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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
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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.¹ 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

Ralph Nader, Founder

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Environmental Protection Agency (EPA) in 1984,² the National Toxicology Program in 1980,³ the International Agency for Research on Cancer in 1990,⁴ the National Institute for Occupational Safety and Health in 1997⁵ and the Agency for Toxic Substances and Disease Registry (ATSDR) in 2000.⁶ 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).⁷ 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.⁸ 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,^{9,10} 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 agency stated that: "The strength of the epidemiological data leads OSHA to conclude that occupational exposures to chromium (VI) must be reduced," in fact, the agency stressed that the PEL "*must be greatly reduced.*" *Id.* (emphasis added). Accordingly, OSHA said that it was considering a new standard 10 to 100 times lower than the existing standard: "OSHA is preliminarily considering a new TWA PEL in the range of 0.5 - 5.0 $\mu\text{g}/\text{m}^3$, measured and reported as chromium (VI)." *Id.* Even at these greatly reduced levels, the agency acknowledged, there would be a significant risk of excess cancer deaths. "OSHA preliminarily estimates that the risk of excess lung cancer deaths over a working lifetime at a new PEL of 0.5 micrograms [as Cr(VI)] per cubic meter of air ranges from 0.9 to 4.4 excess lung cancer deaths per thousand exposed workers." *Id.* The much higher risks associated with the existing PEL, the agency stated, more than justified a new standard:

[T]he epidemiological data on cancer mortality associated with chromium (VI) exposures are sufficient for the Agency to proceed with reduction of chromium (VI) exposures through regulation. The evidence of material impairment from exposure to chromium (VI) is strong and of high quality. *There appears to be no dispute that the current PEL is too high, and the sooner the PELs are reduced, the sooner the risk of death from lung cancer due to occupational chromium (VI) exposure will be reduced.* In addition, the number of cases of asthma, dermatitis, nasal septum perforation, and skin ulceration due to chromium (VI) will also be reduced. The risk estimates for chromium (VI) are similar to risk estimates from exposures to other substances that have been regulated through the Section 6(b) rulemaking process. (*Id.*, emphasis added)

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,

A handwritten signature in cursive script, appearing to read "Peter Lurie".

Peter Lurie, MD, MPH
Deputy Director

A handwritten signature in cursive script, appearing to read "Sidney M. Wolfe".

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Director
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-
- ¹ 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.
- ² 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).
- ³ US Department of Health and Human Services. 9th Report on Carcinogens, National Institute for Environmental Health Sciences, Research Triangle Park, NC, 2000.
- ⁴ 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.
- ⁵ 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>).
- ⁶ 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.
- ⁷ 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.
- ⁸ 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.
- ⁹ Mancuso TF. Chromium as an industrial carcinogen: part I. American Journal of Industrial Medicine 1997;31:129-39.
- ¹⁰ 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.

**UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

No.

**PUBLIC CITIZEN HEALTH RESEARCH GROUP, and
PAPER, ALLIED-INDUSTRIAL, CHEMICAL &
ENERGY WORKERS INTERNATIONAL UNION,**

Petitioners,

v.

**ELAINE CHAO, SECRETARY OF LABOR, and
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,**

Respondents.

**On Petition to Review the Inaction of the United States
Department of Labor**

BRIEF OF PETITIONERS

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February 2002

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 and 3rd Cir. LAR 26.1.1(a), the undersigned hereby certifies that neither Public Citizen Health Research Group (an unincorporated unit of Public Citizen Foundation, Inc., a non-profit corporation) nor the Paper, Allied-Industrial, Chemical & Energy International Union, a labor organization, is a for profit corporation, and neither has parent or subsidiary corporations.



David C. Vladeck

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INTRODUCTION

Since 1994, the Occupational Safety and Health Administration (“OSHA”) has acknowledged that one million American workers are at grave risk of lung cancer and other illness because OSHA’s exposure limit for hexavalent chromium is inadequate. More than eight years have passed since OSHA promised to tighten its standard, yet OSHA has not even taken the first step in promulgating a rule – issuing a notice of proposed rulemaking. Now, for the first time since 1994, OSHA does not even have a target date for issuing a proposed rule on hexavalent chromium, let alone for completing the rulemaking.

In 1993, petitioners Public Citizen Health Research Group and the Paper, Allied-Industrial, Chemical & Energy Workers International Union (“PACE International Union”)¹ petitioned OSHA to replace its current exposure limit for hexavalent chromium of 100 micrograms per cubic meter of air with a new limit of .5 micrograms per cubic meter. OSHA admitted that the existing standard was too high, but did not issue a notice of proposed rulemaking. In 1998, this Court denied a petition to compel OSHA and the Secretary of Labor to take action on hexavalent chromium. The Court based its ruling in large part on the agency’s representations that it intended to issue a proposed rule by September 1999 and that it was

¹ Formerly, the Oil, Chemical & Atomic Workers Union.

awaiting the results of a “breakthrough study” on the health risks of hexavalent chromium. *Oil, Chemical & Atomic Workers Union v. OSHA* (“*Oil Workers*”), 145 F.3d 120, 122 (3d Cir. 1998).

In the four years since the Court’s decision, the agency’s target dates for issuing a proposed rule have come and gone. Meanwhile, the “breakthrough study” was published in August 2000. Although the study confirmed the gross inadequacy of OSHA’s standard, the agency did nothing. OSHA has now postponed further action indefinitely.

Deference to an agency’s priorities and timetables only goes so far. At some point, a court must tell an agency that enough is enough. This Court should grant this petition, order the agency to end its unreasonable delay, and direct it to promulgate a proposed rule and a schedule for finalizing the rule forthwith.

JURISDICTION

The Administrative Procedure Act, 5 U.S.C. § 706(1), creates a right of action by an aggrieved person to compel unlawfully withheld or unreasonably delayed agency action. When the action sought is the promulgation of an occupational exposure standard under 29 U.S.C. § 655, the federal courts of appeals have exclusive jurisdiction under 29 U.S.C. § 655(f), which this Court has interpreted to provide “jurisdiction to conduct judicial review over health and safety standards issued by the Secretary of Labor, as well as over claims in which

the Secretary has not yet acted but where her delay is allegedly unreasonable.” *Oil Workers*, 145 F. 3d at 122.

STATEMENT OF RELATED CASE

This matter was previously before this Court and resulted in this Court’s decision in *Oil Workers*, 145 F.3d at 120. Counsel are unaware of any other case or proceeding that is in any way related, completed, pending, or about to presented before this Court or any other court or agency, state or federal.

STATEMENT OF ISSUE

In light of (a) the substantial health risks hexavalent chromium poses to over one million American workers, (b) OSHA’s repeated commitment to issue a revised hexavalent chromium standard because its current standard is inadequate, and (c) nine years of consideration by the agency without any rulemaking action whatsoever, have respondents engaged in unreasonable delay in violation of the Occupational Safety and Health Act and the Administrative Procedure Act?

STATEMENT OF THE CASE

A. Hexavalent Chromium is Carcinogenic and Toxic at Levels Substantially Lower than the Existing Exposure Limit.

This case involves no hotly contested scientific issues. Rather, there is a longstanding scientific consensus that hexavalent chromium is toxic and carcinogenic at levels far below those OSHA permits. OSHA itself has repeatedly

acknowledged that its standard places workers at significant risk of suffering fatal lung cancer and other acute health effects.²

Hexavalent chromium, "chromium(VI)," is an oxidation state of the metal chromium (Cr), which is most often found in nature in its trivalent state (also referred to as chromium(III)). Lurie Decl., ¶3. Hexavalent chromium compounds are rare in nature but often produced by industry. They are widely used in chrome plating, stainless steel welding, ferrochromium alloy production, and wood preservation. Other uses include the production of chromates, chromate pigments and dyes, rust and corrosion inhibitors, drilling muds, textiles, batteries, candles, rubber, cement, and copier toner.

The dangers of hexavalent chromium have long been recognized. Lurie Decl., ¶4. Acute effects include ulceration, necrosis, and perforation of the nasal septum; asthma; dermatitis; and skin ulceration. More significantly, chronic inhalation of hexavalent chromium causes lung cancer. The World Health Organization's International Agency for Research on Cancer determined in 1990

² The references in this brief are to the Declaration of Peter Lurie, M.D., M.P.H., the Deputy Director of petitioner HRG (hereinafter "Lurie Decl., ¶__"). Dr. Lurie's declaration, in turn, refers to studies, agency statements, risk assessments and other documents in OSHA's docket, that are attached as Exhibits to the Lurie Declaration or are available on line.

that hexavalent chromium is carcinogenic. *Id.*³ The EPA has classified inhaled hexavalent chromium as a human carcinogen since 1984, and it confirmed that classification in a review of the toxicological data in 1998. *Id.*; *see also* EPA, *Toxicological Review of Hexavalent Chromium* (1998).⁴ Since 1980, the Department of Health and Human Service's National Toxicology Program has designated the hexavalent chromium compounds as known human carcinogens. *Id.*⁵ HHS' Agency for Toxic Substances and Disease Registry (ATSDR) designated hexavalent chromium one of its "Top 20 Hazardous Substances." *Id.* ATSDR's *Toxicological Profile for Chromium*, published in September 2000, surveyed the literature and concluded that "[t]he available human and animal data are sufficient for determining that chromium is carcinogenic following inhalation exposure." *Toxicological Profile*, at 246.⁶

Hexavalent chromium is unusual in that the primary evidence of its carcinogenicity comes not from animal studies, but from 50 years of epidemiological studies of workers exposed to hexavalent chromium. In short, the principal evidence is actual human body counts. "Results of occupational

³ See <http://193.51.164.11/monoeval/crthall.html>.

⁴ See <http://www.epa.gov/IRIS/toxreview/0144-tr-pdf>.

⁵ See http://ehis.niehs.nih.gov/roc/ninth/known/chromium_hex_omps.pdf.

⁶ See <http://www.atsdr.cdc.gov/toxprofiles/tp7.pdf>.

epidemiological studies of chromium-exposed workers are consistent across investigators and study populations. Dose-response relationships have been established for chromium exposure and lung cancer.” EPA, *Toxicological Review*, at 31. Lurie Decl., ¶4. Similarly, ATDSR concluded:

Studies of chromate production workers, who are exposed to a variety of chromium compounds both hexavalent and trivalent, and chromate pigment industries, where exposure is mainly to chromium(VI), have consistently demonstrated an association with respiratory system cancer. Studies in chrome platers, who are exposed to chromium(VI) and other agents, including nickel, generally support the conclusion that certain chromium(VI) compounds are carcinogenic.

Toxicological Profile, at 56. Lurie Decl., ¶4.

Soon after the Occupational Safety and Health Act went into effect in 1970, OSHA established a “national consensus standard” for inhalation exposure to hexavalent chromium under 29 U.S.C. § 655(a). Lurie Decl., ¶5. The Act required that the Secretary of Labor, as soon as practicable, promulgate occupational safety and health standards based on existing national consensus standards. Such standards did not reflect OSHA’s independent judgment about the appropriate standard, but put into place some generally agreed upon “lowest common denominator” standard to provide workers some measure of protection pending OSHA’s consideration of the appropriate standard. S. Rep. No. 1282, 91st Cong., 2d Sess. 6 (1970), *reprinted in* 1970 U.S.C.C.A.N. 5177, 5182-83.

The hexavalent chromium standard adopted in 1971 was based on a 1943 standard recommended by the American National Standards Institute (ANSI). Lurie Decl., ¶6 (Exhibit 1). The ANSI standard was based on reports from the 1920s concerning noncancer effects of chromium exposure, and did not take cancer risks into account. *Id.* OSHA's 1971 consensus standard, which remains in force, took the form of a permissible exposure limit ("PEL") for hexavalent chromium in workplace air of 1 milligram per 10 cubic meters (1 mg/10 m³), reported as chromic acid (CrO₃). 29 C.F.R. 1910.1000, Table Z-2.⁷ Translated into the more common measurement of micrograms (thousandths of a milligram, or "µg") per cubic meter, the standard is 100 µg/m³, reported as CrO₃.⁸

The PEL for hexavalent chromium in general industry is a "ceiling" limit: the concentration of hexavalent chromium in workplace air may not exceed that level at any point in a shift, even if the time-weighted average ("TWA") concentration over the eight-hour period is lower. Lurie Decl., ¶5 (Exhibit 1). A

⁷ The table refers to hexavalent chromium as "chromic acid and chromates."

