

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

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April 9, 2008

Dr. Julie Gerberding  
Director, Centers for Disease Control and Prevention, and  
Administrator, Agency for Toxic Substances and Disease Registry  
1600 Clifton Road NE  
Atlanta, Georgia 30333

Dear Dr. Gerberding:

The Subcommittee on Investigations and Oversight of the House Science and Technology Committee is continuing to investigate the Agency for Toxic Substances and Disease Registry (ATSDR). The Committee's concerns go well beyond the agency's indefensible handling of its February 2007 Health Consultation regarding formaldehyde levels in travel trailers provided to victims of Hurricanes Katrina and Rita by the Federal Emergency Management Agency (FEMA) or ATSDR management's treatment of whistleblower Dr. Chris De Rosa. As part of our continuing investigation, the Committee has learned of several other issues where members of the public and ATSDR insiders believe that political pressure and the influence of industry has resulted in the production of deficient, incomplete and/or muted reports, studies or Health Consultations.

One of those issues involves the agency's investigation of potential off-site beryllium exposure to the public from the Brush Wellman beryllium manufacturing facility in Elmore, Ohio. Documents obtained by the Committee raise serious questions about the influence politically-connected companies may have on ATSDR's role in investigating this and other potential public health hazards. One of those documents from September 2005, said that "Brush Wellman management" ... "resisted [ATSDR's] investigation through various means, including political pressure on" the local county commissioners.<sup>1</sup> Another one of ATSDR's own documents from April 2006, said ATSDR's investigation into beryllium related health issues was "scaled back significantly from the approach contemplated earlier, based in part on consideration of concerns raised by the County Commissioners and Brush Wellman."<sup>2</sup> These documents paint a troubling portrait of an agency charged with protecting the public's health.

Beryllium is a rare, light-weight metal that was widely used in the production of U.S. nuclear weapons. It continues to find uses in aerospace, defense and other industries

<sup>1</sup> "Brush Wellman: Elmore, Ohio Exposure Investigation," NCEH/ATSDR Hot Issue, 9/9/2005.

<sup>2</sup> "ATSDR Brush Wellman Background Paper," 4/14/2006.

where strong, light materials are needed—such as in aircraft, missiles and satellites. When beryllium dust is inhaled or absorbed through the skin it can lead to chronic beryllium disease (CBD), a devastating respiratory disease. Just like formaldehyde, some people become “sensitized” to beryllium and may develop CBD. Others may be exposed to beryllium, but never become ill. Some people who are sensitized to beryllium never exhibit symptoms, while others may suffer severe health effects.

Occupational exposures to beryllium and resulting health consequences have been known for years, particularly among former nuclear weapons plant workers. The Brush Wellman Elmore plant has had 267 confirmed cases of occupational exposures to beryllium, according to the Department of Labor. Non-occupational exposures to beryllium overall, throughout the country, however, have been more difficult to document although some cases exist. In addition, cases of chronic beryllium disease are often misdiagnosed adding to the difficulty in documenting cases of the disease.

In 2001, then-Senator Mike DeWine of Ohio asked ATSDR to investigate whether or not air emissions of beryllium from the Elmore plant or the off-site transport of beryllium dust on workers’ clothes from the site posed a health hazard to area residents. The agency released a Health Consultation on this issue in July 2002 that found current emissions of beryllium from the Brush Wellman factory did not present a public health hazard. But the report also concluded that it did not have sufficient data to determine if residents were at risk from previous beryllium releases from the plant. The report recommended completing two environmental sampling investigations of beryllium exposures that would include collecting samples from residences of Brush Wellman workers and others living near the plant. The agency also planned to collect residential environmental samples from the homes of other area beryllium workers.

In July 2003, ATSDR staff held a public meeting in Elmore to discuss their plans to test the soil, vehicles, air, surface and carpet in nearly 75 homes near the site. According to the ATSDR press release at the time: “The agency completed a health consultation regarding this site last year and determined that an exposure investigation was necessary to assess the level of beryllium present in the homes and vehicles of those who work or live near the Brush Wellman facility.”<sup>3</sup> In 2005, two of three peer reviewers who evaluated the agency’s environmental sampling plan recommended the plan go forward.<sup>4</sup> Despite that, however, ATSDR never conducted any of its planned environmental tests in Elmore, Ohio. It is unclear why the tests were cancelled, although ATSDR documents suggest the tests may have been casualties of political pressure.

In March 2006, ATSDR announced new plans to offer free blood tests – known as the beryllium lymphocyte proliferation test (BeLPT) – for up to 200 Elmore community members.<sup>5</sup> The tests were developed as a screening tool to identify individuals who may

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<sup>3</sup> ATSDR Media Announcement: “ATSDR Seeks Community Input on Protocol for Beryllium Exposure Investigation in Elmore, Ohio,” June 30, 2003. <http://www.atsdr.cdc.gov/NEWS/elmoreoh070203.html>

<sup>4</sup> “Appendix 6 – Peer Review Comments and ATSDR Responses,” undated ATSDR document from 2005.

<sup>5</sup> ATSDR Media Announcement: “ATSDR to Offer Blood Tests for Beryllium Sensitization in Elmore, Ohio,” March 27, 2006. [www.atsdr.cdc.gov/NEWS/elmoreoh032706.html](http://www.atsdr.cdc.gov/NEWS/elmoreoh032706.html)

be sensitized to beryllium. The tests are not perfect and like all screening tests they may identify some individuals as being sensitized to beryllium who are not sensitized and they may miss identifying some people who actually are sensitized. This was one reason Brush Wellman claimed to oppose the test, although the company actually provides this same test for its own workers. Nevertheless, documents obtained by the Committee show that the company was adamantly opposed to the tests, in part, supposedly because the tests would raise unnecessary concerns about beryllium exposure in Elmore, Ohio.

At this same time, in 2006, Brush Wellman, Inc. was deciding whether to expand its beryllium facility in either Elmore, Ohio or Delta, Utah. Letters from Richard J. Hipple, the President and Chief Operating Officer of Brush Engineered Materials Inc., the parent company of Brush Wellman, Inc., responsible for the Elmore plant show he feared that ATSDR's health investigations would have a negative impact on the company's possible expansion of the Elmore site.

On March 28, 2006, Richard Hipple, wrote to then Senator DeWine complaining of ATSDR's plans to offer free tests for beryllium sensitization to up to 200 residents of Elmore.<sup>6</sup> The letter raised concerns about the scientific validity of the tests and expressed concern that ATSDR's efforts could draw negative media attention to Brush Wellman's plans to expand the Elmore site. "[W]hy would Elmore residents embrace an expansion of our beryllium facility to add more production at the site if ATSDR is convinced further investigation is needed and you support it?" Hipple asked Senator DeWine. The letter claimed that if ATSDR's plans went forward its study would be seen "as the origin of a junk science program that led to a loss of property values, loss of jobs and perhaps a loss of a major local employer."

A few days later Hipple fired off a letter to then-Ohio Governor Bob Taft.<sup>7</sup> Hipple thanked the governor for his efforts in attempting to help the company secure a new strategic beryllium production plant in Ohio and then reiterated his distress over the planned ATSDR study. "It will be very difficult to announce an Elmore Ohio site selection decision with the media attention and community uncertainty that we believe will result from ATSDR's latest unilateral and unscientific based actions. I very much appreciate your offer to meet with Secretary [of Health and Human Services, Mike] Leavitt," wrote Hipple. Governor Taft responded promptly. That same day he penned a hand-written note to Secretary Leavitt, telling him that he had spoken with Hipple about an "expansion project Ohio is competing for. Actions by ATSDR are a deterrent to choosing Ohio," wrote Governor Taft. "Please have someone look into this and get back to me."<sup>8</sup>

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<sup>6</sup> Richard J. Hipple, President and Chief Operating Officer, Brush Engineered Materials, Inc., letter to Senator Mike DeWine, March 28, 2006.

<sup>7</sup> Richard J. Hipple letter to Ohio Governor Bob Taft, April 3, 2006.

<sup>8</sup> Handwritten note from Governor Bob Taft to the Honorable Mike Leavitt, Secretary of the Department of Health and Human Services (HHS), April 3, 2006.

In June 2006, Ohio Governor Bob Taft announced a \$100,000 business development grant to Brush Wellman Inc. for costs associated with its anticipated expansion of the Elmore, Ohio beryllium site.<sup>9</sup> In September, Brush Wellman announced its decision to expand the Elmore site at a cost of \$40 to \$60 million. The expansion would add 25 new positions to the estimated 600 person workforce and eliminate the need to curtail 120 jobs at the site. In November 2006, ATSDR announced the results of their beryllium tests. Only 18 people participated in those tests, but none of them were found to be sensitized to beryllium. In December 2006, ATSDR released a "revised" Health Consultation on beryllium exposures in Elmore. But the report asked the same questions it posed in 2002 regarding whether or not Elmore-area residents had been exposed to beryllium either from the plant's air emissions or the transport of dust from beryllium workers' clothing off-site. In addition, it recommended the same environmental sampling tests that the agency recommended in the original 2002 report.

