

PRECEDENTIAL

Filed December 24, 2002

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 02-1611

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

v.

ELAINE CHAO, SECRETARY OF LABOR;
OCCUPATIONAL SAFETY AND HEALTH
ADMINISTRATION,

*Color Pigments Manufacturers Association Inc.,
Intervenor

**Chrome Coalition,
Intervenor

*(Pursuant to Court's Order dated 4/2/02)
**(Pursuant to Court's Order dated 4/3/02)

On Direct Petition Pursuant to the Administrative
Procedure Act,
5 U.S.C. S 706

Argued: November 5, 2002

Before: BECKER, Chief Judge, McKEE and
HILL,* Circuit Judges.

(Filed December 24, 2002)

* The Honorable James C. Hill, United States Circuit Judge for the
Eleventh Circuit Court of Appeals, sitting by designation.

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OPINION OF THE COURT

BECKER, Chief Judge.

This opinion addresses a Petition by Public Citizen Health Research Group ("Public Citizen") to review the inaction of the United States Department of Labor, specifically the Occupational Safety and Health Administration ("OSHA"), and to require OSHA to commence a rulemaking that would lower the permissible exposure limit for hexavalent chromium. It is not disputed that hexavalent chromium, which is widely used in various industries and which has been classified as a carcinogen, can have a deleterious effect on worker health. The National Institute for Occupational Safety and Health ("NIOSH") has for several decades recommended that OSHA adopt a far more stringent permissible exposure limit ("PEL") for hexavalent chromium than the consensus standard it promulgated in 1971. In response to a 1993 petition for rulemaking, OSHA agreed that there was clear evidence that exposure to hexavalent chromium at the consensus level can result in excess risk of lung cancer and other chromium-related

illnesses, and announced that it was initiating a rulemaking that it expected would conclude in 1995. However, nearly a decade after this announcement, nothing has happened, evincing a clear pattern of delay.

This matter was before us once before, in *Oil, Chemical & Atomic Workers Union v. OSHA*, 145 F.3d 120 (3d Cir. 1998). In that case, we declined Public Citizen's request to compel agency action, for we concluded that the facts did not yet "demonstrate [that OSHA's] inaction is . . . unduly

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transgressive of the agency's own tentative deadlines." 145 F.3d at 124. At that time, OSHA represented that it intended to issue a proposed rule by September 1999, and we found such a deadline permissible in light of alleged competing policy priorities, including the Clinton Administration's ergonomics initiative. Yet, at the time of oral argument in this case, which was nine years after OSHA initially announced its intention to begin the rulemaking process, no rulemaking had yet been initiated, and it appeared that none would be in the foreseeable future. Indeed, at oral argument, OSHA's counsel admitted the possibility that OSHA might not promulgate a rule for another ten or twenty years, if at all.

We concluded that the delay had become unreasonable, and that while competing policy priorities might explain slow progress, they could not justify indefinite delay and recalcitrance in the face of an admittedly grave risk to public health. We therefore determined to grant the petition and to direct OSHA to proceed expeditiously with its hexavalent chromium rulemaking process. This opinion was drafted on an expedited basis and was circulating to the panel when we received OSHA's announcement that it had instituted the long-sought rulemaking process, stating that: "The health risks associated with occupational exposure to hexavalent chromium are serious and demand serious attention. . . . We are committed to developing a rule that ensures proper protection to safeguard workers who deal with hexavalent chromium." OSHA News Release of Dec. 4, 2002, available at <http://www.osha.gov>.

This notice appears to have been prompted by the displeasure clearly evidenced by the panel during oral argument, especially the question posed to counsel whether they would be receptive to mediation regarding the timeframe for a judicially-ordered rulemaking. Notwithstanding OSHA's long delay, we salute the agency upon its recent action and accompanying recitation, and trust that it will have a good result. That said, it does not moot this proceeding because the agency's action does not resolve an important facet of the case, namely Public Citizen's request that we order OSHA to issue a proposed rule within 90 days and supervise OSHA's progress.

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Accordingly, we will publish the opinion that had been prepared to resolve the remedy issue, and will direct that Public Citizen and OSHA submit to a course of mediation for sixty days before The Honorable Walter K. Stapleton. If the parties cannot agree to a workable timetable during that period, the panel will issue and enforce a schedule of its own device. We note in this regard that the recitation of this case's history and our ratio decidendi, which provided the impetus for OSHA's commendable action, will inform the proceedings to follow.

I. Facts and Procedural Posture

Hexavalent chromium is a compound found only rarely in nature but used widely in industry -- for chrome plating, stainless steel welding, alloy production, and wood preservation. The dangers of exposure to it have long been recognized, and include ulceration of the stomach and skin, necrosis, perforation of the nasal septum, asthma, and dermatitis. More significantly, there is strong evidence that inhaled hexavalent chromium is carcinogenic. Since 1980, the Department of Health and Human Service's National Toxicology Program has designated various hexavalent chromium compounds as human carcinogens. The Environmental Protection Agency has been in accord since 1984, and it confirmed its carcinogenic classification of the compound in a review of the toxicological data in 1998. EPA, Toxicological Review of Hexavalent Chromium (1998), available at <http://www.epa.gov/IRIS/toxreview/0144-tr-pdf>. Disturbingly, the primary evidence of hexavalent chromium's carcinogenicity comes not from animal studies, but from epidemiological studies of workers exposed to it; in short, as Public Citizen states, "the principal evidence is actual human body counts." [Pet. Br. at 5.]

