BERYLLIUM'S PUBLIC RELATIONS PROBLEM: PROTECTING WORKERS WHEN THERE IS NO SAFE EXPOSURE LEVEL

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In a dramatic announcement on a national television news magazine in April 2000, Bill Richardson, Secretary of the U.S. Department of Energy (DOE), acknowledged that his agency collaborated with the beryllium industry to defeat a 1975 attempt by the Occupational Safety and Health Administration (OSHA) to reduce workers' exposure to beryllium, a collaboration that was brought to public attention in a 1999 investigation by *Toledo Blade* reporter Sam Roe.[1] "Priority one was production of our nuclear weapons," Richardson stated. "[The] last priority was the safety and health of the workers that build these weapons."[2] The Secretary's declaration was remarkable; rarely do the most senior officials in government admit deception that resulted in death and disability of its own citizens. Yet, for those in the public health community, the Secretary's candid announcement was long overdue.

Scores of workers employed in the production of nuclear weapons had been diagnosed with chronic beryllium disease (CBD), a progressive and irreversible inflammatory lung disease, and there was increasingly powerful evidence that CBD was associated with exposure at levels below the permissible exposure limit in place at the time. In response to this evidence, the beryllium industry waged a concerted campaign to delay a more protective workplace exposure standard. Eventually, when the scientific evidence became so great that it was no longer credible to deny that workers developed CBD at levels permitted by an outdated exposure limit, the beryllium industry responded with a new rationale to delay promulgation of a more protective standard.

In the television interview, Secretary Richardson described how DOE was changing course, lowering the level that triggered protection for beryllium-exposed workers in the U.S. nuclear weapons complex from 2.0 $\mu g/m^3$ to 0.2 $\mu g/m^3$. The agency's new Chronic Beryllium Disease Prevention Program was designed to provide further protection for workers from a substance so insidious that no safe level of exposure has ever been established.

The DOE rule covers only workers employed in the nuclear weapons complex. Although OSHA has acknowledged the inadequacy of its present workplace beryllium exposure standard, which generally applies to workers in the private sector, the agency has not updated it. Researchers at the National Institute for Occupational Safety and Health (NIOSH) have estimated that there are between 28,000 and 107,000 private-sector workers potentially exposed to beryllium in the U.S.; all but 1,500 of these workers are employed outside the primary beryllium industry.[3]

This case study presents a history of the knowledge and public policy concerning the prevention of beryllium-related disease, focusing primarily on the role of the U.S. beryllium industry in shaping the policies of the regulatory system. A similar investigation has been performed in the United Kingdom.[4] The present study is based on a review of documents and on the personal knowledge of one of the authors, who, as Assistant Secretary of Energy for Environment, Safety and Health, directed the agency's efforts to issue a stronger beryllium exposure limit and develop a program to provide compensation payments to workers with CBD. Some of the documents cited were obtained from government files and others were provided by attorneys who obtained them in litigation.

THE FIRST BERYLLIUM WORKPLACE EXPOSURE LIMIT

The first significant industrial use of beryllium occurred in the 1930s, in the production of fluorescent lamp tubes. Soon after the metal was first introduced, at least 45 workers from fluorescent lamp factories in Massachusetts developed a form of chemical pneumonitis now known as acute beryllium disease (ABD); some died from the disease.[5] It quickly became apparent that workers could not safely work with beryllium without respiratory protection.

Beryllium's importance grew dramatically with the Manhattan Project—the secret initiative to construct atomic weapons—and the subsequent growth of the nuclear weapons industry, fueled by the Cold War. This lightweight metal is a vital component of nuclear weapons. Beryllium slows down the speed of neutrons released when the uranium atom is split in the atomic

chain reaction; this action facilitates the splitting of more atoms, thereby increasing a weapon's power or "yield." In the early years of U.S. nuclear weapons production, workers at and community residents living near production facilities developed beryllium disease. Although most of these cases among workers and community residents could be attributed to private facilities that supplied materials to the Atomic Energy Commission (AEC), rather than to the AEC's own facilities, the agency recognized that the situation was sufficiently serious to threaten the agency's ability to produce nuclear weapons.

