determined to fully implement the FDAAA and take any additional measures that may be needed to uphold the highest scientific and ethical standards for our agency's critically important AC system.

Randall Lutter, PhD[a]
William A. McConagha, JD[a]

[a]Food and Drug Administration, Department of Health and Human Services, Washington, DC

REFERENCES

1. Wood SF, Perosino KL. Increasing transparency at the FDA: the impact of the FDA Amendments Act of 2007. Public Health Rep 2008;123:527-30.
2. Lurie P, Almeida CM, Stine N, Stine AR, Wolfe SM. Financial conflict of interest disclosure and voting patterns at Food and Drug Administration Drug Advisory Committee meetings. JAMA 2006;295:1921-8.
3. Food and Drug Administration (US). Comment on financial conflict of interest disclosure and voting patterns at Food and Drug Administration Drug Advisory Committee meetings [cited 2007 Jul 21]. Available from: URL: http://www.fda.gov/oc/advisory/analysis.html
4. Food and Drug Administration (US). Draft guidance for FDA Advisory Committee members and FDA staff: voting procedures for Advisory Committee meetings [cited 2007 Nov 15]. Available from: URL: http://www.fda.gov/oc/advisory/VotingGuidance.html
5. Food and Drug Administration (US). Guidance for the public, FDA Advisory Committee members, and FDA staff: public availability of Advisory Committee members' financial interest information and waivers [cited 2007 Oct 29]. Available from: URL: http://www.fda.gov/oc/advisory/waiver/ACdisclosure1007.html
6. Ackerley N, Eyraud J, Mazzotta M. Measuring conflict of interest and expertise on FDA Advisory Committees. Submitted to the U.S. Food and Drug Administration, 2007 [cited 2007 Oct 26]. Available from: URL: http://www.fda.gov/oc/advisory/ERGCOIreport.pdf

BERYLLIUM HISTORY AND PUBLIC POLICY

The January/February issue of *Public Health Reports* included an opinion piece by David Michaels and Celeste Monforton titled, "Beryllium's Public Relations Problem: Protecting Workers When There Is No Safe Exposure Level," in *Public Health Chronicles*. The authors' version of "a history of the knowledge and public policy concerning the prevention of beryllium-related disease" and "the role of the U.S. beryllium industry"[1] is inaccurate and incomplete. For the sake of brevity, I will only address the major inaccuracies and omissions.

Distortions of the 1975 beryllium OSHA rulemaking

The claim that the government's withdrawal of the 1975 Occupational Safety and Health Administration (OSHA) proposal was a purely political decision is incorrect. The 1975 OSHA proposal to lower the eight-hour Permissible Exposure Limit (PEL) from 2.0 micrograms beryllium per cubic meter of air ($\mu g/m^3$) to 1.0 $\mu g/m^3$ was to address the alleged risk of cancer, not chronic beryllium disease (CBD). The cancer epidemiology study[2] used by OSHA to support the proposal was done by scientists from the National Institute for Occupational Safety and Health (NIOSH) and OSHA. It is significant to note that it was the beryllium industry that originated the request for this epidemiology study.

Because of concerns regarding the quality of the study, NIOSH requested an independent scientific peer review of the draft study by the Centers for Disease Control and Prevention (CDC). This review resulted in many recommended technical changes to the methods of analysis and conclusions. However, it was determined later that two of the three listed authors of the study actually submitted the paper for publication four days before the peer reviewers were to meet. The third listed author on the published study is Dr. Bayliss. The other two authors listed Dr. Bayliss on the study without his permission. Dr. Bayliss was originally the primary researcher on this study and had already published two NIOSH reports on his work. When this study was published, he raised his concerns over the serious shortcomings of the study to the NIOSH leadership (he had previously relayed the same concerns to the other two authors). NIOSH directed Dr. Bayliss to raise his concerns directly to CDC, which he did in a 30-page letter[3] to Director William H. Foege, MD. Dr. Bayliss' letter demonstrated that the authors failed to use the proper death rates in calculating the number of expected lung cancer deaths in the cohort. When Bayliss corrected their error, the difference between the expected death rate and the actual death rate in the cohort was no longer statistically significant. In addition, Dr. Bayliss pointed out that the authors overstated the number of actual worker deaths due to lung cancer by inappropriately including a cancer case of someone who had never worked at the plant.