⁸ Because the 100 µg/m³ limit is reported "as CrO₃," the actual permitted amount of hexavalent chromium under the standard is approximately 52 µg/m³, since 52% of the mass of a CrO₃ molecule is chromium. Measurements that report only the mass of hexavalent chromium are said to be reported "as Cr(VI)." The existing PEL is thus 100 µg/m³ reported as CrO₃ or 52 µg/m³ reported as Cr(VI). Because petitioners' proposed PEL, like the existing standard, is reported as CrO₃, references herein to measurements of hexavalent chromium will be expressed as CrO₃ unless otherwise specified.

separate regulation, 29 C.F.R. § 1926.55, Appendix A, establishes the PEL for hexavalent chromium in the construction industry. That limit is also $100 \mu\text{g}/\text{m}^3$ reported as CrO_3 , but it is an eight-hour TWA limit, meaning that even if the concentration exceeds $100 \mu\text{g}/\text{m}^3$ at some point in the day, there is no violation unless the average concentration over an eight-hour period exceeds $100 \mu\text{g}/\text{m}^3$. Thus, the TWA standard for the construction industry is less stringent than the ceiling standard for general industry.

Shortly after OSHA promulgated the consensus standard, the National Institute for Occupational Safety and Health (“NIOSH”), the agency responsible for conducting research and making recommendations to OSHA for the prevention of occupational disease and injury, urged OSHA to adopt a PEL for hexavalent chromium of $1 \mu\text{g}/\text{m}^3$ (as Cr(VI)), or $1.9 \mu\text{g}/\text{m}^3$ reported as CrO_3 – a level 1/52 of the existing standard. Lurie Decl., ¶7. At that time, NIOSH concluded that the evidence for carcinogenicity of a few specified hexavalent chromium compounds was lacking, but that all other forms of hexavalent chromium were carcinogenic. Subsequently, however, NIOSH concluded that all forms of hexavalent chromium should be considered carcinogenic, and it recommended that the $1.9 \mu\text{g}/\text{m}^3$ standard be applied to all hexavalent chromium compounds. *Id.*

In 1995, OSHA commissioned a comprehensive risk assessment for hexavalent chromium. Lurie Decl., ¶11 (Exhibit 5). The risk assessment, known

as the “Crump Report,” concluded that exposure at the current PEL over a 45-year working lifetime could be expected to result in between 88 and 342 excess cancer deaths per thousand workers. Crump Report at 67 (Table 8). That is, up to 34% of workers so exposed would unnecessarily die of lung cancer. Moreover, the Crump Report concluded that significant numbers of excess cancer deaths could be expected even at much lower exposure levels. Exposure at levels as low as 2 $\mu\text{g}/\text{m}^3$, the Report concluded, could be expected to result in between 1.8 and 8.9 excess cancer deaths per thousand workers, while exposures at 1 $\mu\text{g}/\text{m}^3$ would yield .9 to 4.4 excess cancer deaths per thousand workers. *Id.*⁹

The Crump analysis, sponsored by OSHA, provides striking evidence of OSHA’s longstanding awareness that its existing standard does not protect workers against substantial risks of lung cancer. Indeed, OSHA’s November 1996 semiannual regulatory agenda specifically endorsed Crump’s analysis. Lurie Decl., ¶12 (Exhibit 4-F). OSHA explicitly acknowledged: “*There appears to be no dispute that the current PEL is too high*” (emphasis added). *Id.*¹⁰

⁹ The Crump Report cited measurements of exposure to hexavalent chromium as Cr(VI) instead of as CrO_3 . Thus, in Crump’s Table 8, the current PEL is represented by 52 $\mu\text{g}/\text{m}^3$, 2 $\mu\text{g}/\text{m}^3$ (as CrO_3) is equivalent to Crump’s 1 $\mu\text{g}/\text{m}^3$ exposure level, and 1 $\mu\text{g}/\text{m}^3$ correlates to Crump’s .5 $\mu\text{g}/\text{m}^3$ level.

¹⁰ A 1999 study comparing evidence of carcinogenicity of various substances to existing PELs also concluded that hexavalent chromium was the leading candidate for a major PEL reduction. *See* Lurie Decl., ¶19 (Exhibit 13).

The Crump analysis was based on data that, while convincing, did not control for effects of smoking, which could have accounted for some of the excess cancer deaths if the studied populations of chromium-exposed workers smoked more than the general population. The most recent major epidemiological study on hexavalent chromium eliminates this uncertainty by taking into account the smoking history of the subject population. Lurie Decl., ¶19. The study, by a team of Johns Hopkins researchers, was first presented publicly in 1995 but not published until 2000. The Johns Hopkins study showed that, even controlling for the effects of smoking, hexavalent chromium exposures well below the current PEL are associated with major risks of lung cancer. Herman J. Gibb *et al.*, *Lung Cancer Among Workers in Chromium Chemical Production*, 38 Am. J. Industrial Medicine 115 (2000) (Exhibit 14).

The Johns Hopkins study followed a large cohort of workers at a Baltimore chromate production plant. Detailed exposure estimates for the employees were based on roughly 70,000 contemporaneous measurements of airborne hexavalent chromium at the plant, and information on the workers' smoking status came from company medical records. The researchers compiled information on dates and causes of death among the workers from 1950 through 1992. *See id.* at 117.

The Johns Hopkins study concluded that it "present[ed] the best opportunity to date of evaluating the lung cancer exposure-response relationship from exposure

to hexavalent chromium.” *Id.* at 124. In comparison to the best previous studies, the Johns Hopkins study

had a larger cohort, more lung cancer deaths, and had smoking information for most of the cohort. Many of the exposure estimates of the current study are from direct measurements; a portion were from models using contemporary data. More important, however, the ambient measures or estimates of exposure were concurrent with the work history and are of hexavalent chromium directly, not derived from other measures. Furthermore, the cumulative exposure groups in the current study represent lower exposures than those ... [in a prior] study, providing better risk estimates at these lower levels of exposure, an important consideration for quantitative risk assessment.

Id.

The Johns Hopkins study’s conclusion was unequivocal: “The current study confirms the elevated lung cancer risk from hexavalent chromium exposure observed in other studies” *Id.* The researchers found that the existing PEL fell within the highest exposure quartile of their studied population – where exposure was associated with a “significantly elevated” ratio of observed-to-expected lung cancer deaths. Chromium-exposed workers were 2.24 times as likely to die from lung cancer as a nonexposed population. *Id.* at 122, 125. Even exposures at the NIOSH recommended level of $1 \mu\text{g}/\text{m}^3$ (reported as Cr(VI)) fell within the study’s second-highest exposure quartile, which also had a significantly elevated ratio of observed-to-expected cancer deaths of 1.57. *Id.* at 122, 125. The Johns Hopkins study thus strongly confirms that the existing PEL poses a grave cancer risk to workers, and that even much lower levels pose significant risks.

Exposures at and below the existing PEL also cause other adverse health effects. A second study published by the Johns Hopkins researchers found that the median exposure level at which workers experienced symptoms such as nasal septum deterioration and skin ulceration was approximately $20 \mu\text{g}/\text{m}^3$. Herman J. Gibb *et al.*, *Clinical Findings of Irritation Among Chromium Chemical Workers*, 38 Am. J. Industrial Medicine 127 (2000) (Exhibit 15). That $20 \mu\text{g}/\text{m}^3$ was the *median* means that in fully half of the cases these effects occurred at even lower levels. The ATSDR's *Toxicological Profile* reports that "[b]reathing in high levels (*greater than $2 \mu\text{g}/\text{m}^3$*) chromium(VI), such as in a compound known as chromic acid or chromium(VI) trioxide, can cause irritation to the nose, such as runny nose, sneezing, itching, nosebleeds, ulcers, and holes in the nasal septum" (emphasis added). Lurie Decl., ¶4. The "high levels" that cause these adverse effects are a fraction of the existing standard. ATSDR has calculated that the "minimal risk level" for acute health effects resulting from intermediate-term (i.e., approximately one year) exposures to air containing hexavalent chromium particulates is $1 \mu\text{g}/\text{m}^3$, and the minimal risk level for hexavalent chromium mists is $.005 \mu\text{g}/\text{m}^3$ – both far below the existing standard. *Id.*¹¹

¹¹ These minimum risk levels are for noncancer risks. No minimum risk level for cancer can be computed.

B. Many Workers Are Exposed at Levels that Pose Significant Risks

OSHA estimates that 1,000,000 U.S. workers are regularly exposed to hexavalent chromium in the workplace. Lurie Decl., ¶3 (Exhibit 4-P). The predominant exposure route for industrial workers is through inhalation of airborne hexavalent chromium dust particles or mist. “Workers in industries that use chromium are one segment of the population that is especially at high risk of chromium exposure. Occupational exposure from chromate production, stainless steel welding, chromium plating, and ferrochrome and chrome pigment production is especially significant since the exposure from these industries is to chromium(VI).” EPA, *Toxicological Profile*, at 308. Lurie Decl., ¶4.

Exposures in industries using hexavalent chromium compare unfavorably with levels determined to present excess cancer risks and other health effects in epidemiological studies. The National Toxicology Program’s *Ninth Report on Carcinogens*, issued in 2000, reports that “[t]he typical concentration ranges of chromium(VI) in ... industries are: stainless steel welding, 50-400 $\mu\text{g}/\text{m}^3$; chromate production, 100-500 $\mu\text{g}/\text{m}^3$; chrome plating, 5-25 $\mu\text{g}/\text{m}^3$; ferrochrome alloys, 10-140 $\mu\text{g}/\text{m}^3$; and chrome pigment, 60-600 $\mu\text{g}/\text{m}^3$.” Lurie Decl., ¶4. These exposures substantially exceed levels associated with acute effects such as nasal septum deterioration, and fall within ranges found to present substantial excess cancer risks by the Johns Hopkins study and the Crump risk assessment. *Id.*

OSHA exposure data also show that workers remain subject to substantial hexavalent chromium exposures. Petitioners' analysis of OSHA's database of workplace monitoring results for hexavalent chromium reveals that measurements taken from 1990 through 2000 continued to show significantly elevated hexavalent chromium exposures, and that reported median nonzero exposures did not decline over the decade. Lurie Decl., ¶25 (Exhibit 20).

The OSHA database contains both ceiling and TWA measurements from a variety of industrial settings. *Id.* Of those measurements that showed detectable levels of hexavalent chromium,¹² the median concentrations reported were 10 $\mu\text{g}/\text{m}^3$ for TWA measurements and 40.5 $\mu\text{g}/\text{m}^3$ for ceiling readings. *Id.*¹³ Both levels are substantially higher than those at which acute health effects can be expected and are well within the Johns Hopkins study's highest exposure quartile, which was associated with a more than doubled cancer risk. *Id.* Among ceiling measurements in OSHA's database where hexavalent chromium was detected, 38.3% were above the existing 100 $\mu\text{g}/\text{m}^3$ PEL, and 61.1% fell between the petitioners' .5 $\mu\text{g}/\text{m}^3$ proposed standard and the existing limit, while only .6% were

¹² The 53.6% of measurements detecting no hexavalent chromium are excluded from the analysis, because measurements showing no exposure by definition cannot provide a representative picture of the levels of hexavalent chromium being breathed by workers who *are* exposed.

below $.5 \mu\text{g}/\text{m}^3$. Among TWA measurements, 21.3% exceeded $100 \mu\text{g}/\text{m}^3$, 65.5% fell between petitioners' proposed $.5 \mu\text{g}/\text{m}^3$ standard and the existing $100 \mu\text{g}/\text{m}^3$ PEL, and 13.2% fell below petitioners' proposed standard. *Id.* Thus, the great majority of readings showing the presence of hexavalent chromium fell within the zone shown by the Johns Hopkins and Crump analyses to pose substantial dangers to workers.

Monitoring results from the chrome plating and polishing industry (the largest subcategory in OSHA's database) also show significant worker exposure. *Id.* The median nonzero exposures in plating and polishing were $8.2 \mu\text{g}/\text{m}^3$ for TWA measurements and $23 \mu\text{g}/\text{m}^3$ for ceiling measurements – again, levels shown to cause elevated cancer risks and acute health effects. *Id.* Of the nonzero hexavalent chromium measurements in plating and polishing, 7.7% of the TWA measurements were above the existing PEL and 81.5% fell between the existing PEL and the standard sought by petitioners. *Id.* Of nonzero ceiling measurements in the industry, 9.8% exceeded $100 \mu\text{g}/\text{m}^3$, and 90.2% fell between $.5 \mu\text{g}/\text{m}^3$ and $100 \mu\text{g}/\text{m}^3$. Thus, almost 90% of the measured TWA exposures and 100% of the

¹³ Ceiling measurements are higher than TWA measurements, as periods of relatively low exposure tend to cancel out periods of high exposure in a TWA.

ceiling exposures fell within the zone of substantial risk above petitioners' .5 $\mu\text{g}/\text{m}^3$ proposed standard. *Id.*¹⁴

Thus, the inadequacy of OSHA's existing standard is not just a matter of theoretical concern. Many workers continue to be exposed at levels between petitioners' proposed standard and the existing PEL – levels that present significant health risks.

