ATTACHMENT 1 to OSC-12

DISCLOSURE OF A SUBSTANTIAL DANGER TO PUBLIC HEALTH: FAILURE TO TEST FOR CHRONIC BERYLLIUM DISEASE AMONG OSHA INSPECTORS

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Background:

The U.S. Occupational Safety and Health Administration (OSHA), in addition to its statutory responsibility to help protect approximately 100 million U.S. workers from safety and health hazards in their jobs, also has an obligation to protect its own employees from hazards they encounter in the course of their OSHA work. OSHA's treatment of its own employees is directly linked to its ability to protect the remainder of the nation's workers. Private industry has successfully argued that if OSHA does not choose to afford a particular protection to its own employees, it should not be permitted to require that private employers must do so.

OSHA currently employs approximately 1,200 inspectors, who spend the majority of their work-time in the field, investigating (and were therefore exposed to) some of the most dangerous conditions in modern workplaces. Between 1,000 and 2,000 retired OSHA inspectors are still living. Because conditions (especially exposure to toxic substances) in U.S. workplaces were generally more adverse in the 1970s and 1980s when these inspectors were active, their risk of developing chronic disease from on-the-job exposures during that time period is generally higher than that of their active counterparts.(1)

Of the many health hazards U.S. workers are exposed to, the toxic metal beryllium is unusual, both in its potency (high risk of disease following extremely low exposures) and the fact that one of the adverse consequences of exposure—a progressive and generally fatal lung disease known as chronic beryllium disease (CBD)— apparently results only from exposure to this one substance.(2)

Hundreds of U.S. workers have already died of CBD, many of them current and former workers at Department of Energy (DOE) sites. DOE has long since responded to this situation (see below) by implementing a broad-scale early detection and testing program for its current and former workers. The cornerstone of DOE's testing program, as well as programs implemented by some private employers, is a blood test that researchers have refined over the past 10 years called the beryllium lymphocyte proliferation test (BeLPT). The BeLPT can reliably detect whether the

subject has become “sensitized” to beryllium he or she has already been exposed to. Sensitization is somewhat akin to being allergic to a particular substance; no one can contract CBD without first becoming sensitized to beryllium. However, roughly 1/3 to ½ of sensitized individuals never develop CBD, especially if the employer uses the positive test result as an early warning and the employee is removed from any future exposure to beryllium.(3)

Persons testing positive on the BeLPT are often urged to undergo more extensive testing, some of it minimally invasive, to check for early stages of CBD itself; in this way, the BeLPT can help diagnose CBD up to 10 years before severe symptoms are manifest. In some studies reported in the medical literature, up to 50% of BeLPT-positive individuals also had early (not otherwise detectable) CBD. The earlier the CBD disease process is detected, the more likely it is that the afflicted individual may prolong his or her remaining life through treatment (there is no cure for CBD, but steroid medication can slow the damage done to lung tissue), lifestyle changes (e.g., quitting smoking) and avoidance of additional beryllium exposure.

Issue:

Beginning in 1999, OSHA senior scientific and medical staff explored the BeLPT and worker testing programs at DOE and elsewhere in the hope of convincing the Agency leadership to adopt a similar program for OSHA inspectors who had been exposed to beryllium. In March 2001, headquarters staff briefed the Assistant Secretary (A/S) and recommended a pilot testing program. In the first phase of the recommended program, all of the current OSHA inspectors (approximately 200 individuals) who, according to OSHA’s historical database, had personally taken samples in the workplace with documented airborne beryllium concentrations of more than 0.2 micrograms per cubic meter (µg/m3) would be offered a chance to receive the BeLPT (see below for a discussion of exposure levels and risk of disease).

No action was taken.

In April 2002, A/S John Henshaw convened a meeting of the “OSHA Executive Board” (OEB) at which the beryllium issue was discussed. After extensive debate, Mr. Henshaw cut short the discussion by announcing two decisions he had made on this subject: (1) OSHA would not offer the BeLPT to any retired inspectors, or any information explaining why they might want to receive the test and where in the U.S. testing and medical counseling is available; and (2) OSHA would not provide the BeLPT to any active inspectors, but *might* in the future offer the test to some inspectors, although this would only occur as part of the

regular medical examination program in which an inspector receives a general physical exam approximately every three years.

Mr. Henshaw emphasized at the April 2002 meeting, and at a subsequent OEB meeting in November 2002, that his decisions on beryllium, like all decisions reached in the OEB, are confidential and not to be discussed outside the OEB without his permission. In fact, in the November 2002 meeting he strongly warned all OEB members not to talk to the media about this or similar issues.

