NO ORAL ARGUMENT HAS BEEN SCHEDULED.

No. 08-1061

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

METWEST, INC.

PETITIONER

v.

OCCUPATIONAL SAFETY & HEALTH REVIEW COMMISSION AND SECRETARY OF LABOR

RESPONDENTS

ON PETITION FOR REVIEW OF A FINAL ORDER OF
THE ADMINISTRATIVE REVIEW BOARD

BRIEF FOR THE SECRETARY OF LABOR

GREGORY F. JACOB
SOLICITOR OF LABOR

JOSEPH M. WOODWARD
ASSOCIATE SOLICITOR FOR
OCCUPATIONAL SAFETY AND HEALTH

CHARLES F. JAMES
COUNSEL FOR APPELLATE LITIGATION

SCOTT GLABMAN
SENIOR APPELLATE ATTORNEY

U.S. DEPARTMENT OF LABOR
FRANCES PERKINS BUILDING, ROOM S-4004
200 CONSTITUTION AVENUE, N.W.
WASHINGTON, D.C. 20210-0001
(202) 693-5493

JULY 2008

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties

The parties before the Occupational Safety and Health Review Commission were the Secretary of Labor (Complainant) and MetWest, Inc. (Respondent).

MetWest and the Secretary of Labor are the only parties before this court. The Commission, an independent tribunal, is a party in name only and, like a district court, has no stake in the outcome of this case.

B. Rulings

The ruling under review is a Commission final order, issued December 17, 2007, in *MetWest, Inc.*, 22 BNA OSHC 1066 (No. 04-0594, 2007). (App. at 354.)

C. Related Cases

This case has not previously been before this court or any other court. I am not aware of any related cases pending before this court or any other court.

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SCOTT GLABMAN
Attorney for the Secretary of Labor

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STATUTES AND REGULATIONS:

MISCELLANEOUS:

GLOSSARY

BD	Becton Dickinson, manufacturer of blood tube holders and needles
Commission	Occupational Safety and Health Review Commission
Needlestick Act	Needlestick Safety and Prevention Act
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act
Pronto	Becton Dickinson Pronto Quick Release Holder (blood tube holder)
Removal Provision	29 C.F.R. § 1910.1030(d)(2)(vii), the provision of the Bloodborne Pathogens Standard that bans the removal of contaminated needles, subject to certain exceptions. The removal provision includes the cited provision here, subsection (d)(2)(vii)(A).
SHIB	Safety and Health Information Bulletin, an OSHA guidance document

JURISDICTIONAL STATEMENT

The petition seeks review of a final order of the Occupational Safety and Health Review Commission under the Occupational Safety and Health Act of 1970 (OSH Act or the Act), 29 U.S.C. §§ 651-678. On March 1, 2004, Respondent Secretary of Labor issued a citation to Petitioner MetWest, Inc. after inspecting its South Federal patient service center in Denver, Colorado.[1] (App. at 185.) The Commission obtained subject matter jurisdiction under section 10(c) of the Act. OSH Act, 29 U.S.C. § 659(c).

A Commission ALJ affirmed the citation on May 5, 2006, and the Commission affirmed the ALJ's decision on December 17, 2007. (App. at 353, 362.) On February 14, 2008, MetWest filed a petition for review with this court. This court has jurisdiction because the petition was filed within sixty days of the date of the Commission's final order. OSH Act, 29 U.S.C. § 660(a).

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[1] The Secretary has delegated her responsibilities under the OSH Act to the Assistant Secretary for Occupational Safety and Health, who heads OSHA. The terms "Secretary" and "OSHA" are used interchangeably here.

STATEMENT OF THE ISSUES

1. The removal provision of the bloodborne pathogens standard, 29 C.F.R. § 1910.1030(d)(2)(vii), prohibits the removal of contaminated needles from blood tube holders unless the employer can demonstrate that no alternative is feasible or that the removal is medically necessary. The question presented is whether the Commission properly held that MetWest violated that provision where, without invoking either exception, the company removed contaminated needles from reusable blood tube holders instead of immediately disposing of the blood tube holders and attached needles after each patient's blood was drawn.