C. OSHA's Delay Regulating Hexavalent Chromium.

Based on then-existing evidence of the inadequacy of OSHA's standard, petitioners in July 1993 petitioned OSHA to impose a .5 $\mu\text{g}/\text{m}^3$ emergency temporary standard for hexavalent chromium under 29 U.S.C. § 655(c) and then issue a notice of proposed rulemaking for a new PEL of .5 $\mu\text{g}/\text{m}^3$ as an eight-hour TWA. Lurie Decl., ¶8 (Exhibit 2).

OSHA took seven months to respond. OSHA's two-page response declined to promulgate an emergency standard, finding that "the extremely stringent judicial and statutory criteria for issuing" an emergency standard were not met." Lurie Decl., ¶9 (Exhibit 3). OSHA acknowledged, however, that its existing standard was inadequate: "OSHA agrees that there is clear evidence that exposure to CrVI

¹⁴ Results in other industries are also indicative of significant exposures. Among ceiling measurements in the aircraft industry, the median nonzero hexavalent chromium exposure was 184 $\mu\text{g}/\text{m}^3$. The median nonzero TWA measurement in that industry was 12 $\mu\text{g}/\text{m}^3$.

at the current PEL of 100 $\mu\text{g}/\text{m}^3$ can result in an excess risk of lung cancer and other CrVI-related illness.” *Id.* Accordingly, OSHA committed to commence a rulemaking:

OSHA ... is beginning a Section 6(b) rulemaking for occupational exposure to CrVI. We are preparing the necessary health and economic impact assessments to support this regulatory action. We anticipate that Notice of Proposed Rulemaking will be published in the Federal Register *not later than March 1995.* (*Id.*, emphasis added)

Almost immediately, OSHA fell behind schedule. Only a month after OSHA’s response to the rulemaking petition, OSHA’s April 1994 semi-annual regulatory agenda reported that the date for the issuance of a proposed rule had already slipped to May 1995. Lurie Decl., ¶10. By May 1995, the timetable slipped again, to December 1995. *Id.*

Thus began a pattern OSHA followed for the next six years: The agency would publish a timetable, continue to say it would meet that schedule until it was clearly impossible, and then publish a new schedule pushing back the date for a proposed rule by months or years, beginning the cycle anew. *Id.*¹⁵ Thus, the November 1995 agenda reset the date for a proposed rule to July 1996; the May 1996 agenda moved the anticipated notice date to June 1997; and the November 1996 agenda moved it again, to September 1997. *Id.*

¹⁵ Copies of the agency agendas during the relevant time period are attached as Exhibits 4-A through 4-P.

Meanwhile, the agency continued to acknowledge the deficiencies of its existing rule and the significant number of workers whose health is at risk.

OSHA's November 1996 regulatory agenda contained an extensive discussion of the agency's position on the hexavalent chromium standard. Lurie Decl., ¶12 (Exhibit 4-F). In it, the agency forthrightly stated: "OSHA acknowledges that the risks of serious adverse health affects at the current PEL are significant." The agency's estimate of the number of workers affected underscored the gravity of the risk: "OSHA estimates that more than 1 million workers are exposed to hexavalent chromium on a regular basis in all industries." *Id.* The existing PEL, the agency recognized, exposed these workers to serious hazards:

Exposure to chromium (VI) is known to cause lung cancer, bronchial asthma, nasal septum perforations, skin ulcers, and irritative dermatitis. Chromium (VI) causes ulcers of the skin and acute irritative dermatitis among workers exposed to chromium alloys and chromium-plated objects. Inhalation of chromium (VI) aerosols at levels of about 100 µg/m³ may give rise to necrosis in the nasal septum, leading to perforation. Bronchial asthma may occur as a result of inhalation of low levels of chromium (VI) dust or fumes.

* * *

OSHA has performed a preliminary quantitative risk assessment using all epidemiological studies for which dose-response information was available. OSHA preliminarily estimates that the risk of excess lung cancer deaths over a working lifetime at the current PEL ranges from 88 to 342 excess lung cancer deaths per thousand exposed workers. (*Id.*)

Despite its recognition of the need for action, OSHA failed to issue a proposed rule in 1997, as the November 1996 agenda projected. The agency had been subjected to pressure by industry groups insistent that it defer rulemaking until the Johns Hopkins study became available, since, in industry's view, the study was "expected to be the most accurate and complete database on chromium exposure and mortality available." Lurie Decl., ¶¶14-15 (Exhibits 6 to 9).

Although OSHA did not formally defer its notice of proposed rulemaking until the study became available, it stated its intention "to include the results of the Johns Hopkins study in the NPRM" (Lurie Decl., Exhibit 10) – which would be impossible if OSHA acted before the Johns Hopkins study was released. *Id.*

OSHA's failure to act led petitioners, on March 3, 1997, to request that it commit to a timetable for the hexavalent chromium rulemaking. Lurie Decl., ¶17 (Exhibit 11). Instead, OSHA took another step backward: Its April 1997 agenda announced that the expected issuance of a proposed standard would be delayed by another full year, to September 1998. Lurie Decl., ¶10. Then, in a letter dated August 4, 1997, OSHA denied petitioners' request that it commit to a timetable for issuance of a new PEL. *Id.* (Exhibit 12). OSHA's letter attributed the agency's lack of progress to limited agency resources and competing high priority projects

that were nearing completion.¹⁶ The letter stated, however, that “[a]s we complete these other high-priority projects, we are committed to refocusing Agency resources onto chromium (VI) and other high-priority projects.” *Id.* The Agency further stated that while it had “no intention of unduly delaying the rulemaking process” pending completion of the Johns Hopkins study, it expected the study to be available in time to be considered in the rulemaking process. The letter concluded:

Consequently, OSHA intends to move ahead as quickly as we can on the chromium (VI) rulemaking. We regret that OSHA is not further along in the process, but assure you that the Agency is fully committed to completing this rulemaking as expeditiously as the Agency’s resources permit. (*Id.*)

On October 13, 1997, petitioners filed in this Court a petition to compel OSHA to issue a proposed rule on hexavalent chromium and finalize it as quickly as possible. Two weeks later, in its October 1997 regulatory agenda, OSHA belied its commitment “to move ahead as quickly as we can” by pushing back the expected date for a proposed rule by another year, to September 1999. Exhibit 4-H. In its response to the petition for review, OSHA highlighted its intention to act

¹⁶ The higher priority tasks referred to were finalizing the respirator standard (completed in 1998), issuing a proposed rule on tuberculosis exposure (notice of proposed rulemaking issued in 1997; finalizing rule no longer a priority), finalization of exposure standards for 1,3-butadiene and methylene chloride (completed in 1996 and 1997, respectively), and the development of a Safety and Health Program Standard (since shelved). Lurie Decl., ¶17 (Exhibit 12).

by September 1999, but it elliptically added: “[T]hat date reflects circumstances as OSHA knows them to date and it is a virtual certainty that unanticipated intervening events will affect OSHA’s workload in the interval between now and then.” Lurie Decl., ¶18; Sec. Labor’s Answer, No. 97-3522, at 10. OSHA also said hexavalent chromium would take a backseat to the assertedly more important “Safety and Health Program standard” (an initiative since abandoned), and that the hexavalent chromium rulemaking would be slowed by the need to consider feasibility, by compliance with the Small Business Regulatory Enforcement Fairness Act (“SBREFA”), 5 U.S.C. § 609, and by budget constraints. *Id.*

On March 13, 1998, this Court denied the petition. *Oil Workers*, 145 F.3d at 120. The Court held that the facts did not yet “demonstrate inaction that is ... unduly transgressive of the agency’s own tentative deadlines.” *Id.* at 124. The court accepted OSHA’s explanations for the delays and its representation that it anticipated a rulemaking proposal in September 1999:

Because of many unanticipated factors – the release of a breakthrough study on workers exposed to chromium which necessitated detailed examination, ‘the results of the November 1994 elections’ in Congress, government shutdowns, budget cuts, the need to study potential compliance with a new PEL, the need to consult with small businesses and the reprioritizing of other agency projects – OSHA has not issued a notice of proposed rulemaking on hexavalent chromium. It now anticipates a September 1999 date as its tentative deadline for a rulemaking proposal.

Id. at 122. In light of those factors, as well as the agency's scientific expertise and its claim that it was working diligently, the court declined to intervene. *Id.* at 124.

Following this Court's ruling, OSHA maintained the pretense that it would issue a proposed rule in September 1999 in each of its regulatory agendas through April 1999. Lurie Decl., ¶10. After September 1999 came and went, the agency announced in its November 1999 agenda that the new target date was June 2001. *Id.*

Meanwhile, the long-awaited Johns Hopkins study was finally published in August 2000. (The results of the study, albeit not the data, had been available to OSHA since 1995.) Lurie Decl., ¶16. As explained in more detail above, the Johns Hopkins study confirmed that the existing PEL does not adequately protect worker health, and that the PEL sought by petitioners errs, if at all, on the side of permissiveness.

Petitioner Public Citizen obtained the Johns Hopkins study before it was published. On July 11, 2000, Public Citizen wrote to OSHA head Charles Jeffress, summarizing the study's results. Lurie Decl., ¶23 (Exhibit 16). The letter stated:

The study demonstrates that lung cancer death rates [in the studied population] were almost double what would otherwise have been expected for this group and may even be elevated at air chromium levels below those we have recommended as a new standard With these data finally in hand, there can be no further justification for failing to immediately promulgate regulations to reduce worker exposures to this hazardous chemical. (*Id.*)

OSHA never answered Public Citizen's letter.

Instead of spurring OSHA into action, the Johns Hopkins study provoked only more delay. By the time OSHA's November 2000 agenda was published, the agency had pushed the date for a proposed rule back to September 2001. Lurie Decl., ¶10. The May 2001 agenda announced a further delay of only two months. *Id.* That might have suggested that the agency was getting close to issuing a notice, if not for the fact that the agency's Director of Safety Standards, Marthe Kent, had stated publicly only a few weeks earlier that the hexavalent chromium regulation was "on hold."¹⁷ Not surprisingly, no proposed rule appeared in November 2001 – the tenth time that OSHA had missed its target date.

OSHA's latest agenda, issued on December 3, 2001, reflects yet another retreat from the agency's commitment to issuing a new hexavalent chromium PEL. Lurie Decl., ¶10 (Exhibit 4-P). A hexavalent chromium rulemaking is still on the agenda, and OSHA still acknowledges that the substance causes cancer and affects a million U.S. workers. But for the first time since 1994, the agency no longer even pretends to have a target date for a proposed rule. Instead, the rulemaking is

¹⁷ Transcript of Meeting of OSHA Advisory Committee on Construction Safety and Health, March 15, 2001 (http://www.osha-slc.gov/doc/acssh/transcripts/acssh_031501.html).

now denominated a “long-term action,” and the “timetable” for action states that the date for a proposed rule is “to be determined.” *Id.*

At the same time, none of the items OSHA formerly said had “priority” over the hexavalent chromium rulemaking is listed as a “priority” in the agency’s current regulatory plan. Lurie Decl., ¶24 (Exhibits 17 & 18). Rather, the actions that OSHA told petitioners had priority over hexavalent chromium in 1997 have either been completed or excised from the agency’s list of priorities. Of seven matters that were considered OSHA “priorities” in its November 2000 regulatory plan (Exhibit 17), only two have been completed (issuance of a “steel erection” standard and a final rule on recording and reporting occupational illnesses and injuries). Of the remaining five, two (the ergonomics rule and the “Safety and Health Program standard,” much ballyhooed in OSHA’s *Oil Workers* brief) not only are no longer priorities, but have disappeared from the agency’s agenda.¹⁸ A third, the tuberculosis standard, for which a proposed rule was issued over four years ago, remains on the agenda but it is no longer a priority and has no timetable

¹⁸ A much watered-down version of the “Health and Safety Program standard,” renamed “Illness and Injury Prevention,” is listed as a “long-term action,” and the agenda states that OSHA “is considering a number of regulatory and non-regulatory alternatives” to such a rule. Ironically, the agenda lists a Safety and Health Programs standard for the construction industry as a “completed action” – even though the agency is no longer considering such a standard. Lurie Decl., ¶24; Exhibit 19.

for final action. *Id.* The remaining two (crystalline silica exposure and employer payment for personal protective equipment) are off the priority list and demoted to "long-term actions." *Id.*; *see also* Exhibits 17 & 18.