Soon after the Occupational Safety and Health Act took effect in 1970, OSHA established a 100 $\mu\text{g}/\text{m}^3$ permissible exposure limit ("PEL") for inhalation exposure to hexavalent chromium.¹ That level did not reflect OSHA's independent

1. Two things are noteworthy about this limit. First, it represents an absolute ceiling, not a time-weighted average. That is, at no time can a

judgment about the appropriate standard, but rather constituted a "lowest common denominator" consensus standard to provide workers some measure of protection pending OSHA's consideration of the optimal long-term standard. S. Rep. No. 1282, 91st Cong., 2d Sess. 6 (1970), reprinted in 1970 U.S.C.C.A.N. 5177, 5182-83. The 1971 standard remains in effect. However, although today's foremost health concern regarding hexavalent chromium is its carcinogenicity, OSHA did not take that into account when promulgating the standard; rather, it was based on a 1943 recommendation by the American National Standards Institute, which in turn was based on reports generated in

the 1920s, none of which considered chromium's carcinogenic effects.

Shortly after OSHA promulgated the consensus standard, 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 of 1.9 $\mu\text{g}/\text{m}^3$, a level 1/52 of the existing standard. At that time, NIOSH concluded that the evidence of the carcinogenicity of a few specified hexavalent chromium compounds was lacking, but that all other forms were carcinogenic. (Lurie Dec. P 7.) 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 such compounds. (Id.)

particular environment's level permissibly rise above 100 $\mu\text{g}/\text{m}^3$, even if its time-weighted average is far lower. The construction industry alone is permitted to use time-weighted averaging. See 29 C.F.R. S 1926.55.

Second, the 100 $\mu\text{g}/\text{m}^3$ limit is reported as "CrO₃." However, as only 52% of the mass of a CrO₃ molecule is chromium, the actual permitted amount of hexavalent chromium is approximately 52 $\mu\text{g}/\text{m}^3$, reported as Cr(VI), the pure form. The existing permissible exposure limit is thus 100 $\mu\text{g}/\text{m}^3$, reported as CrO₃, or 52 $\mu\text{g}/\text{m}^3$, reported as Cr(VI). Because both Public Citizen's proposed PEL and the existing PEL are reported as CrO₃, we will refer to that measurement throughout this opinion unless otherwise stated. We also note that Cr(VI), CrVI, and CrO₃ all refer to hexavalent chromium; because we faithfully reproduce quotations that use different notations, there is a lack of uniformity in our opinion.

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In 1993, Public Citizen petitioned OSHA to issue an emergency temporary standard that would set a PEL of 0.5 $\mu\text{g}/\text{m}^3$ as an 8-hour weighted average. The Occupational Safety and Health Act requires OSHA to issue an emergency temporary standard without the usual notice-and-comment procedures if it finds that such action is needed to protect employees against grave danger. 29 U.S.C. S 655(c). OSHA denied the petition because it contended that "the extremely stringent judicial and statutory criteria for issuing" an emergency standard were not met. (Dear Letter at 2.) It did, however, acknowledge that its existing standard was inadequate: "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." (Id.) It therefore announced that

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.)

This timetable was short-lived. Only a month after its response to Public Citizen's rulemaking petition, OSHA reported that the date for issuance of a proposed standard had slipped from March to May 1995, and by May 1995 the anticipated issuance date had been pushed back again to December 1995. Thus began a pattern of delay -- the November 1995 agenda reset the date to July 1996; the May 1996 agenda moved it to June 1997; and the November 1996 agenda moved it again, to September 1997.

Amidst this ongoing delay, OSHA commissioned a comprehensive risk assessment of hexavalent chromium. This assessment, which became known as the "Crump Report," concluded that exposure at the current PEL (100 $\mu\text{g}/\text{m}^3$) over a 45-year working lifetime could be expected to result in between 88 and 342 excess cancer deaths per thousand workers. Moreover, the Crump Report concluded that significant numbers of excess cancer deaths could be

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expected even at much lower levels of exposure. For example, exposure at 2 $\mu\text{g}/\text{m}^3$ could be expected to result in between 1.8 and 8.9 excess cancer deaths per thousand workers, while exposure at 1 $\mu\text{g}/\text{m}^3$ would yield 0.9 to 4.4 excess cancer deaths per thousand workers.²

OSHA's November 1996 semiannual regulatory agenda endorsed the Crump analysis, and OSHA explicitly acknowledged that "[t]here appears to be no dispute that the current PEL is too high" and "must be greatly reduced." (Lure Dec. P12.) Accordingly, OSHA stated that it was considering a new standard 10 to 100 times lower than the existing one: "OSHA is preliminarily considering a new TWA [Time-Weighted Average] PEL in the range of 0.5 - 5.0 $\mu\text{g}/\text{m}^3$, measured and reported as chromium (VI)." (Id.) Even at that level, it noted, there would be significant risk of excess cancer deaths. (Id.)

