Attachment 3

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 02-1611

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

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

Neither OSHA nor its supporting intervenors contest that there is powerful evidence that hexavalent chromium is carcinogenic at exposure levels much lower than OSHA's existing permissible exposure limit ("PEL"). Indeed, OSHA identifies no basis for doubting its prior position, announced in 1996, that the PEL poses a significant risk to workers and that "[t]here appears to be no dispute that the current PEL is too high." Lurie Dec., Exh. 4-F. Nor do OSHA and the intervenors offer evidence that a reduction of the existing 100 $\mu g/m^3$ PEL is not feasible.

Also uncontested is the agency's history of delay over the nine years since petitioners sought a new PEL and the eight years since the agency committed to begin a rulemaking. OSHA acknowledges that it has missed every timetable it set for the hexavalent chromium rulemaking — including the one in its brief to this Court four-and-a-half years ago, in which it repeatedly told the Court it was "committed" to a rulemaking and stated that it had set September 1999 as the date for a proposed rule. *See* Sec. Labor's Answer, No. 97-3552, at 21, 23, 24, 10.

Further, OSHA acknowledges that it has had the published results of the Johns Hopkins epidemiological study (which it told this Court it was waiting for in 1998) for two years, and it does not deny that it had access to the study's results half a decade before that. OSHA also does not deny that the "higher priority"

rulemakings it told this Court were delaying the hexavalent chromium rulemaking in 1998 have all either been completed, abandoned or dropped as priority items. And OSHA pointedly refrains from arguing that any of the current "priorities" in its regulatory agenda is more significant from the standpoint of worker health or safety than the hexavalent chromium rulemaking. Indeed, OSHA says its current priorities were designated as such not because they are more important than hexavalent chromium, but simply because it could complete them quickly, and they are "therefore not a fair indicator of the agency's priorities." Sec. Labor Br. 32. But OSHA identifies no *other* rulemakings that are more important than hexavalent chromium, either.

Despite all this, OSHA offers no assurance of prompt action on hexavalent chromium. Far from it. Although it identifies no evidence that has led it to reconsider its repeatedly stated view that the existing PEL is far too high (indeed, the new study only strengthens the evidence), OSHA now repudiates what it told this Court four-and-a-half years ago: It is no longer committed to a rulemaking, and it refuses even to hint at when it may take some definite action. OSHA says only that it plans to go back *before* square one with a "request for information" in August of this year. Thus, after nine years, OSHA has devised a plan that falls short even of the "advanced notice of proposed rulemaking" that the court in

Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1155 (D.C. Cir. 1983), condemned as the "least responsive course short of inaction."

OSHA's assertion that this is an acceptable course that this Court is powerless to alter flies in the face of precedent. It rests on a fundamentally misguided view of the agency's discretion under the Occupational Safety and Health Act and the Court's power under the APA to combat unreasonable delay in agency action. While the agency's authority to set priorities and direct its activities is undoubtedly broad, it is not unlimited. The OSH Act imposes a duty on OSHA to act with reasonable speed to eliminate significant risks to workers, relying not on scientific certainty but on the best *available* scientific evidence. Both the reasonableness of the agency's pace and its claimed "priorities" are judicially reviewable, and when OSHA has dawdled in addressing a recognized, substantial occupational health issue threatening one million American workers, the courts may step in to require action. Such intervention is well warranted here.

I.
THIS COURT SHOULD REACH THE MERITS.

A. The Court Has Subject-Matter Jurisdiction.

OSHA agrees that this Court has subject matter jurisdiction. Intervenor the Chrome Coalition, however, without citing any authority, contends that 29 U.S.C. § 655(f) confers subject matter jurisdiction only on the court of appeals for the circuit in which the petitioner "resides or has his principal place of business."

Granted, petitioner PACE International Union's principal place of business is Nashville, Tennessee (though it has locals and members who live and work in this Circuit), and petitioner Public Citizen Health Research Group is in Washington, D.C. But that does not deprive this Court of jurisdiction, because § 655(f)'s provision for review where the petitioner resides determines venue, not jurisdiction. Since the Supreme Court's decision in *Panhandle Eastern Pipe Line Co. v. Federal Power Comm'n*, 324 U.S. 635, 638-39 (1945), the courts have regularly read circuit-selection clauses in statutes providing for review of agency action in the courts of appeals as venue provisions. *See, e.g., Federal Power Comm'n v. Texaco, Inc.*, 377 U.S. 33 (1964); *National Wildlife Federation v. Browner*, 237 F.3d 670, 672-76 (D.C. Cir. 2001) (citing cases); *New York v. EPA*, 133 F.3d 987, 990 (7th Cir. 1998). The same principle applies to § 655(f). *See United Steelworkers of America v. Marshall*, 592 F.2d 693, 697 (3d Cir. 1979) (discussing venue under § 655(f)); *Industrial Union Dept. v. Bingham*, 570 F.2d 965, 970, n.9 (D.C. Cir. 1977).

Venue, unlike subject matter jurisdiction, "relates to the convenience of the parties," not judicial power. *Panhandle Eastern*, 324 U.S. at 639. Hence, "it may be waived by any party, including the government." *Id.*; *see also National Wildlife Federation*, 237 F.3d at 675. The government agrees that this Court is a proper forum. Sec. Labor Br. 1. Even assuming that intervenors may object to venue

when the government has not, the Chrome Coalition has *not* objected to *venue* nor filed a motion for transfer of venue before merits briefing, the appropriate way to contest venue. *See National Wildlife Federation*, 237 F.3d at 674 ("the standard remedy for improper venue is to transfer the case to the proper court"). Having raised only a meritless jurisdiction argument and asked only for dismissal, the Coalition has waived any venue objection. *Id.* at 675-76.

Moreover, the Coalition's assertion that the petitioners are "forum shopping" is absurd. Having lost in this Court once before (in a proceeding where no one, including the Coaltion, objected to venue), petitioners bent on forum shopping would have *avoided* returning. Petitioners assumed the other parties — and the Court — would share their view that if circumstances now justify the relief they seek, this Court should be the one to say so. If, however, the Court decides the government's acceptance of venue is not dispositive and the Chrome Coalition's jurisdictional argument may be treated as a venue objection, the proper remedy is transfer to the Sixth Circuit, where PACE has its headquarters.[1]

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[1] This would also be the proper course if § 655(f)'s venue clause were jurisdictional. Under 28 U.S.C. § 1631, "[w]henever ... a petition for review of administrative action, is ... filed with ... a court and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action ... to any other such court in which the action ... could have been brought ...."

B. PACE, Whose Standing is Uncontested, Is a Party.

Before the government and the intervenors filed their briefs, petitioner PACE International Union filed a notice withdrawing its petition for review, and then filed a notice withdrawing its withdrawal. The government and intervenors argued that PACE's could not reenter the proceedings. The motions panel, however, ruled that "[t]he notice of petitioners to withdraw their prior withdrawal (which, for the purpose of these motion proceedings, we treat as a notice of reinstatement of the petitioners) is GRANTED, subject to the decision of the merits panel as to the effect of these procedural matters." Because *no one* contests that PACE has members exposed to hexavalent chromium in the workplace and has standing to challenge the agency's delay in issuing a PEL, the government concedes that "there do not appear to be any further procedural or standing issues for the merits panel to resolve." Sec. Labor Br. 3, n.1. Because PACE's standing is not in issue, nothing about "the effect of these procedural matters" remains to be decided.