Meanwhile, OSHA has elevated five formerly lower-priority matters to "priority" status. *Id.* (Exhibit 18). The items OSHA now calls "priorities" are: (1) "improving" language in existing standards; (2) "clarifying" the respirator rule; (3) negotiating a rule to update shipyard fire prevention standards; (4) revising a rule on highway signs to conform with Department of Transportation rules; and (5) adopting clearer language in an existing rule on emergency exits. (Exhibit 17). None of these "priorities" involves risks to workers of the magnitude posed by hexavalent chromium. None relates to the promulgation of exposure standards, and thus none would require the attention of the agency toxicologists and epidemiologists qualified to prepare a hexavalent chromium standard.

SUMMARY OF ARGUMENT

The Occupational Safety and Health Act requires the Secretary of Labor to promulgate standards to eliminate, to the maximum extent feasible, significant threats to the health of workers. 29 U.S.C. § 655(b). The evidence unequivocally establishes that hexavalent chromium poses a significant risk at the current PEL. The Act therefore requires the Secretary to set a new, drastically lower standard.

OSHA has unreasonably delayed fulfilling this statutory mandate. This Court held in *Oil Workers* that the APA's command that agency action not be "unreasonably delayed," 5 U.S.C. § 706, applies with full force to OSHA rulemakings. 145 F.3d at 123. Nearly nine years have elapsed since petitioners first sought revision of the hexavalent chromium standard. Eight years have passed since OSHA acknowledged the inadequacy of the existing standard. OSHA's failure to act in that time constitutes unreasonable delay. Indeed, no case we could find countenanced a delay this protracted, especially where, as here, the lives of a million American workers hang in the balance.

This Court held four years ago that OSHA's delay did not yet warrant judicial intervention. OSHA's inaction can no longer be defended. Since this Court ruled, OSHA has not only missed by more than two years what it told the Court was its target date for action; it has now disavowed any target date and postponed action indefinitely. Meanwhile, the excuses offered by the agency have, one by one, disappeared: The Johns Hopkins study that industry pressed the agency to consider was published 18 months ago, underscoring the urgent need for a more stringent standard. The projects the agency claimed had a higher priority have been completed or abandoned. And the agency's new "priorities" are comparatively trivial and pose no obstacle to acting on hexavalent chromium.

Whatever the situation four years ago, the agency's continued inaction can no longer be tolerated. If judicial review of unreasonably delayed agency action is to mean anything, there must be a remedy here.

STANDARD OF REVIEW

The question in this case – whether respondents have acted to fulfill their statutory duty under the Occupational Safety and Health Act to ensure that workers do not suffer a material impairment of health without unreasonable delay – has two components that are subject to different standards of review. The first component, whether respondents have a duty to act, is a legal question on which review is *de novo*. *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 641 (1980). The second component, whether respondents have acted with reasonable dispatch, is a question on which the Court gives deference to the agency. *Oil Workers*, 145 F.3d at 124.

ARGUMENT

I.

THE OCCUPATIONAL SAFETY AND HEALTH ACT REQUIRES THE ELIMINATION OF SIGNIFICANT WORKPLACE HEALTH RISKS.

Section 6(b) of the Occupational Safety and Health Act requires the Secretary of Labor, “in promulgating standards for toxic materials or harmful physical agents,” to “set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer

material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.” 29 U.S.C. § 655(b). The requirement that OSHA exposure standards ensure that no employee suffer material impairment “requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment.”

Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 639 (1980). When the Secretary finds that existing conditions or standards pose a significant risk, however, she must act: “[B]oth the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm.” *Id.* at 641.

Although a “significant risk” determination is the predicate for action, the standard for showing such a risk is not overly demanding. The agency is not “required to wait for deaths to occur,” as it has done here, *id.* at 655, but may act based on predictions. Where exposure to a substance presents a one in one thousand risk of death, for instance, “a reasonable person might well consider the risk significant.” *Id.* The Act does not require OSHA to calculate the exact probability of harm or “to support its finding that a significant risk exists with anything approaching scientific certainty.” *Id.* at 656. Forced to operate on the frontiers of scientific knowledge, the Secretary must rely on the best available

evidence and make decisions supported by “a body of reputable scientific thought.” *Id.*; see also 29 U.S.C. § 655(b)(5) (requiring use of “best available evidence”); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1266 (D.C. Cir. 1980).

These standards require replacement of the hexavalent chromium PEL. OSHA has long acknowledged that the existing limit – a thirty-year-old national consensus standard that was based on a standard promulgated thirty years before that, without regard to cancer risks – provides little meaningful protection to workers exposed to a known human carcinogen. By OSHA’s own calculations, based on the best epidemiological studies available in 1996, exposure at the permitted level over a working lifetime would yield 88 to 342 excess lung cancer deaths per thousand workers – dwarfing the one in one thousand risk that, according to Supreme Court in *American Petroleum Institute*, 448 U.S. at 655, a reasonable person would consider significant.¹⁹ Thus, as OSHA acknowledged in 1996, the risks presented by hexavalent chromium “are similar to risk estimates from exposures to other substances that have been regulated through the Section

¹⁹ See also *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1502 (D.C. Cir. 1986) (holding that 63.4 to 109.3 excess deaths per thousand workers exposed to ethylene oxide for a working lifetime at the existing exposure standard of 50 ppm constituted a “significant risk,” as did the 1.2 to 2.3 excess deaths per thousand workers that would be expected to result from exposure at the proposed standard of 1 ppm).

6(b) rulemaking process” – a conclusion confirmed by the Johns Hopkins study.

The evidence so far exceeds the quantum necessary under the Act to justify a new standard that OSHA’s intransigence is inexplicable. OSHA is not supposed to wait for deaths to occur before acting to protect worker health. *American Petroleum Institute*, 448 U.S. at 655. Congress intended that OSHA *avert* worker deaths, not just count them. For that reason, the agency may regulate and typically has regulated hazardous substances based largely on extrapolations of human risks from health effects observed in animal studies. *See, e.g., Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986). By contrast, the principal evidence of hexavalent chromium’s carcinogenicity is a half-century’s worth of epidemiological studies demonstrating that many excess cancer deaths have occurred and are occurring among exposed workers.

Moreover, as detailed above, a great many workers are still exposed to hexavalent chromium at levels that place them at considerable risk. OSHA estimates that one million workers are regularly exposed to hexavalent chromium. And OSHA’s database of workplace measurements of hexavalent chromium over the last decade shows that the great majority of measurements exceeded petitioners’ proposed standard and fell in the zone that, as the Johns Hopkins study demonstrates, presents significant cancer risks.

At the same time, the exposure data indicate the feasibility of petitioners' proposed standard. Over 13% of the measured nonzero TWA exposures were below $.5 \mu\text{g}/\text{m}^3$, showing that reduction of industrial exposures to that level is technologically feasible. Lurie Decl., ¶25 (Exhibit 20). The exposure data for the plating and polishing industry further support the feasibility of the proposed standard. There, although the majority of TWA measurements in OSHA's database exceeded the proposed standard, 10% were below $.5 \mu\text{g}/\text{m}^3$, and the median figure of $8.2 \mu\text{g}/\text{m}^3$ indicates that a significant number of other measurements were within striking distance of the proposed standard. *Id.*

Thus, as OSHA has repeatedly acknowledged, the existing standard is legally inadequate because it presents a significant risk to workers and is not the lowest feasible standard. OSHA must therefore promulgate a new standard that assures, to the fullest extent feasible, that no worker will suffer a material impairment even if exposed for a working lifetime at the maximum level permitted. The current PEL does not even come close to this standard. As OSHA recognized over five years ago, a reduction in the standard by a factor of as much as 200 is necessary to satisfy the statutory criterion of maximum feasible worker protection.

II. OSHA HAS UNREASONABLY DELAYED PROMULGATION OF A NEW HEXAVALENT CHROMIUM STANDARD.

A court in reviewing an unreasonable delay claim is “called upon to balance the importance of the subject matter being regulated with the regulating agency’s need to discharge all of its statutory responsibilities under a reasonable timetable.”

Oil Workers, 145 F.3d at 123. The court must consider a number of factors:

First, the court should ascertain the length of time that has elapsed since the agency came under a duty to act. Second, the reasonableness of the delay should be judged in the context of the statute authorizing the agency’s action. Third, the court should assess the consequences of the agency’s delay. Fourth, the court should consider “any plea of administrative error, administrative inconvenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources.”

Id. (quoting *The Raymond Proffitt Foundation v. EPA*, 930 F. Supp. 1088, 1102 (E.D. Pa. 1996) (quoting *In re International Chemical Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992))).

Here, even assessed with deference to agency priorities and timetables (*see id.*), these factors now point unequivocally toward a finding of unreasonable delay. Since the *Oil Workers* decision, the delay has gone from lengthy to extreme. Such delay, in the context of a statute intended to eliminate significant health risks, is particularly unacceptable because the inevitable consequence will be more deaths and illnesses that could be prevented by agency action. And practical difficulties, agency priorities, and like considerations can no longer justify inaction.

A. The Agency's Delay is Extreme.

Eight-and-one-half years have now passed since petitioners asked OSHA to lower the hexavalent chromium standard, and nearly eight years have gone by since OSHA acknowledged that the existing standard is inadequate and committed to commence a rulemaking. OSHA's initial target date for a proposed rule – March 1995 – is now nearly six years in the past, and OSHA has missed all ten targets it has set for itself, including the September 1999 date that it proffered to this Court. Now, OSHA has abandoned the fiction of target dates altogether, and has designated the hexavalent chromium rulemaking a “long term action” with a timetable “to be determined.” After nearly nine years, the first formal step in a new rulemaking whose necessity the agency has repeatedly acknowledged remains on indefinite “hold.”

This delay is much more aggravated than delays courts have condemned in other cases, and no case we have found countenanced a delay as protracted as the one here. In *In re International Chemical Workers Union*, 958 F.2d 1144 (D.C. Cir. 1992), the D.C. Circuit found that OSHA had unreasonably delayed promulgating a new standard for cadmium (another carcinogenic metal) and ordered OSHA to issue a final rule within five months. In that case, a petition seeking action by OSHA had first been filed in 1986. As here, OSHA had denied a request for an emergency temporary standard but acknowledged the need for a new

rule. Also, as in this case, the court had denied a petition to compel OSHA to act in 1987, based in part on OSHA's prediction that it would issue a proposed rule by December 1987, with a final rule likely 18 months later. OSHA promptly fell two years behind that schedule, and only after a new court challenge was filed did it issue a proposed rule in February 1990. Two years later, when OSHA's estimated date for a final rule had slipped to August 1992, the court had had enough. The court observed:

[E]ven if finally completed by August 31, 1992, the cadmium rulemaking will have taken over six years. This is an extraordinarily long time, in light of the admittedly serious health risks associated with the current permissible levels of cadmium exposure under the 20-year-old standards still in place. Whether the delays at every stage are the result of the agency's 'persistent excess of optimism,' ... or attributable to bureaucratic inefficiencies, ... there must be an end to the process sometime soon. Under the circumstances, we do not see how any further delay ... – resulting in continued exposure of workers to dangerous levels of cadmium – could be excusable.

Id. at 1150 (citations omitted).

The parallels to this case are striking: the agency's acknowledgment of the serious inadequacy of its existing standard; its pledge to undertake rulemaking; its persistent inability to meet its own timetables; and its failure to come close to the target it proposed to the court to avoid a writ of mandamus. The principal difference is that the delay in this case is much more extreme – the length of the delay here is *already* two-and-a-half years longer than the six-year delay from start

to completion that the *Chemical Workers* court called “extraordinarily long,” and here there is no end in sight.

Similarly, in *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), the court imposed a deadline for a proposed rule on facts much less aggravated than those here. In *Auchter*, the agency had been petitioned in 1981 for a new exposure standard for ethylene oxide (“EtO”), a carcinogenic substance to which an estimated 75,000 hospital workers were exposed. The existing consensus standard permitted exposures roughly 50 times higher than the standard the petitioners requested. As here, the agency refused to issue an ETS, but acknowledged the insufficiency of the existing standard and committed to commence a rulemaking. The agency issued an “advance notice of proposed rulemaking” in 1982, but it still had not issued the proposed rule as of 1983, and it estimated that a final rule would not be issued until the fall of 1984.²⁰

The court observed that by issuing only an “advance notice of proposed rulemaking,” OSHA had “embarked on the least responsive course short of

²⁰ An “advance notice of proposed rulemaking” is not a formal rulemaking step – it simply advises interested parties that the agency is considering taking some regulatory action. Thus, issuance of an “advance notice of proposed rulemaking” in *Auchter* was comparable to the agency’s 1994 announcement in this case that it intended to commence a hexavalent chromium rulemaking.

inaction.” *Id.* at 1153. The court found unacceptable the anticipated delay of over three years from the beginning of the rulemaking process to its completion:

There is an obvious need, apparent to OSHA, for an EtO standard that reflects, as the current standard does not, the mutagenic and carcinogenic potential of the chemical. Because it is also plain that industry efforts fall a considerable distance from taking every worker exposed to EtO out of the grave danger zone, a more than three-year span from Public Citizen’s petition to projected final regulation is not tolerable. OSHA’s failure to date to issue even a notice of proposed rulemaking – some eighteen months after announcing its intention to commence rulemaking – is in our judgment, and in light of the risk to current and future lives, agency action unreasonably delayed.