Addressing these events in its present brief, OSHA contends that it was then concerned with methodological imperfections in the available data. For example, the Crump Report did not control for the effects of smoking or asbestos, factors obviously related to lung cancer incidence; if the studied populations of chromium-exposed workers smoked more than the general population, smoking could have accounted for some of the excess deaths. Industry groups therefore pressured OSHA to wait for the results of the then-forthcoming Johns Hopkins study, which, in the industry's view, was "expected to be the most accurate and complete database on chromium exposure and mortality available." (Id. at P 14-15.) OSHA also represents that budget cuts, government shutdowns, and new responsibilities under the Small Business Regulatory Enforcement Fairness Act of 1996 limited the resources available for hexavalent chromium rulemaking. In August 1997, OSHA explained to Public Citizen that work on the

rule was continuing, but that these considerations had delayed progress and prevented it from expediting the rulemaking. (Letter of Greg Watchman to Dr. Sidney M. Wolfe.)

2. The Crump Report cited measurements of exposure as Cr(VI) instead of as CrO₃. The numbers here reflect conversion to CrO₃ measurements.

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Public Citizen, discouraged by what it viewed as a pattern of inaction, urged OSHA in March 1997 to commit to a timetable for rulemaking. (Lurie Dec. P17.) Instead, in its April 1997 agenda, OSHA announced that the expected issuance of a proposed standard had been delayed a full year, to September 1998, (id. at P10), and in a letter to Public Citizen declined to commit to a more concrete timetable. (Watchman Letter at 2.)

In late 1997, Public Citizen filed a petition in this Court for review of OSHA's allegedly unreasonable delay. See *Oil Workers*, 145 F.3d at 120. It contended that expedited action on a new rule was needed because, as OSHA itself had stated in 1996, "the sooner PELs are reduced, the sooner the risk of death from lung cancer . . . will be reduced." (Lurie Dec. P12, citing 1996 OSHA agenda.) However, OSHA disputed this urgency by referencing the Crump Report's failure to control for smoking and asbestos exposure, and Intervenor Chrome Coalition and Color Pigment Manufacturer's Association, who have also intervened in the current case, argued that the existing risk assessments failed to distinguish among the various compounds of hexavalent chromium.

We declined Public Citizen's request to compel agency action, for we concluded that the facts did not yet "demonstrate that inaction is . . . unduly transgressive of the agency's own tentative deadlines." *Oil Workers*, 145 F.3d at 124. Key to our decision was our observation that the Secretary of Labor has "quintessential discretion . . . to allocate OSHA's resources and set its priorities," id. at 123, and while we recognized that "delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake," we determined that OSHA and the Intervenor "raise[d] serious questions about the validity of the data and assumptions underlying [Public Citizen's] calculations." Id. (citations omitted). Given these scientific questions, OSHA's superior technical expertise, and its professed plan to issue a deadline for proposed rulemaking in September 1999, we concluded that OSHA's delay was not yet unreasonable. Id.

Following our ruling, OSHA adhered to its September 1999 pledge in each of its regulatory agendas published

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through April 1999. But it in fact issued no proposed rule in September 1999, and in its November 1999 agenda it announced that its new target date was June 2001. (Lurie Dec. P10.) OSHA explains that this was not a period of inactivity; rather, it completed a number of rulemaking projects, most of which had been pending when Public Citizen filed its first petition in 1993. For example, in 1997, OSHA promulgated a final standard regulating occupational exposure to methylene chloride, a widely-used chemical it found to be carcinogenic. See 62 Fed. Reg. 1494 (Jan. 10, 1997). Likewise, in 1998, it issued a final rule on respirators, and another requiring adequate training for operators of powered industrial trucks. 63 Fed. Reg. 66238 (Dec. 1, 1998). OSHA further explains that in 1999 and 2000, it "focused most of its rulemaking resources on issuing an ergonomics standard before the end of the [Clinton] Administration's term. A proposed rule was issued on November 23, 1999, and a final rule was issued less than a year later, a timetable that required tremendous agency resources." [OSHA Br. at 10 (citations omitted).]

Meanwhile, August 2000 saw the release of the long-awaited Johns Hopkins study on hexavalent chromium. 3 In comparison to previous studies, it

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.

3. Public Citizen alleges that many of the Hopkins study's results, if not its actual data, had been available to OSHA since 1995. [Public Citizen Br. at 23.]

Herman J. Gibb et al., Lung Cancer Among Workers in Chromium Chemical Production, 38 Am. J. Industrial Medicine 115, 124 (2000). The Hopkins Study "confirm[ed] the elevated lung cancer risk from hexavalent chromium exposure observed in other studies." Id. Specifically, it found that chromium-exposed workers were 2.24 times as likely to die from lung cancer as a nonexposed population, id. at 125, and that even exposure at a level of 1 µg/m³, reported as Cr(VI), led to an observed-to-expected cancer mortality rate of 1.57. Id.

Although the Hopkins Study explicitly sought to address the shortcomings in previous empirical research, namely

the lack of controls for smoking, asbestos, and other environmental factors, its release did not spur OSHA into action. The study was released in August 2000, but OSHA's November 2000 agenda pushed the date for a proposed rule back to September 2001. (Lurie Dec. P10.) OSHA's second-most-recent agenda, issued December 3, 2001, reflected another, more radical departure from previous plans: for the first time since 1994, the hexavalent chromium rulemaking was denominated a "long-term action," and the timetable for action stated that the date for a proposed rule was "to be determined." (Lurie Dec. P10.)