2. Whether Commission properly held that the Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901(2000), does not prohibit the Secretary from enforcing the removal provision's ban on the use of reusable blood tube holders.

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in MetWest's principal brief.

STATUTORY AND REGULATORY BACKGROUND

1. *The OSH Act*

The goal of the OSH Act is "to assure so far as possible" safe working conditions for "every working man and woman in the Nation." OSH Act, 29 U.S.C. § 651(b). To achieve this goal, the Act separates rule-making and enforcement powers from adjudicative powers and assigns these respective functions to two different administrative actors: the Secretary and the Commission. *Martin v. OSHRC ("CF&I ")*, 499 U.S. 144, 147, 151 (1991).

The Secretary is charged with promulgating and enforcing workplace health and safety standards; and the Commission is responsible for carrying out the Act's adjudicatory functions. *CF & I*, 499 U.S. at 147. The Secretary prosecutes violations of the Act and its standards by issuing citations requiring abatement of violations and assessing monetary penalties. OSH Act, U.S.C. §§ 658-59, 666. The Commission is an independent agency that is a "neutral arbiter" for adjudicating disputes between employers

and the Secretary that arise from those citations. *Cuyahoga Valley Ry. Co. v. United Transp. Union,* 474 U.S. 3, 7 (1985) (per curiam); *CF&I*, 499 U.S. at 147-48, 154-55.

The employer may contest a citation by filing a written notice of contest with the Secretary within fifteen working days of receiving the citation. OSH Act, 29 U.S.C. § 659(a); *Martin v. Pav-Saver Mfg. Co.*, 933 F.2d 528 (7th Cir. 1991). If an employer contests the citation, a Commission ALJ provides an opportunity for a hearing and issues a decision on the contest. 29 U.S.C. §§ 659(c), 661(j). The Commission may review and modify the ALJ's decision. §§ 659(c), 661(j). Either the Secretary or an aggrieved party may seek judicial review of a Commission final order. § 660(a)-(b).

2. *The Bloodborne Pathogens Standard*

The bloodborne pathogens standard, 29 C.F.R. § 1910.1030, is designed to eliminate or minimize occupational exposure to the hepatitis B virus, the human immunodeficiency virus (HIV) and other microorganisms that are present in human blood and can cause serious illness or death. OSHA, Preamble to Final Rule, Occupational Exposure

to Bloodborne Pathogens, 56 Fed. Reg. 64,004, 64,004, 64,006 (1991); 29 C.F.R. § 1910.1030(b) (definition of "bloodborne pathogens"). These viruses and other pathogens are transmitted through the blood, and workers who are potentially exposed to blood, such as phlebotomists (i.e., blood drawers), are at risk of being infected and contracting and spreading serious disease. Preamble to Final Rule, 56 Fed. Reg. at 64,008. Indeed, phlebotomy injuries are among the highest risk for transmitting bloodborne pathogens because blood drawing involves the use of hollow-bore, blood-filled needles. (App. at 120.) In her rule-making on the standard, the Secretary specifically found that "[n]eedle sticks [or pricks] are a very efficient means of transmitting bloodborne diseases," and concluded that removal of contaminated, i.e., used, needles should not be acceptable as a general practice. Preamble to Final Rule, 56 Fed. Reg. at 64,117-18.

Paragraph (d)(2)(vii) of the standard, the removal provision, prohibits the removal of contaminated needles from medical devices "unless the employer can demonstrate that no alternative is feasible or that [removal] is required by a specific

medical or dental procedure." 29 C.F.R. § 1910.1030(d)(2)(vii)(A); (App. 122.) In addition, "such . . . removal must be accomplished through the use of a mechanical device or a one-handed technique." 29 C.F.R. §1910.1030(d)(2)(vii)(B).