It appears that this political pressure to have ATSDR scale down or cancel its beryllium tests worked, at least in part. The Subcommittee has reviewed one internal ATSDR background paper on the agency's involvement on this issue, dated April 14, 2006, which certainly suggests that Brush Wellman's pressure on the agency had some impact on the agency's investigation.<sup>10</sup> "Brush Wellman and the [Ottawa County] Commissioners suggest that ATSDR's presence in Elmore would raise unfounded health concerns among residents and create a climate that would be hostile to their expansion," the paper notes. The document also acknowledges that ATSDR did curtail its investigation at the behest of industry. "ATSDR's current proposal is scaled back significantly from the approach contemplated earlier, based in part on consideration of concerns raised by the County Commissioners and Brush Wellman," according to the document. Most disturbingly, it appears that ATSDR's leadership played a crucial role in these actions. "ATSDR's senior management will personally review all comments offered by the company and the county commissioners and ATSDR proposed responses to the comments," the document says. The Committee understands that ATSDR Deputy Director Tom Sinks led the agency's handling of its beryllium investigation.

It is unclear what specific influence Brush Wellman's lobbying efforts played on the ATSDR investigation. But in the end only 18 residents were tested for potential beryllium sensitization, although ATSDR planned to test up to 200 individuals. It is unclear why so few residents participated in the tests, but the testing occurred in the summer of 2006, just a few months after Brush Wellman raised objections to the tests. In addition, the agency's plans to conduct environmental sampling of beryllium in the residences of 75 workers were cancelled. That work has never been completed.

Pursuant to the Committee's authority under Rules X and XI of the United States House of Representatives and Rule 3 (a) (5) of the Committee on Science and Technology, we are requesting that you provide copies of all of the records (see attached definition) listed below:

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<sup>9</sup> "Gov. Taft Announces Grants to Businesses, Communities," US Fed News, June 12, 2006.

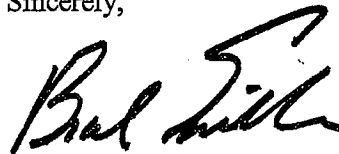
<sup>10</sup> "ATSDR Brush Wellman Background Paper," 4/14/2006.

1. Copies of all records regarding ATSDR and CDC's investigation into potential beryllium exposure in, near or surrounding the Brush Wellman beryllium facility in Elmore, Ohio from January 1, 2006 to present.
2. Please include, any and all records related to the agency's decision not to conduct environmental sampling, as originally planned, of the residences of workers from the Brush Wellman site or other beryllium facilities in Elmore, Ohio.
3. All communications plans, media alerts, flyers, fact sheets, scripts, advertisements, or any other records related to ATSDR's "community outreach" efforts regarding the 2006 beryllium tests offered by the agency.
4. Records of any description from 2005 to the present regarding communications between Dr. Falk, Dr. Frumkin, Dr. Sinks or yourself with any elected official or their staff related to the beryllium study in Elmore, Ohio.

Please provide the requested records to the Subcommittee offices in Room B-374 of the Rayburn House Office Building by 5 p.m. on Wednesday, April 23, 2008. If you have any questions or need additional information, please have your staff contact Douglas Pasternak, Investigations and Oversight Subcommittee professional staff member, at (202) 226-8892, or Dr. Dan Pearson, Investigations and Oversight Subcommittee staff director, at (202) 225-4494.

Your assistance in this matter is greatly appreciated.

Sincerely,



BRAD MILLER  
Chairman  
Subcommittee on  
Investigations & Oversight

cc: JAMES SENSENBRENNER, JR.  
Ranking Member  
Subcommittee on Investigations & Oversight

Attachment

## ATTACHMENT

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



## BRUSH WELLMAN ELMORE, OHIO EXPOSURE INVESTIGATION

### BACKGROUND

The Brush Wellman plant in Elmore, Ohio is the principal producer of beryllium, beryllium alloy, and beryllium oxide in the United States. Elmore is located about fifteen miles southeast of Toledo along Highway 51 (Marcy Kaptur, D-9<sup>th</sup> District, represents Elmore).

- Beryllium is extracted from two ores: beryl and bertrandite, and is used in products in a number of industries, including aerospace, automobile, energy, medicine, and electronics. Exposure to beryllium can lead certain susceptible individuals to develop chronic beryllium disease (CBD), a progressive, granulomatous lung disease. The symptoms include dry cough, shortness of breath, fatigue, and chest pain. CBD can be debilitating and sometimes fatal.
- Sarcoidosis: this is an inflammatory condition in which granulomas are formed. It has no known cause and mimics other disorders such as CBD. Sarcoidosis usually starts in the lungs or lymph nodes in the chest and almost always occurs in more than one organ at a time. It also affects skin, eyes and liver. The cause of this disease is not known and the course of the disease varies greatly among people. In most cases, sarcoidosis is mild and the inflammation that causes the granulomas gets better on its own. In severe cases, sarcoidosis causes scar tissue that permanently damages organs and cause death (usually from cardio-pulmonary changes). Treatment usually does not affect scar tissue.

### HISTORY OF ATSDR'S INVOLVEMENT

**January 5, 2001:** Controlled Correspondence: Senator Mike DeWine (R-OH) sent a request to Dr. Jeffrey Copeland, CDC Director, asking CDC or one of its organizations to conduct an assessment to determine the Elmore community's exposure to beryllium dust. Senator DeWine was concerned because many of his constituents believed they were at risk of exposure from beryllium particles outside the facility. In his letter, Senator DeWine acknowledged that considerable research on beryllium exposure in the workplace had been done but he believed that more work needed to be done outside of the workplace. Senator DeWine wanted ATSDR to determine whether air emissions of beryllium from the plant and the possible off-site transport of beryllium on workers' clothing constitute a health hazard to area residents.

**October 2001:** ATSDR published a health consultation on the Brush Wellman beryllium plant that found that beryllium emissions from the plant were below levels expected to cause adverse health effects and did not pose a public health hazard. However, the health consultation determined that an exposure investigation was necessary to assess the level of beryllium present in the homes and vehicles of those who worked or lived near the Brush Wellman facility.

**July, 2003:** ATSDR began planning for an exposure investigation at the Brush Wellman site. ATSDR proposed to test current and former Brush Wellman workers, residents living near the Brush Wellman plant, local machine shop workers who work with beryllium. It also proposed to test soil and dust from properties near the plant for the presence of beryllium. On **July 14, 2003**, the community was invited to provide input on the protocol.

**July 25, 2002:** ATSDR released a health consultation that concluded:

- 30-day averages of beryllium emissions from the plant did not constitute a public health hazard;
- short-term beryllium release episodes and past violations of the EPA standard in 1980, 1989, and 1990 presented an indeterminate public health hazard to residents immediately north and northeast of the Brush Wellman Elmore facility;
- a lack of adequate information prevented ATSDR from determining whether beryllium taken home on workers' clothing constitutes a health hazard, and therefore this route is classified as an indeterminate public health hazard; and
- the levels of beryllium in well-water samples from private residents near the Elmore Brush Wellman plant presented no public health hazard to residents.

The health consultation recommended that ATSDR determine whether community members might have been exposed to off-site dust transport of beryllium. ATSDR would do so by completing two environmental sampling investigations. It also recommended that Brush Wellman cooperate with authorities in this effort and that the Ohio EPA establish an ongoing dialogue with the Elmore community and perform periodic sampling of well water and ambient air.

**July 25, 2003:** Controlled Correspondence from Senator Mike DeWine to Dr. Julie Gerberding re: clarification of proposed protocol. Correspondence is addressed to Mr. Peter Kowalski, Environmental Health Scientist, ATSDR.

Senator DeWine wrote in response to the public meeting expressing concerns relayed to him through several of his constituents regarding determinations. These constituents voiced concerns regarding the apparent lack of surface standards for the purpose of making health determinations for beryllium hypersensitivity or for chronic beryllium disease. Senator DeWine requested clarification as to why ATSDR selected the testing procedure outlined in the draft exposure investigation protocol. He noted that the Commissioners of Ottawa County, Ohio requested that the US EPA's 30-day ambient air standard for beryllium be used for its ability to make health-based determinations of public health. He asked if this test serve as a viable alternative to the current testing procedure found in the draft exposure investigation protocol?