The challenge to the 1975 OSHA proposal was based on evaluating the quality of the available science and the potential harm of a non-science-based standard against the continued ability of our nation to defend itself. Brush Wellman was not alone in its concern regarding OSHA's proposal to lower the PEL for beryllium based on cancer risk. OSHA's interpretation of the NIOSH study was challenged by the NIOSH science leadership, the Department of Energy (DOE), the Department of Defense (DOD), and a coauthor on the study, as well as others. Overall, OSHA's proposal generated 150 written comments and 40 requests for a public hearing. Simply put, an open and public debate on the quality of the available science is just how a standard setting process is supposed to work.

In this case, the quality of the available science was not adequate to set a standard based on an alleged risk of cancer.

Recent studies find that beryllium should not be classified as a human carcinogen

The fundamental issue of whether beryllium is a carcinogen remains under investigation. The 15-year-old cancer ranking by the International Agency for Research on Cancer (IARC) is in doubt after considering the recent studies by Levy,[4,5] Brown,[6] and Deubner,[7] which provide evidence that exposure to beryllium does not represent a significant risk of cancer to humans. The 2001 study by Sanderson[8] attempted to demonstrate a beryllium exposure response relationship for lung cancer. Levy (2007) and Deubner (2007) identified a significant methodological error in the Sanderson study that effectively negates the use of Sanderson as a dose/response cancer link for beryllium. Levy also provides a reanalysis of the Sanderson study, which demonstrates that when the error is corrected, the resulting conclusion is that the lung cancer in this population was not at all associated with beryllium exposure, whether defined as time worked, or cumulative, mean, or maximum exposure. Deubner confirms the methodological error identified by Levy using repeated data simulations. The error in Sanderson's methodology is further recognized by an independent commentary by Dr. Garabrant[9] that was published concurrently with the Deubner paper. His commentary indicates that this finding is important and can have ramifications, which should be considered for all epidemiology studies.

These epidemiology studies deal with sizeable cohorts exposed to very high levels of beryllium, which are orders of magnitude greater than the OSHA standard. Unconvincing evidence that beryllium workers have excess rates, combined with clear evidence that lung cancer in beryllium workers is not related to degree of exposure, strongly refutes the premise that beryllium is a human carcinogen.

Studies have identified a safe exposure level for workers

While there was uncertainty and debate surrounding the identification of a safe exposure level for workers for several years, the authors' claim that there is no safe exposure level is simply wrong. Every person is exposed to airborne beryllium via windblown dusts (all soil contains beryllium), emissions from the combustion of coal, and tobacco smoke. Additionally, many household products, such as ceiling tiles, fertilizers, detergents, charcoal, and kitty litter, contain beryllium naturally. Obtaining and carefully evaluating good-quality worker exposure data is crucial to understanding CBD and setting occupational exposure limits.

With regard to identifying an occupational exposure limit for beryllium, the authors referenced both the Madl[10] and Schuler[11] studies, but failed to articulate how these studies and the studies by Johnson[12] and Cummings[13] are highly relevant and revealing in identifying an appropriate occupational exposure limit for beryllium based on the potential risk of CBD. Madl, using a large dataset of more than 3,800 personal air samples, is the first study to actually perform a complete dose reconstruction of people defined as beryllium sensitized or diagnosed with CBD. The Madl study dose reconstruction also differentiates between those people with subclinical CBD and clinical CBD. This comprehensive analysis concludes that subclinical CBD and clinical CBD occur at exposures greater than 0.4 $\mu g/m^3$.

