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Joan Claybrook, President

November 20, 2002

OSHA Docket Office  
Docket No. H-0054a  
Room N-2625  
U.S. Department of Labor  
200 Constitution Ave, NW  
Washington, DC 20210  
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DOCKET OFFICER  
DATE NOV 20 2002  
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To Whom It May Concern:

Public Citizen submits these comments in response to the Occupational Safety and Health Administration's (OSHA's) August 22, 2002 Request for Information on Occupational Exposure to Hexavalent Chromium. As OSHA is well aware, Public Citizen, along with the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) is currently in litigation with the agency over its failure to regulate the chemical, despite the agency's acknowledgment on March 8, 1994, that there is "clear evidence that exposure ... at the current PEL ... can result in an excess risk of lung cancer" and other related illnesses.' At that time, the agency undertook to publish a Notice of Proposed Rulemaking (NPRM) in the Federal Register "not later than March 1995." The present Request for Information falls short of this promise; its disingenuousness is underlined by the fact that it comes in the midst of our litigation against the agency, apparently in an attempt to make it appear to the court that the agency is actually taking action. Our comments to the docket, therefore, do not in any way endorse the Request for Information as an adequate response to our lawsuit. For the same reason, our response is not a comprehensive response to the many questions posed by the agency, as many of these issues can be better addressed in the formal rulemaking procedure we are seeking.

In fact, much of the information the agency seeks is already contained in the voluminous reviews that have been conducted by the various U.S. governmental and international bodies that have thoroughly examined the toxicological and epidemiological data on hexavalent chromium. The following groups (in addition to OSHA itself) have reviewed the data and unanimously declared hexavalent chromium to be a carcinogen: the

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Environmental Protection Agency (EPA) in 1984,<sup>2</sup> the National Toxicology Program in 1980,<sup>3</sup> the International Agency for Research on Cancer in 1990,<sup>4</sup> the National Institute for Occupational Safety and Health in 1997<sup>5</sup> and the Agency for Toxic Substances and Disease Registry (ATSDR) in 2000.<sup>6</sup> Of course, the agency knows all this, since it cites several of these documents. The ATSDR review (as well as the epidemiological and animal studies it cites) merits particular attention due to its recency and exhaustiveness.

In addition to these reviews, we would also refer OSHA to the attached documents from our current litigation (see Attachments 1-3) with the agency as well as our 1993 rulemaking petition. Together these represent a comprehensive statement of our views on **many** of the matters addressed by the Request for Information.

When the sought-after information is not already in the docket, it can sometimes be derived from data already in the agency's possession. In particular, we have conducted and recently published, in an occupational health journal, a study based on OSHA's own Integrated Management Information System (IMIS) database. This database contains 813 measurements of hexavalent chromium exposure from inspections performed during the period 1990-2000 (see Attachment 4).<sup>7</sup> There was a statistically significant decline in the number of annual measurements over the study period. The median Time-Weighted Average (TWA) measurement was  $10 \mu\text{g}/\text{m}^3$  (range  $0.01$ - $13,960 \mu\text{g}/\text{m}^3$ ) and the median ceiling measurement was  $40.5 \mu\text{g}/\text{m}^3$  (range  $0.25$ - $25,000 \mu\text{g}/\text{m}^3$ ). Neither median TWA nor median ceiling exposures (if hexavalent chromium was detected) declined significantly during the study period. Overall, 13.7% of TWA measurements were at or below the  $0.5 \mu\text{g}/\text{m}^3$  level we have proposed, 65.0% were above our proposal and no more than the current OSHA Permissible Exposure Limit (PEL) and 21.3% exceeded the **OSHA PEL**. Compared to OSHA measurements, state measurements were less likely to detect hexavalent chromium (40.2% vs. 52.1%) and less likely to issue any citation (**9.3%** vs. 19.1%), including citations for overexposure if the exposure exceeded the PEL (54.8% vs. 78.8%). We concluded that U.S. workers continue to be exposed to dangerously high hexavalent chromium levels, but that sharp reductions in such exposures appear possible in at least some industries. Further investigations should examine whether state plans provide weaker enforcement than federal OSHA.

As the agency is well aware, the key epidemiological study in any discussion of the regulation of hexavalent chromium is the Johns Hopkins/EPA study.<sup>8</sup> The newly published study is the largest, most comprehensive study of the toxicity of hexavalent chromium ever conducted. Compared to its most prominent predecessor, the so-called Mancuso study,<sup>9,10</sup> it has more subjects, longer follow-up and better exposure data, and was able to adjust for smoking. The study demonstrates that lung cancer death rates were almost double what would otherwise have been expected for this group of workers and may even be elevated at air chromium levels below those we have recommended as a **new standard**.

Given the strength of the study's findings, it is no surprise that the Chromium Coalition, an industry group, has contracted with an epidemiological hired gun, the Exponent group, to attack the study. This "critique" is in fact an exercise in nitpicking that leaves the

essential conclusion of the Johns Hopkins/EPA study untouched. Below we address some of the issues raised in this critique.