**August 27, 2003:** Controlled Correspondence from Dr. Julie Gerberding to Senator DeWine's July 25, 2005 letter regarding ATSDR's public comment exposure investigation. In response to the inquiry regarding ATSDR's selection of the testing procedure outlined in the draft investigation protocol, Dr. Gerberding clarified that



ATSDR designed the protocol to determine whether residents may be exposed to beryllium, possibly from workers' taking the metal home on their clothing or from past air emissions from the Brush Wellman plant. In response to the inquiry on whether a 30-day air sample is a reasonable alternative to the current draft protocol, Dr. Gerberding outlined that ATSDR will seriously consider the county's request for 30-day air sampling in the revised protocol. She further indicated that the exposure investigation public comment period had closed August 15, 2003 and that ATSDR would provide additional information after completing the assessment (compiling, reviewing, and formulating responses) of the public comments. Dr. Gerberding offered the services of the ATSDR staff to meet with either Senator DeWine, or his staff, to discuss the content of the protocol.

1. To date, ATSDR has developed and had peer-reviewed a protocol for the investigation.
2. However, the Brush Wellman management has not provided direct comment on the protocol and has resisted the investigation through various means, including political pressure on the Ottawa County commissioners.
3. The Ottawa County Commissioners have also objected to the release of the protocol, citing among other objections (a) that ATSDR is overstepping its authority by including sarcoidosis as a subject of proposed study; (b) that the protocol lacks a control group to compare results; and (c) that a release of the protocol in September rather than in December might adversely affect tourism in the area. Dr. Julie Gerberding has responded to the commissioners' concerns on several occasions, copying Senator DeWine each time.

**August 30, 2005:** Senator Mike DeWine met with County Commissioners. The Senator wants ATSDR to meet with the County Commissioners to brief them about ATSDR's public health consult/protocol for case finding before the September 6th release. In the original roll-out plan for the health consult/protocol, ATSDR planned to brief the Commissioners on September 5th or 6th, but the Commissioners want to be briefed before that.

**September 6, 2005:** Peter Kowalski, MD, the ATSDR lead for this site, has been deployed to New Orleans for two weeks, so the briefing for the County Commissioners is delayed at least two weeks. CDC/W has been notified of Peter's deployment.

ATSDR Brush Wellman Background Paper  
4/14/2006 2:10 PM

**Introduction:** In early 2001 Senator DeWine asked ATSDR to determine whether air emissions of beryllium from the Brush Wellman plant in Elmore, Ohio, or possible off-site transport of beryllium on workers' clothing, constitute a health hazard to the area residents. The Ottawa County Commissioners and Brush Wellman have expressed concerns from the outset: the stated basis for their opposition has changed as ATSDR's work has progressed and other circumstances evolved. At each stage ATSDR has endeavored to work with them and the community at large to address questions and concerns raised about its proposals.

**Initial Findings and Recommendations:** In its 2002 public health consultation ATSDR concluded that current emissions of beryllium from the Brush Wellman facility did not present a public health hazard. However, the Agency also concluded that it did not have the data necessary to determine whether residents were at risk from exposures to beryllium released in the past. The case finding and exposure investigations that, until recently, ATSDR was planning, were intended to address that uncertainty. ~~ATSDR has taken a fresh look at scientific and related other issues.~~ As a result, the Agency recently decided to take a more limited approach to address what the health consultation refers to as an "indeterminate public health hazard".

**ATSDR's current approach:** The Agency recently concluded that while there was not sufficient evidence of health impact at this time to warrant a full case finding study or exposure investigation, data showing beryllium had been released in the past, and the uncertainty left by the earlier report's finding of an indeterminate health hazard, it would be prudent to offer tests for beryllium sensitivity to persons who may have been exposed to beryllium and may be concerned about these past exposure. The current proposal is to offer, as a public service, tests for beryllium sensitization to up to 200 eligible persons, including those who live within a short distance of the facility, and those who could have been exposed through beryllium dust brought home on workers' clothing. The test would be purely voluntary and confidential.

**Issues and Concern expressed by the Ottawa County Commissioners and Brush Wellman:** The current concerns relate to a community service testing plan that ATSDR released for public comment on March 31, 2006. The plan, which is open for public comment through April 30, provides for activities that are significantly more limited than those ATSDR proposed to undertake in the past: in place of a full research study and exposure investigation in residences, which the Commissioners and Company opposed,

The Commissioners and Company have raised these concerns through numerous channels, including several directed to Secretary Leavitt: a letter from the CEO of Brush Wellman; a phone call to Sen. DeWine; and a note from Governor Taft. Their concerns include:

- challenging the need for any further action by ATSDR,

- Arguing that ATSDR's presence could hurt the chances that Brush Wellman's Elmore facility will be chosen to carry out a large contract recently awarded to the Company by the DOE. Selection would mean construction of a state of the art facility and job creation in an economically depressed area. The other location under consideration is in Utah, the site of Brush Wellman's current mining operations. Brush Wellman and the Commissioners suggest that ATSDR's presence in Elmore would raise unfounded health concerns among residents and create a climate that would be hostile to their expansion. However, beryllium sensitization is an indication of past exposure to beryllium; ATSDR's proposed plan should have no bearing on where Brush Wellman builds its new state of the art facility.
- Arguing that the testing method is seriously flawed and unreliable without acknowledging that the company has periodically offered this same test to its own employees.

The Commissioner also made a suggestion, which Senator DeWine reportedly pursued in his conversation with Secretary Leavitt, that the County Health Department, rather than ATSDR, should conduct the testing.

**Steps to accommodate concerns raised by the Commissioners and Brush Wellman:**

1. ATSDR has consistently solicited and seriously considered the concerns of Brush Wellman, the County commissioners, and the community at large, and where appropriate has taken steps to accommodate these concerns. For example, the Agency:

- Has sought and considered public comments on the protocol for the exposure investigation in 2003;
- read a statement prepared by the County Commissioners at ATSDR public meeting in 2003;
- planned to invite public comment on the case finding protocol in 2005, before deciding not to go forward with a case finding study;
- agreed to change the intended schedule for release of the protocols;
- reconsidered its approach, based in part on issues raised by the Commissioners and the company, and decided not to proceed with the case finding or exposure investigation at this time;
- attended a lengthy meeting convened by Sen. DeWine with representatives of Brush Wellman and the County Commissioners on March 24, 2006, to brief them on and answer questions regarding the approach under the new protocol, prior to its release on March 31, 2006; The company president, Mr. Richard J. Hupples, sent a letter to Senator DeWine on March 28, 2006 that inaccurately characterized the purpose and the content of the March 24, 2006 meeting, a meeting in which he did not attend. ATSDR will review and address any scientific comments contained in his letter immediately following the public comment period.

- offered to convene an expert panel in Ottawa County to address the interpretation of testing results, on April 25, 2006: the panel will include representatives of Brush Wellman and the County, as well as other scientists;
- invited public comment for a period of 30 days on the protocol released on March 31, 2006, and before finalizing the protocol will consider comments received.

2. Based on the circumstances -- data showing past releases of beryllium, and ATSDR's earlier finding of an indeterminate health hazard - persons who may be concerned about potential exposure should be offered an opportunity to learn more about their individual status through a test for beryllium sensitization.

3. ATSDR's current proposal is scaled back significantly from the approach contemplated earlier, based in part on consideration of concerns raised by the County Commissioners and Brush Wellman.

4. ATSDR is in an ongoing dialogue with the County Commissioners regarding their suggestion that the County conduct blood testing. Although the suggestion raises some concerns, the Agency has requested further information to allow it to more fully evaluate the proposal.

5. If the County Commissioners and the company are correct that the community is not interested in the testing, then the demand for this service will be limited. Press in response to ATSDR's announcing its release of the protocol for public comment ~~has been~~ limited and neutral.

6. The Commissioners and the Company should be encouraged advised to raise their concerns through the public comment period on the protocol, which is open until April 30, rather than allowing them to bypass this process which ATSDR voluntarily offered precisely for the purpose of inviting and addressing concerns such as those that have been raised. ~~ATSDR's senior management will personally review all comments offered by the Company and the County Commissioners and ATSDR proposed responses to the comments.~~

From the desk of:  
**BOB TAFT**  
Governor

\*\*\* RECEIVED \*\*\*  
Apr 06, 2006 17:07:55 WS# 06  
OFFICE OF THE SECRETARY  
CORRESPONDENCE  
CONTROL CENTER

4/3/06

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To: Hon. Mike ~~Carroll~~ 2006 APR 11: 08

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COMMUNICATIONS CONTROL  
CENTER

Brush E. m. C.O.O.

Hipple mentioned this issue to me on Friday when I called him about an investment/expansion project Ohio is competing for.

Actions by ATSDR are a deterrent to choosing Ohio.

Please have someone look into this & get back to me at 614-644-0802.

Thank you.