The intervenors, however, persist in arguing that PACE is not a party, but they offer no real argument that the motions panel's decision was wrong. The only authority they cite is *Noland v. Flohr Metal Fabricators, Inc.*, 104 F.R.D. 83 (D. Alaska 1984), which addresses the inapposite issue whether a plaintiff may rescind a voluntary dismissal under Federal Rule of Civil Procedure 41.

Before the motions panel, the intervenors made a less strained analogy — albeit one fatal to their position. Citing *Barrow v. Falck*, 977 F.2d 1100 (7th Cir. 1992), they argued that PACE's initial withdrawal of its petition for review was comparable to withdrawal of a notice of appeal. *Barrow*, however, held that a party *may* reinstate a withdrawn appeal if the notice of reinstatement would be timely if treated as a new notice of appeal. *Id.* at 1103 ("A motion to reinstate should be treated as a fresh notice of appeal, effective if time remains under Rule 4 and ineffective otherwise."). That principle supports PACE's reentry because its notice reinstating its petition would be timely if treated as a new petition — since there *is* no time limit on petitions to review agency inaction. The intervenors offer no coherent argument that the motions panel erred in so concluding, and no such argument exists.[2]

C. The Petition Is Not Barred by Res Judicata.

Ironically, immediately after accusing petitioners of "forum shopping," the Chrome Coalition contends that this Court's decision in *Oil, Chemical & Atomic Workers Union v. OSHA* (*Oil Workers*), 145 F.3d 120 (3d Cir. 1998), bars petitioners' claims by res judicata. The argument is frivolous. Unless the Court in

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[2] Because PACE, with uncontested standing, is a party, Public Citizen Health Research Group's standing is irrelevant. *Star Enterprise v. EPA*, 235 F.3d 139, 146 n. 11 (3d Cir. 2000).

Oil Workers decided that delay in issuing a hexavalent chromium rule could *never* be unreasonable — which it did not — it is apparent that a decision upholding the reasonableness of four-and-a-half years of delay (with an end in sight in the form of a promised notice of proposed rulemaking) does not bar a later claim that *nine* years of delay with *no* end in sight is unreasonable.

II.
OSHA HAS A JUDICIALLY ENFORCEABLE DUTY TO ACT PROMPTLY TO ELIMINATE SIGNIFICANT WORKPLACE HAZARDS.

OSHA and the intervenors seek to circumscribe narrowly or eliminate altogether the courts' power to review agency inaction in promulgating standards under the OSH Act. OSHA stresses the broad discretion the Act grants the Secretary to set priorities, and asserts that ordering an agency to issue a notice of proposed rulemaking (as opposed to ordering the completion of rulemaking following issuance of a notice) is incompatible with that discretion. Intervenor CPMA goes further, asserting that because the Act states that the Secretary "may" promulgate standards (29 U.S.C. § 655(b)), the Secretary always has unfettered discretion whether or not to issue a standard. According to CPMA, her duty to issue standards providing maximum feasible protection for workers against significant health risks kicks in only if she decides, in her sole discretion, to issue a standard in the first place. Thus, CPMA asserts, a court may *never* provide relief against delay in issuing a standard.

Both OSHA's argument and CPMA's exaggerated version dramatically overstate the scope of OSHA discretion and undermine the power of the courts to provide relief against unwarrantedly delayed administrative action. If CPMA were correct, the many decisions in this Circuit and others that ordered OSHA to take rulemaking steps would all have been wrongly decided. *See, e.g., In re International Chemical Workers Union*, 958 F.2d 1144 (D.C. Cir. 1992); *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987); *United Steelworkers of America v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1987); *Farmworker Justice Fund v. Brock*, 811 F.2d 613 (D.C. Cir. 1987), *vacated as moot*, 817 F.2d 890 (D.C. Cir. 1987); *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986); *United Steelworkers of America v. Auchter*, 763 F.2d 728 (3d Cir. 1985); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983). This Court's *Oil Workers* decision would also read radically differently if CPMA were correct: Instead of holding the agency's delay reviewable and examining the record to determine whether OSHA had unreasonably delayed, *see* 145 F.3d at 123-24, the Court would simply have held the delay claim not cognizable.

Moreover, the suggestion that delay in issuing a proposed health standard is not judicially remediable reflects a nonsensical all-or-nothing view of the Act, under which the agency *must* reduce significant health risks to the maximum

feasible extent *once it decides to act*, but otherwise may freely ignore or delay indefinitely in addressing such risks. That is not the law. As the Supreme Court held in *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 641 (1980), the Act is "intended to *require* the elimination, as far as feasible, of significant risks of harm" (emphasis added). This Court and others have similarly stressed that the Act imposes a *duty* on the agency to regulate significant risks to health and safety. As this Court put it in *United Steelworkers v. Pendergrass*, the Act "*directed* the Secretary of Labor to promulgate occupational safety and health standards to further the purpose of the OSH Act — that is, 'to assure so far as possible every working man and woman in the Nation safe and healthful working conditions.'" 819 F.2d at 1264 (emphasis added) (quoting 29 U.S.C. § 651(b)).

Similarly, the D.C. Circuit recognized in *Public Citizen HRG v. Tyson* that if a standard "would further reduce a significant health risk and is feasible, then the OSH Act *compels* the agency to adopt it .... OSHA '*shall* set the standard which most adequately assures, to the extent feasible, on the basis of best available evidence, that no employee will suffer material impairment of health.'" 796 F.2d at 1505 (quoting 29 U.S.C. § 655(b)(5); emphasis by court). *See also AFL-CIO v. OSHA*, 965 F.2d 962, 986 (11th Cir. 1992) ("The OSH Act *mandates* that OSHA promulgate the standards that 'most adequately' assure that workers will not be

exposed to significant risks of material health impairment 'to the extent feasible' for the affected industries" (emphasis added)); *Building & Constr. Trades Dept., AFL-CIO v. Brock*, 838 F.2d 1258, 1272 (D.C. Cir. 1988) ("Where a significant health risk exists, the Act *requires* that the agency adopt 'the most stringent standard to protect against material health impairment, bounded only by technological and economic feasibility'" (emphasis added; citation omitted)).

CPMA's suggestion that regulation is purely optional is based on a misreading of the word "may" in 29 U.S.C. § 655(b). The permissive "may" evidently refers to the fact that some of the rulemaking procedures outlined in that subsection (in particular, the use of an advisory committee and the intermediate deadlines) are nonmandatory. It does not mean the Secretary has no duty to promulgate standards to combat significant risks to workers.

Moreover, although the Secretary has discretion to establish priorities to guide the agency in exercising its duty to eliminate significant health risks, that discretion is not unbounded: The statute commands that the Secretary's priorities "*shall*" reflect "due regard to the urgency of the need for mandatory safety and health standards for particular ... work environments." 29 U.S.C. § 655(g) (emphasis added). As this Court has held, the agency's priorities under § 655(g) are judicially reviewable, and the agency thus can be compelled to take action without delay to address significant risks. *United Steelworkers v. Pendergrass*,

819 F.2d at 1267; *United Steelworkers v. Auchter*, 763 F.2d at 738. A decision to defer action in the face of a significant risk is sustainable only if OSHA takes "reasonably prompt steps to fashion ... protection" for workers. *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1310 (D.C. Cir. 1980).