### ***Imprecise measurement of chromium exposure***

Whatever minor complaints the industry may have, it is important to remember that unbiased imprecisions in measurements tend to bias the study results toward a finding of no effect; the finding of so strong an effect in three separate analyses (comparisons with reference population, bivariate, multivariate) is thus noteworthy. In addition, the exposure measurements are contemporaneous and more detailed than has often been available to OSHA in previous rulemaking procedures.

### ***Short-term workers***

The industry points out that some workers were only exposed for short periods of time at the plant. These workers would disproportionately appear in the lower cumulative exposure groups. If these workers had higher lung cancer risks, independent of their exposure to hexavalent chromium, this would tend to flatten out the dose-response curve. Despite this theoretical problem, a strong dose-response relationship was detected.

### ***Adjustment for smoking in the standardized mortality ratios***

While it is true that the standardized mortality ratios were not corrected for smoking (it is possible that the authors have conducted these analyses and simply didn't present them for lack of space), the multivariate analyses did correct for smoking and a strong independent association between hexavalent chromium exposure and lung cancer death was clearly demonstrated.

### ***Confidence intervals for odds ratios***

While the authors did not include confidence intervals for their multivariate odds ratios, they do present p-values, which are an acceptable alternative method of presenting data. (We, too, prefer confidence intervals, but having a preference is a far cry from having a damning criticism.) We suspect that this is most likely a matter of how they wished to present their data, since they would be in possession of the confidence intervals. In any event, confidence intervals are presented for the standardized mortality ratios.

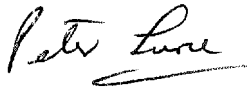
### ***Reference population***

The industry prefers to use Baltimore (rather than Maryland) as the reference population for the standardized mortality ratios. Conveniently, this reduces any effect that could be attributed to hexavalent chromium in these particular calculations. However, using state reference populations is the usual way such studies are done, in part because one can obtain greater statistical precision with the larger state populations. Moreover, many of the workers must have lived outside the city of Baltimore. Finally, even if one accepted

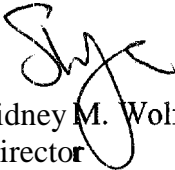
the industry's reference group for the standardized mortality ratio calculations, it remains true that the strong dose-response relationship was present both in bivariate and multivariate analyses.

In sum, there is no such thing as a perfect study, particularly in occupational health. The fact that some industry-funded researchers can identify a few quibbles with the data does not undermine the basic fact that the study was well conducted. It has a design stronger than previous studies of occupational hexavalent chromium exposure and, for that matter, in studies of already regulated occupational carcinogens. The measures of effect are large, internally consistent and in line with that predicted by animal studies. None of these criticisms is enough to justify the inaction that has characterized the agency's response to date.

Yours sincerely,



Peter Lurie, MD, MPH  
Deputy Director



Sidney M. Wolfe, MD  
Director  
Public Citizen's Health Research Group

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<sup>1</sup> Dear JA, Assistant Secretary of Labor for Occupational Safety and Health. Letter to Sidney M. Wolfe, Director, Public Citizen's Health Research Group, March 8, 1994.

<sup>2</sup> US Environmental Protection Agency. Health assessment document for chromium. Environmental Criteria and Assessment Office, Research Triangle Park, NC, 1984 (US EPA-600/8-83-014).

<sup>3</sup> US Department of Health and Human Services. 9th Report on Carcinogens, National Institute for Environmental Health Sciences, Research Triangle Park, NC, 2000.

<sup>4</sup> International Agency for Research on Cancer. IARC monographs on the evaluation of carcinogenic risks to humans, chromium, nickel and welding. 49:49-256. Lyons, France, World Health Organization, 1990.

<sup>5</sup> National Institute for Occupational Safety and Health. Pocket Guide to Chemical Hazards, Appendix C, 1997 (relevant pages available at <http://www.cdc.gov/niosh/ipcs/nengapdx.html#c>).

<sup>6</sup> Agency for Toxic Substances and Disease Registry. Toxicological profile for chromium (Update). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, 2000.

<sup>7</sup> Lurie P, Wolfe SM. Continuing exposure to hexavalent chromium, a known lung carcinogen: An analysis of OSHA compliance inspections, 1990-2000. *American Journal of Industrial Medicine* 2002;42:378-83.

<sup>8</sup> Gibb HJ, Lees PSJ, Pinsky PF, Rooney BC. Lung cancer among workers in chromium chemical production. *American Journal of Industrial Medicine* 2000;38:115-26.

<sup>9</sup> Mancuso TF. Chromium as an industrial carcinogen: part I. *American Journal of Industrial Medicine* 1997;31:129-39.

<sup>10</sup> Mancuso TF, Hueper WC. Occupational cancer and other health hazards in a chromate plant: a medical appraisal. I. Lung cancers in chromate workers. *Industrial Medicine and Surgery* 1951;20:358-63.