* * *

Three years from announced intent to regulate to final rule is simply too long given the significant risk of grave danger EtO poses to the lives of current workers and the lives and well-being of their offspring. Delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake. ... This is particularly true when the very purpose of the governing Act is to protect those lives.

Id. at 1154.

Again, the facts in this case are similar, but the delay here is many times longer, the risk of excess cancers at the existing standard substantially greater, and the number of workers exposed much larger. Measured from the agency’s “announced intent to regulate,” the delay in issuing a notice of proposed rulemaking in this case is already nearly six times as long as the 18-month delay that the court found intolerable in *Auchter*, with no end in sight.

OSHA's delay in promulgating an EtO standard came before the D.C. Circuit again in *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987). By then, OSHA had promulgated a long-term exposure limit but declined to issue a short-term exposure limit ("STEL"), a decision the D.C. Circuit held unlawful in *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986). Nearly a year after *Tyson*, however, OSHA had still not issued a proposed STEL, and did not expect to finish the rulemaking before March 1988. The D.C. Circuit again found the agency's delay excessive: The court said it "[could] not help but note" that regulations "first proposed in 1982, are not final in 1987" and would not become final until 1988 "even assuming that the rulemaking process suddenly changes what has been its essential character and proceeds according to schedule. With lives hanging in the balance, six years is a very long time." 823 F.2d at 628. Although the court "disappointed[ly]" accepted the agency's 1988 timetable for a final rule, it found that "any delay whatever beyond the proposed schedule is unreasonable." *Id.* at 629. Again, the six year delay in *finalizing* the EtO rule, which the court found had reached the very limit of reasonableness, was significantly shorter than OSHA's ongoing delay in *proposing* a hexavalent chromium standard.

In many other matters, courts have held that delays much shorter than that involved here are unreasonable where public health is at stake. In *Oil, Chemical &*

Atomic Workers International Union v. Zegeer, 768 F.2d 1480, 1487 (D.C. Cir. 1985), the court, addressing a delay of over five years in issuing a proposed rule for exposure to radioactive gases, stated that “reasonable time may encompass ‘months, occasionally a year or two, but not several years or a decade.’” (Citation omitted).²¹ In *Public Citizen Health Research Group v. Commissioner, FDA*, 740 F.2d 21 (D.C. Cir. 1984), the court considered the FDA’s four-year delay in issuing a proposed rule requiring Reye’s Syndrome warnings on aspirin labels. Given that (as here) “[a]ll scientific evidence in the record points to” the need for a new rule and that (as here) “the agency itself credited this evidence,” the court found that “[t]he record strongly suggests that the [four-year] pace of agency decisionmaking is unreasonably dilatory.” *Id.* at 34. The four-year period that so troubled the court in *Public Citizen v. Commissioner* began when the CDC developed evidence of a link between aspirin and Reye’s Syndrome in 1980. The comparable period of delay in this case would go back to 1975, when NIOSH informed OSHA of the gross inadequacy of the existing standard.

This Court found a comparable period of delay excessive in *United Steelworkers of America v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1987). There, OSHA had issued an “advance notice of proposed rulemaking” for hazard warning

²¹ In *Zegeer*, the court measured the delay from the filing of a petition seeking a new rule.

standards in 1977, and, after withdrawing one proposed rule, issued a second one and finally promulgated a final rule limited to the manufacturing sector in 1983. In 1985, this court held that the agency must reconsider the decision not to cover nonmanufacturing employees and either include them in the rule or explain why they were excluded. By 1987, the agency still had not issued a notice of proposed rulemaking and did not propose doing so until 1988. This court held that the delay of ten years since the agency first undertook a rulemaking proceeding, and two years since the remand, was unreasonable, and ordered the agency to publish a proposed rule within 60 days.

Even outside the area of public health, the courts have considered delays of the magnitude of the ongoing delay here excessive. In *In re Monroe Communications Corp.*, 840 F.2d 942 (D.C. Cir. 1988), and *Air Line Pilots Association v. CAB*, 750 F.2d 81 (D.C. Cir. 1984), the courts held that five-year delays in, respectively, proceedings involving a broadcast relicensing and claims for unemployment benefits were unreasonable. In *TRAC v. FCC*, 750 F.2d 70 (D.C. Cir. 1984), the court held that delays of five and two years in deciding issues relating to rates of return in the telecommunications industry were sufficiently aggravated to require that the court retain jurisdiction, though the court did not issue a writ of mandamus because the agency promised expeditious action.

In *Potomac Electric Power Co. v. ICC*, 702 F.2d 1026 (D.C. Cir. 1983), the court condemned a nine-year delay in the issuance of a final decision in a ratemaking proceeding, finding that “[h]owever justified a single delay in the course of these proceedings may have been, the limit has been reached.” *Id.* at 1035. A similar delay was held unreasonable in *MCI Telecommunications Corp. v. FCC*, 627 F.2d 322 (D.C. Cir. 1980). And in *Nader v. FCC*, 520 F.2d 182 (D.C. Cir. 1975), the court stepped in to remedy a nine-year delay in another ratemaking proceeding. The court stated:

[N]ine years should be enough time for any agency to decide almost any issue. There comes a point when relegating issues to proceedings that go on without conclusion in any kind of reasonable time frame is tantamount to refusing to address the issues at all – and the result is a denial of justice.

Id. at 206 (emphasis added).

Four years ago, this Court found that OSHA’s delay on hexavalent chromium was not yet egregious. Since then, the agency’s delay has exceeded all reasonable bounds. Indeed, in *no reported decision* has a court tolerated a nine-year delay in promulgating a final standard to address an acknowledged, significant health issue, let alone accepted a nine-year delay before the issuance of a proposed rule. The delay here is unquestionably extreme, whether measured from NIOSH’s 1975 recommendation that the standard be reduced 50-fold, from

petitioners' 1993 petition, or from the agency's 1994 promise to commence a rulemaking.

B. The Interests Protected by the Statute and the Consequences of Delay Strongly Support Judicial Intervention.

This Court's *Oil Workers* decision stressed that the reasonableness of delay "should be judged in the context of the statute authorizing the agency's action" and that "the court should assess the consequences of the agency's delay." 145 F.3d at 123 (citations omitted). As the Court recognized "[d]elays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake." *Id.* at 123 (quoting *Cutler v. Hayes*, 818 F.2d 879, 889 (D.C. Cir. 1987)). Where the "very purpose of the governing Act is to protect [workers'] lives," *Auchter*, 702 F.2d at 1157, Congress cannot be deemed to countenance delays that compromise that goal. The Occupational Safety and Health Act's requirement that no worker suffer a material health impairment even if exposed at the maximum permitted level for his entire working life (29 U.S.C. § 655(b)(5)), reflects intolerance of any significant threat to worker health, and the Act's provisions reflect a policy of expediting rulemaking accordingly. *See* 29 U.S.C. §§ 655(b)(1)-(5).

The inevitable consequence of further delay in promulgating a new PEL for hexavalent chromium will be the continued exposure of workers to levels that pose significant, unacceptable risks to their health. Even before the publication of the

Johns Hopkins study, OSHA acknowledged that exposure to hexavalent chromium at the permissible level over an average 45-year working lifetime would lead to between 88 and 342 excess cancer deaths per thousand workers. This does not mean, of course, that there will be 88 to 342 deaths for every thousand workers exposed to hexavalent chromium, because not all exposures will be at the maximum permitted amount and over a 45-year period. But even far lower exposures present significant cancer risks. OSHA's risk assessment demonstrates that exposures as low as the NIOSH-recommended $1 \mu\text{g}/\text{m}^3$ (as Cr(VI)) – levels well below those that are common in the workplace – can be expected to result in approximately two to nine excess cancer deaths per thousand workers (or two to nine thousand deaths among the million exposed workers, assuming lifetime exposures). The results of the Johns Hopkins study are consistent with this analysis. Other health impairments occur at exposure levels between the existing PEL and petitioners' proposed standard, and petitioners' analysis demonstrates that there are many workers so exposed. As OSHA recognized in 1996, when the exposure standard is lowered, "the number of cases of asthma, dermatitis, nasal septum perforation, and skin ulceration due to chromium (VI) will also be reduced." Further delay will exact a harsh toll on the health of American workers.

C. Practical Considerations and Agency Priorities Cannot Justify Further Delay.

1. The Publication of the Johns Hopkins Study Eliminates Any Excuse for Further Delay.

During the first years of OSHA's consideration of a new hexavalent chromium rule, industry groups urged the agency to wait for the publication of the Johns Hopkins study, which they expected to be superior to existing studies. OSHA apparently acquiesced in this approach. In *Oil Workers*, this Court also highlighted this "breakthrough study" as a key reason for the agency's inaction. 145 F.3d at 122.

The need to wait for publication of the Johns Hopkins study was never apparent. The results were available in 1995, and the agency acknowledged that other available data sufficiently supported the conclusion that a standard many times lower than the existing PEL was required to reduce the significant health risks workers now face. As the D.C. Circuit has put it, under the Occupational Safety and Health Act, OSHA is to make its decision on the basis of the best evidence available, not to wait for "the Godot of scientific certainty." *United Steelworkers v. Marshall*, 647 F.2d at 1266.

Here, however, OSHA waited for what was heralded even by industry opponents of regulation as "the most accurate and complete database on chromium exposure and mortality available." (Exhibit 6). But when the Johns Hopkins study

turned out to provide strong confirmation that the existing standard is inadequate, OSHA was not moved to act. Instead, armed with the best available evidence that a new standard is needed, the agency has opted for indefinite and unexplained further delay. In short, the agency here waited for Godot. But Godot has come and gone, and the agency is still waiting.

2. The Agency's "Priorities" Do Not Justify Further Delay.

In 1997, OSHA told petitioners that it had "higher priority" rulemakings, at the conclusion of which it would turn to hexavalent chromium and other "high priority" matters. (Exhibit 11). These "higher priority" matters included the respirator rulemaking, the tuberculosis standard, the final standards for 1,3-butadiene and methylene chloride, and the Safety and Health Program standard. In its *Oil Workers* brief, the agency highlighted the Safety and Health Program standard as a higher priority because it promised to benefit workers in many industries. But as detailed above, none of these "higher priority" matters remains an agency priority: they have either been completed or dropped.²² The "priorities" that formerly crowded out hexavalent chromium no longer exist.

²² Of the 1997 priorities, only the tuberculosis rulemaking is still active, albeit apparently moribund. Lurie Decl., ¶23 (Exhibits 17 & 18). Given the different stages of the rulemakings and the different expertise of the agency personnel involved, the hexavalent chromium rulemaking would not be likely to delay completion of the tuberculosis rule even if the agency remained committed to finishing it expeditiously.

The agency's current "priorities" are patently insufficient to justify further delay in the hexavalent chromium rulemaking. OSHA's latest regulatory plan lists only five "high-priority items. Lurie Decl., ¶20 (Exhibit 18). None of these "priority" matters involves issues comparable in magnitude to those implicated by the long-delayed hexavalent chromium standard, and none is likely to be impeded by an order requiring the agency to act on hexavalent chromium. *Id.*

The first supposed "priority" matter, entitled "Standards Improvement," is primarily intended to "reduce employers' compliance obligations" by making standards "easier ... to follow" and eliminating "out of date, duplicative, unnecessary or inconsistent" standards. (Exhibit 18). It "does not address specific risks" in the workplace, but is instead aimed at the convenience of employers, not at eliminating significant health risks to employees. *Id.* It hardly rises to the level of importance of reducing the risk of cancer deaths among workers. *Id.*

OSHA's second priority, clarifying the respirator rule, does relate to employee health. *Id.* But marginally improving a rule that has just gone into effect is less urgent than updating a decades-old standard that exposes hundreds of thousands of workers to significant risks of cancer and other adverse health effects. OSHA's regulatory agenda states that the primary reason for modifying the respirator rule is to "reduce compliance confusion among employers"; the agency has made "[n]o independent finding of significant risk" to employees justifying

this regulatory priority. *Id.* Thus, while clarifying the respirator standard may be worthwhile, it is aimed at the convenience of employers rather than worker health, and it hardly justifies elbowing hexavalent chromium aside once more.