The authors failed to consider the strength of the scientific evidence in the study findings of Johnson et al. (2001). Dr. Johnson studied the largest beryllium exposure air sampling dataset at a facility that had a very successful CBD prevention program. In fact, we know of no other air sampling dataset for any substance that more thoroughly characterizes a worker population. The Johnson study includes more than 217,000 personal samples using an exposure assessment strategy that monitored every worker on every day for 36 years at the United Kingdom Atomic Weapons Establishment in Cardiff, Wales. The Johnson study demonstrated that the Cardiff beryllium control model achieved compliance with the United Kingdom 2 $\mu g/m^3$ eight-hour maximum exposure limit more than 98% of the time and prevented clinical CBD.

The 2007 study by Cummings provides an analysis of the effectiveness of Brush Wellman's Beryllium Worker Protection Model, including the use of a recommended exposure guideline of 0.2 $\mu g/m^3$. This study demonstrates that the Beryllium Worker Protection Model, in use since 2000, has been effective in reducing the detection of beryllium sensitization from more than 8% to 1%, a rate that is similar to the background rate found in the non-occupationally exposed population. The Beryllium Worker Protection Model is very similar to the successful exposure control model used at the Atomic Weapons Establishment facility in Cardiff Wales as described by Johnson (2001).

Brush Wellman's Beryllium Worker Protection Model[14] is a comprehensive and multifaceted approach for reducing occupational exposure to beryllium particles. The model focuses on keeping beryllium work areas clean and keeping particles and solutions

containing beryllium out of the lungs, off the skin, off of clothing, in the work process, in the work area, and on the plant site. Worker and management education and motivation are important components. A combination of engineering, work practice, and personal protection approaches are used as needed to attain the reduction in potential occupational exposure. The goal of the Beryllium Worker Protection Model is to prevent sensitization to beryllium, subclinical CBD, and clinical CBD. The Beryllium Worker Protection Model is based on our knowledge, experience, and understanding gained from the most recent joint studies with NIOSH, which include the potential exposure risks posed by the various chemical forms of beryllium and disease prevention methods tailored to specific material processing operations, engineering, work practice control, and personal protective measures that have been demonstrated to be effective in preventing sensitization and CBD at Brush Wellman facilities.

The significant change in the diagnostic criteria for CBD was overlooked

A serious omission in the article is the failure to note the major change in the diagnostic criteria for CBD used in studies beginning in the late 1980s.[15] These changes are important when comparing findings of older studies to newer studies. The older studies (pre-1989) refer solely to the identification of people with clinically evident disease (clinical/symptomatic CBD), whereas the vast majority of cases identified in studies since 1989 describe predominantly surveillance-detected cases of CBD where the people have no or little clinical evidence of a health effect or symptomology. Thus, the reference to scores of people in DOE being diagnosed with CBD obscures the fact that most of these people have subclinical CBD with no clinical symptoms. This fact is highly relevant because the prevention of a material impairment of health, such as clinical CBD, is the appropriate regulatory basis to use when setting an appropriate exposure limit for beryllium.

The beryllium blood test is not a reliable worker screening test

The discussion of the Beryllium Blood Lymphocyte Proliferation Test (BeBLPT) omits the most recent study findings on this topic, namely the 2006 articles by Borak[16] and Cher[17] and the 2007 study by Donovan.[18] The Cher article identifies systematic performance problems with the labs performing the BeBLPT, and the Borak article evaluates the value of BeBLPT using World Health Organization evaluation criteria. The studies by Donovan and Cher demonstrate that the BeBLPT is not a reliable indicator of beryllium sensitization (BeS) due to the inconsistent performance of the test, the absence of a standardized method of testing, inconsistent test interpretation, the variability of test outcomes, and the reversion of positive results to normal after retesting over time. Donovan also confirms the detection of BeBLPT identified beryllium sensitization in the general non-occupationally exposed population and demonstrates, longitudinally, the on/off detection of positive BeBLPTs in individual beryllium workers.