OSHA explained that paragraph (d)(2)(vii) is not intended to prohibit removal of contaminated needles under all circumstances, and that removal by "one-handed" techniques or mechanical means may be appropriate in some instances. Preamble to Final Rule, 56 Fed. Reg. at 64118. The agency emphasized, however, that removal by these methods is not acceptable as a general practice, because "use and immediate discard into a readily accessible sharps container" reduces the risk of employee exposure. *Ibid*. Thus, removal of contaminated needles is permitted only in "certain situations" outlined in paragraph (d)(2)(vii) (A) and then only through the use of a mechanical device or one-handed technique. *Ibid*.

The ban on routine removal of contaminated needles includes the removal of such needles from blood tube holders following a blood drawing procedure. (App. at 122.) Where

reusable blood tube holders are used, the holder with its attached needle must be immediately disposed of after each use unless the employer demonstrates that the feasibility or medical necessity exception applies. (App. at 122-23.) OSHA regards the increased manipulation required to remove a contaminated needle from a blood tube holder as unnecessary and potentially hazardous to phlebotomists and other health care workers who may later come into contact with the unprotected needle (e.g., nursing assistants, housekeepers, maintenance personnel). (App. at 120.)

3. *The Needlestick Safety and Prevention Act*

The Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901(2000), MetWest's Br., Add. at 18, was enacted to encourage the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, and safer work practices to reduce occupational exposure to bloodborne pathogens. *Id.*, § 2, 114 Stat. at 1901-02, MetWest's Br., Add. at 18-19. The Act specifically requires the Secretary, among other things, to amend paragraph (c) of the bloodborne pathogens standard to require

employers to update their exposure control plans to (1) reflect changes in technology; and (2) document annually consideration and implementation of appropriate commercially available and effective safer medical devices to eliminate or minimize occupational exposure. *Id.*, § 3(4), 114 Stat. at 1903, MetWest's Br., Add. at 20.

STATEMENT OF FACTS

1. MetWest is a wholly owned subsidiary of Quest Diagnostics, one of the largest clinical laboratories in the United States, operating about 2,000 patient centers nationwide. (App. at 196, 263, 267, 343.) MetWest's South Federal patient service center in Denver employs two phlebotomists, who routinely collect blood samples using a reusable blood tube holder called the Becton Dickinson (BD) Pronto Quick Release Holder (Pronto), which is fitted with both a blood tube and a double-ended needle. (App. at 343-44, 355-56.) The front or "patient end" of the needle is inserted into the patient's vein; the back end punctures a stopper in the blood tube. (App. at 344.) A phlebotomist discharges the double-ended needle from the holder into a container for sharp

items (sharps container) by depressing a push-button-needle-release mechanism with one finger after drawing blood. (App. at 199-200, 212, 278, 344, 356.) This method allows MetWest to reuse blood tube holders anywhere from twice to about 30 times before disposing of a holder. (App. at 199, 201.)[2]

2. MetWest's practice of removing needles from blood tube holders exposes employees to the hazard of being struck by the back end of the contaminated needle. (App. at 201, 317, 344.) Such exposure poses a health risk because employees may come in contact with bloodborne pathogens, such as HIV and the hepatitis B virus, which could result in death. (App. at 203, 205, 240, 344, 353.) Exposure occurs when the needle is clicked off the Pronto blood tube holder and the back end of the needle is no longer protected by the hard plastic of the blood tube holder. (App. at 101, 203.) Although the back end of the needle is covered with a thin

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[2] Before the bloodborne pathogens standard was adopted, phlebotomists typically used a two-handed, or hand-towards-hand technique to dispose of contaminated needles. The two-handed removal technique involves holding the contaminated needle with one hand and unscrewing it from the blood tube holder with the other. (App. at 272.) The standard banned this procedure as too dangerous. (App. at 311-12.)

rubber sheath, the sheath provides minimal protection from back-end needle stick injuries. (App. at 204, 224-25.) The longer a phlebotomist holds a needle, the greater the risk of a needle stick injury. (App. at 247, 255.)