The agency's third priority – updating the shipyard fire protection standard – is directed at eliminating a safety hazard to workers: the small number of deaths and approximately 50 serious burns that occur annually in the nation's 75,000-member shipyard workforce. *Id.* We do not mean to trivialize this hazard, but its magnitude is much lower than the cancer threat hexavalent chromium poses to a million workers. More significantly, revising this *safety* standard would not be impeded by compelling the agency to move ahead on hexavalent chromium, a *health* standard, especially since the shipyard fire protection standard is to be updated through a negotiated rulemaking process. The negotiators involved in working with affected groups to update requirements for “fire extinguishers, sprinkler systems, detection systems, alarm systems, and fire brigades” will not be the same as the agency epidemiologists and toxicologists who would develop the hexavalent chromium standard. *Id.*

The fourth agency “priority” consists simply of making OSHA's highway signs standard consistent with DOT standards. *Id.* The impetus for this “priority” is not elimination of significant risks to workers, but comes from “concerns raised by stakeholders” (i.e., affected employers). *Id.* Updating OSHA's highway

signage standard will not involve significant agency resources: The agency plans to adopt wholesale DOT's rules through a "direct final rule." *Id.* This "priority" is thus trivial both in comparative importance to hexavalent chromium and in the degree to which it will occupy the time and attention of agency decisionmakers.

OSHA's last "priority" is completing a new emergency exit rule – another change prompted by "concerns raised by stakeholders" and aimed at "using clearer language" to achieve "fewer disputes about violations." *Id.* The principal object of this rulemaking is to "rewrite the standard in simple, easy-to-understand language" – again, perhaps a worthy goal but hardly on a level with preventing fatal lung cancers. *Id.* Moreover, this proposed rule does not involve the same agency experts whose scientific judgment is called for in promulgating a hexavalent chromium standard, and, in any event, it is nearly complete. The proposed rule was issued almost seven years ago, a public hearing was held almost five years ago, and the agency anticipates finalizing the rule this June. *Id.*

Notably, *none* of OSHA's new "priorities" involves protecting workers against significant health risks posed by exposure to specific hazardous substances. Instead, the agency has given priority to tinkering with the rules, clarifying them for employers' benefit (in four of the five "priority" matters), and addressing only the least controversial matters of health and safety (e.g., fire extinguishers), and then only through negotiation with industry.

Deference to agency priorities in the face of a prolonged refusal to fulfill a statutory obligation to address a significant health risk can only go so far. The Court's obligation to remedy unreasonable delay empowers it to evaluate critically an agency's claims that compelling it to act will divert resources from higher priority matters. In *Zegeer*, for example, the D.C. Circuit reviewed "the listing of [the agency's] current rulemaking (and rule withdrawal) activities," and found that the agency had "not demonstrate[d] that expediting the radiation standards rulemaking is likely to crowd out agency action on items of higher priority." 768 F.2d at 1488. Similarly, in *Auchter*, the court considered three other matters OSHA claimed would be disturbed if the court compelled action on EtO and found that two would not be impeded because they were long-pending and near completion, and the third was less urgent because fewer workers were affected. 702 F.2d at 1157.

In this case, the matters that OSHA once claimed were higher priorities have been completed, abandoned, or "deprioritized," while the agency's new priorities are less urgent and unlikely to be significantly affected by committing agency resources to the long-deferred hexavalent chromium rulemaking. Agency "priorities" can no longer be permitted to stand in the way of the agency's statutory obligation to safeguard workers affected by hexavalent chromium.

3. Limited Agency Resources Cannot Forestall Action on Hexavalent Chromium.

Four years ago, OSHA blamed its delay in part on “the results of the November 1994 elections’ in Congress, government shutdowns, [and] budget cuts.” *Oil Workers*, 145 F.3d at 122. Even in 1998, those events were rapidly receding into the past. Now, the years that have passed since the 1994 elections and the 1995 government shutdown would by themselves constitute an unreasonable delay even if the agency’s inaction before those events were completely disregarded.

OSHA’s other excuses have also disappeared. The pattern of budget cuts that impeded OSHA in the early to mid-1990s has been reversed. OSHA’s appropriations for safety and health standards have doubled since 1995, with major increases in 1997, 2000, 2001, and 2002. Most recently, Congress’ fiscal year 2002 budget DOL provided a more than 8% *increase* in OSHA’s safety and health standards budget. OSHA’s current regulatory plan indicates that despite these increases, OSHA intends to scale back its health and safety standard-setting activity, pursuing an apparent policy of doing less with more. Whatever was true seven or even four years ago, resource constraints are no excuse for inaction now.

The other rationalization for inaction OSHA offered four years ago is also off target. In its *Oil Workers* brief, OSHA pointed to “the need to consult with small businesses” (145 F.3d at 122) under the then-recently enacted Small

longer enough to demonstrate that OSHA has fulfilled its obligation to take action without unreasonable delay. “[M]otion is not necessarily the same thing as progress – as the protagonist of ‘Charlie on the MTA’ well knew.” *In re Monroe Communications Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988).

The length of time this issue has been pending without even the first formal rulemaking step being taken; the disappearance, one by one, of each of the agency’s excuses for inaction; the ever-growing body of evidence documenting the inadequacy of the existing standard; the absence of genuinely competing agency priorities; and the agency’s recent decision to postpone action without even setting an aspirational timetable for issuing a proposed rule – all these factors combine to make this a case where judicial patience and understanding must be at an end. The D.C. Circuit’s words in *Brock* are fitting here:

We understand that technical questions of health regulation are not easily untangled. We understand that an agency’s limited resources may make impossible the rapid development of regulation on several fronts at once. And we understand that the agency before us has far greater medical and public health knowledge than do the lawyers who comprise this tribunal. But we also understand, because we have seen it happen time and time again, that action Congress has ordered for the protection of the public health all too easily becomes hostage to bureaucratic recalcitrance, factional infighting, and special interest politics. *At some point, we must lean forward from the bench to let an agency know, in no uncertain terms, that enough is enough.*

823 F.2d at 627 (emphasis added).

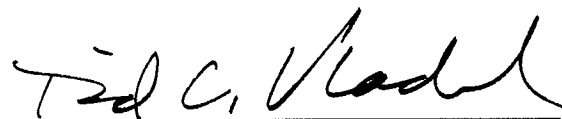
Under such circumstances, the Court has authority to order the agency to act by a definite date, and to report to the Court on its progress in meeting that deadline. “If the court finds unreasonable delay it must fashion an appropriate remedy, which may include ordering rulemaking to begin immediately and proceed expeditiously, and ordering periodic reports to the court concerning the pace of the rulemaking.” *Public Citizen Health Research Group v. Commissioner*, 740 F.2d at 35; *see also, e.g., Pendergrass*, 819 F.2d at 1270 (ordering issuance of a proposed rule within 60 days); *Auchter*, 702 F.2d at 1157 (ordering issuance of a proposed rule within 30 days).

The agency’s delay fully justifies such an order here. To allow completion of the SBREFA requirements, the court should permit the agency 90 days in which to issue a proposed rule, and should require the agency to submit a schedule for finalizing the rule within 12 months thereafter, with progress reports submitted by the Assistant Secretary of Labor for Occupational Health and Safety every 60 days. Only in this manner can there be reasonable assurance that OSHA will conclude the rulemaking process promptly. Even with such a schedule, the rulemaking will have taken more than 10 years from petitioners’ initial request for action – action the agency long ago promised to take “as quickly as we can.” It is too late to fulfill that promise. But it is not too late to prevent further needless risks to the lives and health of workers.

CONCLUSION

For the foregoing reasons, the petition for review should be granted, and the Court should require respondents to: (1) issue a notice of proposed rulemaking to establish a new hexavalent chromium standard within 90 days; (2) submit a schedule for completing the rulemaking within 12 months of the notice; and (3) file a progress report to the Court every 60 days until the rule is finalized.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "David C. Vladeck", written over a horizontal line.


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February 2002

CERTIFICATE OF COUNSEL

I, David C. Vladeck, counsel of record for petitioners, am a member of the
bar of this Court.



David C. Vladeck

CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing brief of petitioners
have been served this 1st day of ^{March}~~February~~ 2002, by hand delivery upon
counsel for respondents:

The Honorable Eugene Scalia
Acting Solicitor of Labor
United States Department of Labor
200 Constitution Ave., NW
Washington, DC 20210


David C. Vladeck

CERTIFICATE OF WORD COUNT

Pursuant to Rule 32(a)(7)(C), Fed. R. App. P., I hereby certify that the foregoing brief is in compliance with the word limitations set forth in Rule 32(a)(7)(B) inasmuch as the brief contains fewer than 14,000 words, when measured by Word 1997 (which counted 12,131 words), the word processing program used to prepare the brief, or Word Perfect version 6.1 (which counted 12,636 words), which was used to double-check the number of words in the brief.

A handwritten signature in black ink, appearing to read "D. C. Vladeck", written over a horizontal line.

David C. Vladeck

**UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

No.

**PUBLIC CITIZEN HEALTH RESEARCH GROUP, and
PAPER, ALLIED-INDUSTRIAL, CHEMICAL &
ENERGY WORKERS INTERNATIONAL UNION,**

Petitioners,

v.

**ELAINE CHAO, SECRETARY OF LABOR, and
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,**

Respondents.

**On Petition to Review the Inaction of the United States
Department of Labor**

**DECLARATION OF PETER LURIE, M.D., M.P.H.,
AND ACCOMPANYING EXHIBITS
SUBMITTED BY PETITIONERS**

February 2002

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OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,**

Respondents.

DECLARATION OF PETER LURIE, M.D., M.P.H.

Peter Lurie, M.D., M.P.H., declares as follows:

1. I am the Deputy Director of Public Citizen Health Research Group ("HRG"), which was founded in 1971 by Ralph Nader and Dr. Sidney Wolfe. HRG is a part of Public Citizen, Inc., a non-profit membership organization with approximately 150,000 members nationwide. Public Citizen is devoted to protecting the rights of consumers, workers, citizens and other U.S. residents. HRG promotes that goal by, among other things, seeking to ensure that

government regulations protect members of the public from exposure to hazardous materials in their homes, workplaces, and communities.

2. I have worked as a researcher and advocate in the field of public health since 1984. I received my M.D. from the Albert Einstein College of Medicine in 1987 and an M.P.H. in epidemiology from the University of California at Berkeley in 1991. I held research and clinical fellowships at the University of California at San Francisco from 1990 to 1993, and was an assistant professor at UCSF in the Department of Epidemiology and Biostatistics and the Department of Family and Community Medicine from 1993 to 1998. From 1997 to 1999 I was a visiting assistant research scientist at the University of Michigan. I was employed by HRG as a medical researcher from 1984 to 1985 and as a research associate from 1993 to 1998. I became Deputy Director of HRG in 1999. My areas of expertise include HIV prevention and epidemiology, pharmaceutical policy, occupational health policy, and tobacco policy.

3. This declaration is submitted in support of the Petition filed in this Court by petitioners HRG and the Paper, Allied-Industrial, Chemical & Energy International Union to compel the respondents, Secretary of Labor Elaine Chao and the Occupational Safety and Health Administration (OSHA), to cease their unreasonable delay in issuing a notice of proposed rulemaking to alter OSHA's permissible exposure limit, or PEL, for the carcinogenic substance hexavalent

chromium. Hexavalent chromium, also referred to as "Cr(VI)," is an oxidation or "valence" state of the metallic element chromium (Cr). Hexavalent chromium is found in a number of chemical compounds, including chromic acid (CrO_3) and the family of compounds referred to as "chromates." Although hexavalent chromium compounds are not commonly found in nature, they are widely produced and used in industry. Hexavalent chromium is used in chrome plating, stainless steel welding, ferrochromium alloy production, wood preservation, chromate pigments and dyes, rust and corrosion inhibitors, drilling muds, textiles, batteries, candles, rubber, cement, and copier toner. OSHA estimates that approximately one million U.S. workers are regularly exposed to hexavalent chromium in the workplace. 66 Fed. Reg. 61880 (Dec. 3, 2001) (Exhibit 4-P attached hereto).

