squibb, a toxicologist at the University of Maryland, found that the agency’s conclusions were based on minimal information, some Air Force studies ATSDR relied on for its conclusions failed to measure important exposure pathways, and ATSDR failed to conduct an adequate assessment of whether or not some chemicals migrated off-base. “It is questionable as to whether ATSDR’s conclusion that no public exposure to contaminants occurred through the domestic use of groundwater in the past is correct,” wrote Squibb.⁴²

³⁹ See: “Link between unexploded munitions in oceans and cancer-causing toxins determined,” the University of Georgia, News Release, February 18, 2009, available here: <http://www.uga.edu/aboutUGA/research-bombs.html>; Maria Miranda Sierra, “Carcinogens found in marine life in island of Vieques in Puerto Rico,” Caribbean Net News, February 21, 2009, available here: <http://www.caribbeannetnews.com/news-14429--21-21--.html>; John Lindsay-Poland, “Health and the Navy in Vieques,” Fellowship of Reconciliation, Puerto Rico Update, Number 32, Spring 2001, available here: <http://www.forusa.org/programs/puertorico/archives/0401healthnavy.html>; Azadeh Ansari, “Undersea bombs threaten marine life,” CNN, February 26, 2009, available here: <http://www.cnn.com/2009/TECH/science/02/26/undersea.munitions.cleanup/index.html>;

⁴⁰ Dr. Arturo Massol-Deya, et. al., “Trace Elements Analysis in Forage Samples from a US Navy Bombing Range (Vieques, Puerto Rico),” International Journal of Environmental Research and Public Health, August 14, 2005; available here: <http://www.mdpi.com/1660-4601/2/2/263>.

⁴¹ “Public Health Assessment, Kelly Air Force Base, San Antonio, Bexar County, Texas,” Prepared by Agency for Toxic Substances and Disease Registry, September 9, 1999, available here: http://www.atsdr.cdc.gov/HAC/pha/kelly/kel_toc.html.

⁴² “Technical Review of the Public Health Assessment, Phase I for Kelly Air Force Base, San Antonio, Bexar County, Texas, Conducted by Division of Health Assessment and Consultation, Agency for Toxic

In a 2002 critique of another ATSDR report on the Kelly Air Force Base, Squibb found that ATSDR did not evaluate cumulative risks of exposure for certain chemicals.⁴³ She also told a local reporter that ATSDR examined health risks from exposure to soil from a part of the base only after the site had been cleaned up and remediated. “It does not appear that ATSDR has considered health risks associated with soil that migrated from this site prior to remediation,” said Squibb.⁴⁴

Seven years after Dr. Squibb’s comments, the issues of off-site contamination at Kelly Air Force Base were still swirling around the local community. “I don’t know much about science,” San Miguel, one local resident said last month, “but there are 13 homes on this block and 11 of those families have had someone die from cancer. That is what is bothering me,” he said. “Where did that come from?”⁴⁵

Trichloroethylene (TCE) Groundwater Contamination in Elkhart, Indiana

Earlier this month, ATSDR released a draft Public Health Assessment (PHA) on groundwater contamination from trichloroethylene (TCE) and other chemicals at what is known as the Lusher Avenue Site in Elkhart, Indiana. Contamination in the area has stretched back to the mid-1980s and last year EPA designated it a Superfund site and placed it on the National Priorities List (NPL). There are a number of potential sources of environmental pollution in the area including a rail yard, pharmaceutical manufacturer, plastic and metal fabrication plants and a musical instrument fabrication facility. The area has a population of 2,597 people, including 286 children six years old or younger.⁴⁶

In 1989, EPA established a drinking water standard or Maximum Contaminant Level (MCL) for TCE of 5 parts-per-billion (5 ppb). Municipal water systems are required to test water for TCE concentrations every three months. If any levels exceed the MCL, they are required to notify the public via newspapers, radio, TV networks and other means and to provide alternative drinking water supplies to the public.⁴⁷ In the past, TCE contamination in the drinking water systems in Lusher were discovered in many of the several hundred private wells in the area. Residents were provided with

Substances and Disease Registry (ATSDR), Released for Public Comment, September, 1999,” Prepared by Katherine S. Squibb, PhD, Program in Toxicology, University of Maryland, Baltimore (undated), available here: https://afarpaar.lackland.af.mil/ar/getdoc/KELLY/KELLY_AR_3299.pdf.