Needle sticks can happen in several ways. Employees can get bumped while discharging the needle into the sharps container and accidentally touch an unprotected needle. (App. at 224, 316.) The blood tube holder may not disengage, especially if it is used 30 times or more, causing the needle to bounce back out of the sharps container. (App. at 224, 316.) The needle may fall on the floor or a table, posing a potential risk of exposure. (App. at 224-25, 317.) An employee may pick up a needle by hand, or otherwise not follow correct disposal procedures. (App. at 281.) Even if employees use a forceps to pick up needles from the floor, the employees could drop the forceps or be bumped. (App. at 226.) Employees may also touch unprotected needles sticking out of overfilled sharps containers. (App. at 204, 224, 344.)

Between 2000 and 2001, the International Healthcare Workers Safety Center reported 148 needle stick injuries

caused by phlebotomy needles in the 90 hospitals tracked. (App. at 221-22, 344.) Twelve of the reports described injuries from the back end of the phlebotomy needle. (App. at 221, 344.) Five reporters said that they were removing the needle from a blood tube holder. (App. at 221, 344.) The actual number of needle sticks is probably much greater than the Safety Center reported because there are about 6,000 hospitals in the United States, and the Centers for Disease Control and Prevention estimates that needle sticks are underreported by about 50%. (App. at 216, 239-40.)

3. The advantage of single-use blood tube holders is that, unlike reusable tube holders, they do not require removal of the needle and are discarded with the attached needle into sharps containers. (App. at 122-23, 200, 348.) The single-use blood tube holder also provides some protection from the back end of the needle because the needle is not exposed during disposal. (App. at 167, 317.)

When the bloodborne pathogens standard was issued in 1991, single–use blood tube holders were not widely available; thus, a flat prohibition on removing needles from blood tube

holders would have been infeasible then. (App. at 312, 316, 323, 347, 356.) Indeed, according to two of MetWest's witnesses, there were not enough blood tube holders of any type then, single-use or reusable, for every blood tube holder to be discarded after a single use:

> Q. Good afternoon. You testified that in the early 90's after the Bloodborn [sic] Pathogen [sic] Standard was promulgated, if OSHA had required that blood tube holders not be reused, it would have basically put an end to health care in the country?
>
> A. It certainly would have put it on hold because we would have run out of product to use.
>
> Q. You're saying there simply weren't enough blood tube holders to do it, correct?
>
> A. That is correct.

(*Id.* at 316 (Terry Jo Gile, MetWest's safety consultant), *accord id.* at 312 (Gile), 323 (Clettes Lewis, Quest's health and safety director)).

During the 1990s, however, various models of single-use blood tube holders were developed, and there is now an adequate supply of the devices. (App. at 228, 231, 265, 348.) BD manufactures a single-use blood tube holder for its Eclipse

needle. (App. at 102.) Other companies also make single-use blood tube holders. (App. at 173, 177-80.)

About 400 of Quest's California facilities routinely use Sims Portex single-use blood tube holders. (App. at 263-64, 339-40, 348, 352.) It would be feasible for MetWest's South Federal facility to switch to single-use holders. (App. at 268, 348.) In fact, in April 2002, Quest's phlebotomists ranked the BD Single Use Holder above the BD Pronto Holder, but Quest could not switch then because, unlike now, BD could not provide enough devices. (App. at 143.)

4. After inspecting MetWest's South Federal center, the Secretary issued a citation on March 1, 2004, alleging that the company committed a serious violation of 29 C.F.R. § 1910.1030(d)(2)(vii)(A) by permitting employees to remove contaminated needles from reusable blood tube holders. (App. at 185.) The citation proposed a penalty of $1,875. (*Ibid.*) After MetWest timely contested the citation, the case was assigned to a Commission ALJ for hearing.

DECISIONS BELOW

1. *The ALJ's Decision*

The ALJ found that MetWest violated 29 C.F.R. § 1910.1030(d)(2)(vii)(A) because the company removed phlebotomy needles from reusable blood tube holders at its South Federal facility without showing that alternatives were infeasible or that removal was medically required. (App. at 350.) The ALJ also assessed the full proposed penalty of $1,875. (App. at 353.)