Coming soon after the success of the Manhattan Project, the AEC had a group of very capable scientists who had virtually invented the field of radiation protection.[6] The agency focused its attention on beryllium, funding numerous studies at laboratories and universities throughout the country. In many ways, the AEC had no choice but to tackle the problem directly. Because the weapons complex was now the nation's primary consumer of beryllium products, the AEC tacitly assumed responsibility for researching the health perils the valuable metal posed. In a 1947 report, entitled "Public Relations Problems in Connection with Occupational Diseases in the Beryllium Industry," the AEC openly acknowledged problems of both "obvious moral responsibility" and public relations, the latter exacerbated by the fact that, unlike the remote research and bomb-making facilities, some of the beryllium-processing factories were located in more populous areas. The 1947 report states bluntly that, "There is no doubt at all that the amount of publicity and public indignation about beryllium poisoning could reach proportions met with in the cases of silicosis or radium poisoning." It also noted that the industry was already reporting problems recruiting workers "because of local prejudice . . . engendered by actual and rumored experience with beryllium poisoning."[7]

Most importantly, AEC environmental health specialists developed a standard for limiting beryllium exposure. To avoid this public relations problem, the agency applied the standard in its own facilities, and incorporated mandatory adherence to the standard into its contracts with manufacturers from which it purchased beryllium products.

The history of the AEC beryllium standard is legendary. According to one version, it was developed in a 1948 discussion held in the back seat of a taxi by Merril Eisenbud, an AEC industrial hygienist, and Willard Machle, a physician who was a consultant to the firm building the Brookhaven Laboratory in Long Island, New York. In his autobiography, Dr. Eisenbud reports that he and Dr. Machle selected 2 $\mu g/m^3$ (two micrograms of beryllium in each cubic meter of air) for workplace exposures and 0.01 $\mu g/m^3$ for community exposures "in the absence of an epidemiological basis for establishing a standard."[8] Instead, the scientists used what Herbert Stokinger of the U.S. Public Health Service later described as "crude analogy."[9]

The AEC tentatively adopted these exposure limits in 1949, and then reviewed them annually for seven years before permanently accepting them.[9] OSHA later adopted the 2 $\mu g/m^3$ limit when it first issued workplace exposure limits in 1971. While the story of the "taxicab standard" has often been retold, a recent reviewer of the historical data has suggested that the workplace standard was actually selected on the basis of feasibility rather than Eisenbud's calculations.[10]

In 1948, the 2 $\mu g/m^3$ standard was a great step forward. It was very stringent for its time, and its acceptance was probably aided by two factors. The first was that it addressed a severe problem: the human cost of beryllium disease was so great that it truly threatened the AEC's mission. Second, nuclear weapons production was well funded, essentially a cost-plus operation in which the participating companies were assured a healthy profit. For the most part, the weapons plants were "government-owned, contractor-operated." They were run by private employers with the U.S. government reimbursing their costs, plus an additional percentage awarded as profit. The largest U.S. manufacturer of beryllium products was Brush Wellman; Brush (as it often was called) was both a vendor to the U.S. government and a contractor, operating a government-owned facility for the AEC in Ohio from 1950 to 1956.[11]

The standard was a great success; ABD virtually disappeared and few new CBD cases were diagnosed. But it was not long before questions arose about the level of beryllium exposure necessary to cause CBD.

WAS THE FIRST BERYLLIUM WORKPLACE EXPOSURE LIMIT ADEQUATELY PROTECTIVE?