⁴³ “Review of ATSDR Petitioned Public Health Assessment, Kelly Air Force Base,” Conducted by Katherine S. Squibb, PhD, Program in Toxicology, University of Maryland, Baltimore, June 11, 2002, available here: https://afarpaar.lackland.af.mil/ar/getdoc/KELLY/KELLY_AR_3278.pdf.

⁴⁴ Roddy Stinson, “Round on the Kelly-toxins mystery trail: ‘dioxins and furans,’” San Antonio Express-News, March 26, 2002.

⁴⁵ Anton Caputo, “Kelly area homes retested by EPA,” San Antonio Express-News, February 6, 2009, available here: <http://www.mysanantonio.com/news/environment/39182822.html>.

⁴⁶ “Public Health Assessment for Lusher Avenue Groundwater Contamination, Elkhart, Elkhart County, Indiana,” Public Comment Release, Prepared by: U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, March 1, 2009, p. 21, (hereafter referred to as ATSDR Lusher Site PHA, available here: http://www.atsdr.cdc.gov/NEWS/lusher_03022009.html).

⁴⁷ “Consumer Factsheet on: TRICHLOROETHYLENE,” U.S. Environmental Protection Agency, available here: <http://www.epa.gov/OGWDW/dwh/c-voc/trichlor.html>

alternative water supplies or filtration systems were installed. A new round of sampling in 2005 and 2006 found some wells had TCE levels of up to 700 ppb, exposing an estimated 200 people to these contaminants.

The recent ATSDR health assessment concluded that: “Most adverse health outcomes are not anticipated at Lusher because the TCE concentration in most private wells is less than 100 ppb.”⁴⁸ However, ATSDR’s own 1997 Toxicological Profile on trichloroethylene cites several studies showing associations between exposures to much lower levels of TCE exposure and health effects, such as neural tube defects, for instance.⁴⁹ In addition, it cites another study of residents in Tucson, Arizona that were exposed to TCE levels between 6 and 239 ppb. The study found that the children of mothers who lived in this area in their first trimester of pregnancy were 2 ½ times more likely to develop congenital heart defects than children of mothers not exposed to TCE during pregnancy.⁵⁰ Yet, the ATSDR health assessment says that there have been exposures at the Lusher site as high as 700 ppb, “*However, most TCE exposures at Lusher were and are less than 100 ppb and indicate little to no risk for heart defects in newborns.*” [Emphasis in the original].⁵¹

The ATSDR assessment does say: “People drinking well water which contains TCE at levels greater than 300 ppb have an increased risk of developing cancer.” It bases this assertion on another ATSDR study that examined a cancer cluster in Woburn, Massachusetts in 1986 and found that there were more than twice as many childhood cases of leukemia as expected while the TCE contamination in the water was only 267 ppb. How ATSDR now justifies asserting that there is no increased risk of cancer below 300 ppb or that there is no risk of heart defects in newborns from the exposures in Lusher appears to be scientifically unfounded and misleading.⁵²

The Public Health Assessment also failed to mention a 1994 study cited in ATSDR’s own Toxicological Profile of trichloroethylene. The study found that in a review of 1.5 million residents in 75 towns monitored for TCE levels between 1979 and 1987, females exposed to drinking water in excess of the EPA maximum contaminant level (MCL) of 5 ppb had a significant elevation of total leukemias, including childhood leukemias, acute lymphatic leukemias, and non-Hodgkin’s lymphoma. The recent ATSDR report also failed to mention that a 1996 study by the Massachusetts Department of Health found that the risk of leukemia in the group of Woburn, Massachusetts women exposed to TCE in utero were 8 times higher than a control group.⁵³

While none of these studies in and of themselves are conclusive evidence of clear links between TCE exposures and these specific health problems, they are part of the

⁴⁸ ATSDR Lusher Site PHA, p.12.

⁴⁹ “Toxicological Profile for Trichloroethylene,” U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, September 1997, p. 84, (hereafter referred to as ATSDR TCE Tox Profile) available here: <http://www.atsdr.cdc.gov/toxprofiles/tp19.pdf>.

⁵⁰ ATSDR TCE Tox Profile, p. 85.

⁵¹ ATSDR Lusher Site PHA, p. 13.

⁵² ATSDR Lusher Site PHA, pp. 14-15.

⁵³ ATSDR TCE Tox Profile, pp. 90-91.

scientific public health record on these issues. Omitting them from a public health document that is trying to assess the public health threats from TCE to the community in and around the Lusher site appears short-sighted at best and scientifically misleading.