The basis for the beryllium exposure limit was scientifically sound

The authors' reference to a "taxi cab standard" is grossly misleading and fails to recount a history that is well documented.[19,20] One of the "two scientists" cited as being involved with the development of a beryllium occupational standard was Dr. Merril Eisenbud, the preeminent authority on beryllium health and safety of the time. He and his colleagues at the Atomic Energy Commission, after considerable deliberation, decided to recommend a beryllium standard based on an empirical analogy with other toxic metals such as lead, mercury, and arsenic. Based on the assumed toxicity and relative atomic weight compared to the other toxic metals, it was determined that the occupational standard for beryllium would be set at between 2 and 5 micrograms. Only the final decision to recommend either 2 or 5 $\mu g/m^3$ as the recommended occupational exposure limit was decided during the taxi ride to the meeting at which they were to present their recommendation.

The authors repeat the misleading claim of case reports from the 1970s and 1980s that CBD was occurring at levels below the 2 $\mu g/m^3$ PEL. It has been clearly demonstrated that these studies presented exposure values that cannot be used to determine compliance with an eight-hour PEL.[21,22] Simply put, comparing median values to a PEL ignores 50% of the exposure values above the median. Exposures in these studies typically exceeded the PEL 10% of the time. It is misleading to use these studies to test the efficacy of a PEL or to establish a new one. The following provides additional insights into the studies referenced by the authors.

Shima[23] reported only general area sample data and sampled at a frequency of two times per year as required by Japanese regulation. It is well established that exposures in the personal breathing zone of the workers would have been much higher than the area sample results used by Dr. Shima. In addition, Shima noted general area sample results as high as 40 $\mu g/m^3$ and the existence of cases of acute beryllium disease,

which are known to require exposures to soluble compounds of airborne beryllium higher than 100 μg/m^3. The Japanese beryllium standard is based upon and requires the use of area sampling.

The study by Cullen[24] has been criticized within the scientific community as not accurately representing worker exposures. Dr. Eisenbud's review of the Cullen study stated, "Since the affected employees were exposed for 10 to 20 years before the samples were collected, it cannot be said that the exposure histories were reconstructed in a meaningful way." In an article in the April 1998 *IRIS*, entitled "Toxicological Review of Beryllium and Compounds,"[25] the Environmental Protection Agency chose not to select the Cullen study as a principal study ". . . because no historical exposure monitoring data were available and worker exposure levels were estimated using a small amount of monitoring data." In addition, Cullen himself reported in the article that 10% of the worker exposures were higher than the PEL, and air sample results ranged from 0.22 to 42.3 μg/m^3.

In an effort to try to continue their portrayal of beryllium as posing an uncontrollable, ongoing health concern, the authors offer up 31 cases of CBD in Quebec. Almost all of the Quebec cases have been diagnosed at a copper smelting facility operated by Noranda Corporation. This facility recycled metal dross from Brush Wellman's primary beryllium operations. Before shipping its metal dross and byproducts from its beryllium alloy operations to Noranda, Brush Wellman met with Noranda to review appropriate procedures and was assured that Noranda could safely handle and recycle these drosses, which contain more than 10% beryllium and are very dusty. Brush Wellman has documented evidence that Noranda mishandled the drosses using front-end loaders and no ventilation controls. Exposures at Noranda were measured in excess of the 2 μg/m^3 PEL.

The 1999 DOE beryllium rulemaking adopted the 2.0 μg/m^3 PEL

Dr. Michaels lauds the DOE's efforts to issue a "stronger beryllium exposure limit" when in fact the authors' telling of the 1999 DOE rule history should have included, with its description of the DOE action level, the key point that the DOE rule actually adopted the 2.0 μg/m^3 eight-hour PEL for beryllium. If the science challenging the 2.0 μg/m^3 PEL was as certain as the authors describe, the DOE should have had little trouble lowering the DOE's beryllium PEL as part of its rulemaking.

Clear record of customer communication

The authors' criticism of scientists within and hired by the beryllium industry as having a credibility problem that should result in a discounting of the science generated by those efforts is totally without merit. If anything, the beryllium industry has to be more certain of the science it supports or performs than anyone else because if the industry doesn't have a solid basis for its own actions and its safety recommendations to its customers, it is the beryllium industry that will suffer the legal liability and loss of business. The greatest moral and financial incentive of the beryllium industry has been and continues to be that beryllium disease is prevented by people understanding how to work safely with beryllium-containing materials.

