United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 17, 2008 Decided April 3, 2009

No. 08-1061

METWEST INC., A SUBSIDIARY OF QUEST DIAGNOSTICS INCORPORATED, DOING BUSINESS AS QUEST DIAGNOSTICS, PETITIONER

v.

SECRETARY OF LABOR, RESPONDENT

On Petition for Review of a Final Order of the Administrative Review Board

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Brent I. Clark argued the cause for petitioner. With him on the briefs were *James L. Curtis*, and *Elizabeth L. Ash*. *Lawrence P. Postol* entered an appearance.

Jonathan L. Snare, Attorney, U.S. Department of Labor, argued the cause for respondent. On the brief were *Joseph M. Woodward*, Associate Solicitor, *Charles F. James*, Counsel for Appellate Litigation, and *Scott Glabman*, Senior Appellate Attorney.

Before: GINSBURG and HENDERSON, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* RANDOLPH

RANDOLPH, *Senior Circuit Judge*: The main question in this petition for judicial review of a decision of the Occupational Safety and Health Review Commission is whether MetWest, Inc. can be held liable for violating a regulation governing the removal of needles from equipment used to extract blood. Relying on *Alaska Professional Hunters Association, Inc. v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999), and other decisions of this court, the company claims that the Occupational Safety and Health Administration (OSHA) improperly altered the interpretation of its regulation without engaging in notice and comment rulemaking.

I.

In 1991, OSHA promulgated safety standards aimed at preventing the transmission of bloodborne pathogens in the workplace. *See* Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64,004 (Dec. 6, 1991). Several of these standards apply specifically to phlebotomists – the medical professionals who draw blood from patients at hospitals, doctors' offices, nursing homes, and clinics. The safety standard at issue in this case regulates the removal of needles after blood has been drawn.

The basic blood-drawing device consists of three parts: the needle, the blood tube holder, and the blood tube. The needle extends out of the front of the blood tube holder, a plastic device similar to a syringe but with an open back end. The blood tube, typically a glass tube with a rubber top, fits into the open back end of the blood tube holder. When the tube is inserted into this open end, its rubber top is pierced by the "back end" of the needle, which sticks out slightly into the back of the blood tube holder. The phlebotomist inserts the needle into the patient's

arm; blood enters the needle and travels through it into the blood tube. When the tube is filled, the phlebotomist withdraws the needle from the patient's arm and removes the blood tube from the holder. The next step is to discard the needle.

Originally, phlebotomists removed used needles with a "two-handed" technique – they placed a plastic cap over the front of the needle and then unscrewed it manually. By the time OSHA promulgated its safety standards in 1991, medical suppliers had developed reusable blood tube holders that allowed for "one-handed" needle removal – the phlebotomist pressed a button on the blood tube holder and released the needle into a safe container. Although this method still exposed phlebotomists to a risk of needlesticks from the back end of the used needle, it was considered far safer than the original two-handed removal techniques. During the 1990s, medical suppliers also developed and marketed "single-use" blood tube holders. These devices became widely available and widely used beginning in 2003. With the single-use tube holder the phlebotomist does not remove the needle after use; he simply discards the holder and its attached needle into a safe container. Single-use holders are more costly than reusable holders, but they reduce the chances of injury due to "back end" needlesticks.

OSHA's 1991 regulation provides that "[c]ontaminated needles and other contaminated sharps shall not be bent, recapped *or removed* unless the employer can demonstrate [1] that no alternative is feasible or [2] that such action is required by a specific medical or dental procedure." 29 C.F.R. § 1910.1030(d)(2)(vii)(A) (emphasis added). Even if the employer demonstrates that bending, recapping, or removing the needle qualifies under one of these exceptions, the process "must be accomplished through the use of a mechanical device or a one-handed technique." *Id.* § 1910.1030(d)(2)(vii)(B). Initially, OSHA declined to enforce this section against