The ALJ rejected MetWest's argument that the meaning of the word "removed" in the removal provision is limited to "removed by hand using a traditional two-handed technique" and that the provision therefore permits the company's one-handed removal technique. (App. at 345-46.) Instead, the ALJ found that the plain language of the removal provision prohibits the removal of contaminated needles unless no feasible alternative is available. (App. at 349.)

The ALJ also determined that the Secretary has consistently interpreted the removal provision in accordance with its plain meaning. (App. at 349.) The ALJ rejected

MetWest's contrary assertion that the Secretary's bloodborne pathogen publications showed her intent to limit the term "removal" to "two-handed or hand-toward hand removal," (i*bid.*), i.e., to permit the use of a mechanical device or a one-handed technique. The ALJ noted that such a reading would render meaningless the provision's subsections (A) and (B), (*ibid.*), which set out the infeasibility and medical necessity exceptions and specify that removal under these exceptions must be achieved through the use of a mechanical device or a one-handed technique.

The ALJ further held that the Secretary's decision to prohibit removal of needles from reusable blood tube holders after earlier permitting the practice did not represent a change in her interpretation of the standard, requiring notice-and-comment rule-making, but only a discretionary change in enforcement policy. (App. at 350). The ALJ noted that in 1992, when single-use blood tube holders were not widely available, the Secretary permitted removal of needles from reusable blood tube holders under the removal provision's exceptions. (*Ibid.*) Since the early 2000's, however, the ALJ

observed, the Secretary has not permitted such needle removal, except in very rare cases, because single-use blood tube holders have become widely available. (*Ibid.*)

The ALJ also ruled that the Needlestick Safety and Prevention Act (Needlestick Act) does not preclude the Secretary from enforcing the specific requirements of the removal provision. (App. at 351.) The ALJ held that the applicable provisions of the Needlestick Act require only that employers annually consider the implementation of safer medical devices as they become feasible and available. (*Ibid.*) The ALJ concluded that the Act does not permit employers to substitute their safety judgments for those of the Secretary, or disregard the express requirements of the standard. (*Ibid.*)[3]

2. *The Commission's Decision*

The Commission affirmed the ALJ on the basis that the plain language of the removal provision prohibits all contaminated needle removal except where the employer can

[3] The ALJ also rejected MetWest's greater hazard and collateral estoppel defenses. (App. at 351-52.) MetWest has since disavowed any intention of asserting the former defense, (App. at 355 n.3), and has dropped the latter.

demonstrate infeasibility or medical necessity. (App. at 357.) Like the ALJ, the Commission rejected MetWest's argument, that the standard prohibits only two-handed, not one-handed, removal techniques. (*Id.* at 358). The Commission found that the standard permits the use of a one-handed removal technique only as an exception to the general prohibition on removal where the employer can demonstrate that no alternative is feasible or that such action is required by a medical procedure. (*Ibid.*)

The Commission further rejected MetWest's argument that a literal reading of the removal provision would absurdly prohibit removal of phlebotomy needles from patients' arms, as well as removal of blood-filled tubes from blood tube holders, on the basis that a literal reading would permit both removals under the medical necessity exception. (App. at 358 n.5.)

The Commission also agreed with the ALJ that the Secretary has interpreted the removal provision consistently and in accordance with its plain meaning since the provision was adopted in 1991. (App. at 359-60.) Pointing to the

unavailability of single-use blood tube holders in the early 1990s, the Commission noted that the Secretary implicitly permitted the removal of contaminated needles (i.e., the use of reusable holders) then under the infeasibility exception. (*Id.* at 359-60). The Commission found that the Secretary did not change her interpretation of the removal provision when she required employers, once single-use holders became generally available, to demonstrate that an exception applied before she would permit the use of reusable holders. (*Ibid.*) The Commission noted that the Secretary had allowed the use of reusable holders in the 1990s because single-use holders were unavailable, but she changed her enforcement policy to require that single-use holders be used, unless the employer could demonstrate that the exceptions applied, once improved technology made single-use holders more widely available. (*Ibid.*)