Even the cases the government cites demonstrate that an agency's freedom to establish priorities has its limits. For example, in *American Horse Protection Association v. Lyng*, 812 F.2d 1 (D.C. Cir. 1987), the court ordered the agency to either issue a notice of proposed rulemaking to replace an inadequate standard (a standard protecting show horses) or provide an explanation why not — even though the statute simply "authorize[d]" the agency to issue regulations as it "deem[ed] fit." 15 U.S.C. § 1828.[3]

Similarly, the government cites *National Congress of Hispanic American Citizens v. Usery*, 554 F.2d 1196 (D.C. Cir. 1977), for the proposition that the OSH Act affords the agency "traditionally broad discretion" to set priorities. Sec. Labor

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[3] The government incorrectly says *Lyng* holds that its actions must be tested under the "arbitrary and capricious" standard. In *Lyng*, the agency responded to a petition for rulemaking by issuing a final decision *not* to regulate, and the court held such a decision reviewable under the "arbitrary and capricious" standard. Here, by contrast, OSHA answered a petition for rulemaking not with a denial, but with a *decision to initiate rulemaking*. Whether that promised rulemaking has been unreasonably delayed is determined not under the "arbitrary and capricious" standard, but under the multi-factor *Oil Workers* test. 145 F.3d at 123.

Br. 34. That is true as far as it goes: In *Usery*, the court did defer to the agency's priority-setting discretion in holding that a delay of less than five years in finalizing field sanitation regulations for migrant workers was not unlawful.[4] But two years later, when the standards were still not complete and the Secretary had refused to commit to a timetable for finalizing them, the case again reached the D.C. Circuit, which admonished:

> Where 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.*
>
> It is not enough for the Secretary merely to state that the standard will not be issued over the next 18 months. If other priorities preclude promulgation of a field sanitation standard within that frame, then the Secretary *must* provide a timetable at least for the standard in question which covers a larger period.

National Congress of Hispanic American Citizens v. Marshall, 626 F.2d 882, 890-91 (D.C. Cir. 1979) (emphasis added).[5]

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[4] The specific issue decided was that the regulatory timetables of 29 U.S.C. § 655(b) are not mandatory. *See* 554 F.2d at 1199-1200.

[5] In this case, of course, the agency, despite having "deem[ed] [the] problem significant enough to warrant initiation of the standard setting process," now has no plans to "shepherd" the standard through the process, nor any "timetable."

Thereafter, the Secretary did commit to a timetable, but then reneged and withdrew the standard. By then the D.C. Circuit had had enough and ordered the agency to promulgate the standard within 30 days, finding unreasonable any further delay in the face of a recognized and substantial health issue (a decision that was vacated as moot when the Secretary complied). *Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d at 631-33. Thus, while *Usery* establishes that the Act does not displace agency discretion to set priorities, the broader lesson is that courts must step in when discretion is invoked to cover for dilatory action in the face of a recognized threat to worker health — even when the threat (in *Usery*, denial of bathroom facilities) is much less severe than the one here (exposure to carcinogens).

Given that fundamental principle, the government's assertion that the courts may only intervene to combat delay after a notice of proposed rulemaking has been issued, and that compelling issuance of a notice of proposed rulemaking is inherently incompatible with agency discretion, is without legal foundation. Thus, courts have ordered issuance of notices of proposed rulemaking — not only, as the government acknowledges, in *Public Citizen HRG v. Auchter*, 702 F.2d 1150, but also in *United Steelworkers v. Pendergrass*, 812 F.2d 1263.

The government's attempts to distinguish those cases are unconvincing at best. The government asserts that in *Public Citizen HRG v. Auchter* the agency

conceded it had no competing priorities that a rulemaking would displace. But here, too, one can search the government's brief in vain for identification of any "priorities" it considers more important than hexavalent chromium. As for *Pendergrass*, the government says the order there was based on this Court's determination that the delay in issuing a notice of proposed rulemaking violated the mandate in *United Steelworkers v. Auchter*, 763 F.2d 728. That is so, but the cases together still establish the courts' power to combat agency inaction by requiring issuance of a proposed rule. If this Court lacked such power, its mandate in *Steelworkers v. Auchter* could not have compelled the agency to issue a notice.

Moreover, the contention that there is a fundamental distinction between ordering an agency to *initiate* rulemaking and ordering it to *complete* rulemaking is contradicted by the government's own theory of agency discretion. As the government argues, an agency retains the discretion not to regulate even after issuing a proposed rule if, after considering the record of the notice-and-comment process, it determines that the rule is not warranted. A notice of proposed rulemaking, as the government insists, is a preliminary, not final, determination of the need for regulation. Nonetheless, the government apparently concedes the power of the courts, established in a host of cases, to remedy unreasonable delay in rulemaking after such a preliminary determination. *See* Sec. Labor Br. 37-41. If that is so, the same principle applies here, where the agency already decided to

initiate a rulemaking proceeding in its formal response to petitioners' rulemaking petition. Preliminary though that decision was, it opened a process that the agency may be compelled to complete without unreasonable delay.

The logic of the government's position would, taken seriously, completely eviscerate the courts' power to compel agency action unreasonably delayed. The government asserts that it cannot be compelled to proceed because it "has not made a 'finding' of significant risk" for hexavalent chromium. Sec. Labor Br. 34. Simultaneously, the government insists that it only makes the "threshold finding of significant risk when it issues a *final* rule for a toxic chemical." *Id.* If such a formal "finding" is a necessary predicate for compelling the agency to take action, then the agency could *never* be compelled to take action until it had actually issued a final rule — rendering completely ineffective the APA's provisions for compelling agency action unreasonably delayed.

III.
THE AGENCY HAS FAILED TO EXCUSE ITS INACTION.

No one contests that, in response to petitioners' 1993 rulemaking petition, OSHA acknowledged that "there is clear evidence that exposure to CrVI at the current PEL of 100 $\mu g/m^3$ can result in an excess risk of lung cancer and other CrVI-related illnesses." Lurie Dec., Exh. 3. Also uncontested is that the only major piece of new evidence — the Johns Hopkins study — added to the weight of evidence by analyzing the most extensive set of occupational exposure data ever

studied and showing a statistically significant dose-response relationship between hexavalent chromium and lung cancer after controlling for smoking. Critically, neither OSHA nor the intervenors cite any recent evidence pointing the other way.[6] Nonetheless, in the face of this uncontradicted and growing body of evidence — including the very study industry implored the government to wait for before issuing a new rule — the agency and intervenors attempt to defend OSHA's continued inaction on a number of grounds, all unpersuasive.

A. The Agency's Generic Excuses for Delay Are Inadequate.

OSHA defends its failure to reach the proposed rule stage nine years into the process by asserting that the norm is that it takes OSHA "10 years to develop and promulgate a health or safety standard." Sec. Labor Br. 20. Even assuming the accuracy and legitimacy of this estimate, there is no possibility that OSHA, left to its own devices, would come close to completing this rulemaking within ten years of the 1993 rulemaking petition. Moreover, the suggestion that ten years is an *acceptable* norm is not supported by the source OSHA cites. The ten-year figure

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[6] The only recent piece of independent scholarship submitted by either intervenor (the De Flora article attached by CPMA to the Robinson Declaration) acknowledges that "epidemiological studies carried out in certain occupational settings consistently show that (unidentified) chromium(VI) compounds can be carcinogenic for the lower respiratory tract," Robinson Dec., Exh. 4, at 6, and that the industries where carcinogenicity has been shown include chromate pigment production. *Id.*

comes from GAO testimony that, in turn, cited a June 6, 2000, report of the National Advisory Committee on Occupational Safety and Health (NACOSH) on *OSHA's Standards Development Process*.[7] The NACOSH report characterized the average ten-year process for promulgating standards as "excessive," "inefficient and ineffective to the detriment of a healthy workplace" and said that the result of OSHA's delays was that "hundreds of workers continued to be killed or seriously injured annually." OSHA's position thus boils down to the proposition that if it engages in a *pattern* of delay — a pattern regularly condemned by the courts — no single rulemaking that conforms to the pattern can be called unreasonably delayed. OSHA's poor record of completing rulemakings in a timely manner is hardly a persuasive response to the observation that "nine years *should* be enough time for any agency to decide almost any issue." *Nader v. FCC*, 520 F.2d 182, 206 (D.C. Cir. 1975) (emphasis added).