The work that went into the adoption of Brush Wellman's Beryllium Worker Protection Model demonstrates the falsity of the authors' charge that Brush Wellman has used "public relations in lieu of science." To help answer the scientific questions about a safe exposure level for beryllium, Brush Wellman has worked cooperatively with government, academic, and private researchers on more than 40 published scientific studies since 1990.

Also false is the authors' claim that the "beryllium industry waged a concerted campaign to delay a more protective workplace standard." It was Brush Wellman that sponsored studies, conducted by the National Jewish Medical Center at its own plants, that provided the clear scientific evidence identifying the uncertainty of the effectiveness of the current OSHA PEL. Brush sent a letter to all of its customers in 1996 that stated, "At this time, it is uncertain whether persons exposed only below the standard can become sensitized to beryllium or develop clinical signs or symptoms of CBD." The letter also stated, ". . . it remains the best practice to maintain concentrations of all atmospheric contaminants as low as feasible, and continue to work to improve exposure control practices and procedures." This letter was sent three years before the DOE rulemaking was adopted.

Brush Wellman has worked tirelessly for nearly 60 years to help ensure that people work safely with beryllium-containing materials. The company first put warning labels on its products and sent letters to all of its customers warning them of the potential health hazards associated with manufacturing beryllium-containing materials in 1949. As the scientific knowledge advanced, we updated our warnings and repeatedly sent out and made new information available to

our customers. This is hardly an example of an industry that put public relations ahead of concerns for protecting worker health. The best example of the authors' skewed presentation of industry communications is their emphasis on the Hill and Knowlton professional media relations proposal submitted to Brush Wellman. Contrary to the authors' statements, we did not hire Hill and Knowlton nor implement its proposal.

Brush Wellman continues to perform scientific studies to evaluate the potential exposure risks and has developed numerous communication tools to directly assist downstream users. An innovative tool called the Interactive Guide to Working Safely with Beryllium and Beryllium-Containing Materials (Interactive Guide) has been recently developed to communicate the elements of the Beryllium Worker Protection Model. The Interactive Guide is available on CD and operates from most personal computers. The Interactive Guide provides both employers and employees with tools and guidance to work safely with these important and beneficial materials. Upon completion of the Interactive Guide, users are provided with a printable action plan and information to address most types of operations and tasks performed on beryllium-containing materials in an industrial environment. A copy of the guide can be requested by visiting www.brushwellman.com and selecting Contact EH&S.

The societal benefits of beryllium make the world a safer place

The authors' analysis also fails to consider the incredible range of benefits beryllium-containing products bring to society. In many instances, no other material can deliver the same performance and reliability demanded of today's high technology products and systems. Beryllium metal, beryllia ceramics, and beryllium-containing alloys are making the world a better, more connected, and safer place. You'll find them at work helping to ensure our national defense and homeland security, and saving lives through the use of beryllium in air bag sensors, fire control sprinkler heads, mammography X-ray equipment, and medical lasers.

Dr. Michaels is a paid expert witness in beryllium litigation

Dr. Michaels' has not published beryllium industrial hygiene or medical research; however, he has provided litigation support serving as a paid expert witness for plaintiffs in beryllium litigation. Consistent with this role, as a hired advocate for plaintiff's counsel, he has sought to "manufacture certainty" by applying a hindsight approach to criticize the good works of dedicated beryllium researchers.

In closing, the authors' suggestion to end the industrial use of beryllium is not justified by their incomplete telling of the beryllium story. The scientific knowledge and methods to have workers work safely with beryllium are at hand and have been demonstrated. The authors seem to want the truth, but the number of inaccuracies and omissions in this article belie their ability to accurately convey the full truth.

Marc Kolanz, CIH[a]
Brush Wellman Inc.

[a]Marc Kolanz is a Certified Industrial Hygienist employed for the past 27 years by Brush Wellman Inc., a fully integrated producer of beryllium-containing materials.