Finally, the Commission rejected MetWest's argument that the Needlestick Act precludes enforcement of the removal provision. (App. at 360 n.8.) The Commission found no basis for MetWest's claim that Congress tacitly approved OSHA's

contemporaneous enforcement policy of permitting the use of reusable blood tube holders. (*Ibid.*) The Commission noted that OSHA permitted such devices only under the exceptions clause of the removal provision, and stopped doing so, absent the employer's required demonstration that an exception applied, when single-use devices became generally available. (*Ibid.*)[4]

SUMMARY OF THE ARGUMENT

The plain meaning of the removal provision of the bloodborne pathogens standard, 29 C.F.R. § 1910.1030(d)(2)(vii), prohibits the removal of contaminated needles from blood tube holders unless the employer can demonstrate that no alternative is feasible or that the removal is medically necessary. It is undisputed that MetWest did not make such a demonstration and thus the company was properly cited for removing contaminated needles from reusable blood tube holders instead of immediately disposing of the blood tube holders and attached needles after each

[4] The Commission also ruled against MetWest on certain evidentiary and procedural issues, which MetWest has not raised on appeal. (App. at 360-62.)

patient's blood was drawn. Contrary to MetWest's assertions, neither the removal provision nor its regulatory history shows that the intent of the provision was to ban only removals by a two-handed technique and not removals by a one-handed technique or a mechanical device.

MetWest's principal argument is that, after a decade of interpreting the removal provision to permit the use of reusable blood tube holders, the Secretary improperly changed her interpretation, without rule-making, to ban the use of such devices. MetWest's argument does not withstand scrutiny. Every one of the Secretary's enforcement policy statements on the removal provision closely follows the provision's plain meaning: that removal of contaminated needles is prohibited as a general practice unless the employer can demonstrate infeasibility or medical necessity. In the period just after the standard was issued, the Secretary accepted the industry's position that withdrawal of needles from reusable blood tube holders was necessary because there were not enough holders available to use these devices only once. As single-use blood tube holders became widely

available, however, the Secretary stated that each employer seeking to remove needles from reusable blood tube holders must demonstrate the existence of circumstances necessitating such removal, such as the inability to buy single-tube blood tube holders because of a supply shortage.

MetWest also argues that the Needlestick Safety and Prevention Act (Needlestick Act) tacitly approved the Secretary's contemporaneous acceptance of reusable blood tube holders, and that the Secretary's subsequent ban on the use of these holders violates the Needlestick Act's requirement that employers select a safer medical device.

These arguments are untenable. The Needlestick Act neither addresses the removal provision nor endorses the use of reusable blood tube holders. There is no basis for reading the statute as prohibiting the Secretary from enforcing the removal provision's ban on the use of reusable blood tube holders. Moreover, there is nothing in the statute that permits employers to ignore the specific requirements of the removal provision, or to substitute their own judgment for the express requirements of an OSHA standard. Thus, the Needlestick Act

does not authorize MetWest's violation of the removal provision.

ARGUMENT

I. *MetWest Violated the Removal Provision by Removing Contaminated Needles from Reusable Blood Tube Holders Without Demonstrating Infeasibility or Medical Necessity.*

A. *Absent Such a Demonstration, the Plain Meaning of the Removal Provision Prohibits Removal of Contaminated Needles from Blood Tube Holders Regardless of the Method of Removal.*

1. This issue involves the interpretation of a provision of an OSHA standard. Questions of textual interpretation are issues of law and are decided *de novo*. *Yousuf v. Samantar*, 451 F.3d 248, 251 (D.C. Cir. 2006). If the meaning of the provision is plain, it must be given effect. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984). If, however, the provision is ambiguous, the agency's interpretation must be upheld so long as it is reasonable, i.e., sensibly conforms to the standard's wording and purpose. *Martin v. OSHRC ("CF & I ")*, 499 U.S. 144, 150-51 (1991).