OSHA offers a number of explanations for the delay that has now become indefinite. It notes that "[t]he day the [Bush] Administration took office, it instructed the agencies that any new regulatory actions must be reviewed and approved by a department or agency head appointed after January 20, 2001." [OSHA Br. at 13-14, citing Andrew H. Card, Jr., Memorandum for the Heads and Acting Heads of Executive Departments and Agencies (Jan. 20, 2001).] As it was not headed by a presidential appointee until August 3, 2001, OSHA contends that it could not begin to set its new regulatory priorities until that time. Even then, it asserts, two extraordinary unforeseen events -- the attacks on the World Trade Center and Pentagon and the anthrax mailings -- required it immediately to divert significant resources to safety efforts. See Testimony of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, before the House Subcommittee on Labor, Health, and Human Services, 2002 WL 2010818 (Feb. 14, 2002).

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Even amidst these distractions, OSHA represents, it has continued to evaluate the need for a new hexavalent chromium rule. It claims that from 1998 through the present, it has "engaged outside organizations to work on pertinent aspects of the health-risk and feasibility issues that would arise in an OSHA rulemaking." [OSHA Br. at 11]. For example, ToxiChemica International has worked on evaluating an update of an epidemiological study of workers exposed to hexavalent chromium, and NIOSH has investigated the mechanistic relationship between hexavalent chromium and cellular events related to lung carcinogenesis. OSHA has also conducted more than twenty visits to worksites where hexavalent chromium is present to determine patterns of employee exposure, specific routes of exposure, and types and costs of engineering controls and personal protective equipment used in particular industries.

In OSHA's submission, the problem is that it "believes that the information now available is inconclusive on important issues, such as whether the epidemiological studies . . . apply to all Cr VI compounds and the utility of the data to establish a dose-response relationship." [Id. 16.] Although the Hopkins Study was a step forward, OSHA points out that its authors acknowledged certain limitations, particularly in estimating the cumulative

exposure for the different individuals in the cohort. [Id. at 26.] The study also did not resolve the dispute over whether all hexavalent chromium compounds present the same degree of risk. [Id. at 27.] Because OSHA has decided that it would benefit from public input and expert criticism on these issues, it has published a request for information (RFI) in its August 2002 regulatory agenda. After the time for response, OSHA states, it will evaluate all of the information available and decide how to proceed. See 67 Fed. Reg. 33308, 33342-43 (May 13, 2002).

Public Citizen brought the present petition for review alleging that "[d]eference to an agency's priorities and timetables only goes so far," and arguing that, "at some point, a court must tell an agency that enough is enough." [Public Citizen Br. at 2.] The Administrative Procedure Act, 5 U.S.C. S 706(1), creates a right of action by an aggrieved

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party to compel unreasonably delayed agency action. When the action sought is the promulgation of an occupational exposure standard under 29 U.S.C. S 655, the federal courts of appeals have exclusive jurisdiction under 29 U.S.C. S 655(f), which we have interpreted to provide "jurisdiction to conduct judicial review over the 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.

II. Discussion

In denying Public Citizen's earlier petition to compel a hexavalent chromium rulemaking, we acknowledged "the quintessential discretion of the Secretary of Labor to allocate OSHA's resources and set its priorities." *Oil Workers*, 145 F.3d at 123. At the same time, however, we recognized that the Secretary's discretion is not unbounded, and noted our obligation under the APA to "compel agency action unlawfully withheld or unreasonably delayed." *Id.* (quoting 5 U.S.C. S 706(1)). Our polestar is reasonableness, and while in 1997 we found reasonable OSHA's delay in the face of scientific uncertainty and competing regulatory priorities, we now find ourselves further from a new rule than we were then. We examine each of OSHA's justifications in turn.⁴

4. Intervenors Chrome Coalition and Color Pigment Manufacturer's Association, Inc. ("CPMA") filed amicus briefs arguing, inter alia: that our prior decision in *Oil Worker* is res judicata upon this case since the facts are similar; that the Occupational Safety and Health Act imposes on OSHA no duty to act; that Public Citizen's risk assessments and scientific conclusions should be stricken due to methodological defects; that Public Citizen lacks standing; that Public Citizen's analysis fails to distinguish among various forms of hexavalent chromium; and that we lack subject matter jurisdiction because Public Citizen has not pled that its principal place of business is within our jurisdiction. We have

considered each of their concerns and find them to be without merit. We note specifically that, under the Supreme Court's decision in *Panhandle Eastern Pipe Line Co. v. Federal Power Comm'n*, 324 U.S. 635, 638-39 (1945), courts have read circuit-selection clauses in statutes providing for review of agency action in the courts of appeals as venue provisions, not jurisdiction provisions. Also, while CPMA may be correct that a regulatory distinction ought to be drawn between chrome pigments and other types of hexavalent chromium compounds, CPMA may raise this concern as part of the rulemaking process.

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A. Has OSHA's Delay Been Excessive?

In 1993, OSHA acknowledged that the existing hexavalent chromium standard is inadequate and "that there is clear evidence that exposure to Cr VI 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." (Dear Letter at 2.) That was fully nine years ago, and its first target date for a proposed rule -- March 1995 -- is now more than seven years past. OSHA has missed all ten of its self-imposed deadlines, including the September 1999 target it offered to this Court in *Oil Workers*. Far from drawing closer to a rulemaking, all evidence suggests that ground is being lost. OSHA's December 2001 regulatory agenda demoted the rulemaking from a "high priority" to a "long term action" with a timetable "to be determined." In fact, at oral argument, OSHA's counsel admitted the possibility that another ten or even twenty years might pass before it issues a rule, if it ever does.