As a consequence, OSHA inspectors (active and retired) do not know that OSHA has a list of those known to have been exposed to high levels of beryllium (see below), that a test exists to identify those who have been sensitized or have contracted early CBD, and that OSHA to date does not intend to act on this information.

As of October 2003, no present or former OSHA employee has been offered a BeLPT, although at least four years have now elapsed since OSHA senior staff began preparing a protocol for testing. Even if OSHA decided today to offer testing as part of the regular medical examination program (not, as was recommended, as a separate program that would not depend on the scheduled examinations), two to three more years might elapse (i.e., six or seven years in total from OSHA's first opportunity to address this problem) before some exposed inspectors receive a blood test.

CBD is a rapidly-progressive, often painful disease with grave consequences; therefore, continued delay over several years or more could result in one or more OSHA employees developing fatal CBD that could have been detected, averted, and/or treated at an earlier stage.

The medical literature confirms that cases of CBD or sensitization can develop within a few *months* following one's first exposure to beryllium. It is impossible even for a knowledgeable inspector to completely avoid potentially hazardous exposures to beryllium, because many of the exposures will occur in workplaces where s/he is sampling for other substances, and is unaware that beryllium is being used in that workplace. New uses for the metal are being developed every year because the sole producer of the metal continues to market it outside of its initial uses in the aerospace industry and into industries such as electronics, sporting goods, dental prosthetics, etc. Without a testing program, OSHA employees continue to run the risk of sustaining exposures that could cause harm that will remain undetected until it is too late to mitigate the damage.

There are two distinct sets of consequences of continued delay in beginning a testing program: (1) some inspectors who already have beryllium in their bodies will progress to sensitization or clinical disease;

and (2) others who were first exposed to beryllium while OSHA was deferring or denying testing, as well as those whose first exposure will occur in 2003 or thereafter, may become sensitized or contract CBD needlessly.

Although I am a nationally recognized expert in the quantitative risk assessment of occupational and environmental disease, and have extensive experience evaluating exposure-response relationships, I am not an expert on beryllium per se. However, I have discussed this issue extensively with the nation's preeminent physician treating CBD patients,(4) and he has told me that in his opinion: (1) at least 1 to 2 percent of OSHA's active and retired inspectors (i.e., between 3 and 10 individuals) likely already are sensitized to beryllium based on their known and likely exposure histories; and (2) for every year of continued delay that number could grow, as could the number of sensitized inspectors who progress to clinical disease.

Significance of Danger to Public Health:

1. *Extent of Beryllium Exposure among OSHA Inspectors and Retirees.*

OSHA has a database containing sampling results dating back to approximately 1979 where beryllium was detected during an inspection. The database documents the exact concentrations found and the name of the inspector who took the sample. Usually, the inspector clips a portable sampling pump onto the clothing of a facility employee and spends part of the next eight hours checking the function of the sampler, while at other times continuing inspection activity elsewhere in the plant. Therefore, the amount of beryllium the facility employee is exposed to during the eight-hour shift may either overestimate the exposure the OSHA inspector sustained (if the inspector spends some of the shift in an area of lower beryllium concentration) or underestimate it (if the converse is true). In some cases, cross-checking the database reveals that one or more other OSHA employees were also inspecting the same facility on the same day, so they too can be presumed to have had some exposure to beryllium, though perhaps not as much as that of the inspector who took the sample.

I do not have access to the entire database, but was given as Regional Administrator a list of current and former inspectors in our Region who appear within the database (with the actual sampling results redacted, although I was told only results above 0.2 µg/m3 were included). My list indicates that about 20 percent of the active Region VIII inspectors (15 persons) have taken samples where beryllium was found at greater than 0.2 µg/m3; some of these workers appear two or more times on the list. OSHA has routinely documented violations of the beryllium permissible

exposure limit (PEL) of 2 µg/m3, so some of these inspectors were probably exposed to levels this high or higher.(5)

If Region VIII is representative of the rest of the country (which is a conservative assumption, since much of the machining of beryllium alloy takes place in the eastern U.S.), then 20 percent of inspectors known to have been exposed equates to roughly 250 OSHA personnel nationwide. In addition, 16 retired inspectors for Region VIII show up on the list I was given, which would correspond to another 250 or so retired inspectors nationwide.

It is important to note that these measured exposures *must* be a subset of the true extent of the number of OSHA personnel exposed and of the cumulative amount of beryllium each has inhaled, because OSHA inspectors only take the trouble to sample for a particular substance if there is evidence or reasonable suspicion that workers are being overexposed to it. Thus, in some unknown fraction of the many hundreds of inspections a typical OSHA compliance officer would conduct during his/her career, *beryllium was present in workplace air but never sampled for*. The list confirms that most of the facilities sampled were foundries or metal casting establishments. Electronics plants, metal recycling facilities, dental laboratories, sporting goods manufacturers, and other establishments where beryllium could have been used do not tend to appear on the list.