In 1952, Harriet Hardy, a pioneering occupational physician who had investigated some of the earliest cases of beryllium disease for the Massachusetts Division of Industries, established the Beryllium Case Registry (BCR) at the Massachusetts General Hospital. Previously, Dr. Hardy had been a consultant to the AEC, assisting in the investigation of beryllium disease among workers at the nuclear weapons laboratory in Los Alamos, New Mexico. Dr. Hardy received funding for the BCR from the AEC to collect ABD and CBD case reports, to track the disease, and to aggregate a sufficient number of cases to conduct epidemiologic analyses.[12–14] As of 1972, the BCR had recorded at least

20 CBD cases among workers who started employment after 1949, the year the AEC standard was adopted.[15] By 1975, that number had risen to at least 36,[16] suggesting the disease might be occurring in workers whose exposure was below the 2 μg/m^3 exposure limit. Moreover, CBD had been diagnosed in people with no workplace exposure to the metal, including individuals who simply laundered the clothes of workers, drove a milk delivery truck with a route near a beryllium plant, or tended cemetery graves near a beryllium factory.[15]

Although the acute illness was seen typically among workers exposed to very high levels of soluble forms of beryllium, the distribution of the chronic form of beryllium disease did not follow the usual exposure-response model seen for most toxic substances, and CBD was seen among workers and community residents without substantial exposure histories. As early as 1951, Sterner and Eisenbud recognized that exposure levels were not correlated with CBD severity, and hypothesized an immunological susceptibility.[17]

Evidence gathered by the BCR supported the theory that CBD risk was mediated by an immunological susceptibility. In 1966, *Beryllium: Its Industrial Hygiene Aspects* was published under the direction of the American Industrial Hygiene Association for the AEC. Dr. Stokinger, the editor of the text, asserted: "Numerous cases of the chronic disease have occurred from exposures to seemingly *trivial* concentrations of a beryllium compound that at higher levels produced no effect; no dose-response relationship appears to hold"[9] (emphasis added). It was becoming increasingly clear that the classic dose-response relationship did not apply to this metal, and that it might not be possible to identify a threshold below which no CBD cases would occur.

In these early years, the community cases were evidently viewed as anomalous, or the result of episodes of high exposure. CBD incidence among workers did drop dramatically with the reduced exposure associated with the AEC standard, leading to contemporary speculation that the 2 μg/m^3 exposure limit might be overly conservative.[9,18] The failure of these experts to recognize CBD in people with limited beryllium exposure may have been caused by limitations in contemporary diagnostic measures, or simply the absence of people with limited exposure.

Throughout the 1970s and 1980s, CBD case reports involving workers whose exposures were below 2 μg/m^3 continued to emerge. In 1974, for example, representatives of NGK, a Japanese beryllium producer that also operated a U.S. facility, traveled to the U.S. to meet with U.S. beryllium industry executives. The Japanese delegation brought a report of five CBD cases that had occurred among workers exposed below the 2 μg/m^3 limit.[19,20] Similar cases occurred at U.S. plants, including four cases among workers at a single metal refinery who were consistently exposed to beryllium below 2 μg/m^3.[21]

In parallel to the development of knowledge on the causation and natural history of CBD, scientific evidence on the carcinogenic nature of beryllium emerged in the 30 years following the end of World War II. The evidence became sufficiently strong enough that in September 1975, the Director of NIOSH notified OSHA: ". . . there is ample scientific evidence that beryllium in all likelihood represents carcinogenic risk to man."[22] OSHA had been considering a rule to protect workers exposed to beryllium, and with this validation from its sister research agency, OSHA officially proposed a workplace beryllium standard in 1975.[16] Following the political decision to shelve that proposal, federal efforts to strengthen worker protection from beryllium became dormant.