OSHA responds that Public Citizen's concerns about the missed deadlines and recent reclassification are misconceived. It explains that under the Regulatory Flexibility Act, 5 U.S.C. S 602, agencies must publish regulatory agendas that include all rules the agency intends to propose or promulgate that are "likely to have a significant economic impact on a substantial number of small entities." A rule's inclusion in an agency's agenda does not, however, require the agency to consider or act on that item. See 5 U.S.C. S 602(d). The Secretary of Labor has recently stated her belief that "it is inappropriate to routinely set target dates that the agency cannot meet and intends to list only realistic target dates in future regulatory agendas," *Daily Labor Report* (BNA, Apr. 22, 2002), but OSHA represents that this is an act of grace, not necessity: "[B]ecause an item's listing in the regulatory agenda does not mean that the agency must consider or act on that item, the listing of unrealistic or unachieved target dates cannot be a basis for compelling the agency to act." [OSHA Br. at 33.]

Regarding hexavalent chromium's recent downgrade to a "long-term project," OSHA clarifies that this is a reflection of whether the rulemaking will be completed in a short

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period of time and represents that the designation carries no implication about a rulemaking's relative importance to other matters OSHA is considering. [OSHA Br. at 31.] The items listed as "high priority" in the December 2001 agenda, it says, were simply those on which OSHA intended to take action in fiscal 2002. See 66 Fed. Reg. 61221 (Dec. 3, 2001). It therefore contends that the priority downgrade was more a clarification than a change in the agency's priorities.

We find neither of these explanations satisfactory. We agree with OSHA insofar as its failure strictly to follow its published agenda is not actionable, but this defense misses the point: OSHA's persistent failure to meet deadlines is not the disease itself, but rather a symptom of its dilatory approach to the hexavalent chromium rulemaking process. Similarly, even if OSHA's decision to downgrade the project's priority truly represents a clarification rather than a change, it still gives clear evidence that at least another year will pass before OSHA takes even the first formal step toward promulgating a rule. Incidentally, we are skeptical of OSHA's reassurance that the reclassification has no substantive implications, for five years ago it represented to this Court that it intended to issue a proposed rule in September 1999. Not only did it fail to issue a rule in 1999, it concedes even now that it is far from doing so.

Section 6(b) of the Occupational Safety and Health Act requires the Secretary of Labor 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. S 655(b). The Supreme Court has found that this language compels action: "[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." *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 641 (1980). As such, the agency's priorities are judicially reviewable, and this Court and others have compelled OSHA to take action to address significant risks.

See, e.g., *United Steelworkers of America v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1987); *In re International Chemical Workers Union*, 958 F.2d 1144 (D.C. Cir. 1992); *Public Citizen Helath Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987). Indeed, OSHA itself does not seriously contest the existence of a private cause of action compelling it to proceed with a rulemaking.

We find extreme OSHA's nine-year (and counting) delay since announcing its intention to begin the rulemaking process, even relative to delays other courts have condemned in comparable cases. Indeed, in no reported

case has a court reviewed a delay this long without compelling action. In *Chemical Workers Union*, 958 F.2d at 1144, for example, petitioners had first requested that OSHA promulgate a rule for cadmium in 1986. Similar to this case, the court had denied an initial petition to compel OSHA to act, based in part on OSHA's prediction that it would issue a proposed rule later that year. When it failed to issue a proposed rule until 1990 and estimated that a final rule would not be forthcoming until 1992, the court said:

[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 twenty-year-old standards still in place. . . . 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). It therefore granted petitioner's motion to impose a deadline for completion of the cadmium rulemaking. *Id.* The length of the delay here is already two-and-a-half years longer than the delay the D.C. Circuit found unacceptable, and no proposed rule is in sight.

Similarly, in *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), OSHA had been petitioned in 1981 for a new exposure standard for ethylene oxide ("EtO"), a carcinogenic substance to which an

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estimated 75,000 hospital workers were exposed. As in the case at bar, the agency refused to issue an emergency temporary standard, but acknowledged the current standard's insufficiency and began the rulemaking process. It issued an "advance notice of proposed rulemaking" in 1982, but it 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. The court found the anticipated three-year delay unacceptable, stating that:

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. See also *Brock*, 823 F.2d at 628, 629 ("With lives hanging in the balance, six years is a very long time," and "any delay whatever beyond the proposed schedule is unreasonable."); *Oil, Chemical & Atomic Workers*

International Union v. Zegeer, 768 F.2d 1480, 1487 (D.C. Cir. 1985) (addressing a delay of over five years in issuing a proposed rule for exposure to radioactive gases, and stating that a "reasonable time may encompass months, occasionally a year or two, but not several years or a decade").

OSHA contends that among these cases, only in *Auchter* did a court compel the agency to issue a proposed rule; the others dealt with situations where the agency had issued a proposed rule but was allegedly dilatory in issuing a final regulation. It further notes that the D.C. Circuit later characterized *Auchter* as "one of the exceptionally rare cases where this court has actually issued an order compelling an agency to press forward with a specific project." *In re Barr Laboratories, Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991). OSHA also points out that in *Auchter*, the court had been "persuaded, largely by agency concessions, that the project backed by plaintiff was plainly more 'urgent'

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than any that the project's acceleration might retard," *id.*, and it emphasizes that no similar concession exists here.