In the end, ATSDR's conclusions on the Lusher site seem fuzzy at best. Inconsistencies in other ATSDR reports have been a long standing frustration by both local communities and other federal agencies, particularly EPA. In its conclusions on the Lusher site, for instance, ATSDR wrote: "ATSDR categorizes the site as a past public health hazard. Due to uncertainties concerning sources, continuing migration of contaminants, and private well use, the site could pose a future public health hazard. Currently, exposure has been mitigated or lessened through provision of alternate water and filter systems for private well users with contaminated water. However, there may be private wells that still need to be tested."⁵⁴ Until ATSDR begins to focus on the scientific integrity and basic clarity of its public health documents with renewed energy, care and focus the agency will continue to be mired down in problems and garner distrust from the local communities it is supposed to serve.

Dr. Frumkin's National Conversation

In recent weeks Dr. Frumkin has unveiled an NCEH/ATSDR initiative he calls: "The National Conversation on Public Health and Chemical Exposures." He has grand plans. "[N]ow is an opportune time to revitalize the public health approach to chemical exposures," he wrote recently in the *Journal of Environmental Health*.⁵⁵ As part of this effort he wants to have a broad dialogue that aims to identify gaps in the public health approach to chemical exposures and identify solutions for strengthening the public health approach to chemical exposures.

Dr. Frumkin has held several internal ATSDR "all hands meetings" where he has briefed agency employees on his initiative and he organized a small meeting in Washington, D.C. on Friday, March 6th with environmental organizations. He has personally met with many public health and environmental groups in an attempt to drum up support for his initiative.

A few weeks ago he met with Stephen Lester, Science Director of the Center for Health, Environment and Justice and its Executive Director, Lois Gibbs, the local activist from Love Canal in New York who spearheaded an environmental investigation when she discovered her children's elementary school was built on a toxic waste dump. Dr. Frumkin was apparently seeking advice on how to help reorganize or reform ATSDR to make it more responsive to the concerns of local communities. Lester told him that all he needed to do was follow the recommendations he and other local community groups

⁵⁴ "Public Health Assessment for Lusher Avenue Groundwater Contamination, Elkhart, Elkhart County, Indiana," Public Comment Release, Prepared by: U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, March 1, 2009, p. 21, available here: http://www.atsdr.cdc.gov/NEWS/lusher_03022009.html.

⁵⁵ Howard Frumkin, M.D., M.P.H., Dr.P.H., "The Public Health Approach to Chemical Exposures: A National Conversation," *Journal of Environmental Health*, Volume 71, Number 7, March 2009.

gave to ATSDR back in 1990. Virtually nothing has changed, Lester says. The problems, as well as many of the solutions, remain the same. Lester had been through this once before and is not very hopeful that any real change will come to the agency.

For a twelve year period from 1986 to 1998, Dr. Barry Johnson served as the Assistant Administrator of ATSDR and by all accounts he was a deeply dedicated and compassionate public servant. In 1990 he attempted to reach out to local community groups to begin a dialogue in order to help rectify the agency's poor image and to move the agency into a new direction, producing scientifically valid studies, identifying causes of environmental contamination causing harm to human health and obtaining the respect and trust of the local communities ATSDR is supposed to protect. Dr. Johnson had contacted the Center for Health, Environment and Justice (then called the Citizen's Clearinghouse for Hazardous Wastes). Because of Lois Gibbs' presence, the organization had clout with many local environmental groups and communities.

There were several meetings between ATSDR and local community groups as a result of Barry Johnson's organizing efforts. The groups produced a long-list of problems, observations and recommendations. Many of them seem to have withstood the test of time and are equally relevant and significant today. "Health officials look for every possible reason other than the obvious as the causative factor in evaluating health problems." "Studies do not address problems and do not lead to action; instead they seem to look for ways to dismiss problems." One asked: "Is there a need for ATSDR? Should ATSDR exist given that it is not providing what citizens want and need."⁵⁶

The momentum from those meetings soon faded. Four years later Lester wrote: "Today we continue to see many of the same investigation strategies that ATSDR and CDC has been using for years—investigating health problems with scientific methods that are highly questionable and inappropriate. They consistently ask the wrong questions, use inappropriate comparison groups, dilute exposed populations with unexposed populations, eliminate exposed people from their studies and use other ill-conceived scientific methods to evaluate health problems in communities. In the end, they find no health problems because they used methods destined to fail from the beginning and because their studies are often "inconclusive by design."⁵⁷

The integrity of the data ATSDR produces is critical to gaining the public's trust and successfully addressing important environmental public health issues. These flawed reports have very direct impacts on the safety and health of the public. The public health documents emanating from ATSDR should adhere to a clear, consistent and scientifically credible and defensible standard. Yet, in far too many instances that is not the case.