employers who supplied their employees with reusable blood tube holders. OSHA followed this course even though such holders required manual needle removal. In October 2003, the agency issued a guidance document stating that using reusable blood tube holders likely violated 29 C.F.R. § 1910.1030(d)(2)(vii). Occupational Safety & Health Admin., Disposal of Contaminated Needles and Blood Tube Holders Used for Phlebotomy (Oct. 15, 2003). The guidance document also made clear that single-use holders were the safest type of blood tube holder and were, as of 2003, widely used in the phlebotomy industry. *Id.* OSHA's current policy is to enforce the provisions of 29 C.F.R. § 1910.1030(d)(2)(vii).

MetWest's parent company operates roughly 2,000 clinical testing facilities in the United States, only 400 of which employ single-use blood tube holders. MetWest typically supplies its phlebotomists with reusable holders. In February 2004, an OSHA compliance officer inspected a MetWest facility in Denver, Colorado. The officer issued the facility a citation for allowing its employees to remove needles from reusable blood tube holders in violation of 29 C.F.R. § 1910.1030(d)(2)(vii)(A). After an Administrative Law Judge and the Occupational Safety and Health Review Commission upheld the citation, MetWest filed this petition for judicial review.

MetWest contends that OSHA, in several guidance documents and other interpretations issued during the 1990s, interpreted 29 C.F.R. § 1910.1030(d)(2)(vii) to permit the removal of needles from reusable blood tube holders in all circumstances. Then OSHA's 2003 guidance document and its enforcement policy changed the interpretation. Relying on a line of cases in this circuit, notably *Alaska Professional Hunters*, 177 F.3d at 1034, MetWest argued that OSHA had effectively amended its rule without the notice and comment rulemaking required by the Administrative Procedure Act, 5 U.S.C. § 553.

The first problem with MetWest's argument is that OSHA has never interpreted 29 C.F.R. § 1910.1030(d)(2)(vii) to allow the use of reusable blood tube holders in all situations. The guidance documents OSHA issued in the 1990s do not purport to establish such a sweeping rule. Each of the documents merely indicates that one-handed removal may be permitted when it is medically required or when no feasible alternative exists.[1] We have held that conditional or qualified statements,

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[1] A guidance document issued in March 1992 stated in pertinent part: "Bending, recapping, or removing contaminated needles by hand is prohibited as a general practice. However, certain circumstances may exist in which these actions are necessary; e.g. when . . . removing the needle from a phlebotomy collection apparatus." Office of Health Compliance Assistance, OSHA Instruction CPL 2-2.44C at 19 (Mar. 6, 1992). A February 1, 1993 document used nearly identical language, stating that while removing needles is prohibited, removal using a "one hand [] method . . . may be necessary when . . . removing the needle from a phlebotomy collection apparatus such as a vacutainer." Occupational Safety & Health Admin., Most Frequently Asked Questions Concerning the Bloodborne Pathogens Standard (Feb. 1, 1993). A March 9, 1993 letter to a reusable blood tube holder manufacturer again states that the use of such devices "may be necessary" and concludes: "we believe that [the product's] intended use does not appear to violate the requirements of 29 CFR 1910.1030. . . . Please bear in mind that OSHA does not endorse or approve products and that the final determination regarding compliance is made in the workplace by direct compliance officer observation of employee work practices and taking into account all factors pertaining to the use of such a device at the particular worksite." Occupational Safety & Health Admin., Letter to Alan A. Wanderer, M.D. (Mar. 9, 1993). In a 1999 instruction on enforcement procedures, OSHA restated that needle removal may be necessary in some circumstances. It also instructed its compliance officers that, in evaluating one-handed removal procedures, they "should determine if the circumstances warrant needle removal. If they do not, paragraph (d)(2)(vii)(A), which prohibits needle removal