While we acknowledge that *Auchter*, *Chemical Workers Union*, and the other cases are in some ways distinguishable from this one, we nonetheless regard them as valuable precedent. For example, in *Auchter*, even though OSHA admitted that the plaintiff's project was the most urgent on its agenda, the case at bar is not ultimately distinguishable because the extremity of delay more than overcomes the fact that hexavalent chromium does not dominate OSHA's list of priorities. We also note that although the D.C. Circuit termed cases in which courts order agencies to press forward with a specific project "exceptionally rare," the initial decision to make hexavalent chromium a "high priority" came from OSHA itself, not this Court. It was also OSHA's decision to announce in 1993 that it was "beginning a . . . rulemaking for occupational exposure to Cr VI," and that it "anticipate[d] that Notice of Proposed Rulemaking will be published . . . not later than 1995." (*Lurie* Dec. P9.) At all events, we think it "exceptionally rare" that an agency would for years classify an action as a "high priority," only to demote it to a "long term project" upon the release of a study that provides more convincing evidence of the danger than had previously existed.

We are satisfied that OSHA's delay in this case is objectively extreme, and we find its regression alarming in the face of its own 1996 statement that "[t]here appears to be no dispute that the current PEL is too high." We therefore conclude that, absent a scientific or policy-based justification for its delay, we must compel it to act.

B. Does Scientific Uncertainty Justify OSHA's Delay?

In *Oil Workers*, the first installment of this case, Public

Citizen relied upon the Crump Report's finding that between 88 and 342 out of every 1,000 workers exposed to hexavalent chromium will die from cancer attributable to that exposure. 145 F.3d at 123. We recognized, however, that there were "serious questions about the validity of the data and assumptions underlying Petitioner's calculations." Id. For example, as the Intervenors noted, it was "wrong to

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assume that all workers in industries dealing with chromium in some way or another are exposed to 100 $\mu\text{g}/\text{m}^3$ hexavalent chromium, every working day for 45 years." Id. We likewise observed that some workers breathe through respirators that protect them from exposure to chromium, and that Public Citizen's calculations failed to distinguish between lead chromate and other hexavalent chromium compounds with potentially different carcinogenicities. Id. at 124. Finally, and most importantly, we were troubled by the Crump Report's failure to control for smoking and asbestos inhalation, two factors likely related to lung cancer incidence. Id.

Based on this imperfect science and our recognition that "OSHA . . . possesses enormous technical expertise we lack," we concluded that we were "not in a position to tell the Secretary how to do her job." Id. OSHA offers several reasons for us to continue that deferential posture. First, OSHA allegedly "has not yet completed its evaluation of the Hopkins study." [OSHA Br. at 26.] It points out that the study's authors acknowledged certain limitations of their data, particularly in estimating the cumulative exposure for different individuals in the cohort, and also that the study did not address the previous dispute over whether all hexavalent chromium compounds present the same degree of risk. [Id. at 26-27.] OSHA summarizes that, "even assuming the Hopkins study is the most useful single study available, it does not answer all of the technically complex questions about carcinogenicity and other health effects that OSHA would need to resolve in developing a Cr VI rule." [Id. at 27.]

Second, OSHA alleges that "Public Citizen virtually ignores the other critical components of a Cr VI rulemaking." [Id.] One of OSHA's requirements is that a standard must be technologically feasible, and given that one governing hexavalent chromium would apply to numerous industries, the feasibility analysis is quite complex. While it admits that it has successfully addressed issues of comparable complexity in the past, it notes that "these efforts have not been successful where courts have found insufficient rigor in the agency's analysis of scientific and economic issues." [Id. at 30] See, e.g., Industrial Union

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Dep't, 448 U.S. at 662 (invalidating benzene standard); AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992) (vacating

standard setting new exposure limits for over 400 substances). The bottom line, OSHA states, is that "[t]he belief that a chemical may be carcinogenic does not lead easily to the appropriate PEL for that chemical," and forcing it to issue a rule prematurely will likely result in that rule being overturned in court. [OSHA Br. at 24.]

We agree with OSHA that the evidence may be imperfect, that the feasibility inquiry is formidable, and that premature rulemaking is undesirable. But given the history chronicled above, we find these concerns insufficient to justify further delay in regulating hexavalent chromium. First, while it is true that the Hopkins study's authors recognized certain limitations of their data,

the epidemiological data as of the mid-1990s were sufficient for EPA, ATSDR, NIOSH, the National Toxicology Program, and the International Agency for Research on Cancer to find hexavalent chromium carcinogenic; for OSHA to commence a rulemaking proceeding; and for OSHA's contractor to estimate that exposures at a fraction of the current PEL would result in significant excess cancer deaths.

[Public Citizen Reply Br. at 19-20.] Moreover, OSHA based its delay on its professed desire to consider that study because of its superior data and ability to control for smoking. It was released in August 2000, more than two years ago, but it has hardly facilitated the rulemaking process.⁵ OSHA now offers it as a justification for further inaction, claiming that it has not completed its evaluation of the study's findings and that the study's conclusions "can be much better assessed when experts in the field have had the opportunity to review and criticize it." [OSHA Br. at 27.]