Bob Taft



Brush Engineered Materials, Inc.  
17876 St. Clair Ave.  
Cleveland, OH 44110  
216-486-4200

Richard J. Hipple  
President and  
Chief Operating Officer

Direct Dial: 216-333-6815  
Cell Phone: 216-403-3275

April 3, 2006

The Honorable Bob Taft  
Governor of Ohio  
77 S. High St., 30<sup>th</sup> Floor  
Columbus, OH 43215-6117

Dear Governor Taft:

Thank you very much for taking the time to call us on Friday to offer your help in securing the new strategic Beryllium production plant for the state of Ohio. Also, your efforts on tort reform and reducing the costs of doing business are essential to secure long-term employment in Ohio. The global economy is challenging many of our historic models, and we must quickly adapt or be subject to becoming a secondary economy. We just recently celebrated our 75<sup>th</sup> anniversary as an Ohio corporation and are looking forward to the next seventy-five years here in Ohio!

The efforts and current financial incentive proposal by the Ohio Department of Development team are greatly appreciated. As you might expect, it is a close race between Elmore Ohio (where we have the world's largest worldwide beryllium and beryllium alloy manufacturing facility) and the competing location where our mining operation is located. You asked whether there were any issues that you could help to overcome to make Ohio the "winning" location. There are two:

- First, we face a \$2 - \$3 million expense for demolition and site preparation of the old beryllium plant building at our Elmore Ohio facility. The alternate site does not have demolition requirements, making the site prep far less extensive and costly. If Ohio could find a way to help here, it would be a major advantage to site the new plant in Elmore Ohio. The new building and equipment will be the most modern beryllium production plant in the world.
- Second, the ongoing involvement of the Agency for Toxic Substances and Disease Registry (ATSDR) in the community around our Elmore Ohio plant. *It will be very difficult to announce an Elmore Ohio site selection decision with the media attention and community uncertainty that we believe will result from ATSDR's latest unilateral and unscientific based actions.* I very much appreciate your offer to meet with Secretary Leavitt to help explain how the ATSDR is continuing its investigation well beyond the original scope of Senator DeWine's request, without any evidence of a beryllium-related health risk in the community. I offer the following background information to supplement your meeting with Secretary Leavitt. *This meeting is crucial as time is of the essence for Ohio!*

In 2001, in response to a request by Ohio Citizen Action, Senator Mike DeWine asked the ATSDR to study whether beryllium air emissions from Brush Wellman's Elmore plant and the possible off-site transport of beryllium dust on workers' clothing presented a health hazard to area residents. The initial ATSDR consultation was completed in 2002 with the agency concluding that air emissions from Brush Wellman do not pose a health threat to the Elmore community. The report also acknowledged the extensive measures by Brush to prevent off-site transport of beryllium by workers, including showers and company-provided clothing that remains on site. These measures to prevent off-site drag-out of beryllium into workers homes or the community have been in place since at least 1957.

Governor Bob Taft  
April 3, 2006  
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Despite these conclusions and the assurances to the public that we believe they provide, the ATSDR is now planning to blood test 200 persons in the Elmore area community. *In a March 24, 2006 meeting, ATSDR Deputy Director Thomas Sinks told Brush Wellman and Ottawa County representatives that no immediate health concerns exist and ATSDR has found nothing that supports a case study investigation at this time.* Dr. Sinks could offer up no reason for the blood testing other than to say that ATSDR believes "something needs to be done" as a service to the community for those that remain concerned.

What makes this all so senseless and wasteful is there is no longer any pressure by Ohio Citizen Action or any demand from anyone in the community for ATSDR to continue its actions in Ottawa County. To illustrate:

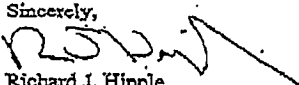
- Upon learning of our extensive community and worker protection efforts, Ohio Citizen Action concluded its Brush Wellman campaign on September 17, 2002 and subsequently publicly declared the company a "Good Neighbor." In fact, in October of 2006, Ohio Citizen Action ceremoniously gave Brush Wellman a special recognition award for its health and safety efforts with workers and the community.
- No one in the community is eager for the ATSDR to return. *In fact, the community has strongly - and in overwhelming numbers - opposed the continuation of the ATSDR study.* Only one letter of nearly 123 public comment letters received by the ATSDR was supportive of the agency's approach. The Ottawa County elected officials have also expressed their objections regarding the ATSDR's program as it is currently designed.
- There have been no cases of community beryllium illness in the company's 53 years of operating in Ottawa County, and the plant beryllium emissions are *significantly* below the EPA standards.
- A 2006 review by the Ottawa County Health Department found there is no increased incidence of respiratory diseases in Ottawa County. In fact, the Ottawa County rates are below both the State of Ohio and national rates.
- The proposed ATSTR blood testing program is very unreliable and has no baseline data to which the results can be compared. Collecting data with no means for scientific interpretation will likely result in great community confusion and quite possibly cause serious unnecessary damage to property values. An extreme waste of tax dollars!

It is complicated to understand all of the issues and events that have led to the current ATSDR plan. I am including with this letter three attachments that provide additional understanding of what has transpired. If it would be of help to you, our Vice President of Environmental Health and Safety, Marc Kolanz, or our consultant, Randy Schumacher, are available to assist you in Washington at any time. Attached are: 1) a letter from Mr. Arndt, the President of the Ottawa County commissioners, to Senator DeWine, 2) comments from a well-respected health expert from Yale (Dr. Borak) who is serving as the commissioner's health expert, and 3) a letter that was recently sent to Senator DeWine from me.

Again, I very much appreciate your willingness to convey the aforementioned concerns to Secretary Leavitt. *The Ottawa County elected officials have expressed their objections regarding the ATSDR's program as it is currently designed. They would be very much interested in a less drastic approach if only the ATSDR would work with them.*

Please feel free to call me at any time if I can be of any assistance in clarifying these important issues. Most importantly, thank you again for all your time and consideration on the site prep costs, and the ATSDR.... it is essential to make Ohio a "winner".

Sincerely,

  
Richard J. Hipple



Brush Engineered Materials, Inc.  
17876 St. Clair Ave.  
Cleveland, OH 44110  
216-486-4200

Richard J. Hipple  
President and  
Chief Operating Officer

Direct Dial: 216-383-6815

March 28, 2006

The Honorable Mike DeWine  
United States Senate  
140 Russell Building  
Washington, DC 20510

Dear Senator DeWine:

You asked that I contact you if things did not proceed well in reaching a reasonable compromise with the Agency for Toxic Substances and Disease Registry (ATSDR) on the scientific issues. As you undoubtedly know by now, Brush Wellman attended a meeting this past Friday, March 24, hosted by your office with ATSDR and Ottawa County Commissioners office representatives. My senior science staff expected that this meeting would finally provide the opportunity, as you had promised, for a **cooperative resolution of the scientific questions to enable a consensus that meets the needs of ATSDR, Brush Wellman, Inc. and Ottawa County. It was not.** ATSDR came to the meeting having already made up its mind on what it plans to do in Elmore, and nothing either Brush Wellman or the County Commissioners said dissuaded the agency from its predetermined agenda. At most, it was a courtesy meeting. At the worst, you are being used as the unilateral reason for ATSDR's continuing action which may leave you accountable for any public outrage.

The decisions that the ATSDR announced yesterday are likely to seriously damage Brush Wellman's reputation in the Elmore community, unfairly elevate concerns about potential beryllium health effects with our customers and in the Elmore community, and increase the likelihood of litigation by plaintiff's lawyers using the ATSDR as justification.

During the meeting, we pointed out that ATSDR has thoroughly reviewed Ottawa County Health Department records and found there is no increased incidence of respiratory diseases in Ottawa County. In fact, the Ottawa County rates are below both the State of Ohio and national rates. Dr. Thomas Sinks of the ATSDR claimed that there have been community cases of CBD. When questioned on this, Dr. Sinks could only identify a single case in the entire 53 years the Elmore plant has been in operation and he did not know that this spousal case was related to an in-plant industrial beryllium



The Hon. Mike DeWine  
March 28, 2006  
Page 2

accident and not to beryllium air emissions (this person lived 35 miles upwind of the Elmore plant). Dr. Sinks also stated that ATSDR believes there is significant community interest in its investigation, despite the fact that Ohio Citizen Action stopped its campaign against Brush Wellman over two years ago and even gave Brush Wellman a special recognition award in 2005 for health and safety improvements. Dr. Sinks could offer no basis to support his claim and he ignored the point made by Commissioner Steven Arndt that only 1 of 123 public comment letters to the ATSDR favored ATSDR continuing its investigation. These facts, combined with ATSDR's earlier finding that Brush Wellman's beryllium emissions pose no increased health risk to Elmore residents, should have been enough to justify stopping any further investigation in the community.