including statements that something "may be" permitted, do not establish definitive and authoritative interpretations. *See, e.g.*, *Darrell Andrews Trucking, Inc. v. Fed. Motor Carrier Safety Admin.*, 296 F.3d 1120, 1126 (D.C. Cir. 2002); *Hudson v. FAA*, 192 F.3d 1031, 1035 (D.C. Cir. 1999); *compare Envtl. Integrity Project v. EPA*, 425 F.3d 992, 998 (D.C. Cir. 2005). None of the policy statements MetWest cites come close to the "express, direct, and uniform interpretation present in *Alaska Professional Hunters*." *Ass'n of Am. R.Rs. v. Dep't of Transp.*, 198 F.3d 944, 950 (D.C. Cir. 1999).

We have also held that so long as a new guidance document "can reasonably be interpreted" as consistent with prior documents, it does not significantly revise a previous authoritative interpretation. *Air Transp. Ass'n of Am. v. FAA*, 291 F.3d 49, 57–58 (D.C. Cir. 2002) (quotation omitted). All of the documents MetWest cites are consistent with each other and with the text of 29 C.F.R. § 1910.1030(d)(2)(vii). The only logical reading of § 1910.1030(d)(2)(vii) is that it bans all needle removal unless an employer can demonstrate that no other alternative to removal is feasible, in which case removal is permitted using the one-handed technique. OSHA's guidance documents have always indicated that employers permitting their employees to remove needles should "demonstrate that no alternative . . . is feasible" by including a "written justification (supported by reliable evidence)" in their exposure control plans.[2] Occupational Safety & Health Admin., Directive CPL

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unless no alternative is feasible or it is required by a specific medical procedure, should be cited." Occupational Safety & Health Admin., Directive CPL 2-2.44D, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (Nov. 5, 1999).

[2] Employers are required to "establish a written Exposure Control Plan designed to eliminate or minimize employee exposure"

2-2.44D, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens at 22 (Nov. 5, 1999). This requirement, included in the first guidance document on the regulation, remained nearly unchanged in the last guidance document issued before MetWest's 2004 citation. *See* Office of Health Compliance Assistance, OSHA Instruction CPL 2-2.44C at 19 (Mar. 6, 1992); Occupational Safety & Health Admin., Disposal of Contaminated Needles and Blood Tube Holders Used for Phlebotomy (Oct. 15, 2003). The only meaningful difference between OSHA's early guidance documents and its later ones is that the later documents explicitly state that compliance officers should "review [the laboratory's] exposure control plan" for a "determination that no alternative is feasible" if laboratory employees are still removing needles from reusable blood tube holders. Occupational Safety & Health Admin., Directive CPL 2-2.69, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (Nov. 27, 2001). This change in enforcement policy was to be expected, as the availability of single-use blood tube holders increased significantly between 1992 and 2004, eventually providing a "feasible" alternative to reusable holders and rendering one-handed removal unnecessary and therefore prohibited under § 1910.1030(d)(2)(vii).

Even if OSHA had interpreted 29 C.F.R. § 1910.1030(d)(2)(vii) to permit the use of reusable blood tube holders in all circumstances, this case would still not fit within the framework of *Alaska Professional Hunters*. We there held that an agency's practice of advising affected entities – in a prior agency adjudication and the consistent advice of agency officials over a 30-year period – that a regulation did not apply to them established "an authoritative departmental interpretation" that could not be changed without notice and comment. 177 F.3d at

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under 29 C.F.R. § 1910.1030(c).

1034–35.[3] A fundamental rationale of *Alaska Professional Hunters* was the affected parties' substantial and justifiable reliance on a well-established agency interpretation.[4] *Id.* at 1035; *see also Ass'n of Am. R.Rs.*, 198 F.3d at 950. People in the lower 48 states had pulled up stakes and moved to Alaska. They and others within Alaska had opened hunting and fishing "lodges and built up businesses dependent on aircraft, believing their flights were [not] subject to" certain commercial flight regulations. *Alaska Prof'l Hunters*, 177 F.3d at 1035.[5] Forcing guide pilots to comply with regulations developed for commercial airlines would have driven Alaska's hunting and

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[3]The advice came from the FAA's Alaskan regional office rather than central headquarters in Washington, D.C. We viewed this of no moment because, during the relevant period, the FAA had decentralized its operations. *Alaska Prof'l Hunters*, 177 F.3d at 1032, 1035.