4. Exposure to airborne hexavalent chromium causes a variety of acute health effects, including irritation, ulceration, perforation, and necrosis of the nasal septum, asthma, dermatitis, and skin ulceration. Inhalation of hexavalent chromium is also a cause of lung cancer. Epidemiological studies dating back over fifty years, as well as animal studies, have demonstrated a relationship between exposure to hexavalent chromium and lung cancer. Since 1990, chromium has been designated a human carcinogen by the International Agency for Research on Cancer, an agency of the World Health Organization. *See* <http://193.51.164.11/monoeval/crthall.html>. The Environmental Protection

Agency has classified hexavalent chromium as a human carcinogen since 1984, and confirmed that classification in a major review of the toxicological data in 1998. Environmental Protection Agency, *Toxicological Review of Hexavalent Chromium* (1998) (available at <http://www.epa.gov/IRIS/toxreviews/0144-tr.pdf>). The National Toxicology Program of the Department of Health and Human Services has designated the hexavalent chromium compounds calcium chromate, chromium trioxide (chromic acid), lead chromate, strontium chromate, and zinc chromate as “known human carcinogens” in each of its biannual Reports on Carcinogens since 1980. See, e.g., National Toxicology Program, *Ninth Report on Carcinogens* (2000) (relevant portions available at http://ehis.niehs.nih.gov/roc/ninth/known/chromium_hex_comps.pdf). The Agency for Toxic Substances and Disease Registry (ATSDR), another component of HHS, has designated hexavalent chromium as one of its “Top 20 Hazardous Substances.” See <http://www.atsdr.cdc.gov/cxcx3.html>. ATSDR concluded in September 2000 that “[t]he available human and animal data are sufficient for determining that chromium is carcinogenic following inhalation exposure.” ATSDR, *Toxicological Profile for Chromium 246* (2000) (available at <http://www.atsdr.cdc.gov/toxprofiles/tp7.pdf>).

5. In 1971, shortly after it was created by Congress, OSHA established a PEL for occupational exposures to airborne hexavalent chromium compounds,

acting under the “national consensus standards” provision of the Occupational Safety and Health Act. 29 U.S.C. § 655(a). The consensus standard PEL, which remains in force today, is 1 milligram per 10 cubic meters, or, as it is more commonly expressed, 100 micrograms per cubic meter ($100 \mu\text{g}/\text{m}^3$). 29 C.F.R. § 1910.1000, Table Z-2 (standard for general industry); 29 C.F.R. § 1926.55, Appendix A (standard for construction industry). The relevant regulations refer to hexavalent chromium as “chromic acid and chromates.” The $100 \mu\text{g}$ standard is reported as micrograms of chromic acid (CrO_3) rather than of hexavalent chromium itself. Since 52% of the mass of a molecule of CrO_3 is attributable to the chromium atom, the $100 \mu\text{g}/\text{m}^3$ standard reported as CrO_3 is equivalent to a standard of $52 \mu\text{g}/\text{m}^3$ of hexavalent chromium (or Cr(VI)). The hexavalent chromium PEL for general industry is a “ceiling” standard, meaning that the level of hexavalent chromium may not exceed the standard at any given point in time, even if the average level over a longer period of time is lower. See 29 C.F.R. § 1910.1000, Table Z-2. By contrast, the PEL for the construction industry is measured as an 8-hour time-weighted average (“TWA”), meaning that the level at any given time may exceed $100 \mu\text{g}/\text{m}^3$ as long as the average concentration spread over an 8-hour shift is below that level. 29 C.F.R. § 1926.55, Appendix A. The construction industry standard is thus less rigorous than the standard for general industry. An OSHA interpretive memorandum dated February 14, 1991, confirms

that the general industry standard is to be enforced as a ceiling, not an 8-hour TWA. See Exhibit 1.

6. According to the 1991 OSHA interpretive memorandum, the consensus standard PEL was based on a decades-old standard promulgated by the American National Standards Institute – a standard that did not consider the cancer risks of exposure to hexavalent chromium:

The current OSHA PEL for these compounds was adopted from a 1943 ANSI Standard. The justification for the ANSI Standard is based on 1924 and 1928 reports on the non-malignant effects (dermatitis and skin ulceration and perforations of the nasal septum) of chromium compounds. Thus, our current PEL is based on observations reported more than 60 years ago. It has now been established by the International Agency for Research on Cancer (IARC) that Chromium VI compounds are carcinogenic to humans.

Exhibit 1.

7. Because the $100 \mu\text{g}/\text{m}^3$ standard does not provide protection against risks of cancer resulting from exposure to hexavalent chromium, the National Institute for Occupational Safety and Health (NIOSH), the arm of the Centers for Disease Control and Prevention responsible for conducting research and making recommendations for the prevention of work-related disease and injury, recommended to OSHA in 1975 that the PEL be lowered to $1 \mu\text{g}/\text{m}^3$ (reported as Cr(VI)) as an 8-hour TWA for those hexavalent chromium compounds that NIOSH concluded were carcinogenic. See NIOSH, *Criteria for a Recommended Standard: Occupational Exposure to Chromium(VI)* (1975) (available at

<http://www.cdc.gov/niosh/76-129.htm>. The NIOSH standard equates to approximately $2 \mu\text{g}/\text{m}^3$ reported as CrO_3 . Subsequently, NIOSH concluded that its proposed limit should apply to all hexavalent compounds, because all such compounds should be considered carcinogenic. NIOSH, *Pocket Guide to Chemical Hazards*, Appendix C (relevant pages available at <http://www.cdc.gov/niosh/ipcs/nengapdx.html#c>).

8. In July 1993, Public Citizen and the Oil, Chemical & Atomic Workers Union (now PACE International Union) petitioned the Secretary of Labor to commence a rulemaking to lower the PEL for hexavalent chromium to $.5 \mu\text{g}/\text{m}^3$ (as CrO_3) measured as an 8-hour TWA. The petitioners also sought promulgation of an emergency temporary standard of $.5 \mu\text{g}/\text{m}^3$. A true and correct copy of the petition is attached as Exhibit 2.

9. OSHA took approximately seven months to respond to the petition. On March 8, 1994, Joseph Dear, Assistant Secretary of Labor for Occupational Safety and Health, sent Public Citizen a letter stating that OSHA had determined not to issue an emergency temporary standard, but had decided to commence a rulemaking proceeding to establish a new PEL for hexavalent chromium. The letter stated that "OSHA agrees that there is clear evidence that exposure to CrVI at the current PEL of $100 \mu\text{g}/\text{m}^3$ can result in an excess risk of lung cancer and other CrVI-related illnesses." According to the letter, OSHA "anticipate[d] that [a]

Notice of Proposed Rulemaking will be published in the Federal Register not later than March 1995.” A true and correct copy of the letter is attached as Exhibit 3.

10. In April 1994, the Department of Labor published its semiannual regulatory agenda. Among the OSHA proceedings listed in the agenda was a rulemaking proceeding for occupational exposure to hexavalent chromium. The April 1994 agenda stated that the anticipated schedule for issuing a notice of proposed rulemaking for hexavalent chromium was May 1995. A true and correct copy of the entry for hexavalent chromium in the April 1994 regulatory agenda is attached as Exhibit 4-A. Copies of each subsequent regulatory agenda entry for hexavalent chromium from November 1994 through December 2001 are attached as Exhibits 4-B through 4-P. As these documents demonstrate, OSHA’s May 1995 agenda moved the target date for issuance of a notice of proposed rulemaking back to December 1995 (Exhibit 4-C); the November 1995 agenda pushed the date back to July 1996 (Exhibit 4-D); the May 1996 agenda changed the target date to June 1997 (Exhibit 4-E); the November 1996 agenda changed the target to September 1997 (Exhibit 4-F); the April 1997 agenda changed the target to September 1998 (Exhibit 4-G); the October 1997 agenda changed the target to September 1999 (Exhibit 4-H); the November 1999 agenda changed the target to June 2001 (Exhibit 4-L); the November 2000 agenda changed the target to September 2001 (Exhibit 4-N); and the May 2001 agenda changed the target to November 2001

(Exhibit 4-0). In the December 2001 agenda, the hexavalent chromium rulemaking is listed as a "long-term action," and the anticipated date for issuance of a notice of proposed rulemaking is "to be determined." Exhibit 4-P.

11. As part of its consideration of the issue of hexavalent chromium, OSHA contracted with the K.S. Crump Division of ICF Kaiser to perform a comprehensive risk assessment for hexavalent chromium based on existing epidemiological studies. In May 1995, Crump published its *Evaluation of Epidemiological Data and Risk Assessment for Hexavalent Chromium* (the "Crump Report"), a true and accurate copy of which is attached as Exhibit 5. The Crump Report's conclusions were based principally on what were at that time "the best of the available quantitative epidemiological data" (Report at 2) on the effects of airborne exposure to hexavalent chromium, the Mancuso (1975) and Hayes (1979) studies of lung cancer among workers at chromium production facilities in Ohio and Baltimore, respectively. The Crump Report concluded that these data provided a basis for deriving "relatively consistent" risk estimates (Report at 2). The Crump Report used the Mancuso and Hayes data to develop estimates of the numbers of excess cancer deaths that could be expected to result from exposure to particular levels of hexavalent chromium, and concluded that exposure at the current PEL over an average working lifetime of 45 years (the conventional standard for risk assessment for industrial exposures) could be expected to result in

between 88 and 342 excess cancer deaths per thousand workers. Crump Report at 67 (Table 8). In other words, up to 34% of workers so exposed would unnecessarily die of lung cancer. Moreover, the Crump Report concluded that significant numbers of excess cancer deaths could be expected even at much lower exposure levels. Exposure at levels as low as the NIOSH-recommended $2 \mu\text{g}/\text{m}^3$ (as CrO_3), the Report concluded, could be expected to result in between 1.8 and 8.9 excess cancer deaths per thousand workers. Crump Report, 67 (Table 8).

OSHA endorsed the Crump analysis in its November 1996 regulatory agenda entry for hexavalent chromium (Exhibit 4-F). The agenda entry stated that "OSHA acknowledges that the risks of serious adverse health affects at the current PEL are significant." Indeed, OSHA went so far as to say that "[t]here appears to be no dispute that the current PEL is too high" (emphasis added). The agency's estimate of the number of workers affected by hexavalent chromium underscored its assessment of the significance of the issue: "OSHA estimates that more than 1 million workers are exposed to hexavalent chromium on a regular basis in all industries." The agency went on to summarize and quantify the health effects of exposure to hexavalent chromium at the current PEL:

Exposure to chromium (VI) is known to cause lung cancer, bronchial asthma, nasal septum perforations, skin ulcers, and irritative dermatitis. Chromium (VI) causes ulcers of the skin and acute irritative dermatitis among workers exposed to chromium alloys and chromium-plated objects. Inhalation of chromium (VI) aerosols at levels of about $100 \mu\text{g}/\text{m}^3$ may give rise to necrosis in the nasal

septum, leading to perforation. Bronchial asthma may occur as a result of inhalation of low levels of chromium (VI) dust or fumes.

* * *

OSHA has performed a preliminary quantitative risk assessment using all epidemiological studies for which dose-response information was available. OSHA preliminarily estimates that the risk of excess lung cancer deaths over a working lifetime at the current PEL ranges from 88 to 342 excess lung cancer deaths per thousand exposed workers.

13. The 1996 agenda went on to state that OSHA's assessment of the scientific evidence had led it to conclude that a new PEL was essential: "The strength of the epidemiological data leads OSHA to conclude that occupational exposures to chromium (VI) must be reduced." (Exhibit 4-F.) Moreover, the agency asserted, "[a]ny new PEL for chromium (VI) *must be greatly reduced*" (emphasis added). Accordingly, OSHA indicated that it was considering a new standard: "OSHA is preliminarily considering a new TWA PEL in the range of 0.5 - 5.0 $\mu\text{g}/\text{m}^3$, measured and reported as chromium (VI)." Because the existing standard equates to 52 $\mu\text{g}/\text{m}^3$ reported as Cr(VI), a new PEL in the range of .5 to 5 $\mu\text{g}/\text{m}^3$ reported as Cr(VI) would represent a decrease by a factor of approximately 100 at the low end and approximately 10 at the high end of the range. Even at these greatly reduced levels, the agency acknowledged, there would be a significant excess of cancer deaths. "OSHA preliminarily estimates that the risk of excess lung cancer deaths over a working lifetime at a new PEL of 0.5 micrograms per cubic meter of air [as CrVI] ranges from 0.9 to 4.4 excess lung cancer deaths

per thousand exposed workers.” The much higher risks associated with the existing PEL, the agency stated in 1996, were more than sufficient to justify a new standard:

OSHA is of the opinion that the epidemiological data on cancer mortality associated with chromium (VI) exposures are sufficient for the Agency to proceed with reduction of chromium (VI) exposures through regulation. The evidence of material impairment from exposure to chromium (VI) is strong and of high quality. *There appears to be no dispute that the current PEL is too high, and the sooner the PELs are reduced, the sooner the risk of death from lung cancer due to occupational chromium (VI) exposure will be reduced.* In addition, the number of cases of asthma, dermatitis, nasal septum perforation, and skin ulceration due to chromium (VI) will also be reduced. The risk estimates for chromium (VI) are similar to risk estimates from exposures to other substances that have been regulated through the Section 6(b) rulemaking process. (Emphasis added).