While OSHA halted its efforts to strengthen the beryllium standard, NIOSH continued to conduct epidemiologic studies on cancer risk associated with beryllium exposure. Studies by NIOSH researchers found elevated risk of lung cancer among beryllium factory workers[23,24] and among cases on the BCR.[25] Although the scientists consulting for the beryllium industry have disputed this evidence,[26–29] both the International Agency for Research on Cancer and the U.S. National Toxicology Program have classified beryllium as a human carcinogen.[30,31]

It is now understood that CBD is initiated by an immune system response to beryllium particles; the adverse health effects of beryllium exposure begin well before the disease can be diagnosed with a chest x-ray or pulmonary function test.[32] The first published reports of CBD diagnosed using the blood lymphocyte proliferation tests (BeLPT) appeared in 1983.[33] By the end of the decade, the diagnostic techniques had progressed significantly, allowing clinicians to more easily identify individuals with beryllium sensitization (BeS), an immunologic condition that is a precursor to CBD.[34,35]

Using the BeLPT as a screening tool, researchers have found CBD prevalence rates ranging from 0.1% to 4.4% among beryllium-exposed workers in the nuclear weapons, ceramics, primary beryllium manufacturing, metal machining, and copper-beryllium alloy industries, with BeS prevalence in these groups from 0.9% to 9.9%. In most of these surveys, workers identified through the BeLPT as beryllium sensitized then were given clinical evaluations to determine whether they had CBD. Depending upon the workplace, the

CBD rate among workers with BeS ranged from 9% to 100%.[36–48]

Among these studies are several that have diagnosed CBD or BeS among workers who had been reported to have had only bystander exposure to beryllium, including administrative workers and security guards.[40,41] Clinical follow-up studies have suggested that individuals with BeS progress to CBD at a rate of 6% to 8% per year in the first years of follow-up. However, it is not known if all individuals with BeS will eventually progress to CBD, and the majority of BeLPT positives do not appear to develop CBD after five to 10 years of follow-up.[49]

PUBLIC RELATIONS IN LIEU OF SCIENCE

The accumulating evidence of adverse health effects associated with beryllium exposure created a challenge for the beryllium industry. If government agencies formally designated beryllium as a carcinogen, or as a substance for which there is no safe exposure level, the economic consequences for the industry could be significant. The industry's customers would be more likely to pursue substitutes for the lightweight metal.[50–52]

The beryllium producers decided to take a proactive approach to shaping the interpretation of the literature on the health effects of beryllium. Aspects of the program were detailed in a 1987 internal Brush Wellman memo, with the subject line: "Proposed program for filling need for new and accurate beryllium health and safety literature." The memo by Martin B. Powers, a retired Brush executive who was a consultant to the company, and Dr. Otto P. Preuss, Corporate Medical Director, warned:

> . . . the literature on Be published in the last twenty years has been very damaging. The literature is constantly being cited, either to our doctors at medical meetings in rebuttal of the Brush experience, or by potential customers, as the cause of their unwillingness to use our products. Federal Government regulatory agencies, such as OSHA and EPA, publish much of this material and then in the absence of good data, cite these erroneous documents to support regulatory activities.
>
> What is needed to combat this situation is a complete, accurate and well written textbook on Be health and safety. It will have to be financed by Brush (or Brush and NGK?) and the bulk of the work done by Marty Powers and Otto Preuss. To be fully acceptable and credible, however, it will have to be published under the auspices of some not-for-profit organization such as a university or medical group. . . . In addition to the book, we should have a number of medical papers published in prestigious medical books.[53]

Beryllium: Biomedical and Environmental Aspects was published in 1991; its editors were a respected academic physician, along with Martin Powers and Otto Preuss.[54]

In the face of increasing evidence about the toxic effects of their products, the beryllium industry also turned for assistance to the public relations (PR) firm, Hill and Knowlton.[55] This firm has gained much notoriety for its now well-known efforts in manufacturing and promoting scientific uncertainty for the tobacco industry.[56,57] In its proposal explaining to Brush Wellman how it could help, Hill and Knowlton echoed the AEC PR problem memo of 1947:

> Beryllium undoubtedly continues to have a public relations problem. We still see it cited in the media, as well as in our conversations with people who should know better, as a gravely toxic metal that is problematic for workers. . . . We would like to work with Brush Wellman to help change these common erroneous attitudes. We envision a public relations program designed to educate various audiences . . . to dispel myths and misinformation about the metal.[58]

Hill and Knowlton proposed to prepare "an authoritative white paper on beryllium . . . [that] would serve as the most definitive document available on beryllium." The PR firm also suggested projects to engage outside scientists in independent review of Brush Wellman materials "to nurture relations with the Environmental Protection Agency" and "to challenge all unfair or erroneous treatment in the media to set the record straight."[58]

Appended to the letter was a document in which Hill and Knowlton boasted of their experience assisting other corporations that faced regulatory difficulties stemming from their production of hazardous products, including asbestos, vinyl chloride, fluorocarbons, and dioxin, although no mention was made of the firm's work for cigarette manufacturers. Matthew Swetonic, the staff person proposed to direct the PR campaign, had been a key player in Hill and Knowlton's campaign on behalf of a cigarette manufacturer to convince the public that nonsmoker exposure to environmental tobacco smoke was harmless[59] and to "create a favorable public climate" to assist in defeating lawsuits filed by smokers with lung cancer.[60] In addition, Swetonic had previously performed PR work for Johns-Manville, the asbestos producer, and had been the first full-time executive secretary of the Asbestos Information Association, an organization founded by the asbestos industry to counter the evidence of that mineral's deadly properties.[61]

Once hired, it appears that Hill and Knowlton sought to reassure Brush Wellman's customers of the

safety of beryllium. The firm drafted a letter for Brush to send to its beryllium ceramic customers, asking them to "consider these facts:"

— No occupational cases of Be disease have developed since the 1940s when the standards first were put into effect.

— No occupational cases of Be disease have ever been found when exposure was at or even near standards.[62]

The files reviewed for this case study do not reveal whether this letter was sent.

CHALLENGING THE EVIDENCE

By the late 1980s, the continued diagnosis of workers with CBD or BeS, many of whom had relatively modest beryllium exposure histories, raised concerns among health and safety professionals who previously believed the 2 μg/m^3 taxicab standard was adequate to protect workers from CBD. Dr. Eisenbud, who first proposed that standard and who later served as a consultant to Brush Wellman, notified the company in 1989 that "he did not feel that he could defend the 2 microgram standard any longer."[63]

The rising number of CBD cases also contributed to an increase in litigation. Brush Wellman management recognized that a change in the OSHA standard could be used in legal suits brought by sick workers. "Maintaining the existing [OSHA] standard is fundamental to successfully defending against any product liability litigation," a Brush official asserted in 1989.[63] This effort was an integral part of Brush Wellman's Health, Safety and Environment Strategic Plan in 1991:

> Employ legal means to defeat unreasonably restrictive occupational and emission standards and to challenge rulemaking and other regulatory activities that seek to impose unreasonable or unwarranted changes. Resist an attempt to make the existing occupational exposure standard of 2 micrograms/cubic meter, as measured and calculated by Brush, more restrictive. The standard is safe, it is one of the most stringent standards, and it is fundamental to our product liability defense.[64]

Recognizing that there was no evidence of a safe level of exposure to beryllium, in 1991 DOE began the process of lowering the beryllium exposure limit to reduce workers' risk of developing CBD. The change was opposed by the beryllium industry, whose position is summarized in this excerpt from a 1992 Brush Wellman letter to DOE:

> We regret that DOE apparently still intends to abandon the existing standard of over 40 years standing with no evidence, either that the existing standard is unsafe or that the new proposed standard affords any greater degree or [sic] safety. The NIOSH recommendation of 1977, which fortunately no one ever adopted, of 0.5 micrograms, introduced an element of confusion that can only be compounded by DOE's proposed introduction of a third number. A proliferation of numbers as "standards" can only weaken the acceptance, and therefore, the efficacy of the individual protection afforded. Confusion is never in the best interests of the worker.[65]

Progress on a more protective rule was also impeded by opposition within DOE. The offices responsible for manufacturing nuclear weapons production argued that money spent protecting workers would mean less money for their arms production. The debate continued for several years, leaving the rule in limbo.