To the extent that there are nontextual issues here, this court reviews Commission decisions under a "highly

deferential standard." *Montgomery Kone, Inc. v. Secretary of Labor*, 234 F.3d 720, 722 (D.C. Cir. 2000). The court must uphold the Commission's factual findings if they are "supported by substantial evidence on the record considered as a whole," and must uphold the Commission's other conclusions if they are not arbitrary, capricious, an abuse of discretion or otherwise contrary to law. OSH Act, 29 U.S.C. § 660(a); *A.E. Staley Mfg. Co. v. Secretary of Labor*, 295 F.3d 1341, 1345 (D.C. Cir. 2002).

The language of the removal provision unambiguously prohibits the removal of contaminated needles from blood tube holders unless the employer can demonstrate infeasibility or medical necessity: "Contaminated needles . . . shall not be . . . removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure." 29 C.F.R. § 1910.1030(d)(2)(vii)(A). Since "removed" is not defined in the standard, that term must be given its ordinary, common meaning of "take[n] away, withdraw[n]." *American Fed'n of Employees v. Glickman*, 215 F.3d 7, 10-11 (D.C. Cir. 2000);

American Heritage Dictionary of the English Language (4th ed. 2000) (definition of "remove"). Thus, the plain language of the removal provision bans the withdrawal of contaminated needles from a blood tube holder, by any method, absent the employer's demonstration that the infeasibility and medical necessity exceptions apply.

It is undisputed that MetWest did not even invoke the infeasibility or medical necessity exceptions, let alone demonstrate that these exceptions applied here. Indeed, MetWest could hardly have done so since about 400 of its sister Quest facilities routinely use single-use blood tube holders, (App. at 263-64, 339-40, 348, 351-52), and MetWest's own witness testified that using such holders at the company's South Federal facility would be feasible, (*id.* at 268, 348). Thus, since MetWest removed contaminated needles from reusable blood tube holders without demonstrating that an exception applied, the Commission properly found that MetWest violated the removal provision.

B. *MetWest's Interpretive Arguments are Without Merit.*

MetWest argues that notwithstanding the plain meaning of the regulatory text, the preamble demonstrates that the removal provision bans only two-handed needle removal techniques. MetWest Br. at 18-20. MetWest also asserts that the standard cannot be interpreted to prohibit "any removal under any circumstance," because that interpretation would mean that a needle could not be removed from a patient's arm and a blood tube could not be removed from its holder. *Id.* at 20. Neither of these claims is remotely persuasive.

MetWest's reading of the preamble is decidedly selective at best. It is true that OSHA was concerned about two-handed removals, as MetWest notes, and paragraph (d)(2)(vii)(B) prohibits such removals absolutely. As the preamble explicitly states, however, OSHA also regarded other methods of removal as unacceptable as a general practice. 56 Fed. Reg. at 64,118. OSHA agreed that one-handed removal or recapping may be necessary in certain circumstances, but stated, "it should not be construed that these two actions are acceptable as a

general practice." *Ibid.* Therefore, OSHA explained, the final rule prohibits removal of contaminated needles unless no alternative is feasible or such action is required by a specific medical procedure, and in *addition*, the final rule requires that any removal be accomplished by a mechanical device or one-handed technique.[5] *Ibid.* MetWest's suggestion that OSHA intended to prohibit only two-handed needle removal techniques, is simply wrong.[6]

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[5] The removal provision in the proposed rule stated that "[u]sed needles . . . shall not be . . . recapped, or resheathed *by hand* . . . [or] removed from disposable syringes." Proposed Rule, 54 Fed. Reg. 23,042, 23,135 (May 30, 1989) (emphasis added). The final rule does not contain the phrase "by hand." The final preamble explains that commenters mistakenly interpreted the phrase to imply that one-handed techniques or the use of mechanical devices to accomplish recapping or removal were totally prohibited. 54 Fed. Reg. 64,118. One-handed removal techniques are not totally prohibited, the preamble explains, but their use is limited to situations where removal is necessary i.e., where the employer can demonstrate that no alternative is feasible or that the removal is required by a specific medical procedure. 56 Fed. Reg. at 64,118. *Ibid.*