We are unconvinced. Public Citizen points out that, as the study was published in a peer-reviewed journal, experts in the field have already had the opportunity to criticize it.

5. Indeed, the Hopkins study's results were first presented publicly in 1995. [Public Citizen Br. at 10, 44.]

[Id. at 20.] Notably, in the two years since its publication, "no response or letter criticizing it has been published." [Id.] Especially since many of the study's findings have been available since 1995, see *supra* at note 5, the time for examining it has passed; we also note that, if further professional criticism is absolutely necessary, the notice-and-comment process will provide an ample opportunity.

Nor do we find persuasive OSHA's broad assertion that the Hopkins study "does not answer all of the technically complex questions . . . that OSHA would need to resolve in developing a Cr VI rule." [OSHA Br. at 27 (emphasis added).] This is obviously true, but without more it is

irrelevant, for the Occupational Safety and Health Act does not require scientific certainty in the rulemaking process. Indeed, read fairly, the Act virtually forbids delay in pursuit of certainty -- it requires regulation "on the basis of the best available evidence," 29 U.S.C. S 655(b)(5) (emphasis added), and courts have warned that "OSHA cannot let workers suffer while it awaits the Godot of scientific certainty." *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1266 (D.C. Cir. 1980).

OSHA points to one specific shortcoming of the Hopkins study -- that it "did not address the previous dispute over whether all hexavalent chromium compounds present the same degree of risk." [OSHA Br. at 27] That is indeed a question it did not resolve, and this uncertainty is the principal topic of Intervenor CPMA's brief, which argues that the lead chromate used in pigments is not as carcinogenic as other hexavalent chromium compounds. The Hopkins study casts no light on this issue because its test population did not work in the pigment industry, but even without better data than that which existed in *Oil Workers* in 1997, we find this uncertainty insufficient to delay rulemaking further. Even if the chromate in pigments is not carcinogenic, an argument that, tellingly, OSHA itself does not offer, requiring concrete findings on this distinction would effectively hold hostage the thousands of workers who are exposed to non-pigment hexavalent chromium. We will not sanction that result when, "even though OSHA acknowledges that this issue was flagged in the prior litigation over four years ago, OSHA does not

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claim to have done anything to resolve it." [Public Citizen Reply Br. at 24.]⁶

Finally, while we are sympathetic to OSHA's claim that a thorough feasibility analysis is both highly important and quite difficult, we cannot allow an imperfect analysis to justify indefinite delay. OSHA first announced a rulemaking nine years ago, and by its own account it has been examining the issue through NIOSH for at least four years. OSHA does not explain why this particular feasibility determination requires an extreme length of time, and it does not offer even a projection of how much time it might ultimately require. In such a situation, our traditional agency deference begins to resemble judicial abdication, and we conclude that scientific uncertainties and technical complexities, while no doubt considerable, can no longer justify delay. Judges on this court are not paid to decide the easy cases, and neither is OSHA. Difficult challenges go with the territory, and courts and agencies regularly surmount them. The notice-and-comment process should itself provide a fertile forum for gathering information on feasibility.

C. Do Competing Priorities Justify OSHA's Delay?

Although OSHA insists that since *Oil Workers* it has

continued to work on health-risk and feasibility issues relating to an eventual hexavalent chromium rulemaking, it admits that the project has not been a priority. In *Oil Workers*, of course, we noted "the quintessential discretion of the Secretary of Labor to allocate OSHA's resources and set its priorities," 145 F.3d at 123, and OSHA contends that it simply exercised its discretion to concentrate its resources elsewhere. For example, in early 1997, it promulgated a final standard regulating occupational exposure to methylene chloride, a widely-used chemical it found to be carcinogenic. See 62 Fed. Reg. 1494 (Jan. 10, 1997). Shortly thereafter, in early 1998, it issued a final rule on respirators, see 63 Fed. Reg. 1152 (Jan. 8, 1998), and later that year it issued a final rule requiring adequate training for operators of powered industrial trucks. See 63

6. Presumably, the difference in pigments can be addressed in the rulemaking itself.

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Fed. Reg. 66238 (Dec. 1, 1998). During that period, OSHA also completed a revision to its safety standards for longshoring and marine terminals. See 62 Fed. Reg. 40142 (July 25, 1997).

In 1999 and 2000, OSHA submits that it "focused most of its rulemaking resources on issuing an ergonomics standard before the end of the former Administration's term." [OSHA Br. at 10.] Because the Clinton Administration placed such great emphasis on quickly finalizing those standards, the process was remarkably compressed; OSHA issued a proposed rule on November 23, 1999, and a final rule less than a year later, on November 14, 2000, "a timetable that required tremendous agency resources." [Id.] It explains that in addition to the ergonomics standard, the former Administration gave high priority to completing a steel erection standard, see 66 Fed. Reg. 5196 (Jan. 18, 2001), and a recordkeeping rule designed to improve the quality of information about the causes of occupational injuries and illnesses. See 66 Fed. Reg. 5916 (Jan. 19, 2001).