⁵⁶ "Report on a Meeting Between ATSDR and Community Representatives," Citizen's Clearinghouse for Hazardous Wastes, June 30, 1990, Washington, D.C.

⁵⁷ "Promises, Promises: ASTDR...Don't Ask...Don't Tell...Don't Pursue," Stephen Lester, Science Director, Citizens Clearinghouse for Hazardous Waste (renamed Center for Health, Environment and Justice), Everyone's Backyard Newsletter, March/April 1994, p. 15-16.

ATSDR's Leadership Today

Many of the challenges that ATSDR faces every day are not simple. Accurately assessing public health implications from environmental contamination is difficult. The state of the science may not be able to determine the exact cause of a cluster of illnesses no matter how many hours are invested or how high a priority investigating the issue is to ATSDR, a local community or anyone else. But these are not now, nor have they ever been the criticisms that have been leveled against the agency. The criticisms swirl around the simple mistakes, the careless research, the critical scientific omissions, the poorly contrived methods used by the agency to identify the cause of a community's public health concerns and the lack of appropriate fundamental agency policies, such as having a thorough and independent review of ATSDR's public health documents *before* they are released to the public.

None of these problems will ever evaporate or disappear until ATSDR has strong leaders who are committed to ensuring that the agency fulfills its mission and at the same time creates a public health culture that is bolstered by sound science, careful review and an eagerness to actually identify the potential environmental causes of illnesses, ailments or diseases that impact local communities and affect their health and safety. The problems that embroil ATSDR have been present for many years and did not simply emerge under the leadership of Dr. Frumkin.

However, it is apparent from both Dr. Frumkin's handling of the formaldehyde issue as well as other incidents that Dr. Frumkin's actions have contributed to a culture where scientific integrity appears to take a back seat to political expediency and uncomplicated conclusions regardless of their accuracy or potential impact upon the public's health. As the Subcommittee said in its staff report on formaldehyde last year: "It seems unlikely that ATSDR will be capable of fulfilling its core mission of protecting the public health until they have capable leaders willing and able to lead the agency and serve the public." The cases below all reveal the approach taken by the current leadership and their commitment to scientific integrity.

Camp Lejeune, North Carolina

In 1990 ATSDR published a public health assessment that showed a dry-cleaning facility just outside of Camp Lejeune in North Carolina had inappropriately disposed of volatile organic compounds which contaminated the base's water supply.⁵⁸ Another water supply system on the base was contaminated with trichloroethylene (TCE) by the base's own on-site waste disposal practices. In 1997 ATSDR wrote a public health assessment on the potential environmental exposures of U.S. military personnel and veterans who had served at Camp Lejeune in North Carolina and were potentially

⁵⁸ "Public Health Assessment for ABC One Hour Cleaners, Jacksonville, Onslow County, North Carolina," Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, 1990. [The staff report 1st released on March 10, 2009 incorrectly said the off-base dry cleaners contaminated the water supply with trichloroethylene (TCE). The dry cleaners actually contaminated the water supply with tetrachloroethylene also known as perchloroethylene (PCE).]

exposed to TCEs and a host of other toxic substances.⁵⁹ The report, based on flawed data that was available at the time, showed that the levels of exposures believed to have occurred would not pose a health hazard for adults. But it did recommend a follow-up study to evaluate potential health effects to mothers exposed during pregnancy and their children.⁶⁰ ATSDR has conducted numerous health studies on Camp Lejeune since then.⁶¹

In 2003 a Camp Lejeune veteran wrote to the Department of Health and Human Services requesting records referenced in ATSDR's 1997 public health assessment on Camp Lejeune under a Freedom of Information Act (FOIA) request. The response he got back said the records "are no longer in CDC's possession. Specifically, the records were lost during a 1998 office move," an HHS official wrote. "As a result, CDC no longer has records that would respond to your request, other than the public health assessment itself."⁶² However, an ATSDR FOIA officer offered a slightly different explanation. On June 2, 2003, she wrote, "A search of our record failed to reveal any documents pertaining to your request. Program staff stated that the referenced material was either destroyed or misplaced during an agency physical move this past October [2002]."⁶³

Finally, Dr. Frumkin responded to Camp Lejeune veteran and activist Jerry Ensminger about the FOIA responses and the validity of the 1997 Public Health Assessment on May 4, 2007. "As a scientific public health agency, it is important to us that our reports contain the most current and scientifically correct information available at the time," wrote Dr. Frumkin. "We acknowledge that the references used for the development of the 1997 public health assessment are no longer available in the Agency for Toxic Substances and Disease Registry's (ATSDR) files. A move of ATSDR staff resulted in our files of Camp Lejeune-related documents being temporarily relocated. A private contractor mistakenly disposed of the documents," said Dr. Frumkin. "Although unfortunate that the material referenced in the public health assessment is no longer available in ATSDR's files, the original information and data, with the exception of original ATSDR references, may still be available from their original sources."