OSHA also invokes past priorities that have been achieved or discarded and budget cuts that have long since been rectified, but neither explains the current and ongoing delay in its consideration of hexavalent chromium. Accordingly, OSHA says it has been diverted by responsibilities in the wake of the terrorist attacks on our country. OSHA's important role in responding to that crisis, however, fails to

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[7] Http://www.osha.gov/dop/nacosh/nreport.html.

explain delay in promulgation of health standards, since health standards personnel have not played a major role in responding to the events of September 11, 2001. Assistant Secretary for Occupational Safety and Health John Henshaw recently told a Senate Subcommittee that health and safety standards personnel spent fully 100% of their time in 2001 on standards, and have spent the "vast majority" of their time on standards in 2002, except for a little time spent on "guidance/hazard information documents."[8] The response to terrorism thus cannot account for OSHA's past or ongoing inattention to hexavalent chromium.

The agency further asserts that its personnel *have* been working on hexavalent chromium when they had a chance, and it attaches to its brief two declarations purporting to so demonstrate. The declarations, however, reveal that agency personnel have been doing very little: The work has been farmed out to contractors and NIOSH under arrangements established *over four years ago*, in 1998. Nowhere does the government explain why those four years of effort have not put it in position to issue a proposed rule.

B. The Data Are Adequate for a Proposed Rule.

As explained in our opening brief, the epidemiological data as of the mid-1990s were sufficient for EPA, ATSDR, NIOSH, the National Toxicology

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[8] Mr. Henshaw's letter is submitted as an addendum to this brief.

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. Nonetheless, OSHA, at industry's urging, decided its rulemaking should consider the Johns Hopkins study because of its superior exposure data and ability to control for smoking. The study was published two years ago, though OSHA received the results five years earlier.

Although the Hopkins study reinforced the previous studies that supported OSHA's decision to commence rulemaking and its contractor's risk estimates, OSHA now seeks to use the study as an excuse for more delay. OSHA says it "has not yet completed its evaluation of the Hopkins study to determine its implications for a Cr VI rulemaking" and that "[t]he conclusions reached by an epidemiological study can be much better assessed when experts in the field have had the opportunity to review and criticize it." Sec. Labor Br. 26, 27. These assertions do not wash. OSHA has had seven years to consider the results of the study, and fully two years to "review" the final publication. "Experts in the field" have already had the "opportunity to review and criticize it": It was published in a peer-reviewed journal, and in the two years since its publication, no response or letter criticizing it has been published. Notice-and-comment rulemaking will provide a further

opportunity for review if any is needed.[9] There is a limit to how long anyone needs to analyze a single study. OSHA has passed it.

OSHA further asserts that "[t]he authors of the study acknowledge certain limitations" and that it "does not answer *all* of the technically complex questions ... that OSHA would need to resolve in developing a Cr VI rule." Sec. Labor Br. 26, 27 (emphasis added). That is undoubtedly true. But every epidemiological

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[9] The Chrome Coalition has submitted a preliminary critique of the Hopkins study by a paid industry consultant. Although the consultant offers a number of criticisms (many of them inherent in the nature of an epidemiological study examining the effects of occupational exposures in the real world over many years), he does not contest that the study has the most comprehensive set of occupational exposure data for hexavalent chromium ever assembled. Nor does he deny that it shows a statistically significant relationship between hexavalent chromium exposure and cancer even when smoking is controlled for — a relationship that is not dependent on the study's choice of a comparison population for background cancer rates. Moreover, the consultant identifies no other study that reaches conclusions contrary to that of the Johns Hopkins study or its predecessors. And some of his major arguments are scientifically unsound. For example, his assertion that Baltimore rather than Maryland cancer death rates should be used for comparison overlooks that local cancer death rates are considered unreliable for such purposes because the number of such deaths will be relatively small. *See* Infante & Schneiderman, *Formaldehyde, lung cancer and bronchitis*, The Lancet, Feb. 22, 1986, at 436-37. And his claim that the study's tables of observed/expected ratios for cancer deaths do not control for smoking, while correct, neglects that measures of effect as high as those found here (2.24 and 1.57 for the top two exposure quartiles) generally cannot be attributed to "confounders" such as smoking. *See* Siemiatycki, *et al.*, *Degree of Confounding Bias Related to Smoking, Ethnic Group, and Socioeconomic Status in Estimates of the Association Between Occupation and Cancer*, 30 J. Occupational Med. 617 (1988).

study has "limitations" that responsible authors acknowledge. And no study answers *all* questions on any subject. The OSH Act does not require such scientific perfection.

Indeed, the Act does not even *permit* the agency to forgo regulation just because the scientific evidence does not answer all questions. It expressly requires regulation "on the basis of the best *available* evidence," 29 U.S.C. § 655(b)(5) (emphasis added), and courts have warned the agency not to wait for "the Godot of scientific certainty." *United Steelworkers v. Marshall*, 647 F.2d at 1266. Neither the government nor the intervenors have pointed to any better *available* evidence than the Johns Hopkins study, the earlier Crump risk assessment, and the epidemiological studies on which that assessment relied. We are aware of no major ongoing studies, and OSHA and the intervenors have pointed to none. Nor does the government contest that the available evidence is at least as extensive as that on which it has regulated other occupational carcinogens. Indeed, OSHA has regulated carcinogens based on human and animal data much less extensive than the human epidemiological evidence available here. *E.g., Public Citizen HRG v. Tyson*, 796 F.2d at 1486-1503; *International Union v. Pendergrass*, 878 F.2d 383 (D.C. Cir. 1989); *ASARCO, Inc. v. OSHA*, 746 F.2d 483, 494-95 (9th Cir.1984).

C. Any Claimed "Uncertainty" over the Carcinogenicity of Chromium Pigments Cannot Justify OSHA's Delay.

The government further notes that the Johns Hopkins study "does not appear to address the dispute in the earlier litigation over whether all hexavalent chromium compounds present the same degree of risk." Sec. Labor Br. 26-27. The "dispute" the government refers to is the principal topic of the brief of intervenor CPMA, which argues at length that the lead chromate used in pigments is not as carcinogenic as other hexavalent chromium compounds (though even CPMA does not directly assert that chromium pigments are not carcinogenic).[10]

Of course, the Johns Hopkins study does not resolve this issue — and OSHA never expected it to, because the population studied did not work in the pigment industry. But regardless of whether the Johns Hopkins study casts any new light on it, this "dispute" cannot justify OSHA's delay on hexavalent chromium. First, the "dispute" does not call into question the demonstrated carcinogenicity of other

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[10] CPMA also contends that chromium exposures in the pigment industry are held down by the lead standard, which limits airborne lead exposures to 50 $\mu g/m^3$. When lead chromate is the only chromium compound in use, that standard, *if complied with*, also effectively limits chromium exposures to some fraction of the current standard. But this does not mean that the current *chromium* standard is adequate, only that *some* workers in *some* plants would be exposed at a lower level *if* those plants complied with the lead standard. Moreover, CPMA's argument suggests that the pigments industry would not be harmed by a significantly lower standard, as the industry itself claims it is feasible to reduce exposures to a fraction of the existing PEL.

hexavalent chromium compounds that are widely used in industry. The protection of workers exposed to those compounds cannot be held hostage to the purported "dispute" over chromium pigments. Second, OSHA itself does not claim to credit CPMA's position that chromium pigments pose a minimal cancer threat, and does not assert that its inaction results from any uncertainty over the issue. Third, even though OSHA acknowledges that this issue was flagged in the prior litigation over four years ago, OSHA does not claim to have done *anything* to resolve it.