Despite the institutional obstacles, DOE's safety officials continued to promote the proposed rule, hoping eventually to secure a new, more protective exposure limit. The health and safety office sponsored a series of public forums to gather information on beryllium's health effects. At one session, Brush Wellman's Director of Environmental Health and Safety asserted (according to DOE's minutes of the meeting): "Brush Wellman is unaware of any scientific evidence that the standard is not protective. However, we do recognize that there have been sporadic reports of disease at less than 2 μg/m^3. Brush Wellman has studied each of these reports and found them to be scientifically unsound."[66]

This was the industry's primary argument; subsequent studies have demonstrated that the underlying logic to the argument was flawed. It was not difficult to go back into the work history of anyone with CBD and estimate that at some point, the airborne beryllium level may have exceeded the exposure limit. Even if no evidence for overexposure was found, it was assumed that exposure had occurred because the worker had developed CBD. Brush Wellman did this, and then reasoned that the 2 μg/m^3 must be fully protective because everyone who had CBD must have at some point been exposed to levels above the exposure limit.

Although flawed, this tautological construct served as the basis for the defense of the 2 μg/m^3 exposure limit. Talking points prepared for Brush Wellman executives advised:

> You may be asked in some fashion whether or not the 2 μg/m^3 standard is still considered by the company to be reliable. Your answer should be as follows: (*1*) Experience over several decades has, in our view, demonstrated that levels of airborne beryllium within the OSHA threshold limit value afford a safe workplace. (*2*) In most cases involving our employees, we can point to circumstances of exposure (usually accidental), higher than the standard allows. In some cases, we have

been unable (for lack of clear history) to identify such circumstances. However, in these cases we also cannot say that there was *not* excessive exposure.[67] (emphasis in original)

This position, however, could not be maintained indefinitely. As DOE provided medical screenings to more workers, the number of CBD and BeS cases continued to grow, reaching several hundred by the middle of the decade.[68] Moreover, the growing literature reporting cases of CBD associated with low levels of exposure undermined the claim that the old standard was safe.[69] Scores of beryllium-exposed workers who had developed CBD filed civil suits against Brush Wellman, alleging that the firm failed to disclose information about the material's toxicity. Continued denial of the relationship between low-level exposure and CBD was unlikely to be a successful strategy to oppose either the claims raised by sick workers or the attempts by DOE and OSHA to strengthen their beryllium exposure limits. Instead, Brush Wellman asserted that not enough is known to adequately prevent CBD from occurring. If true, then the industry might avoid liability in CBD litigation.

In 1998, Brush Wellman and NIOSH embarked on a collaborative research initiative, conducting medical surveillance of beryllium-exposed workers and examining the beryllium-CBD relationship. The research partnership has been a productive one, producing findings that have substantially contributed to our understanding of CBD.[70]

In December 1998, DOE officially proposed a rule to protect workers from CBD, including an action level of 0.5 μg/m^3 (25% of the OSHA exposure limit), and asked for public comment on the proposal.[68] Brush Wellman no longer asserted that the old exposure limit was effective in preventing CBD, but instead advocated for the position that not enough is known to adequately prevent CBD from occurring. During a public hearing on DOE's proposal in February 1999, a Brush representative offered this new rationale for the agency to delay issuing a new rule. He testified that "important research is underway which may provide a scientific basis for a revision to the occupational standard for beryllium," pointing to studies on particle size, particle number, and particle surface area.[71]