Mr. Ensminger legitimately questions how the leader of a federal scientific public health agency can stand behind a document which contains no supporting information or

⁵⁹ "Public Health Assessment for U.S. Marine Corps Base at Camp Lejeune, Military Reservation, Camp Lejeune, Onslow County, North Carolina," Agency for Toxic Substances and Disease Registry, 1997, available here: http://www.atsdr.cdc.gov/HAC/pha/usmclejeune/clej_toc.html.

⁶⁰ For a good summary of the environmental issues at Camp Lejeune see: J. Wang, et. al., "Camp Lejeune (NC) Environmental Contamination and Management," Multimedia Environmental Simulations Laboratory, Georgia Institute of Technology, available here: http://mesl.ce.gatech.edu/RESEARCH/CampL_GW.htm.

⁶¹ "Camp Lejeune, North Carolina: Home," Agency for Toxic Substances and Disease Registry, available here: <http://www.atsdr.cdc.gov/sites/lejeune>.

⁶² Letter from William A. Pierce, Deputy Assistant Secretary for Public Affairs/Media, Department of Health and Human Services to Mr. Thomas Townsend, November 25, 2003.

⁶³ Letter from Lynn Armstrong, CDC/ATSDR FOIA Officer, Office of Communication, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) to Thomas Townsend, June 2, 2003.

data. He is particularly perturbed by how cavalier Dr. Frumkin has been to this and other critical public health issues. The impact of ATSDR's work has real-world implications for U.S. Veterans and other members of the public. In this instance, the U.S. Veterans Administration has specifically cited the flawed ATSDR public health assessment to deny at least one veteran medical benefit's for illnesses they believe were due to toxic exposures while based at Camp Lejeune on several occasions.⁶⁴

Brush Wellman, Elmore, Ohio – Beryllium Tests

However, in some instances it is clear that Dr. Frumkin and his deputy Dr. Tom Sinks have intentionally tried to diminish the scope and integrity of some of the agency's health consultations. In one investigation that examined potential exposures to beryllium in Elmore, Ohio, Dr. Frumkin and Dr. Sinks clearly prevented ATSDR staff from more adequately informing the local community about the availability of free blood tests in order to test them for potential exposure. Publicly, ATSDR said that it offered up to 200 free tests but that only about 20 individuals responded. But internally, e-mails obtained by the Subcommittee show that Dr. Frumkin and Dr. Sinks intentionally limited advertising the availability of the tests despite strong and repeated arguments from some ATSDR staff scientists.

In February 2006, Dr. Dan Middleton was finally at wits end. In an e-mail to Dr. Sinks, in which Dr. Frumkin and others were copied he wrote: "After a prolonged struggle to bring this investigation forward and innumerable revisions, I find myself at a loss as to how to proceed – I cannot in good conscience lead an investigation that has little chance of success." Middleton said he would like to resolve the issue constructively and suggested a meeting with Dr. Frumkin and Dr. Sinks.⁶⁵

But Dr. Frumkin's reply to Dr. Sinks about the e-mail was less than encouraging. "Tom: Dan is probably right. We need a meeting. This is because he clearly hasn't gotten the message. This study is OFF. There will not be a study along the lines Dan has contemplated. There will be a limited clinical service offered to those (probably few) members of the community who want it. That service will consist of a blood test to look for beryllium sensitization among eligible persons. The outcome will be this: people who are sensitized will be informed of that fact (as will those who are not sensitized), and if they wish their doctors will also be informed. We will provide information to local doctors to help them interpret and act on the results. With that we will be done. Period. Howie."⁶⁶

In mid-June, 2006 Dr. Middleton attempted to gain permission from Dr. Sinks to specifically inform workers in one local machine shop about the beryllium tests. "Isn't it

⁶⁴ Denita L. McCall, Represented by Disabled American Veterans before Department of Veterans Affairs, Rating Decision, January 17, 2007.

⁶⁵ E-mail from Dr. Dan Middleton to Dr. Tom Sinks (cc'd to Dr. Howard Frumkin and other ATSDR officials), Tuesday, February 7, 2006, 9:38 a.m.