That is not the case, however. Dr. Sinks repeatedly stated that ATSDR "needs to do something" and clearly stated that **its further efforts are in response to your original request**. ATSDR plans to offer 200 residents of Elmore the highly questionable blood lymphocyte proliferation test for beryllium (BeBLPT). The agency stated the public health benefit to the community and individuals tested is reassurance, *if the tests come back negative*. Dr. Sinks did not understand that there is a good chance some will be positive but unrelated to Brush Wellman's emissions or work practices. Brush Wellman previously informed ATSDR that 1-2% of the people will test positive who have never worked with beryllium or had exposure to beryllium other than from naturally occurring beryllium. This fact was apparently news to Dr. Sinks, which supports our assertion that the agency has a predetermined agenda and lacks full understanding of the scientific facts associated with the BeBLPT.

The ATSDR recently used the BeBLPT in a community in Tallahassee Florida to re-test three persons who had a single positive test out of a total of 359 persons tested, along with re-testing another six persons whose tests were either "borderline" or uninterpretable. The re-tests were sent to two different labs for analysis. Of these 18 repeated tests, not one confirmed the first test result. **According to the local media reports, this has led to great confusion in the community, lawsuits and calls for resident's homes to be bought out and resident's relocated.** Dr. Sinks was clear that ATSDR does not care about any adverse fallout as the result of its continuing efforts in the Elmore community.

The beryllium medical and science experts who attended the meeting on behalf of Brush Wellman and the independent medical expert from Yale representing the Ottawa County Commissioners questioned ATSDR's proposed investigation and described it as not meeting minimum scientific standards for even a student's Masters-degree program. Dr. Sinks could only repeat his statement that what ATSDR is planning is being deemed a public health service, not a scientific study. Dr. Sinks has erroneously based his comment on an assumption that a negative BeBLPT imparts a confirmation of safety to area residents. Dr. Sinks was not aware that persons have been diagnosed with chronic beryllium disease who never test positive using the BeBLPT. Dr. Sinks further stated that ATSDR plans to summarize the results of the "public health service" to the community, yet readily admitted that no typical scientific controls are being put in place to ensure the accuracy of the results or absence of testing bias.

The Hon. Mike DeWine  
March 28, 2006  
Page 3

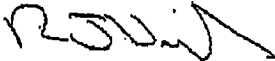
Let's be clear why ATSDR continues to pursue this ill-founded investigation: because you asked for the original study and you will not tell the agency that your request has been satisfied. This is what your staff stated and what ATSDR understands is your intention. Clearly, it is now the DeWine Study, and we believe much more harm than good can come from what ATSDR is about to implement.

We expect a new round of expensive litigation will occur as a result of media-driven community confusion and fear-mongering that will result from ATSDR offering the BeBLPT to Elmore residents. Plaintiff lawyers certainly will learn about the agency's program from the just-released announcement and will coach homeowners to take the test hoping for positive results to justify suing Brush Wellman. Our customers will learn of the DeWine Study, which is likely to put further pressure on them to find substitutes for beryllium. Lastly, why would Elmore residents embrace an expansion of our beryllium facility to add more production at the site if ATSDR is convinced further investigation is needed and you support it?

Senator, we are greatly disappointed in the DeWine Study, especially after the assurances you made to me promising a fair and balanced effort towards consensus on the scientific questions by the ATSDR with Brush Wellman's science experts and the Ottawa County science expert. Your support of ATSDR's program does a disservice to Brush Wellman, our employees, the Elmore community, Ottawa County and our customers. It is unfortunate that, in the future, people in the Elmore community will point to the DeWine Study as the origin of a junk science program that led to a loss of property values, loss of jobs and perhaps a loss of a major local employer.

I am currently in Asia exploring business opportunities, but I would like to discuss this with you directly and soon, especially in light of the ATSDR press release that came out on Monday detailing the ATSDR's plan and schedule without even vetting it through a public review process. I can be reached any time of the day or night that suits your immediate schedule. Please contact my assistant, Sue Zacher, at 216-383-6837, to convey your preference. Time is of the essence.

Sincerely,



Richard J. Hipple

Appendix 6 - Peer Review Comments and ATSDR Responses

*ATSDR's responses to Peer Reviewer comments are italicized.*

Comments of Lee Newman, MD

1. Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?  
Yes (x) No ( ) Unsure ( )

Need for exposure data. There is a definite need for environmental data to assess potential take-home exposure by workers in beryllium facilities and to assess airborne exposures in homes that are in close proximity to the Brush Wellman plant. Although the investigators deleted reference to this paper in their response to public comment, the publication by Sanderson (Sanderson W et al. Beryllium Contamination inside vehicles of machine shop workers. *Appl Occ and Environ Hyg* 1999; 14:223-230) nonetheless remains part of the scientific rationale for this investigation: the well-established, published fact that take-out exposures can occur when beryllium machinists leave the workplace. There is also well-established, published data that community cases of CBD can occur (as illustrated both in both Reading, PA and Lorain OH) in proximity to beryllium-using facilities. Furthermore, in direct contradiction of one of the public comment statements in Appendix 5 ("There are no known cases of non-occupational CBD in the community so why do the testing?"), there has been at least one non-occupational case of the wife of a Brush Wellman Elmore facility employee. She contracted CBD, from take-home exposure, and later died of this disease. (Reference: Newman L and Kreiss K. Non-occupational chronic beryllium disease masquerading as sarcoidosis: Identification by blood lymphocyte proliferative response to beryllium. *Am Rev Respir Dis*, 1992; 145:1212-1214). Thus, further investigation of exposure levels in the homes described in this protocol are warranted.

Potential benefit to the community and to science. The exposure data obtained in this study has the potential to provide important information for the residents of the community and to public health professionals regarding the distribution of beryllium in the community, at levels that may produce health consequences for those exposed. The work will extend the understanding of airborne health hazards in the community surrounding the Brush Wellman plant, thus addressing the concern voiced by U.S. Senator DeWine.

Appendix 6 - Peer Review Comments and ATSDR Responses

2. Can the environmental sampling methods meet the objectives of the investigation?

Yes (x) No ( ) Unsure ( )

The proposed methods are adequate. Analytical method is state of the art with acceptable limit of detection relative to levels that the investigators seek to measure. The sample size, method and duration of sampling should prove adequate to determine if there is detectable air borne beryllium contamination.

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?

Yes (x) No ( ) Unsure ( )

The levels of exposure that the investigators have targeted for this study are levels that have been shown to be sufficient to cause beryllium sensitization and CBD.

4. Are there other sampling strategies that you would employ to achieve the goals of the investigation?

Yes (x) No ( ) Unsure ( )

Questionnaire. The occupational questionnaire is efficient and well done but some additional information about current beryllium work exposure may prove helpful. Specifically, on a given day of home sampling, the airborne levels of beryllium in the home of a beryllium-machine shop worker might be influenced by whether or not he/she did any beryllium-dust related activities on the job that day or previous day. It is common for beryllium machinists in such shops to work on beryllium on an irregular schedule. An airborne plume of beryllium carried home might be missed if the worker was not using beryllium on the day of home sampling.

*ATSDR has revised the protocol so that the work history questionnaire will be given to only those persons at residences where beryllium levels exceeded 10 percent of the EPA RfC (0.002  $\mu\text{g}/\text{m}^3$ ). ATSDR decided not to include an additional question on beryllium work on the day of the sampling because the questionnaire already asks about current beryllium work and hygiene practices.*

Also with regard to the questionnaire, it would probably be helpful to determine the age of the residence. I would suspect that settled beryllium dust that has the potential to be re-entrained in the air might be greater in the older homes within 1 km of the Brush Wellman plant.

*ATSDR agrees with comment. The questionnaire has been revised as suggested.*

## Appendix 6 - Peer Review Comments and ATSDR Responses

Surface sampling. Through my reading of the Appendix and the response to public comment, I understand why the investigators may have elected to not perform surface sampling. Although what they now propose is valid, justifiable, and meritorious, I think that the study would be stronger with collection of pilot data: surface sampling of infrequently cleaned (settled dust) areas of the home. While such measurements could not be directly linked to either air borne exposure or to health risk, these data can provide an indirect indication of cumulative beryllium accumulation and could be analyzed by correlational methods for homes within the 1 km radius. They would be in keeping with the Senator's request to investigate the health hazard, because while sampling the air for beryllium on any given day in someone's home might yield a non-detectable result, sampling on a day when major cleaning occurs (along exposed beams, in attics and crawl spaces, on top of appliances, relocating of furniture etc.) has been shown to increase airborne beryllium levels by re-entraining settled dust.