Brush Wellman turned for assistance to Exponent, Inc., a U.S. firm that provides scientific and technical support to polluters and manufacturers of dangerous products.[72] Exponent, Inc. is a leading practitioner of product defense, a specialization whose objective is to help corporations reduce their regulatory burden and defeat liability claims that arise in the civil justice system.[73,74] With Exponent's assistance, in September 1999, Brush Wellman convened a conference, cosponsored by the American Conference of Governmental Industrial Hygienists (ACGIH), to bring "leading scientists together to present and discuss the current information and new research on the hazards posed by beryllium."[75] At the time of the conference, DOE was a few months away from issuing its final rule and OSHA had signaled its intention to revise its outdated standard. The paper summarizing the proceedings, entitled "Identifying an Appropriate Occupational Exposure Limit (OEL) for Beryllium: Data Gaps and Current Research Initiatives," advocated the same position that DOE officials heard earlier in the year—specifically, that more research is needed on the effects of particle size, of exposure to beryllium compounds, and of skin exposure to CBD risk. Although it is not uncommon for a scientific paper to call for additional research, this paper went further, advocating postponement of any changes in the workplace beryllium-exposure standard: "At this time," the paper concludes, "it is difficult to identify a single new TLV [threshold limit value] for all forms of beryllium that will protect nearly all workers. It is likely that within three or four years, a series of TLVs might need to be considered. . . . In short, the beryllium OEL could easily be among the most complex yet established."[75]

In December 1999, DOE completed its rulemaking, mandating that protection from beryllium exposure be triggered at 0.2 μg/m^3 rather than the 0.5 μg/m^3 level the agency had proposed some months earlier.[76] In its rule, DOE relied on the standard industrial hygiene measure of exposure: full-shift concentration by weight of airborne beryllium. The government's responsibility is to protect public health using the best available evidence. More research was, and is, needed, but because the relationship of CBD to beryllium particle size, number of particles, and surface area was, and remains, poorly understood, the officials responsible for protecting the health of beryllium-exposed workers determined that new policy should not be delayed until this research was completed.

NEW EVIDENCE, BUT NO NEW OSHA STANDARD

Once DOE prepared to issue a proposed rule, OSHA recognized an opportunity to update its own beryllium standard. In written comments to DOE, OSHA's Assistant Secretary acknowledged in 1998 that the current OSHA exposure limit was inadequate, writing ". . . we now believe that our 2 μg/m^3 PEL does not adequately protect beryllium-exposed workers from developing chronic beryllium disease, and there are

adequate exposure and health effects data to support this [DOE's] rulemaking." The letter continues by citing existing data:

> . . . cases of chronic beryllium disease have occurred in machinists where 90 percent of the personal exposure samples found levels of beryllium to be below the detection limit of 0.01 μg/m^3. . . . Viewed from OSHA's regulatory perspective, these DOE study results document risk of sensitization to beryllium of 35-40 per 1,000 workers and risk of chronic beryllium disease to machinists of 94 per 1,000.[77]

Despite these assertions, OSHA did not promptly propose a rule to protect beryllium-exposed workers. When President George W. Bush's Administration took office in 2001, the commitment to regulate beryllium was dropped from OSHA's formal regulatory agenda. Instead the agency announced that it needed more information before deciding how to proceed.[78] As of the summer of 2007, OSHA still had not proposed a new standard.[79]

The scientific knowledge on the risks associated with low-level beryllium exposure continues to accumulate. In the few years since DOE reduced its beryllium exposure limit, researchers have published numerous epidemiologic studies that provide additional evidence that OSHA's 2.0 μg/m^3 standard does not prevent CBD.[41,43,47,48,80,81] In 2005, after reviewing the accumulated evidence, the ACGIH issued a draft threshold limit value of 0.02 ug/m^3, a reduction of two orders of magnitude from the current OSHA standard.[82] Similarly, in 2006, a literature review and editorial supported by Brush Wellman acknowledged that the current OSHA exposure limit "provides insufficient protection for beryllium-exposed workers."[83]