For comparison to the health-based risk information below, note that most experts believe that cumulative exposure (concentration times number of days exposed) is the most reasonable measure of the relevant hazard. An OSHA inspector who (for example) visited 10 establishments during her career where she found beryllium concentrations just at the PEL would have been exposed to 20 µg/m3·days (10 times 2) from those inspections alone, and may have inhaled additional amounts of beryllium during some of the 1000 or more other inspections she conducted for OSHA.

2. *Quantitative Relationship between Beryllium Exposure and Disease.*

Large worker populations consistently exposed to beryllium levels below OSHA's PEL have alarmingly high incidence rates of CBD and/or sensitization. For example, in a large DOE population generally exposed below 1 µg/m3, more than 2% of current workers, and more than 3% of former workers, have become sensitized. For context, the Supreme Court has instructed OSHA to regard a risk of chronic disease as "significant" if the incidence exceeds 0.1%, or one chance in a thousand. Congress has repeatedly authorized EPA to regulate risks where the probability of harm is as low as 0.0001%, or one chance in a million.

Skeptics might claim that elevated risk of disease exceeding 1% occurs only when workers are exposed to beryllium continuously over a long period of time, not occasionally, as OSHA's inspectors are. The medical literature, however, contains a growing variety of examples of sporadic low exposures causing CBD. A growing number of federal and private-sector workers at facilities using beryllium whose jobs were solely clerical in nature now have CBD, demonstrating that occasional and low exposure can be dangerous. One case report in the medical literature discusses CBD in a family member of a beryllium worker, who apparently was only exposed on one occasion when she cared for a worker who was bedridden for a few days and had beryllium dust in his hair. Quantitative evidence of dose-response comes from, among other reports, a study by Kelleher et al. (Journal of Occupational and Environmental Medicine, 2001, vol. 43, pp. 238-249) who recently studied 20 cases of CBD and/or sensitization in employees who had never been exposed to beryllium before coming to work in a facility where beryllium was machined. In two of the cases, workers who developed CBD had been exposed for only two to three *months* to levels as low as 0.02 μg/m3. On the basis of cumulative exposure, these diseased workers had only been exposed to as much beryllium as would an OSHA inspector who took *one* 8-hour sample in an environment where the PEL of 2 μg/m3 was being met.

In other words, any OSHA inspector who took more than one eight-hour sample in his career where beryllium concentrations at the facility met the legal limit, or who took more than 10 samples in his career where the concentrations at the facilities were a factor of 10 below the legal limit, would have been exposed to a quantity of beryllium larger than that known to have already caused disease in other identified U.S. workers.

In other cases, physicians have diagnosed CBD in spouses and children of beryllium-exposed workers. These unfortunate family members presumably were exposed only very infrequently, by coming into contact with beryllium dust on clothing the workers wore home. Deaths from CBD have also been documented in workers at metal reclamation yards, where the only plausible exposures to beryllium would have come from the occasional piece of scrap metal containing beryllium alloy. This is one example of the type of facility an OSHA inspector might encounter many times in a career without ever thinking that she was exposing herself to airborne beryllium.

Lack of Credible Agency Rationale for Failing to Inform or Test:

In my capacity as OSHA Regional Administrator for Region VIII, I participated in virtually all of the internal OSHA debate on this issue. In my professional opinion, there are only four possible reasons why Mr. Henshaw and the other senior OSHA officials who spoke out against

testing (notably David Zeigler, Director of Administrative Programs) do not wish to implement a beryllium testing program at all or in the near future:(6)

- Belief that OSHA personnel are not at high risk of CBD.

Such a belief, given the known and probable levels of exposure to many OSHA inspectors, would fly in the face of a growing body of medical literature about CBD (see above). Immediately before announcing his decisions, Mr. Henshaw said at the April 2002 OEB meeting that "no one at OSHA has ever tested positive on the BeLPT." At the meeting I reminded him that only five OSHA inspectors have ever received the test, because they had worked at DOE sites and were tested under DOE auspices. Elementary statistics dictates that zero positives out of only five tests is still consistent with a very high risk,(7) as well as consistent with zero risk. In addition, Mr. Henshaw's remark ignores the fact that a negative test result can be of substantial value to the individual receiving it; the reassurance that at present, one is not along the path to fatal lung disease may remove a source of major psychological stress and create an additional ethical imperative to provide testing to those who were exposed while doing their jobs for OSHA.