⁶⁶ E-mail from Dr. Howard Frumkin to Dr. Tom Sinks, Tuesday, February 7, 2006 11:15 a.m.

the right thing to do?” Dr. Middleton asked.⁶⁷ In his e-mail response, Dr. Sinks wrote: “good try – no. Let’s run the advertisement. It will include machinists and they may call us.”⁶⁸

In the end, only a small number of individuals asked to be tested. A week later, Dr. Sinks was informed by Dr. Middleton that they had completed 27 interviews for the test and that 21 people are eligible.⁶⁹ Dr. Sinks then forwarded the e-mail to Dr. Frumkin with the subject line: “beryllium testing” saying “pretty good guess!” Dr. Frumkin’s reply to Dr. Sinks, “Wow. I think 20 was our estimate, no?”⁷⁰ The Subcommittee investigated the beryllium issue last year.⁷¹

The design of any scientific study is a critical element in determining the validity of its outcome and ability of the study to identify a problem. Until ATSDR has strong dedicated leaders who are more concerned about the integrity of the reports the agency produces than the potential backlash the agency may receive from corporations, federal agencies or local environmental groups unhappy or dissatisfied with the results of their work ATSDR will never gain the public’s trust or the confidence of independent scientists and public health professionals.

Lead in Washington, D.C.’s Drinking Water

Based on almost two years of work, it is the Subcommittee’s staff’s conclusion that Dr. Frumkin has shown a laissez-faire attitude towards the scientific integrity of the documents and data his agency relies upon to make critical public health decisions. In several instances he has appeared to be more inclined to defend the agencies he directs, the Agency for Toxic Substances and Disease Registry (ATSDR) as well as the CDC’s National Center for Environmental Health (NCEH), than protecting the public’s health by diligently investigating and analyzing potential public health threats based upon sound scientific procedures and methods. His inexcusable defense of the agency’s actions in the formaldehyde issue is perhaps the most glaring example, but there have been others.

In 2002 a change in the drinking water filtration system in Washington, D.C. led to a sharp increase in the levels of lead in the city’s drinking water. This spike which may have presented a health hazard to city residents was not reported by the Washington D.C. Water and Sewer Authority (WASA) or the Environmental Protection Agency (EPA). By early 2004 tests indicated that most homes tested had water lead levels above

⁶⁷ E-mail from Dr. Dan Middleton to Dr. Tom Sinks, Subject: machine shop workers, Wednesday, June 14, 2006, 4:54 p.m.

⁶⁸ E-mail from Dr. Tom Sinks to Dr. Dan Middleton, Subject: RE: machine shop workers, Thursday, June 15, 2006, 5:02 p.m.

⁶⁹ E-mail from Dr. Dan Middleton to Dr. Tom Sinks, Friday, June 23, 2006, 3:01 p.m.

⁷⁰ E-mail from Dr. Howard Frumkin to Dr. Tom Sinks, Saturday, June 24, 2006, 11:49 a.m.

⁷¹ “Subcommittee Investigates CDC’s Handling of Beryllium Exposure Investigation,” April 11, 2008, available here: <http://science.house.gov/press/PRArticle.aspx?NewsID=2154>.

EPA's recommended level of 15 parts per billion (ppb). The public first became aware of the high lead levels in a 2004 story in the Washington Post.⁷²

In March 2004, scientists at the CDC's National Center for Environmental Health, which Dr. Frumkin came to lead the following year, reported that of 201 residents from 98 homes with high water lead levels they tested, none of them had lead levels in their blood that reached a "level of concern."⁷³ Most people interpreted this CDC report as claiming that there was no health threat from drinking Washington, D.C.'s water. A WASA fact-sheet in February 2008, for instance, said: "According to the CDC report, there were no children, from a sample group of 201, identified with blood lead levels above the CDC *level of concern* (>10 micrograms/deciliter) that were not explained by other sources, primarily the conditions of the household paint."⁷⁴

But last month a peer-reviewed paper was released by Marc Edwards, a civil and environmental engineering professor at Virginia Tech and collaborators at Children's National Medical Center that showed, in fact, children in D.C. clearly had high levels of lead in their blood as a result of the D.C. water crisis. They also found that 50% of the data CDC relied on from the D.C. Department of Health regarding the blood tests and water lead levels was flawed.⁷⁵ In addition, it was discovered that more than 6,500 blood tests for a critical period in 2003 and 2004 were lost. Still, Dr. Frumkin told a reporter for Environmental Science & Technology, the journal where the article was published, that even if the data used for the CDC analysis was deeply flawed it would not impact the CDC's conclusions. "No public-health database is perfect," he said. "But this database is not so flawed that it fails. We did a sensitivity analysis to see what happens if data are misclassified. That sensitivity analysis shows that there would need to be a very large amount of data misclassification to alter the conclusions of the study," argued Frumkin.⁷⁶