REFERENCES

1. Michaels D, Monforton C. Beryllium's public relations problem: protecting workers when there is no safe exposure level. Public Health Rep 2008;123:79-88.
2. Wagoner JK, Infante PF, Bayliss DL. Beryllium: an etiologic agent in the induction of lung cancer, nonneoplastic respiratory disease, and heart disease among industrially exposed workers. Environ Res 1980;21:15-34.
3. Bayliss DL. Letter to William H. Foege, MD, Director, Center for Disease Control. 1980 Nov 12.
4. Levy PS, Roth HD, Hwang PM, Powers TE. Beryllium and lung cancer: a reanalysis of a NIOSH cohort mortality study. Inhal Toxicol 2002;14:1003-15.
5. Levy PS, Roth HD, Deubner DC. Exposure to beryllium and occurrence of lung cancer: a reexamination of findings from a nested case-control study. J Occup Environ Med 2007;49:96-101.
6. Brown SC, Schonbeck MF, McClure D, Baron AE, Navidi WC, Byers T, et al. Lung cancer and internal lung doses among plutonium workers at the Rocky Flats Plant: a case-control study. Am J Epidemiol 2004;160:163-72.
7. Deubner DC, Roth HD, Levy PS. Empirical evaluation of complex epidemiologic study designs: workplace exposure and cancer. J Occup Environ Med 2007;49:953-9.
8. Sanderson WT, Ward EM, Steenland K, Petersen MR. Lung cancer case-control study of beryllium workers. Am J Ind Med 2001; 39:133-44.
9. Garabrant DH. Case-control study design: spurious associations between exposure and outcome. J Occup Environ Med 2007; 49:941-2.
10. Madl AK, Unice K, Brown JL, Kolanz ME, Kent MS. Exposure-response analysis for beryllium sensitization and chronic beryllium disease among workers in a beryllium metal machining plant. J Occup Environ Hyg 2007;4:448-66.
11. Schuler CR, Kent MS, Deubner DC, Berakis MT, McCawley M, Henneberger PK, et al. Process-related risk of beryllium sensitization and disease in a copper-beryllium alloy facility. Am J Ind Med 2005;47:195-205.
12. Johnson JS, Foote K, McClean M, Cogbill G. Beryllium Exposure Control Program at the Cardiff Atomic Weapons Establishment in the United Kingdom. Appl Occup Environ Hyg 2001;16:619-30.
13. Cummings KJ, Deubner DC, Day GA, Henneberger PK, Kitt MM, Kent MS, et al. Enhanced preventive programme at a beryllium oxide ceramics facility reduces beryllium sensitization among new workers. Occup Environ Med 2007;64:134-40.

14. Deubner D, Kent M. Keeping beryllium workers safe: an enhanced preventive model. J Occup Environ Hyg 2007;4:D23-30.
15. Kreiss K, Newman LS, Mroz MM, Campbell PA. Screening blood test identifies subclinical beryllium disease. J Occup Med 1989; 3:603-8.
16. Borak J, Woof SH, Fields CA. Use of beryllium lymphocyte proliferation testing for screening of asymptomatic individuals: an evidence-based assessment. J Occup Environ Med 2006;48:937-47.
17. Cher DJ, Deubner DC, Kelsh MA, Chapman PS, Ray RM. Assessment of the beryllium lymphocyte proliferation test using statistical process control. Inhal Toxicol 2006;18:901-10.
18. Donovan EP, Kolanz ME, Galbraith DA, Chapman PS, Paustenbach DJ. Performance of the beryllium blood lymphocyte proliferation test based on a long-term occupational surveillance program. Int Arch Occup Environ Health 2007;81:165-78.
19. Eisenbud M. The standard for control of chronic beryllium disease. Appl Occup Environ Hyg 1998;13:25-31.
20. Eisenbud M. An environmental odyssey: people, pollution, and politics in the life of a practical scientist. Seattle: University of Washington Press; 1990.
21. Kolanz ME, Madl AK, Kelsh MA, Kent MS, Kalmes RM, Paustenbach DJ. A comparison and critique of historical and current exposure assessment methods for beryllium: implications for evaluating risk of chronic beryllium disease. Appl Occup Environ Hyg 2001;16:593-614.
22. Borak J. The beryllium occupational exposure limit: historical origin and current inadequacy. J Occup Environ Med 2006;48:109-16.
23. Shima S. Beryllium poisoning and health care. Sangyo Igaku J 1980;3:14-22.
24. Cullen MR, Kominsky JR, Rossman MD, Cherniack MG, Rankin JA, Balmes JR, et al. Chronic beryllium disease in a precious metal refinery. Am Rev Respir Dis 1987;135:201-8.
25. Environmental Protection Agency (US). Beryllium and compounds. IRIS Substance File. 1998 Apr 3.