14. Despite the strength of the existing data, OSHA was under pressure from industry to defer rulemaking until a new study, being performed by a team of Johns Hopkins and EPA researchers led by Dr. Peter S.J. Lees, was published. In a series of letters, industry groups explicitly requested OSHA to postpone any rulemaking until the results of the study were available. As one of the letters (a true and correct copy of which is attached hereto as Exhibit 6) stated, the study was “expected to be the most accurate and complete database on chromium exposure and mortality available.”

15. OSHA responded to these requests by stating that it would not formally postpone the rulemaking. True and correct copies of OSHA’s responses

to the industry requests are attached hereto as Exhibits 7 to 9. However, OSHA also told petitioners in a letter dated June 30, 1995 (a true and correct copy of which is attached hereto as Exhibit 10), that it intended "to include the results of the Johns Hopkins study" in the notice of proposed rulemaking, thereby effectively acknowledging that the rulemaking would not be initiated until after the study was released.

16. The results of the Johns Hopkins study were publicly disclosed in conference presentations in 1995, 1996, 1997, and twice in 1999. OSHA did not, however, obtain the underlying data, and, according to agency personnel, still has not received it.

17. On March 3, 1997, petitioners wrote a letter to OSHA requesting that it commit to a timetable for the hexavalent chromium rulemaking. (Exhibit 11 hereto.) OSHA responded in a letter dated August 4, 1997. (Exhibit 12 hereto.) OSHA's letter denied the petitioners' request that it commit to a timetable for issuance of a new PEL. The letter attributed OSHA's failure to promulgate a proposed rule on hexavalent chromium to limited agency resources (resulting from funding cutbacks and from the then-recent government shutdowns) and competing high priority projects that were nearing completion or had been recently completed. The higher priority tasks referred to in the letter were revision of the respirator standard (which was completed in 1998), issuance of a notice of

proposed rulemaking on occupational exposure to tuberculosis (issued in 1997), finalization of exposure standards for 1,3-butadiene and methylene chloride (completed in 1996 and 1997, respectively), and the development of a Safety and Health Program Standard (which has since been shelved). The letter stated, however, that “[a]s we complete these other high-priority projects, we are committed to refocusing Agency resources onto chromium (VI) and other high-priority projects.” The Agency further stated that while it had “no intention of unduly delaying the rulemaking process” pending completion of the Johns Hopkins study, it expected that the results of the study would be available in time to be considered in the rulemaking process. The letter concluded:

Consequently, OSHA intends to move ahead as quickly as we can on the chromium (VI) rulemaking. We regret that OSHA is not further along in the process, but assure you that the Agency is fully committed to completing this rulemaking as expeditiously as the Agency’s resources permit. We do appreciate your concerns and look forward to working with you as we proceed.

18. Petitioners filed a petition for review in this Court on October 13, 1997. In OSHA’s response to that petition for review, the agency stated that it intended to issue a notice of proposed rulemaking by September 1999, but added that “that date reflects circumstances as OSHA knows them to date and it is a virtual certainty that unanticipated intervening events will affect OSHA’s workload in the interval between now and then.” Sec. Labor’s Answer, No. 97-3522, at 10. OSHA also informed the Court that its work on the hexavalent chromium standard

had a lower priority than its plan to promulgate the assertedly more important "Safety and Health Program standard." Moreover, OSHA stated that its work on hexavalent chromium would be slowed by the need to consider feasibility of a lower standard, by the need to comply with the Small Business Regulatory Enforcement Fairness Act ("SBREFA"), 5 U.S.C. § 609, and by budget constraints. See Sec. Labor's Answer at 17-18, 20, 24-25. On March 13, 1998, this Court issued its opinion denying the petition. *Oil, Chemical & Atomic Workers Union v. OSHA*, 145 F.3d 120, 122 (3d Cir. 1998).

19. A study published in 1999 used measures of the potency of carcinogens and the weight of the evidence supporting their carcinogenicity to identify chemicals for which a reduction in the PEL was indicated. Hexavalent chromium emerged as the regulatory candidate for which there was the greatest disjunction between the existing evidence and the PEL. The authors stated that "[w]e believe that few doubt that OSHA's current chromium PEL is too high" J.S. Smith & J.M. Mendeloff, *A Quantitative Analysis of Factors Affecting PELs and TLVs for Carcinogens*, 19 Risk Analysis 1223, 1232 (1999) (attached hereto as Exhibit 13).

19. The Johns Hopkins study on lung cancer among chromium production workers was published in August 2000. Herman J. Gibb, Peter S.J. Lees, Paul F. Pinsky, Brian C. Rooney, *Lung Cancer Among Workers in Chromium Chemical*

Production, 38 Am. J. Industrial Medicine 115 (2000) (attached hereto as Exhibit 14). The study followed an expanded cohort of workers at the same Baltimore chromate production plant previously studied by Hayes. Detailed exposure estimates for the employees in the study were based on roughly 70,000 contemporaneous measurements of airborne hexavalent chromium concentration at the plant, and information on the smoking status of the workers was gleaned from company medical records. The vital status of the workers, including dates and causes of death, was determined from 1950 through December 1992. *See id.* at 117.

20. The authors of the Johns Hopkins study concluded that their study population “present[ed] the best opportunity to date of evaluating the lung cancer exposure-response relationship from exposure to hexavalent chromium.” *Id.* at 124. In comparison to previous studies, such as Mancuso’s – which had been the most comprehensive up to that time – the Johns Hopkins study

had a larger cohort, more lung cancer deaths, and had smoking information for most of the cohort. Many of the exposure estimates of the current study are from direct measurements; a portion were from models using contemporary data. More important, however, the ambient measures or estimates of exposure were concurrent with the work history and are of hexavalent chromium directly, not derived from other measures. Furthermore, the cumulative exposure groups in the current study represent lower exposures than those of the Mancuso study, providing better risk estimates at these lower levels of exposure, an important consideration for quantitative risk assessment.

Id.

21. The Johns Hopkins study unequivocally concluded: “The current study confirms the elevated lung cancer risk from hexavalent chromium exposure observed in other studies” *Id.* Even more significantly, the authors of the study found that the existing PEL for hexavalent chromium fell within the fourth (or highest) exposure quartile of their studied population. In this quartile, exposure was found to be associated with a “significantly elevated” ratio of observed-to-expected lung cancer deaths. The authors concluded that there would be 2.24 times the number of cancer deaths among chromium-exposed workers than in an otherwise similar unexposed population. *Id.* at 122, 125. Indeed, even exposures at the NIOSH recommended level of $2 \mu\text{g}/\text{m}^3$ (reported as CrO_3) or at the lower level of $.5 \mu\text{g}/\text{m}^3$ (reported as CrO_3) advocated by the petitioners in this case were found to fall within the study’s third exposure quartile, which also had a significantly elevated rate of lung cancer, with a ratio of observed-to-expected cancer deaths of 1.57. *Id.* at 122, 125. The Johns Hopkins study thus provides strong confirmation that the existing PEL for hexavalent chromium poses an unacceptable cancer risk to workers, and that even much lower levels pose significant risks.

22. Simultaneously with the publication of their cancer study, the Johns Hopkins researchers published a study on other health effects of hexavalent chromium exposure. Herman J. Gibb, Peter S.J. Lees, Paul F. Pinsky, Brian C.

Rooney, *Clinical Findings of Irritation Among Chromium Chemical Workers*, 38 Am. J. Industrial Medicine 127 (2000) (attached hereto as Exhibit 15). That study found that workers exposed to hexavalent chromium experienced symptoms such as nasal septum deterioration and skin ulceration at median levels of approximately $20 \mu\text{g}/\text{m}^3$ – well below the current exposure standard. Because $20 \mu\text{g}/\text{m}^3$ was the median exposure level associated with these symptoms for those who experienced them, it follows that as many workers who experienced such symptoms did so *below* that level as above it.

23. Some time before the publication of the two Johns Hopkins studies, petitioner HRG obtained a copy of them through the Freedom of Information Act. On July 11, 2000, HRG sent a letter to Assistant Secretary of Labor for Occupational Safety and Health Charles Jeffress, which summarized the results of the studies, the delays in their publication, and the delays in OSHA's consideration of the hexavalent chromium issue. (Exhibit 16.) The letter stated:

The study demonstrates that lung cancer death rates [in the studied population] were almost double what would otherwise have been expected for this group and may even be elevated at air chromium levels below those we have recommended as a new standard With these data finally in hand, there can be no further justification for failing to immediately promulgate regulations to reduce worker exposures to this hazardous chemical.

OSHA did not answer the letter.

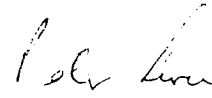
24. OSHA's "regulatory plans" issued in December 2000 and December 2001 are attached as Exhibits 17 and 18. Pertinent portions of OSHA's regulatory agenda issued in December 2001 are attached as Exhibit 19. These Exhibits demonstrate that none of the matters that OSHA previously stated to have a higher priority than the hexavalent chromium rulemaking remains an agency priority today. OSHA's current "priorities," as set forth in its latest regulatory plan, are limited to: (1) "improving" language in existing standards; (2) "clarifying" the recently promulgated rule on using respirators in the workplace; (3) promulgating a negotiated rule updating fire prevention standards in shipyards; (4) revising an existing rule on highway signs to bring it into conformity with Department of Transportation rules; and (5) adopting clearer language in an existing rule on emergency exit routes in workplaces.

25. In an effort to provide information concerning the degree of current worker exposures to hexavalent chromium, I obtained a copy of OSHA's database of exposure measurements under the Freedom of Information Act. The database includes workplace exposure measurements for hexavalent chromium taken between 1990 and 2000. I performed a statistical analysis of the data on those measurements, and prepared a report suitable for publication in a medical journal stating my conclusions, a true and correct copy of which is attached as Exhibit 20.

The statements in the report are truthful and reflect a proper application of generally accepted statistical methods.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 29, 2002.

A handwritten signature in cursive script, appearing to read "Peter Lurie", is written above a horizontal line.

Peter Lurie, M.D., M.P.H.

INDEX OF LURIE EXHIBITS

1. OSHA Memo From Patricia K. Clark to Regional Administrators Regarding Enforcement of the Chromate and Chromic Acid PEL, April 8, 1991
2. Petition Requesting a Reduced Tolerance for Chromium (VI) (Hexavalent Chromium) through an Emergency Temporary Standard Issued under the Authority of the Occupational Safety and Health Act, July 19, 1993
3. OSHA Response to Petition, Letter of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, to Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group, March 8, 1994
4. Exhibits 4A – 4P: OSHA Regulatory Agenda Entries for Hexavalent Chromium, 1994-2001
5. Evaluation of Epidemiological Data and Risk Assessment for Hexavalent Chromium (Crump Report), May, 1995
6. Letter of Richard F. Boggs, Vice President of Organization Resources, Inc., to Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, September 30, 1994
7. Letter of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, to Richard F. Boggs, Vice President of Organization Resources, Inc., November 1, 1994
8. Letter of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, to William A. Sontag, Jr., Director of Governmental Relations, National Association of Metal Finishers, November 1, 1994
9. Letter of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, to Langley A. Spurlock, Vice President, CHEMSTAR, December 9, 1994
10. Letter of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, to Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group, June 30, 1995

11. Letter of Colette G. Mattzie, Staff Attorney, Public Citizen Litigation Group, and Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group, to The Honorable Gregory Watchman, Acting Assistant Secretary of Labor for Occupational Safety and Health, March 3, 1997
12. Letter of The Honorable Gregory Watchman, Acting Assistant Secretary of Labor for Occupational Safety and Health, Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group, August 4, 1997
13. *A Quantitative Analysis of Factors Affecting PELs and TLVs for Carcinogens*, Article by Jeffrey S. Smith and John M. Mendeloff, 1999
14. *Lung Cancer Among Workers in Chromium Chemical Production*, Article by Gibb, Lees, Pinsky, and Rooney, March 20, 2000
15. *Clinical Findings of Irritation Among Chromium Chemical Production Workers*, Article by Gibb, Lees, Pinsky, and Rooney, March 20, 2000
16. Letter of Dr. Peter Lurie, Deputy Director, and Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group, to Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, July 11, 2000
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19. DOL Semiannual Regulatory Agenda, December 3, 2001
20. *Continuing Exposure to a Known Lung Carcinogen: An Analysis of OSHA Compliance Inspections, 1990-2000*, Paper by Dr. Peter Lurie, Deputy Director, and Dr. Sidney M. Wolfe, Director, Public Citizen's Health Research Group