OSHA represents that the delays became worse when the Bush administration took office, for it instructed the agencies that any new regulatory actions must be reviewed and approved by a department or agency head appointed after January 20, 2001. See Andrew H. Card, Jr., Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, (Jan. 20, 2001) available at http://www.whitehouse.gov/omb/inforeg/regreview_plan.pdf. As OSHA was not headed by a presidential nominee until August 2001, it alleges that "it could not begin in earnest to set its new regulatory priorities" until that time, [OSHA Br. at 14], and that even then, unforeseen incidents such as the September 11 attacks and anthrax mailings demanded that it "immediately divert[] significant resources to help ensure that the rescue and cleanup

efforts did not result in further loss of life." [Id. at 15 (citation omitted).]

OSHA lastly represents that, while these competing priorities have admittedly delayed the hexavalent chromium rulemaking, it is now pressing forward on that project. It published a request for information ("RFI") in the Federal

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Register in August 2002 posing specific questions that would be relevant to a rulemaking and inviting the public to submit any other evidence it feels might be helpful to OSHA. Following the RFI, it pledges that it will "evaluate all of the information available on Cr VI . . . and decide how to proceed." [Id. at 16.]

We do not lightly discount these admittedly significant competing priorities, especially those relating to the events of September 11, but when we view the rulemaking's progress over the past nine years, we reach the ineluctable conclusion that hexavalent chromium has progressively fallen by the wayside. This is unacceptable, for as the D.C. Circuit stated, "[w]here the Secretary deems a problem significant enough to warrant initiation of the standard setting process, the Act requires that he have a plan to shepherd through the development of the standard-- that he take pains, regardless of the press of other priorities, to ensure that the standard is not inadvertently lost in the process." *National Congress of Hispanic American Citizens v. Marshall*, 626 F.2d 882, 890-91 (D.C. Cir. 1979).

OSHA chose in 1993 to begin the rulemaking process, announcing its "agree[ment] that there is clear evidence that exposure to Cr VI at the current PEL . . . can result in an excess risk of lung cancer," and its "anticipation that Notice of Proposed Rulemaking [would] be published in the Federal Register not later than March 1995." (Lurie Dec. P9.) However, 1995 came and went without any sign of formal action, only for OSHA in 1996 again to declare that "[t]here appears to be no dispute that the current PEL is too high" and "must be greatly reduced." (Id.) In fact, in 1997 OSHA declared to this Court its intention to promulgate a proposed rule by September 1999. *Oil Workers*, 145 F.3d at 123. That deadline, like the others, passed without action. Now, nine years after the rulemaking process began, we find ourselves without even a hint as to when OSHA might issue a proposed rule, much less a final rule. Indeed, a reasonable person would likely conclude that we are further from a rule today than we were five years ago, a notion that would certainly have alarmed the *Oil Workers* panel. We find apropos the D.C. Circuit's words in *Brock* :

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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 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.

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

We conclude that now is such a time. While competing policy priorities might explain slow progress, they cannot justify indefinite delay and recalcitrance in the face of an admittedly grave risk to public health. Although the agency has commenced a rulemaking proceeding, we will nonetheless grant the petition to review the inaction of the United States Department of Labor as a predicate for our necessary discussion of the remedy.

D. What is the Proper Remedy?

Public Citizen requests that we direct OSHA to issue a proposed rule within 90 days, and to submit a schedule for finalizing the rule within 12 months thereafter. [Public Citizen Br. at 53.] Neither OSHA's brief nor its recent announcement contains a proposed timetable, but it insists that Public Citizen's proposed pace of rulemaking "is unrealistic in light of the procedural, consultative, and analytical duties that constrain OSHA rulemaking and the historical time frames required for OSHA to develop a toxic chemical standard." [OSHA Br. at 42.] For example, the Regulatory Flexibility Act, 5 U.S.C. SS 601-12, requires it to prepare a regulatory flexibility analysis if the rule will have a "significant economic impact upon a substantial number of small entities," a mandate this rulemaking is sure to trigger. Also, the Small Business Regulatory Enforcement

Fairness Act, 5 U.S.C. S 609(b), requires it to convene a review panel to address the rule's potential impacts on small entities. Finally, Executive Order 12866 requires that OSHA submit its proposal, including a detailed economic analysis, to the Office of Management and Budget, which is to review it within 90 days.

While we are certain that the time for action has arrived, we are cognizant of our lack of expertise in setting permissible exposure limits, and we recognize the damage that an ill-considered limit might cause. At oral argument, we presented the parties with a somewhat novel possibility: that they would submit to a course of mediation, conducted by a senior judge of this Court, in which they might work together toward a realistic timetable that we would then

enforce. Both sides stated their willingness to engage in this process, and we think it the most promising way to develop a reasonable and workable schedule. We are, however, highly aware that this presents yet another opportunity for potentially indefinite bargaining and delay. We will therefore submit the matter to mediation for a period not to exceed sixty days, after which time, if the parties have not reached an accord, the panel will promulgate a schedule it deems appropriate. We are pleased that our distinguished colleague, Judge Walter K. Stapleton, has agreed to undertake the mediation.

III. Conclusion

For the foregoing reasons, we hold that OSHA's delay in promulgating a lower permissible exposure limit for hexavalent chromium has exceeded the bounds of reasonableness. We therefore grant Public Citizen's petition to compel OSHA to proceed expeditiously with its hexavalent chromium rulemaking. Deferring our specific remedial order, we direct that the parties appear before Judge Walter K. Stapleton for mediation for a period not to exceed sixty days, following which, if the parties have not agreed on a mutually satisfactory timetable, we will order one of our own.

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A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

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