Dr. Frumkin's statement that a "sensitivity analysis" showed that even flawed data would not change the conclusions of the CDC report struck Professor Marc Edwards as incredible for the leader of a public health agency. Professor Edwards says considering half of the data had flaws in it, it seems highly unlikely that those flaws did not impact the CDC's findings. He says his new report clearly shows that the data and therefore CDC's conclusions were wrong. Dr. Frumkin and the CDC began to back away from their initial claims that were widely interpreted to mean the drinking water was safe.

⁷² 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.

⁷³ "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," Morbidity and Mortality Weekly Report, MMWR Dispatch, Vol. 53 / March 30, 2004, Department of Health and Human Services, Centers for Disease Control and Prevention, available here: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm>.

⁷⁴ "Important Facts For Lead Service Replacement: Program Review," District of Columbia Water and Sewer Authority, February 2008, available here: http://www.dcwasa.com/site_archive/news/documents/LSR%20Program%20Facts.pdf.

⁷⁵ Marc Edwards, et. al., "Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," Environmental Science & Technology, January 27, 2009.

⁷⁶ Rebecca Renner, "Mapping out lead's legacy," Environmental Science & Technology, February 11, 2009, available here: <http://pubs.acs.org/doi/full/10.1021/es8037017>.

In the aftermath of the criticism of the CDC report, Dr. Frumkin said the report had a “clear message,” that “there is no threshold for lead exposure.” Edwards, a civil and environmental engineering Professor was named a MacArthur Fellow last summer by the John D. and Catherine T. MacArthur Foundation and granted \$500,000 (often called a “Genius Grant”) to study drinking water safety issues. Edwards has written several letters to the CDC alleging “possible scientific misconduct by CDC Scientists and Officials” regarding the D.C. lead – drinking water issue. He has not named Dr. Frumkin in these complaints.

But Dr. Frumkin’s public response to his involvement in the D.C. lead drinking water issue is remarkably similar to his actions and inactions undertaken during ATSDR’s response to the formaldehyde issue. In that instance, he argued, after being confronted by Congress that it was not his agency’s fault for issuing a deeply flawed health consultation, but FEMA’s fault for “misinterpreting” the data in the undeniably flawed report. On the D.C. lead issue, Dr. Frumkin e-mailed Ralph Scott, the Community Project Director for the Alliance for Healthy Homes, on Monday, February 16, 2009 and said: “In the Post article of February 11, WASA General Manager Jerry Johnson attributed to CDC the view that “residents’ health had not been affected” by elevated lead levels in DC’s water supply from 2001 to 2004. As I am sure you agree, this persistent misstatement by WASA is regrettable,” wrote Dr. Frumkin. He then went on to defend the CDC report on D.C.’s lead level in drinking water saying the report actually said no levels of lead are safe for children.

Like the formaldehyde report, the CDC report was simply “misinterpreted” by the public and apparently officials at the D.C. Water and Sewer Authority, according to Dr. Frumkin. And like the formaldehyde report, the CDC report on lead levels in D.C.’s drinking water has had health related consequences. School officials in New York and Seattle have cited the flawed CDC report as justification for not appropriately responding to high levels of lead in their water, for instance. Congress’s investigative arm, the Government Accountability Office (GAO) also cited the flawed CDC report and the Congressional Research Service (CRS) used the flawed data in the CDC report because they believed it was scientifically sound and accurate. “None of the 201 persons tested who live in homes with the highest levels of lead in drinking water (i.e., above 300 ppb) had blood lead levels above CDC’s levels of concern,” the CRS report said.⁷⁷ But Professor Edwards’ paper now shows that that conclusion was based on flawed data and is wrong.

Scientific Integrity?