This omission is particularly glaring because CPMA's evidence is hardly brand-new. CPMA relies primarily on studies of European pigment workers published about two decades ago.[11] Other studies, including the principal American study of chrome pigment workers, have shown elevated cancer risks for workers whose primary exposure was to lead chromate. *See* ATSDR, *Toxicological Profile for Chromium* 62-63 (2000).[12] NIOSH, with this information in hand, long ago concluded that all hexavalent chromium compounds, including lead chromate, are carcinogens.[13] HHS's National Toxicology Program has

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[11] Notably, even those studies showed that pigment workers who were exposed to both zinc chromate and lead chromate had elevated risks of lung cancer; they raised doubts only as to workers exposed solely to lead chromate.

[12] *See* http://www.atsdr.cdc.gov/toxprofiles/tp7.pdf.

[13] *See* NIOSH, *Pocket Guide to Chemical Hazards,* Appendix C, http://www.cdc.gov/niosh/ipcs/nengapdx.html#c.

similarly reviewed the evidence and classified lead chromate as a carcinogen since 1980.[14] And the IARC concluded in 1990 that there is "*sufficient evidence* in humans for the carcinogenicity of chromium[VI] compounds ... in ... chromate pigment production" and "*sufficient evidence* in experimental animals for the carcinogenicity of ... lead chromates."[15] CPMA points to no new epidemiological data that would undercut these findings.

Whatever "uncertainty" CPMA's proffered studies may generate is not enough to stand in the way of regulation. CPMA made precisely the same arguments when OSHA promulgated its cadmium exposure standard. OSHA's decision to regulate cadmium in the pigment industry was upheld on the ground that OSHA need not have definitive scientific evidence that all forms of a carcinogenic metal cause cancer if there is a substantial scientific basis for so finding. *Color Pigments Manufacturers Association v. OSHA*, 16 F.3d 1157, 1161 (11th Cir. 1994). The "dispute" raised by CPMA therefore cannot justify inaction: OSHA can and should resolve it without further delay. Moreover, this is precisely

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[14] *See* National Toxicology Program, *Ninth Report on Carcinogens* (2000), http://ehis.niehs.nih.gov/roc/ninth/known/chromium_hex_omps.pdf.

[15] IARC, *Monographs on the Evaluation of Carcinogenic Risks to Humans: Chromium, Nickel and Welding* 213 (1990).

the type of issue that the notice-and-comment rulemaking process is designed to address. Its existence provides no basis for not commencing that process.

D. OSHA Has Had Ample Time to Address Feasibility.

OSHA places great stress on its need to determine the feasibility of any new hexavalent chromium standard. Feasibility is certainly a critical determination the agency must make before imposing a final rule, and petitioners do not assert that the information they have provided is by itself sufficient to establish the feasibility of any particular hexavalent chromium PEL.[16] But petitioners do not ask this Court to specify the standard OSHA should promulgate, only to order it to propose a rule. Feasibility concerns in no way foreclose such an order.

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[16] That information, based on OSHA's own inspection data, does establish that while many employers subject workers to exposure levels that, though within the existing PEL, are hazardous, other employers have been able to reduce exposures to safe levels, suggesting that 100 $\mu g/m^3$ is not the minimum feasible level. *See* Lurie Dec., Exh. 20. Dr. Lurie's analysis has now been accepted for publication in the *American Journal of Industrial Medicine.* CPMA asks this Court to strike this analysis because it is not part of the agency record. CPMA's request, however, overlooks that this is simply an analysis of the agency's *own data*. Moreover, no one seems to take issue with the two major points the analysis suggests, which are that there are significant exposures in many workplaces (if there weren't, of course, feasibility would not be an issue), and that there are other workplaces where exposure levels are minimal (which CPMA itself repeatedly asserts). Finally, if CPMA's argument were accepted, the Court would also be required to strike the materials submitted by both CPMA and the Chrome Coalition.

OSHA has had nine years to study feasibility, and by its own account it has been examining the issue (principally through NIOSH) for at least four years. The need to determine feasibility cannot justify indefinite delay. OSHA neither explains why this particular feasibility determination requires such an unusual length of time, nor provides any information to the Court about how long it thinks it will take to resolve it. After nine years, that is not good enough. Absent evidence that *no* reduction in the current PEL is feasible — and no one has suggested there *is* such evidence, let alone pointed to any — the agency should be ordered to proceed expeditiously with a notice of proposed rulemaking, which will itself provide a basis, through the notice-and-comment process, for definitive resolution of feasibility issues. *See United Steelworkers v. Marshall*, 647 F.2d at 1274 (upholding feasibility determination based on studies prepared *after* proposed rule issued).

OSHA's other claimed reasons that the order petitioners seek would be unwarranted are equally unpersuasive. OSHA invokes the SBREFA process as a reason petitioners' request that it be ordered to notice a new rule within 90 days is unworkable, but it does not explain why a 90-day requirement is incompatible with SBREFA's 75-day timetable, nor does it explain why it has not already begun the SBREFA process or even state how much time it feels that process would require. OSHA also invokes the OMB review provisions of Executive Order 12,866, but it

is well-established that an executive order cannot trump a statutory prohibition on unreasonable delay. *In re United Mine Workers of America Intern. Union,* 190 F.3d 545, 551 (D.C. Cir. 1999). If either the statute or the order must bend, it must be the order. Finally, OSHA asks that any order issued by the Court preserve its power to decide not to issue a proposed rule. But given the agency's failure to point to any evidence contradicting its prior acknowledgment that the existing PEL "must be greatly reduced" (Lurie Dec., Exh. 4-f) or suggesting that no reduction of the PEL is feasible, there is no basis for permitting the agency that option. The issue is not whether the PEL must be reduced, but how much.

CONCLUSION

The government's brief is long on invocations of the agency's discretion to set its priorities and the Secretary's "enormous technical expertise" concerning occupational safety and health. Sec. Labor Br. 29. It is short on any showing that the delay in the issuance of a proposed rule for hexavalent chromium reflects reasoned discretion or technical expertise. The government's brief is barren of any indication that the agency has determined based on its "technical expertise" that it is not necessary to proceed expeditiously on hexavalent chromium. All the evidence, from the agency's own mouth and the record it has assembled, is to the contrary. And the government's current abandonment of the *commitment* it previously made to this Court to engage in a hexavalent chromium rulemaking is

unexplained and unjustified. As one court has warned, "[j]udicial review of decisions not to regulate must not be frustrated by *blind* acceptance of an agency's claim that a decision is still under study." *Sierra Club v. Gorsuch*, 715 F.2d 653, 659 (D.C. Cir. 1983). Yet blind faith is all OSHA offers here. Unless this Court's review of the agency action unreasonably delayed is to become a sterile exercise in deference to bare agency assertions, the relief petitioners seek should be granted.