[4]This is a crucial part of the analysis. To ignore it is to misunderstand *Alaska Professional Hunters* to mean that an agency's initial interpretation, "once informally adopted, freezes the state of agency law, which cannot subsequently be altered without notice-and-comment rulemaking." Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 Admin. L. Rev. 803, 844 (2001); *see also* William Funk, *A Primer on Nonlegislative Rules*, 53 Admin. L. Rev. 1321, 1329–30 (2001); Richard W. Murphy, *Hunters for Administrative Common Law*, 58 Admin. L. Rev. 917, 921–23 (2006).

[5]Their reliance on the FAA's advice was, as we said, "justifiable." The Assistant Chief Counsel's new interpretation of the administrative decision on which the Alaska region had relied was, for reasons we explained, "quite implausible." *Alaska Prof'l Hunters*, 177 F.3d at 1034.

fishing tourism operations out of business.[6] Furthermore, during this 30-year span, the "guide pilots and lodge operators had no opportunity to participate in the development of the . . . regulations" that the FAA had abruptly decided to apply to them. As a result, they were deprived of any opportunity to request changes or exceptions to accommodate the unique circumstances of Alaskan air travel.[7] *Id*. at 1035–36.

The situation here is not comparable. OSHA never established an authoritative interpretation of its regulation on which MetWest justifiably relied to its detriment. The agency reiterated its long-standing policy and announced that it would enforce that policy as reflected in its regulation. This meant that MetWest and others would have to switch from reusable blood tube holders to disposable ones. The feasability of their doing so is clear. MetWest's parent company owns 400 patient service centers that already employ single-use holders. *Alaska Professional Hunters* thus does not apply, and OSHA was not required to engage in notice and comment rulemaking before it ramped up its enforcement of 29 C.F.R. § 1910.1030(d)(2)(vii).

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[6]Congress, recognizing this fact, responded to our decision by specifically exempting Alaskan guide pilots from the FAA's commercial flight regulations. *See* Pub. L. 106-181, § 732, 114 Stat. 61, 169 (Apr. 5, 2000).

[7] FAA regulations have frequently treated Alaska differently than the rest of the United States, and the participation of Alaskan guide pilots and lodge operators very likely would have affected the commercial flight regulations at issue in *Alaska Professional Hunters. See* 177 F.3d at 1035–36 & n.8.

II.

MetWest has one more argument: it may continue to use reusable blood tube holders despite the plain language of 29 C.F.R. § 1910.1030(d)(2)(vii), because the Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000), requires employers to "document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Pub. L. No. 106-430, § 3(4)(B), 114 Stat. at 1903. MetWest argues that this language allowed it to "select reusable blood tube holders over other devices" if it thought – as it claims it did – that reusable holders were the safest medical devices available. Pet'r Br. at 27.

The Needlestick Act does not vest employers with the power and discretion to determine the safest medical device for each of their facilities regardless of the applicable regulations. MetWest cannot substitute its own unsupported judgment about blood tube holders for that of OSHA. *See Fluor Daniel v. Occupational Safety & Health Review Comm'n*, 295 F.3d 1232, 1240 (11th Cir. 2002). Adopting MetWest's interpretation leads to the untenable proposition that Congress barred OSHA from preemptively banning *any* medical device. Further, if MetWest truly believed that reusable blood tube holders were safer than the single-use holders mandated by § 1910.1030(d)(2)(vii), it could have applied for a variance from the regulation pursuant to 29 U.S.C. § 655(d).

For the foregoing reasons, the petition for review is denied.

So ordered.