For a public health agency whose mission is to protect the health of the public from toxic chemicals, the integrity of the science upon which ATSDR bases their

⁷⁷ “CRS Report for Congress: Lead in Drinking Water: Washington, DC; Issues and Broader Regulatory Implications,” Mary Tiemann, Specialist in Environmental Policy, Resources, Science, and Industry Division, Congressional Research Service, Updated January 19, 2005, available here: <http://ncseonline.org/NLE/CRSreports/05jan/RS21831.pdf>.

decisions and the scientific integrity of the public health documents they release to the public should be sacrosanct. But in its investigations of how ATSDR's leadership handled its health consultation on formaldehyde for FEMA last year the Subcommittee found a haphazard approach to clearing, vetting and approving the release of its public health documents. In addition, there was an astounding absence of independent scientific review of documents that are supposed to play a critical role in protecting the public's health and in establishing an appropriate federal response to environmentally threatened communities.⁷⁸ Largely in response to the Subcommittee's investigation Dr. Frumkin asked ATSDR's Board of Scientific Counselors to examine the agency's "Peer Review and Clearance Policies and Practices." The board issued a draft report last October.

The agency's Office of Science, in charge of clearing agency documents for public release, has a small staff and an enormous volume of documents it is supposed to clear, the board's report said. As a result, it lacks the ability to provide in depth scientific expertise to review many documents. Several people told the board that they were concerned that the reviews that took place above the division level were " cursory." In addition, the board wrote that "scientists expressed concern that in trying to achieve its objectives, the Office of Communication Science's wordsmithing can change the intended scientific message in a document." The board also found that there is no clearly written guidance on what documents should be submitted for external peer-review.

But the Board of Scientific Counselors was severely hampered in its review. Interviews were conducted with groups not individuals, for instance. "[S]ome participants may have felt constrained in offering their frank opinions," the board acknowledged. The board also recognized that it received "primarily a management perspective" and did not gather much insight into the concerns or worries of staff scientists. "Approximately 24 managers/team leaders and 7 staff scientists were interviewed across the three panels," according to the board's report. "Moreover, only one agency employee attended the open session for walk-in comments," the report says.

In fact, it seems to the Subcommittee staff that the major focus of the board's review, initiated at the direction of Dr. Howard Frumkin, received an inevitably skewed assessment of these issues. It is unclear if the board received an accurate portrayal of how ATSDR's public health documents are vetted and released to the public by not hearing from the staff scientists and other ATSDR employees who have expressed deep and wide-ranging concerns about this issue for a long time. The fact that a single employee showed up for the board's "open session" suggests that a large cadre of these scientists remains fearful about raising critical issues with ATSDR's leadership involving the scientific integrity of the agency's public health documents and perceived flaws in the scientific design and methodology used to investigate potential public health hazards. In the past year, for instance, the Subcommittee has received numerous communications from ATSDR staff scientists who have raised serious concerns about the willingness,

⁷⁸ "Toxic Trailers - Toxic Lethargy: How the Centers for Disease Control and Prevention Has Failed to Protect the Public Health," Majority Staff Report, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, September 2008, available here: http://democrats.science.house.gov/Media/File/CommDocs/ATSDR_Staff_Report_9.22.08.pdf.

ability and desire of ATSDR's leaders to ensure that only well vetted public health documents based on scientifically defensible positions and assumptions are released to the public.

Conclusion

Protecting the public's health from potential exposures to toxic substances is not an easy task. It can be scientifically challenging, time consuming and resource intensive. The Subcommittee staff suggests that legislative fixes may be necessary to address long-standing structural, procedural and technical issues that appear to have hampered ATSDR's effectiveness and harmed the communities it is supposed to protect.

But more than anything, it is apparent that no fundamental changes will occur until the nearly thousand employees at the NCEH and ATSDR, the vast majority of whom are truly dedicated and committed to protecting the public's health, have leadership that they can follow. The longer ATSDR continues to pursue its role in protecting the public's health as it has for the past three decades, issuing deeply flawed scientific reports, not responding to the concerns of local communities and approaching potential environmental exposures with a mindset that endeavors to disprove any link between the public's ill-health effects and potential exposures to environmental contaminants or toxins, the more people will suffer. After four years leading ATSDR, not only has Dr. Frumkin taken no effective steps to confront those issues, on some specific cases he has contributed to the problems detailed in this staff report. In many instances, ATSDR seems to represent a clear and present danger to the public's health rather than a strong advocate and sound scientific body that endeavors to protect it. Without a leader able and willing to confront those issues, the public's health will continue to be harmed.

- Debra Markwardt's Dogs -



**Birth Defect – Deformed Head and Face - Intestines Outside of Body
- Debra Markwardt's dogs -**



**Hole on Side of Body
- Debra Markwardt's dogs -**



Above -- Jake living on my property in Midlothian

Below - Jake 6-Months Later -- After Living in Another Town



4 confirmed PV cases on a single country road in Schuylkill County