Fear of litigation no longer distorts the debate over the adequacy of the beryllium exposure limit, as most civil litigation involving CBD in the U.S. ended in 2001, following the enactment of the Energy Employees Occupational Illness Compensation Act in 2000. This legislation provides a federal payment of $150,000 plus prospective reimbursement of medical expenses to individuals with CBD who worked for a DOE or AEC contractor or vendor, irrespective of whether they worked directly on products being manufactured for nuclear weapons. To be eligible for this compensation, an individual with CBD must drop legal actions against the government or its contractors or vendors. Since its inception, the program has provided more than $100 million in compensation payments to workers with CBD and their families and has relieved the beryllium industry of a sizable financial liability.

Beryllium exposure continues to be a public health concern at downstream facilities, which are not involved in the primary production of beryllium products, and in communities adjacent to beryllium-processing facilities. In 1999, the diagnosis of a sentinel CBD case in a metals recycling plant in Quebec, Canada, resulted in the diagnosis of 31 additional cases at three metals plants.[84] It also prompted a survey that identified 2,789 workplaces in which beryllium was used, including 63 golf club manufacturers and 15 bicycle manufacturers in that province.[85] There were also eight new cases of community-acquired CBD reported in the U.S. between 1999 and 2002.[86]

At present, it is not possible to identify an occupational exposure limit that will prevent all cases of CBD.[87] Beryllium must therefore be considered a substance for which there is no safe exposure level. It would be prudent public health policy for manufacturers to substitute a less toxic material for beryllium whenever possible. However, in those products and processes in which there is no adequate substitute for beryllium, such as the production of nuclear weapons, exposure should be reduced to the lowest level technically feasible.

LESSONS FOR POLICY MAKERS

The primary lessons of this case study are not new, but bear repeating because they are too often forgotten or ignored. The first is that the absence of evidence is not evidence of absence. In the first decades following the reduction in beryllium exposures in the early 1950s, relatively few new CBD cases were diagnosed. This is likely attributable both to improved working conditions and the limitations of the diagnostic methods available at the time. With the development of the BeLPT, many new cases were diagnosed, no doubt including cases that would not have been previously recognized as CBD.

There were indications before the advent of the BeLPT that the 2.0 μg/m^3 exposure limit was not fully protective. With the diagnosis of CBD and BeS in an increasing number of workers with low exposure, this conclusion became more difficult to avoid. As this evidence accumulated, the beryllium industry had a strong financial incentive to challenge the data, and to oppose regulatory action that would result in a lower exposure limit. It appears this incentive shaped the interpretation given to scientific evidence by scientists employed by the beryllium industry.

This, then, is the second lesson of the case study: The interpretation of scientific data by those with financial incentives must be discounted. Scientists employed by the beryllium industry defended the "taxicab standard" long after it was correctly recognized as inadequate by

independent scientists. In particular, work by scientists employed by firms specializing in product defense and litigation support must be seen for what it is: advocacy, rather than science.

The study illuminates the practice of manufacturing uncertainty, the strategy used by some polluters and manufacturers of hazardous products to prevent or delay regulation or victim compensation.[74,88] The public health paradigm requires using the best available evidence to protect the public. By the early 1990s, the accumulated evidence was sufficient for public heath officials to justify a more stringent workplace beryllium exposure limit. In response, the industry manufactured and magnified uncertainty, producing a series of arguments to explain why the old standard should not be changed. Subsequent research has shown that DOE's 1999 regulatory changes were well-justified, and that a more protective exposure limit is likely preventing CBD and saving lives.

Finally, the findings of this case study underscore the importance of considering the hazards associated with a toxic material through the entire life cycle of the product. While primary producers of beryllium products may be capable of controlling exposures in their own facilities, it is unlikely that most secondary users and recyclers have the expertise, resources, and knowledge necessary to prevent beryllium disease in exposed workers and residents in the communities in which they are based. As a result, it would be prudent public health policy to end the industrial use of beryllium, except in those uses where substitution is not possible.

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