- Concern about the costs of testing.

The BeLPT now costs approximately $150. Therefore, all of the approximately 200 inspectors already identified as exposed to levels high enough to cause CBD could be tested for approximately $30,000, or about 1/15,000th of OSHA's annual operating budget. All retirees could be given informational material about the test for less than $1,000, given the cost of postage and copying.

- Belief that OSHA inspectors who were exposed to beryllium were careless and therefore do not deserve to be tested.

Although I never heard Mr. Henshaw express this sentiment, at least two of the other OSHA Regional Administrators voiced such an opinion at the OEB meeting,

with one of them saying that "if any inspector was exposed to beryllium, it was his own damn fault," citing the internal OSHA policy that inspectors should wear respirators whenever working in a potentially dangerous environment. Given the extreme potency of beryllium and the inability of any respirator to block 100 percent of a pollutant present in workplace air, as well as the difficulty of knowing a priori whether one needs to take precautions against beryllium in any particular workplace, this belief seems extremely short-sighted.

• Concern over liability and/or public image.

I believe this is most likely the true explanation of Mr. Henshaw and Mr. Zeigler's position. In response to my proposal at the April 2002 OEB meeting that OSHA should at least provide information to all exposed retirees if it was not willing to pay for their BeLPTs, Mr. Zeigler said (to closely paraphrase) "imagine the bad press if a retiree reveals that we told him he might need a blood test but he'd have to pay for it himself." I responded that we could always provide the information and pay for the test, but that if public image is the issue we should consider the "bad press" if and when retirees learned that we rejected a proposal to provide them with $1 worth of information that could prolong their lives. The risks of delay or failure to test are so substantial, and the costs of testing so minimal, that in my view, the only plausible reason to defer or deny testing is fear of tort liability. Such a concern is inappropriate for a public agency. No such concern deterred DOE, which has implemented a policy of informing and testing more than 25,000 of its own current and former employees who have been exposed to beryllium. Indeed, DOE's regulations providing for testing emphasize that "the reasonable employer must establish and implement a medical surveillance program for beryllium-associated workers." It is ironic that OSHA has lagged behind DOE and the private sector in this regard. Furthermore, the nation's private workforce does not look to DOE to establish and enforce appropriate workplace safety standards. The nation does, however, look to OSHA for this purpose.

1. Note that approximately half of the U.S. states conduct their own OSHA programs under delegated authority, and collectively employ at least 1,000 additional inspectors. These "state-plan states" generally do not promulgate

rules governing private-sector workers or their own employees until the federal Agency takes the lead. Thus, OSHA's decisions about its own workers also effectively govern how the state-plan inspectors will be treated.

2. Almost all other occupational and environmental diseases have at least several known causes. Therefore, a worker in a dye factory who contracts (for example) bladder cancer may well have been stricken by chemicals in his workplace, but might also have succumbed due to smoking or other factors. A worker with CBD has a unique diagnosis. Based on medical knowledge to date, her illness must be a result of beryllium exposure.
3. Note, however, that unlike allergies most people typically encounter, the immune system of the beryllium-sensitized individual will react to material that is already in the body and that provides a continuous stimulus to the immune system. Beryllium particles deposit deep in the lung tissue and are only very slowly removed from the body .
4. If necessary, I can provide OSC with the contact information for this physician.
5. Note that this PEL was set more than 50 years ago by the Atomic Energy Commission, long before CBD was recognized as a disease. Many expert bodies and agencies around the world have lowered their recommended or required limits to 0.2 µg/m3 or below. The U.S. EPA, for example, has an ambient air standard of 0.01 µg/m3 for beryllium.
6. OSHA cannot credibly claim that it has not studied the issue enough. The written information packet and the protocol have been refined since early 2001. I personally have submitted four separate sets of written comments during this period with the help of several of my staff in Region VIII. I can provide OSC with copies of these comments if requested. The current unimplemented protocol, in my opinion, does not go far enough to offer testing to inspectors who cannot prove they have been exposed to substantial amounts of beryllium, but who have reasonable concerns they may have repeatedly encountered beryllium during inspections they conducted. In most other respects, however, the protocol and the informational material are well written and complete.
7. I believe that the true risk is much lower than this, but with only five negative tests we cannot rule out at a standard 95% level of confidence that in fact the risk to each inspector may be as high as 0.45 (that is, 450 out of every 1000 inspectors tested would be positive, even though the first five were by chance all negative). If the true risk to each inspector was somewhat lower, 0.13 (that is, 130 true positives out of every 1000 tested), there is still a 50/50 chance that the first five inspectors tested would all be negative.