MICHAELS AND MONFORTON RESPOND

We appreciate the opportunity to respond to the critique by Marc Kolanz of Brush Wellman Inc. of our article on the beryllium industry's public relations efforts.[1] Kolanz's letter is an excellent example of our article's primary message—that Brush has waged a concerted campaign over many years to refute the scientific evidence of the health hazards associated with beryllium exposure. The industry's efforts have impeded the replacement of an inadequate workplace beryllium exposure standard, thus placing workers at increased risk of developing beryllium-related diseases.

For the reader who may not have our article in front of them, we presented numerous previously unpublished documents illustrating Brush's efforts to counter the observations by independent scientists that workers exposed at levels below the standard were developing chronic beryllium disease (CBD), demonstrating that the Occupational Safety and Health Administration (OSHA) standard of 2 $\mu g/m^3$ was (and continues to be) inadequate. In his letter, Kolanz does not dispute the existence nor the content of any of these documents.

Kolanz disagrees with our interpretation of various data points in the historical debate over the adequacy of the 2 $\mu g/m^3$ standard. This debate has been resolved. As we note, and as Kolanz acknowledges in his letter, it is now abundantly clear that CBD can and does occur among workers exposed to beryllium at levels far below the current OSHA standard, and that it is necessary to reduce exposure levels by at least an order of magnitude to prevent CBD.

Kolanz has taken the occasion of our article to advance Brush's interpretation of other scientific questions that are at best tangential to our article—in each case promoting what we believe are erroneous assertions that minimize the hazards associated with beryllium exposure. We address these assertions in this response and elsewhere.[2] Because many of the documents we use in this discussion are unpublished, we have posted them on the website of the Project on Scientific Knowledge and Public Policy (SKAPP),[3] so that readers can decide for themselves how these historical records should be interpreted.

Compelling evidence that beryllium is a lung carcinogen

For more than 30 years, Brush Wellman has fought the labeling of beryllium as a carcinogen, motivated by fear that this would greatly reduce its ability to sell its products to downstream manufacturers.[2,4–7] As one industry document stated: "If beryllium is determined to be a carcinogen and so labeled and so regulated it would only be a matter of time until its usage would shrink to a point where it would no longer be a viable industry."[3] We believe this is the reason that Kolanz devotes a sizable portion of his letter to an attempt to show that beryllium is not a lung carcinogen, even though our article only touches briefly on beryllium's carcinogenicity.

Kolanz claims we distort the history of OSHA's efforts during the 1970s to develop a health standard to protect workers from beryllium exposure. We stand by our statement that the rulemaking was shelved following political pressure. This has been documented in a prize-winning series of newspaper articles by journalist Sam Roe[8] and confirmed by the Secretary of Energy.[9] To advance his own interpretation of OSHA's aborted beryllium rulemaking, Kolanz attempts to reopen a long-forgotten dispute from the late 1970s in which one National Institute of Safety and Health (NIOSH) researcher disagreed with two others. Kolanz cites only the position of the dissenting researcher, failing to note that in response to the dispute, OSHA's Assistant Secretary Eula Bingham asked Assistant Secretary for Health Julius B. Richmond to convene a panel of senior scientists to review all the epidemiologic, clinical, and experimental data to help assess whether beryllium