*ATSDR has decided not to perform surface sampling during the initial sampling because of the difficulty interpreting these surface sampling results. ATSDR may recommend additional sampling, including surface sampling, if the beryllium levels approach or exceed the EPA reference concentration.*

The study acknowledges that it will not directly determine the source of the beryllium that may be found in the homes. However, at the time of follow-up sampling, it would be reasonable to consider performing more specific particle analysis in those homes that are found to have elevated levels of beryllium. i.e. instead of simply repeating the sampling, it may be possible to obtain some of the subsequent samples and characterize whether the beryllium particles are beryllium alloy or not. If particles of beryllium-aluminum, beryllium-copper, or beryllium-nickel were detected, for example, this would certainly suggest a point source of exposure (such as a machine shop). The study is valid and meritorious even without investigating the sources of exposure, but it would be strengthened by this additional information.

*ATSDR may recommend additional testing to determine appropriate follow-up actions if the beryllium levels in air present a health hazard, is possible.*

---

Correlating location with exposure levels. As another approach to the question of beryllium source, I would suggest that the investigators add a fourth form of data analysis: Correlate location (i.e. distance from the Brush Wellman plant) with beryllium level in the home for the 50 local residents.

*ATSDR will evaluate the relationship between the beryllium levels and the distance and direction from the Brush Wellman Plant.*

Appendix 6 - Peer Review Comments and ATSDR Responses

Parallel outdoor sampling at time of follow-up sampling. Will there be air sampling conducted outdoors? It would seem reasonable to include simultaneous air sampling both indoors and outdoors as part of the Follow-up sampling protocol, especially if elevated beryllium levels are found in the homes of workers in the contract machine shops.

*ATSDR will consider follow-up air ambient sampling if warranted. However, a number of studies have shown no or a poor correlation between the ambient outdoor and indoor particulate levels [15].*

5. Are there any other comments about the investigation that you would like to make?

I found the protocol clear, concise, and well written. It is likely to provide important information and I commend the investigation team.

6. Select the appropriate category below:

(List recommended changes or reasons for not recommending)

- A. Recommend ( x )  
B. Recommend with Required Changes ( )  
C. Not Recommended ( )

Appendix 6 - Peer Review Comments and ATSDR Responses

Comments of Wayne Sanderson, PhD CIH

1. Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?  
Yes (X) No ( ) Unsure ( )

Yes, it is clearly stated on page 5, that the purpose of this investigation is to measure the airborne levels of beryllium inside the homes of local machine shop workers and residents near the Brush Wellman facility in Elmore, Ohio. This work was specifically requested by concerned citizens through their U.S. Senator, Mike DeWine. Because overt respiratory disease—chronic beryllium disease (CBD)—has not been documented historically among residents near the Brush Wellman facility, I believe it is unlikely that people living near this plant have significantly increased risk for developing this disease. But this question has never been adequately studied and it remains unknown if individuals have developed sensitivity to beryllium due to living near the beryllium plant or living with workers machining beryllium products. There is a level of public concern which should be addressed.

CBD was documented in the 1940s among residents living near beryllium plants in Lorain, Ohio and Reading, Pennsylvania. And, household members of beryllium workers have been shown to develop CBD. However, in recent years Brush Wellman has developed excellent procedures for reducing the migration of beryllium from inside the plant into the community and homes of its workers. It has also reduced environmental air emissions from its production plant in Elmore. However, it remains unknown what beryllium exposure levels residents near this plant may experience inside their homes from current air emissions and residual levels in the environment. It is also not known whether workers at machine shops—not operated by Brush Wellman—in the Elmore area have been afforded the same level of protection to prevent migration of beryllium from their worksites into their homes.

I have high praise for investigators at ATSDR for their efforts addressing this concern. It is a difficult task and they have developed a reasonable approach to evaluating the problem.

Appendix 6 - Peer Review Comments and ATSDR Responses

2. Can the environmental sampling methods meet the objectives of the investigation?

Yes ( ) No ( ) Unsure (x)

Why?

I believe that the current plans to collect two 24-hour air samples at 12 liters/minute at two locations inside the homes of volunteers will measure the general beryllium air levels inside these homes on the particular day which the samples are collected. I suspect that most of these samples will either be very low or below the analytical limit of detection. Unless they are collected on a day when the residents vacuum their floors, implement relatively vigorous cleaning, or are taken nearby while machine shop workers remove potentially contaminated clothing, they may not represent times of greatest exposure potential. This one time sample has limited ability to estimate the average beryllium exposure levels inside the homes. One way to address this would be to increase the sample duration or the number of one-day samples collected inside each home.

These air samples will not be able to determine whether surfaces inside the homes have been contaminated with beryllium, and may not adequately address whether the beryllium may become airborne.

*Residents will be asked to perform routine cleaning and occupy their home for a minimum of 12 hours while two 24 hour air samples are collected. This sampling will be repeated on two occasions if one or both of the two samples initial samples exceeded 10 percent of the EPA Reference Concentration.*

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?

Yes (x) No ( ) Unsure ( )

The sampling results from this study can be directly compared to the Environmental Protection Agency's Reference Concentration for beryllium in air ( $0.02 \mu\text{g}/\text{m}^3$ ). This standard is based on evaluation of toxicological and epidemiological data and is meant to protect the general public from risk of developing chronic lung disease. If air measurements are found to exceed this level, data is being collected which will allow evaluation of risk factors which might be associated with increase air exposure, such as location of the home, occupations of the inhabitants, and cleaning practices.



Appendix 6 - Peer Review Comments and ATSDR Responses

4. Are there other sampling strategies that you would employ to achieve the goals of the investigation?  
Yes (x) No ( ) Unsure ( )

It is disappointing that evaluation of beryllium concentrations on surfaces, such as floors, inside the homes is not going to be conducted as originally planned. It is true that no standards or accepted criteria for safe levels of beryllium on surfaces have been established. The U.S. Department of Energy has proposed limits of beryllium on work surfaces and equipment, but these limits are not based on health effects. However, this effort provides an excellent opportunity to evaluate the beryllium surface concentrations inside the homes of residents living near a large beryllium plant and the potential migration of beryllium inside the homes of machinists who manufacture beryllium products. These measurements would have to be compared to concentrations inside the homes of a control population who did not live near a beryllium plant or work with beryllium products. Background levels of beryllium on residential surfaces are not well documented. It would have to be clearly noted in the protocol that these measurements were for research purposes and could not be compared to prevailing health criteria. However, these measurements would help evaluate the long-term chronic risk of beryllium exposure inside study participants' homes, beyond the current plan to collect a few samples over only a few days.

*ATSDR has decided not to perform surface sampling during the initial sampling because of the difficulty interpreting the health implications of surface sampling data. ATSDR has not ruled recommending additional sampling, including surface sampling, if the beryllium levels exceed the EPA reference concentration.*

Budget and logistic considerations may prevent the possibility of collecting more air samples, but single, 24-hour air samples (two samples will be completed - ATSDR) inside the homes of study participants is very limited for estimating risk. It would be good to increase the number of samples collected, the sampling duration or both. Perhaps at least a winter and summer sampling campaign could be employed.

*ATSDR will recommend follow-up sampling if the initial sampling indicate the presence of a health hazard.*

5. Are there any other comments about the investigation that you would like to make?

In Table 1, column 3, it states that Local residents living within 1 km of the plant will be sampled. Why is one km chosen instead of 1 mile, which would be consistent with the health study?

*ATSDR has revised to protocol include those living within 1 mile of the plant.*

## Appendix 6 - Peer Review Comments and ATSDR Responses

In the methods section, no control group is chosen because it appears the air samples are simply to be compared to the USEPA ambient air standard. However, it would be useful to have samples collected inside a group of comparison homes at a greater distance from the plant.

*ATSDR will not use comparison population because of the limited nature of the sampling investigation.*

It is not stated in the Methods Section—Environmental Sample Collection—where the samples will be collected. Although homes vary considerably, an effort should be made to collect the samples in consistent locations across the homes, such as family gathering areas—kitchens, family rooms, or children's play areas. It is stated in the Appendix, but might also be stated in the Methods Section.

*ATSDR agrees with this comment and has revised the protocol as suggested.*

The selected air flow rate of 11 liters per minute is a considerable air flow through a relatively small 37 mm MCE filter. Has this method been employed before and are the selected sampling pumps been able to maintain a consistent flow rate with a high expected static pressure? Also, in the Appendix the airflow rate is reported to be 11 and 12 liters per minute (page 24).

*ATSDR will test sample train well in advance of the field sampling.*

In Section 6.2, it is noted that a calibrated rotometer will be used to check the flow rate of the sampling pumps. The sampling pumps should first be calibrated against a primary standard and then the flow rate simply checked in the field using the rotometer. I don't think it is good accepted practice to use a rotometer to calibrate airflow pumps.

*ATSDR agrees with the comment and has specified a primary standard for calibration rather than a rotometer.*

On page 24, third line from the bottom the sentence reads "Turn of pump..." This should read "Turn off pump..."