Respectfully submitted,

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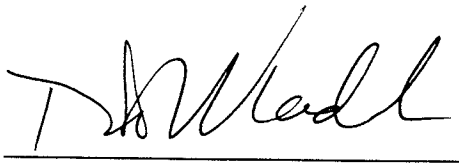
RULE 32(a)(7)(C) CERTIFICATE

I hereby certify that the foregoing Reply Brief for Petitioners complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The Reply Brief is composed in a 14-point proportional typeface, Times New Roman. As calculated by my word processing software (Microsoft Word) the Brief (exclusive of those parts permitted to be excluded under the Federal Rules of Appellate Procedure and the rules of this Court) contains 6,960 words.

Scott L. Nelson

CERTIFICATE OF COUNSEL

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



David C. Vladeck

Attachment 4

AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 42:378–383 (2002)

Continuing Exposure to Hexavalent Chromium, A Known Lung Carcinogen: An Analysis of OSHA Compliance Inspections, 1990–2000

Peter Lurie, MD, MPH* and Sidney M. Wolfe, MD

Background *Hexavalent chromium is widely recognized to be a lung carcinogen. However, the U.S. Occupational Safety and Health Administration (OSHA) has failed to reduce the permissible exposure limit (PEL), despite having acknowledged in 1994 that the current limit is too high. In 1993, Public Citizen and the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) petitioned to lower the PEL from the current 100 μg/m^3 to 0.5 μg/m^3 as an 8-hr time-weighted average (TWA).*

Methods *To assess industry compliance with the current PEL, and to determine the feasibility of achieving the proposed lower limit of 0.5 μg/m^3, we conducted a secondary data analysis of OSHA's Integrated Management Information System (IMIS) database. This database contains 813 measurements of hexavalent chromium exposure from inspections performed during the years 1990–2000.*

Results *There was a statistically significant decline in the annual number of measurements over the study period from 127 in 1990 to 67 in 2000 ($F = 0.0009$; linear regression). The median TWA measurement was 10 μg/m^3 (range: 0.01–13,960 μg/m^3) and the median ceiling measurement was 40.5 μg/m^3 (range: 0.25–25,000 μg/m^3). Neither median TWA nor median ceiling exposures (if hexavalent chromium was detected) declined significantly during the study period ($F = 0.065$ and 0.57, respectively). Overall, 13.7% of TWA measurements were at or below the Public Citizen/PACE proposed standard; 65.0% were between the Public Citizen/PACE proposal and the current OSHA 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%; $P = 0.0007$; chi-square) and less likely to issue any citation (9.3% vs. 19.1%; $P = 0.0003$), including citations for overexposure if the exposure exceeded the PEL (54.8% vs. 78.8%; $P = 0.012$).*

Conclusions *U.S. workers continue to be exposed to dangerously high hexavalent chromium levels, but low exposure levels were found in some industries. Further investigations should examine whether state plans provide weaker enforcement than federal OSHA.* Am. J. Ind. Med. 42:378–383, 2002. © 2002 Wiley-Liss, Inc.

KEY WORDS: hexavalent chromium; OSHA; lung cancer; permissible exposure limit

INTRODUCTION

Hexavalent chromium is used in chrome plating, stainless steel welding, ferrochrome alloy production, wood preservation, and the production of chromate pigments and dyes. Hexavalent chromium compounds also include rust and corrosion inhibitors, drilling muds, textiles, batteries, candles, rubber, cement, and copier toner. The Occupational

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Safety and Health Administration (OSHA) has estimated that approximately one million U.S. workers are currently exposed to hexavalent chromium in their workplaces on a regular basis [Department of Labor, 2001].

The primary evidence for the pulmonary carcinogenicity of hexavalent chromium comes from three studies conducted among chromium production plant workers [Mancuso, 1975; Hayes et al., 1979; Mancuso, 1997; Gibb et al., 2000]. In the most recent and comprehensive of these analyses [Gibb et al., 2000], lung cancer death rates among exposed workers were almost double what would otherwise have been expected for this group even after adjusting for smoking. Hexavalent chromium compounds have been declared a carcinogen by the Environmental Protection Agency in 1984 [US EPA, 1984], the National Toxicology Program in 1980 [US Department of Health and Human Services, 2000], the International Agency for Research on Cancer in 1990 [IARC, 1990], the National Institute for Occupational Safety and Health in 1997 [NIOSH, 1997], and the Agency for Toxic Substances and Disease Registry in 2000 [ATSDR, 2000].

The current OSHA Permissible Exposure Limit (PEL) for hexavalent chromium is 100 $\mu g/m^3$ reported as CrO_3. This is measured as an 8-hr time-weighted average (TWA) in the construction industry and as a ceiling value (the highest value measured in a fixed period of time) for general industry [Martonik, 1995]. To reduce the risk of lung cancer, Public Citizen's Health Research Group (HRG) and the Oil, Chemical and Atomic Workers Union (OCAW, now the Paper, Allied-Industrial, Chemical and Energy Workers International Union, PACE) filed a petition in 1993 with OSHA requesting that the agency lower the PEL for hexavalent chromium to a TWA of 0.5 $\mu g/m^3$, measured as CrO_3.

The purpose of the present study was to assess industry compliance with the existing OSHA standard and the feasibility of complying with HRG/PACE's proposed standard.

METHODS

Through the Freedom of Information Act, we obtained from OSHA an electronic file of the Integrated Management Information System (IMIS) database with all reports of government inspections of workplaces that included measurements of hexavalent chromium exposure for the period 1979–2000. We restricted our analysis to the period 1990–2000 and to hazard code 0686 (chromic acid and chromates, measured as CrO_3). Only personal (lapel) measurements and not area, bulk, wipe or screen samples were included. TWAs and ceiling measurements were included, but not other measures such as blood levels or peak values. Until June 1998, OSHA measured CrO_3 using differential pulse polarography (quantitative lower limit of detection: 19 $\mu g/m^3$) [OSHA, 1990]; thereafter, the agency used ion chromatography (quantitative lower limit of detection: 0.003 $\mu g/m^3$) [OSHA, 1998].

We described the data with percentages for categorical variables and medians for continuous variables using the Stata statistical program [Stata Corporation, 1999]. We conducted separate analyses for the two industries most commonly inspected (plating and polishing and the aircraft industry) and used linear regression to examine trends over time for the key outcome variables: numbers of measurements, exposures and citations. We analyzed the key outcome variables to determine if the data varied according to: whether the measurement was conducted by OSHA or state agencies (Wilcoxon rank sum test); whether or not the inspection was programmed[1] (Wilcoxon rank sum test); and sample year (linear regression, using the medians for each sample year). Only P-values less than or equal to 0.05 (two-tailed) were considered statistically significant.

RESULTS

After the exclusions described in the Methods section, a total of 813 measurements remained. These were obtained in 38 states, with 104 (12.8%) from Michigan and 95 (11.7%) from Texas; all other states represented less than 7% of measurements each. Plating and polishing accounted for 283 measurements (34.8%) and the aircraft industry had 40 measurements (4.9%). No other industry had over 3% of measurements. Programmed inspections accounted for 250 of the 813 measurements (30.8%) and 434 measurements (53.5%) were conducted by Federal OSHA. One hundred eighty measurements (22.1%) were ceiling measurements, 198 (24.4%) were TWAs, and in the remainder, no hexavalent chromium was detected and the measurements were designated in the database as neither ceiling nor TWA. One hundred and eighteen of the measurements (14.5%) led to citations, most commonly for overexposure (84 citations or 10.3% of all measurements).

Cross-tabulations revealed that, compared to OSHA measurements, state measurements were less likely to detect hexavalent chromium (40.2% vs. 52.1%; $P = 0.0007$; chi-square) and less likely to issue any citation (9.3% vs. 19.1%; $P = 0.0003$), including citations for overexposure (5.6% vs. 14.5%; $P < 0.0001$) and citations for overexposure when the exposure exceeded the PEL (54.8% vs. 78.8%; $P = 0.012$). For measurements exceeding the PEL, median OSHA and state measurements were not statistically different ($P = 0.27$; Wilcoxon rank sum).

[1] Programmed inspections may either be entirely random or they may be based on high reported accident rates at a particular facility or knowledge that a particular industry is hazardous. Unprogrammed inspections follow the report of an accident in which a worker is killed or three or more workers are hospitalized. While these categories are not strictly the equivalents of random and for-cause, they are rough approximations, with programmed being close to random and unprogrammed being closer to for-cause.

There was no significant difference between programmed and unprogrammed inspections in the likelihood of issuing a citation (12.0% vs. 15.6%; $P = 0.175$; chi-square).

In 436 measurements (53.6%), no hexavalent chromium was detected. The results of the 377 measurements in which hexavalent chromium was detected are depicted in Table I. The median TWA measurement was 10 $\mu g/m^3$ (range: 0.01–13,960 $\mu g/m^3$) and the median ceiling measurement was 40.5 $\mu g/m^3$ (range: 0.25–25,000 $\mu g/m^3$). There was no relationship between exposure (if detected) and type of inspection (programmed vs. unprogrammed) for either TWA or ceiling measurements ($P = 0.88$ and 0.49, respectively; Wilcoxon rank sum). However, median exposures were higher for federal compared to state measurements for ceiling (30 $\mu g/m^3$ vs. 20 $\mu g/m^3$; $P = 0.0025$) but not for TWA measurements ($P = 0.16$)).

Plating and polishing accounted for 283 measurements (34.8%). In 167 of these measurements (59.0%), no hexavalent chromium was detected. Among TWA measurements with documented exposure, the median exposure was 8.2 $\mu g/m^3$ (range: 0.01–400 $\mu g/m^3$); for ceiling measurements, the median exposure was 23 $\mu g/m^3$ (range: 1–410 $\mu g/m^3$). Median exposures for plating and polishing were lower than for all other industries combined (including measurements where no hexavalent chromium was detected, $P = 0.11$ by Wilcoxon rank sum for TWA measurements ($P = 0.0014$); for ceiling measurements 23 $\mu g/m^3$ vs. 100 $\mu g/m^3$).

The aircraft industry accounted for 40 measurements (4.9%). In 14 of these measurements (35%), no hexavalent chromium was detected. For those with detectable hexavalent chromium, the median TWA measurement was 12 $\mu g/m^3$ (range: 0.2–2,400 $\mu g/m^3$) and the median ceiling measurement was 184 $\mu g/m^3$ (range: 5.3–25,000 $\mu g/m^3$).

Table II presents the exposure data, if hexavalent chromium was detected, in relation to HRG/PACE's proposed PEL of 0.5 $\mu g/m^3$ as a TWA and OSHA's current PEL of 100 $\mu g/m^3$ as a TWA for construction and as a ceiling for general industry. Ceiling measurements were more likely to exceed both the OSHA PEL and HRG/PACE's proposed PEL. Overall, 13.7% of TWA measurements were at or below the HRG/PACE proposed standard, 65.0% were above the HRG/PACE proposal and no more than the current OSHA PEL and 21.3% exceeded the OSHA PEL. The findings were generally similar for plating and polishing.

For TWA measurements, 40.1% were at or below 5 $\mu g/m^3$ and 61.9% were at or below 25 $\mu g/m^3$. The corresponding figures for ceiling measurements were 10.6 and 38.3%. For plating and polishing, 46.2% of the TWA measurements were at or below 5 $\mu g/m^3$ and 64.6% were at or below 25 $\mu g/m^3$. For ceiling measurements in that industry, 9.8% met a 5 $\mu g/m^3$ cutoff and 51.0% did so at 25 $\mu g/m^3$.

For the period 1990–2000, as depicted in Figure 1, there was a statistically significant decline in the total number of measurements per year from 127 in 1990 to 67 in 2000 ($R^2 = 0.72$; $F = 0.0009$; linear regression); this was evident among ceiling measurements ($R^2 = 0.37$; $F = 0.049$), but not among TWA measurements ($F = 0.21$). Neither median TWA nor median ceiling exposures (if hexavalent chromium was detected) declined significantly during the study period ($F = 0.065$ and 0.57, respectively). However, there was a statistically significant decline in the number and percent of measurements in which no hexavalent chromium was detected ($R^2 = 0.84$; $F = 0.0001$ and $R^2 = 0.61$; $F = 0.0047$, respectively), although this did not seem to be related to the change to the more sensitive analytic method adopted by OSHA in 1998. There was also a statistically significant

TABLE I. Hexavalent Chromium Exposures (as $\mu g/m^3$ CrO_3) in OSHA Inspections, 1990–2000

	Median	Range	5th percentile	95th percentile	Mean
All measurements					
TWA measurements (n = 197)	10	0.01–13,960	0.2	1,000	266.1
Ceiling measurements (n = 180)	40.5	0.25–25,000	2.5	2,953.1	593.1
Plating and polishing					
TWA measurements (n = 65)	8.2	0.01–400	0.34	125	31.9
Ceiling measurements (n = 51)	23	1–410	3	200	49.5
Aircraft					
TWA measurements (n = 7)	12	0.2–2,400	N/A	N/A	N/A
Ceiling measurements (n = 19)	184	5.3–25,000	N/A	N/A	N/A

Note: The results in this table are only for measurements in which hexavalent chromium was detected. No hexavalent chromium was detected in 436 of the total of 813 measurements (53.6%), in 167 of 283 measurements in plating and polishing (59.0%) and in 14 of 35 measurements in aircraft (35%). For measurements in which no hexavalent chromium was detected, the database does not state whether these were TWA or ceiling measurements. See text for description of detection limits.

TABLE II. Compliance With Health Research Group/PACE Proposal (0.5 μg/m^3 CrO_3) and OSHA Permissible Exposure Limit (100 μg/m^3) in OSHA Hexavalent Chromium Measurements (No. (%))

	<=HRG/PACE proposal	>HRG proposal & <=OSHA PEL	>OSHA PEL
All measurements			
TWA measurements (n = 197)	27 (13.7)	128 (65.0)	42 (21.3)
Ceiling measurements (n = 180)	1 (0.6)	110 (61.1)	69 (38.3)
Plating and polishing			
TWA measurements (n = 65)	7 (10.8)	53 (81.5)	5 (7.7)
Ceiling measurements (n = 51)	0 (0)	46 (90.2)	5 (9.8)
Aircraft			
TWA measurements (n = 7)	3 (42.9)	2 (28.6)	2 (28.6)
Ceiling measurements (n = 19)	0 (0)	7 (36.8)	12 (63.2)

Note: The results in this table are only for measurements in which hexavalent chromium was detected. No hexavalent chromium was detected in 436 of the total of 813 measurements (53.6%), in 167 of 283 measurements in plating and polishing (59.0%) and in 14 of 35 measurements in aircraft (35%). For measurements in which no hexavalent chromium was detected, the database does not state whether these were TWA or ceiling measurements. See text for description of detection limits. Also see text for explanation of TWA vs. ceiling measurements in OSHA PELs.

decline in the number of measurements exceeding the PEL per year ($R^2 = 0.65$; $F = 0.0029$).