*The protocol has been revised as noted.*

## Appendix 6 - Peer Review Comments and ATSDR Responses

On page 26, item 3 under 11.0 Rotometer Calibration, it will be difficult to use even a 1 liter bubble burette to calibrate the rotometer at 12 liters per minute (bubble start to stop = 5 seconds). I recommend using either a high-volume Gilibrator, SKC Dri Cal, or a larger bubble burette to calibrate the pumps and the rotometer.

*ATSDR agrees with comment and has specified an electronic primary standard for calibration e.g. Dri-Cal or Gilibrator.*

On page 27 the comment is made that exposure investigation will negatively impact property values. This seems like an unacceptable reason to not evaluate potential public health problems. If in fact residents are at risk of developing a serious lung disease, the long-term medical costs may outweigh a potential drop in their property values. On the other hand, if beryllium levels are found to be low and no sensitivity or lung disease is found, the potential fear that residents have will be alleviated.

*ATSDR agrees with this comment.*

On page 28, the spacing seems to be a bit off. It is a bit errant elsewhere in the comment and response section.

*ATSDR has modified the spacing.*

Also, on page 28 it is stated that the study will not benefit Ottawa County. Lack of identified disease or exposure will certainly lessen residents concern about risk for chronic beryllium disease, but if sensitivity, beryllium lung disease, and high exposures are found, then public health measures may be implemented to reduce peoples' health risk. I found many of the criticisms of the ATSDR protocol in Appendix 5 to be obstructionistic and ridiculous.

On page 31, third paragraph from the bottom the word 'of' was omitted from the first sentence. Also, The word Comment near the bottom of page 34 should be bolded rather than italicized.

*These format and grammar errors have been corrected.*

Appendix 6 - Peer Review Comments and ATSDR Responses

On page 49, second paragraph, it would be helpful if the criticizer could provide a reference for the statement "...one could expect a sensitization rate of 20 to 40 people within the 2000 people living within three miles of the Elmore plant, even if the Elmore plant never existed." I struggle frequently with an estimate of the false positive rate for the beryllium lymphocyte proliferation test. I do not believe an accurate estimate of false positives for this test exists and I do not believe this statement can be backed up.

*The companion case finding protocol contains a detailed discussion of beryllium lymphocyte proliferation test.*

6. Select the appropriate category below:

(List recommended changes or reasons for not recommending)

D. Recommend ( x )

E. Recommend with Required Changes ( )

F. Not Recommended ( )

Aside from addressing the minor comments I have noted above and my disappointment that no surface sampling will be conducted, I recommend this protocol for implementation.

Appendix 6 - Peer Review Comments and ATSDR Responses

Comments from Milton Rossman, MD

1. Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?

Yes (x) No ( ) Unsure ( )

Are there any other comments?

No

2. Are there other sampling strategies that you would employ to achieve the goals of the investigation?

Yes ( ) No ( ) Unsure (x)

The purpose of this study is to measure the airborne levels of beryllium in the home of local machine shop workers and in the home of individuals who live within 1 km of the Brush Wellman plant in Elmore. The levels determined will be compared to EPA's reference concentration for beryllium. However, the real purpose of this investigation is to determine whether contamination has occurred in the past. Thus, while the residents may be reassured that at the time of the sampling, there were not elevated levels of beryllium in their houses, the study will do little to reassure the residents that contamination did not occur in the past or that it could not occur in the future.

*ATSDR will clearly communicate the limitations of the sampling to the prospective participants. They will determine whether the benefit of the investigation outweighs its limitations.*

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint? Yes

The environmental sampling will meet the purposes of the investigators since direct measurements of air samples will be done.

Appendix 6 - Peer Review Comments and ATSDR Responses

4. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?

While air sampling will give results that will reflect the airborne levels of beryllium in the homes at the time of investigation, it may not mean the contamination has not occurred in the past. It does not rule out that significant exposure may have occurred in the past but now has been either cleaned up or diluted by time. Thus, negative results will probably do little to reassure the community that contamination has not occurred in the past. However, positive results will show that contamination has occurred.

*As noted above, ATSDR will clearly communicate the limitations of the sampling to the prospective participations. They will determine whether the benefit of the investigation outweigh its limitations.*

5. Are there any other comments about the investigation that you would like to make?

Yes (x) No ( ) Unsure ( )

Consideration should have been done to sample for 1 week rather than just one day. Because the strategy relies on re-suspension of beryllium in the contaminated house, a longer sampling strategy might lead to more activities in the house the might lead to the detection of abnormal levels. Examples of this might be washing clothes, taking off work clothes, and vacuuming and cleaning at the end of a week or on a normal cleaning day rather than on a day when it might have been done a day or two before. In addition, depending on whether the sampling was done on a week day or a weekend, members of the household may or may not be in the home on the day of the sampling.

*Residents will be asked to perform routine cleaning and occupy their home for a minimum of 12 hours while two 24-hour air samples are collected. This sampling will be repeated on two separate occasions if one of the two samples initial samples exceeded 10 percent of the EPA Reference Concentration.*

6. Select the appropriate category below:

(List recommended changes or reasons for not recommending)

Recommend ( )

Recommend with Required Changes ( )

Not Recommended (x)

## Appendix 6 - Peer Review Comments and ATSDR Responses

Clearly this proposal is in conjunction with the case finding proposal. Combining the immunologic surveillance and the detection of abnormal air levels will be most useful, however I would suspect that the immunologic surveillance would be a more sensitive technique to determine if exposure has occurred.

*This protocol will have similar participation criteria to the case finding protocol. ATSDR will attempt compare results to the extent possible. ATSDR also supports exposure-based environmental sampling because substantial past air emission from the Brush Wellman - Elmore Plant and of the possibly of worker-take-home from machine shop workers.*

In the consent form, under risks it should be noted that a negative air sample does not rule the possibility of past or future exposure.

*ATSDR agrees with comment. The consent form has been revised as noted.*



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**ATSDR MEDIA ANNOUNCEMENT**  
**ATSDR Seeks Community Input on Protocol**  
**for**  
**Beryllium Exposure Investigation in Elmore,**  
**Ohio**

**For Immediate Release: June 30, 2003**

**Public Meeting To Be Held July 14, 2003**

ATLANTA – The Agency for Toxic Substances and Disease Registry (ATSDR), a public health agency of the U.S. Department of Health and Human Services, has made available for public comment the draft protocol for an exposure investigation to be conducted in Elmore, Ohio. The public comment period will run from July 15 to August 15.

A public meeting will be held from 6:30 p.m. to 8:30 p.m. on Monday, July 14, 2003. At the meeting ATSDR representatives will provide further information about the exposure investigation and will answer questions from community members present. The meeting will be held at:

Elmore Community Center  
410 Clinton St.  
Elmore, Ohio 43416

The protocol will outline the process for collecting samples to be gathered as part of an exposure investigation to determine levels of beryllium in homes and areas near the Brush Wellman Plant. The facility produces beryllium and products containing beryllium. Exposure to beryllium dust in the workplace is linked to a serious lung disease.

ATSDR is conducting the investigation to determine whether higher-than-background exposures to beryllium may be occurring in the community. The agency completed a health consultation regarding this site last year and determined that an exposure investigation was necessary to assess the level of beryllium present in the homes and vehicles of those who work or live near the Brush Wellman facility.

The health consultation also found that beryllium emissions from the plant are below levels expected to cause adverse health effects and do not pose a public health hazard.

Because the investigation will require that samples be taken from properties around the site, ATSDR is seeking input on the protocol from the local community. The draft Exposure Investigation Workplan (protocol) will be available on July 8 for public review and comment at the following repository:





## ATSDR MEDIA ANNOUNCEMENT

### ATSDR to Offer Blood Tests for Beryllium Sensitization in Elmore, Ohio Agency to host public availability session April 25

**For Immediate Release: March 27, 2006**

ATLANTA - The Agency for Toxic Substances and Disease Registry (ATSDR) announced today a plan to provide a community service to people living or working near the Brush Wellman facility in Elmore, Ohio, who remain concerned about past beryllium exposures and their health. The plan includes a free blood test for beryllium sensitization.

As reported in its 2002 public health consultation, ATSDR does not think that current releases of beryllium from Brush Wellman pose a risk to people's health. In that report, ATSDR could not draw conclusions about people's health risks from past, short-term beryllium releases from the plant. People who remain concerned about their individual past exposures can volunteer for a blood test to learn if they may have been affected.

The blood test can determine if an individual has been sensitized - a kind of allergic response - to beryllium from past releases to the environment. People who are sensitized may or may not develop a lung disease called chronic beryllium disease (CBD). The test itself does not determine if people are sick.

ATSDR Director Howard Frumkin, M.D., Dr. P.H., said, "We are taking this approach to provide people a service that should address their remaining concerns. People whose test results are normal can be reassured that they are not likely at risk for beryllium disease. People who learn they are sensitized to beryllium can work with their physicians to care for their health appropriately."

The agency will host a public availability session April 25 to meet with community members and discuss the plan. The session will be held from 4-8 p.m. at Woodmore High School, 633 Fremont Street, Elmore, Ohio.

ATSDR will test up to 200 people who are considered most likely to benefit from this screening test. This includes people who meet the following enrollment criteria:

- residents living within approximately 1 ¼ miles of the boundaries of the Brush Wellman facility;
- workers from local machine shops that contract to machine beryllium alloys, and their household contacts;
- household contacts of Brush Wellman workers;

Harris-Elmore Public Library  
238 Toledo St.  
Elmore, Ohio 43416

The public comment period will run from July 15 through August 15. Comments must be made in writing and sent to:

Chief, Program Evaluation, Records and Information Services Branch  
ATSDR  
1600 Clifton Road, N.E.  
Mailstop E-60  
Atlanta, GA 30333

Comments received, without the names of individuals who submitted them, and ATSDR's response to the comments will appear in an appendix to the final exposure investigation protocol. Names of those who submit comments, however, will be subject to release for requests made under the U.S. Freedom of Information Act.

Community members seeking information on the procedures or the content of this draft protocol should contact ATSDR Health Assessor Peter Kowalski or Community Involvement Specialist Loretta Bush in Atlanta toll-free at 1-888-422-8737 or call ATSDR Regional Representative Clayton Koher in Chicago at 312-353-6086. Callers should reference the Brush Wellman exposure investigation protocol.

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Members of the news media may request an interview with ATSDR staff by calling Elaine McEachern or Petro Kacur in the ATSDR Office of Policy and External Affairs at 770-488-0700.

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U.S. Department of Health and Human Services

- people in the area diagnosed with sarcoidosis, a disease with lung changes that resemble the changes in CBD.

Interested persons who meet the enrollment criteria may call ATSDR toll-free at 1-866-577-4258 from 8 a.m. - 8 p.m. (EST), Monday through Friday. Individuals may call now to leave their name and phone number. In May, ATSDR will begin collecting more information from callers to determine if they meet the enrollment criteria. Callers meeting the criteria will be enrolled on a first-come, first-served basis.

While ATSDR plans to provide information to local physicians about the disease and the testing program, individual test results and information collected will be kept confidential.

The plan for blood testing will be available for public review March 31 through April 30 on the ATSDR Web site at <http://www.atsdr.cdc.gov/sites/brushwellman/protocol.pdf> and at the locations listed below. During the public comment period, residents can review and comment on the testing plan or proposed activities. Comments received will be considered for the final testing plan. ATSDR plans to finalize the testing plan in May and begin the testing program this summer.

Residents can review the document at these Harris-Elmore Library locations:

328 Toledo Street  
Elmore, OH 43416

Genoa Branch  
602 West Street  
Genoa, OH 43430

Comments should be mailed to:  
ATSDR Records Center  
1600 Clifton Road, N.E. (MS E-60)  
Atlanta, Ga. 30333

Or, they may be provided via e-mail to: [ATSDRRecordsCenter@cdc.gov](mailto:ATSDRRecordsCenter@cdc.gov); Subject: Brush Wellman - Elmore, OH.

Community members seeking more information may call ATSDR Medical Epidemiologist Dan Middleton, M.D., MPH, toll-free at 1-888-422-8737.

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Members of the news media can request an interview by calling the NCEH/ATSDR Office of Communication at 770-488-0700.

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## ATSDR MEDIA ANNOUNCEMENT

### ATSDR Presents Beryllium Sensitization Test Results at Nov. 15 Public Meeting in Elmore

**For Immediate Release: November 13, 2006**

ATLANTA - The Agency for Toxic Substances and Disease Registry (ATSDR) will announce the collective results of its testing for beryllium sensitization at a public meeting in Elmore, Ohio, on Nov. 15. The meeting is 6:30-7:30 p.m. at the Elmore Community Center, 410 Clinton St.

Testing results will not be announced before the public meeting.

A public health agency of the U.S. Department of Health and Human Services, ATSDR this past summer offered certain people living or working near the Brush Wellman facility in Elmore free blood testing to determine if they are sensitized to beryllium.

Eighteen persons volunteered for the testing. Those eligible for the testing were:

- residents living within approximately 1 ¼ miles of Brush Wellman facility boundaries;
- workers from local machine shops contracted to machine beryllium alloys, and the worker's household contacts;
- household contacts of Brush Wellman workers;
- people in the area diagnosed with sarcoidosis, a disease with lung changes that resemble the changes in a lung disease called chronic beryllium disease (CBD).

Beryllium sensitization is a kind of allergic response to beryllium exposure. People whose immune systems have been sensitized to beryllium are at higher risk for CBD.

ATSDR's public health consultation report in 2002 on the Brush Wellman facility found that releases of beryllium from the plant at that time were not a public health hazard.

However, ATSDR could not draw conclusions about people's health risks from possible past, short-term beryllium releases. To help community members answer that question, the agency offered the recent beryllium sensitization testing as a public service.

Community members seeking more information should call ATSDR Health

Communication Specialist Loretta Bush at 404-498-1742 or Medical Epidemiologist Dr. Dan Middleton at 404-498-0565 between 9:00 a.m. and -5:00 p.m. (Eastern).

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**Members of the news media can request an interview with ATSDR staff by calling the NCEH/ATSDR Office of Communication at 770-488-0700.**

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SOURCE: Brush Wellman Inc.

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## Brush Wellman Inc. Selects Elmore, Ohio as Site for Proposed Primary Beryllium Facility

CLEVELAND, Sep 18, 2006 (BUSINESS WIRE) – Brush Wellman Inc. announced today that it has selected Elmore, Ohio as the site for the proposed \$40 to \$60 million primary beryllium facility. Brush Wellman considered existing plant sites at Elmore and Delta, Utah for the investment.

Approximately 25 additional jobs are expected to be created to operate and maintain the facility. A significant number of construction and support positions will be created outside of Brush Wellman related to the project.

Primary beryllium is the feedstock material used to produce beryllium metal products. The nation's only primary beryllium production facility, one of a number of units operated by Brush Wellman in Elmore, was closed in 2000 due to several factors, including equipment obsolescence at the facility and the availability of a large supply of primary beryllium from the government stockpile. The Elmore facility presently employs 580 workers.

The preferred location for the proposed facility was determined, in part, through the design and engineering work that has occurred over the past year under a \$9 million contract from the Department of Defense's (DOD) Defense Production Act, Title III Program. Middough Consulting of Cleveland is the primary design and engineering firm contracted for the project.

In selecting the location, Brush Wellman cited state and local incentives, as well as the availability of a workforce experienced in primary beryllium production, start up support and proximity to other support services.

Greg Gregory, Primary Beryllium Facility Project Manager, commented, "The Ohio and Utah alternatives were extremely competitive, which made this a tough decision. Both sites offered advantages including excellent existing work forces and strong local and state support." In either case, he explained, there are benefits for the other facility as part of the beryllium production and supply chain. By locating this facility at Elmore, for example, Delta could see an eventual increase in production of some 25%. Brush Wellman's Utah operations mine and mill ore into an intermediate form for Elmore. Another benefit is the preservation of approximately 120 jobs at Elmore related to the further processing of beryllium metal.

In an innovative public-private cost-sharing partnership under the Title III program, Brush Wellman will provide technology, land, buildings and an ongoing operation for the facility, while the government will fund engineering, design and equipment. Financing for the building is being provided by the Cleveland-Cuyahoga County Port Authority. The first phase of the contract, design and engineering, is expected to be completed over the next year. The total cost of the facility will be determined through the design process. The second phase will involve construction and start up of the facility and is expected to require an additional two to three years following completion of phase one. Funding for the second phase will require additional governmental approval.

The Defense Production Act is the primary legislation for ensuring domestic availability of industrial resources and critical technology items essential for national defense. The Title III Program provides a vehicle to create, maintain, modernize or expand domestic production capability for technology items, components and resources essential for national defense and for which there is insufficient production capacity to meet those needs. Title III stimulates investments in key production resources to increase the supply, improve the quality and reduce the cost of advanced technology and reduces U.S. dependency on foreign sources of supply for critical materials.

Brush Wellman Inc., the world's only fully integrated producer of beryllium, beryllium-containing alloys and beryllia ceramic, is a wholly-owned subsidiary of Brush Engineered Materials Inc. (NYSE:BW). Brush Engineered Materials, commemorating its 75th year in 2006, is headquartered in Cleveland. The Company, through its wholly-owned subsidiaries, supplies worldwide markets with beryllium products, alloy products, electronic products, precious metal products, and engineered material systems.

[www.beminc.com](http://www.beminc.com)