Using combined TWA and ceiling measurement data, there were statistically significant (or very nearly so) declines in the number of citations per year ($R^2 = 0.36$; $F = 0.051$; linear regression) and numbers of citations for overexposure per year ($R^2 = 0.55$; $F = 0.0092$). There was no change in the proportion of exposures exceeding the PEL that resulted in citations for overexposure ($F = 0.16$). Four citations for exposures under the 100 μg/m^3 PEL were identified (0.6% citation rate), all above 60 μg/m^3. There were 80 citations for exposures above the PEL, for a citation rate of 72.1%.

DISCUSSION

This study has used OSHA inspection data to assess recent occupational exposure to hexavalent chromium. We

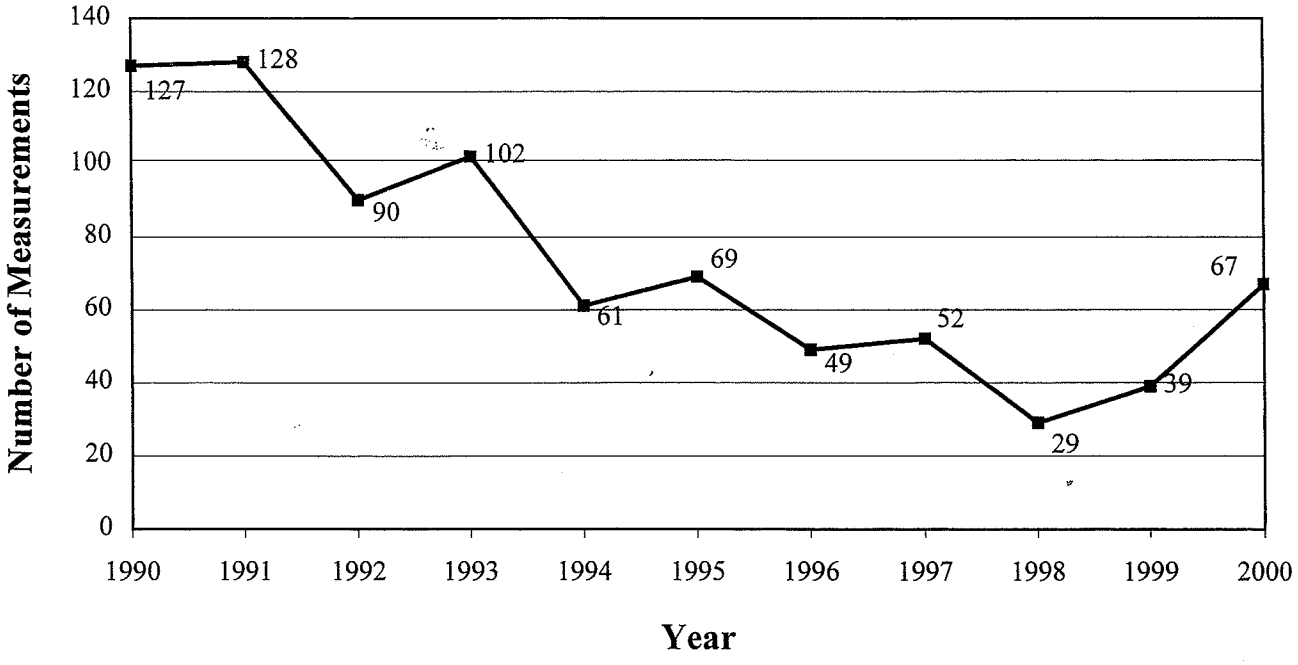

FIGURE 1. Trends in numbers of OSHA measurements, 1990–2000.

found that while levels of chromium in many measurements continue to exceed the current OSHA PEL of 100 $\mu g/m^3$, a substantial fraction are compliant with that PEL. Many are also compliant with the proposed HRG/PACE PEL of 0.5 $\mu g/m^3$. Evidence for compliance with the proposed lower standard, becomes especially strong if measurements below the limit of detection, a category comprising 54% of all measurements are included in the analysis. These data suggest that a drastically lower PEL for chromium is technically possible in at least some industries, including the largest industry represented in the OSHA database, plating and polishing. The need for regulation is underscored by our finding that median levels of exposure to hexavalent chromium failed to decline significantly in American workplaces, during the decade of the 1990s.

Our analysis also revealed that a statistically significant decline in the number of hexavalent chromium measurements conducted by OSHA occurred between 1990 and 2000, a finding consistent with observations in the paper and pulp industry [Coble et al., 2001] (also using IMIS data) and overall trends in OSHA inspections [Lurie et al., 1999]. Moreover, there is not strong evidence that the relatively few remaining inspections are better targeted to permit more effective enforcement, a specific goal of the Clinton administration's Reinventing Government program.

Chromium is a potent carcinogen. A risk assessment undertaken under contract to OSHA estimated that 9–34% of workers exposed at the OSHA PEL for a working lifetime would die from lung cancer as a result of hexavalent chromium exposure [Crump, 1995]. It was on this basis that HRG/PACE petitioned OSHA to reduce the current standard to 0.5 $\mu g/m^3$.

On March 8, 1994, OSHA denied the petition, but admitted in its response that "there is clear evidence that exposure...at the current PEL...can result in an excess risk of lung cancer" [Dear, 1994] and other related illnesses. The agency also undertook to publish a Notice of Proposed Rulemaking (NPRM) in the Federal Register "not later than March 1995." After the promised NPRM failed to transpire, HRG/PACE sued OSHA in the United States Court of Appeals for the Third Circuit in Philadelphia on October 13, 1997. On March 13, 1998, the court ruled against HRG/PACE, finding that the delay did not justify court intervention [OCAW v. OSHA, 1998]. In its submissions to the court, OSHA indicated that an NPRM would be published by September 1999, a promise that also went unfulfilled. On March 4, 2002 HRG and PACE again filed suit against OSHA.

This analysis also shows markedly lower citation rates for state programs compared to federal OSHA. Although the Occupational Safety and Health Act permits state agencies to fulfill OSHA functions, we are not aware of any systematic analysis of the equivalence of the two programs. Such an analysis is needed urgently.

This analysis is subject to the limitation that OSHA may have collected data in certain workplaces on the basis of suspicions that high levels of hexavalent chromium would be present there. In other instances, the purpose of the test may have been to exclude the presence of hexavalent chromium. However, there was no relationship observed in the data between whether the inspection was programmed or unprogrammed and exposure levels. A second limitation is that in 54% of measurements no hexavalent chromium was detected and in such cases the database does not distinguish between TWA and ceiling measurements. We excluded measurements in which no hexavalent chromium was detected from many analyses, because these represented about half of all measurements and so the median including the undetectable exposures is not meaningful. There is no clear indication why a particular measurement was a TWA or a ceiling, but the percentages of TWA and ceiling inspections did not change over time and were unaffected by whether the inspection occurred in plating and polishing or not (data not shown).

Reducing the PEL for hexavalent chromium remains an urgent priority. As OSHA itself recognized in 1996,

> "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) will be reduced" [Department of Labor, 1996].

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