[6] Acceptance of MetWest's reading that the standard prohibits only removal by two-handed techniques deprives paragraph (d)(2)(vii)(A) of any meaning. Two-handed removal is absolutely prohibited under paragraph (d)(2)(vii)(B). Paragraph (d)(2)(vii)(A), which permits removal when alternatives are infeasible or removal is medically required, must necessarily

MetWest's additional claim that a prohibition on "any removal under any circumstance" would produce absurd results is simply irrelevant because the standard does not prohibit removal under all circumstances. MetWest Br. at 20. The standard prohibits removal of contaminated needles unless no alternative is feasible or removal is required by a specific medical procedure. As the Commission properly found, both removal of the contaminated needle from the patient's arm and removal of a full blood tube from a blood tube holder are indisputably medically necessary and therefore permitted under a literal reading of the standard. (App. at 358 n.5).[7]

Moreover, the removal provision must be considered in the context of the standard as whole. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) ("The

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prohibit removal by other than two-handed techniques or it is pointless.

[7] Contrary to MetWest's assertion, withdrawing a full blood tube from a blood tube holder is not covered by the removal provision since the provision applies only to contaminated *sharps*, and an unbroken blood tube is not a sharp. 29 C.F.R. §§ 1910.1030 (b) (definition of "contaminated sharps"); 1910.1030(d)(2)(vii).

meaning - or ambiguity - of certain words or phrases may only become evident when placed in context"). The plain meaning of other provisions of the standard shows that the standard contemplated removal of such needles from patients' arms and of blood tubes from blood tube holders: the definitions of "needleless systems" and "sharps with engineered sharps injury protections" state that these devices are intended to collect or withdraw bodily fluids. The standard also includes a provision for placing blood in a container during collection, handling, processing, storage, transport or shipping, 29 C.F.R. § 1910.1030(d)(xiii), a provision that presupposes that full blood tubes would be removed from blood tube holders. Furthermore, the standard's definition of "engineering controls" includes sharps disposal containers, which would not be necessary unless the needles were removed from patients' arms. 29 C.F.R. § 1910.1030(b). Thus, MetWest's *reductio ad absurdum* is invalid: the meaning of the removal provision is clear and is consistent with the other provisions of the standard concerning withdrawal, collection and storage of blood.

C. *The Secretary Has Consistently Interpreted the Removal Provision in Accordance With its Plain Terms.*

MetWest points to OSHA guidance documents as further support for its claim that the standard prohibits only two-handed removal techniques. MetWest Br. at 4-7, 9-10, 21-23. MetWest argues that OSHA guidance materials issued during the 1990s did not suggest that all removals of all contaminated needles were banned, and in one instance, approved a type of reusable blood tube holder. MetWest Br. at 4-6. MetWest claims that OSHA abruptly changed its policy in 2001 by issuing a guidance document suggesting that reusable blood tube holders do not comply with the standard. MetWest Br. at 9. Thereafter, according to MetWest, OSHA banned all removals of contaminated needles from medical devices. *Ibid*. Such a ban, in MetWest's view, amounts to an improper amendment of the standard. MetWest Br. at 21-23. MetWest is wrong on all counts.

1. As we have demonstrated, the regulatory text is not ambiguous; therefore, it is not necessary to resort to extrinsic guidance documents to determine the standard's meaning.

Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 842-43 (1984). In any event, OSHA's guidance materials for the bloodborne standard have consistently interpreted paragraph (d)(2)(vii) to prohibit the removal of contaminated needles as a general practice, but to allow the use of a mechanical device or a one-handed technique in the limited circumstances in which the agency believed such removal to be necessary.

Thus, OSHA Instruction CPL 2-2.44C (Mar. 6, 1992), (App. at 8), (quoted in MetWest's Br. at 5), says that removing contaminated needles by hand is "prohibited as a general practice," but is necessary when a needle is removed from a phlebotomy device such as a vacutainer, i.e., a blood tube holder. The clear implication is that OSHA recognized that the removal of needles from reusable blood tube holders fit within an exception in paragraph (d)(2)(vii)(A). This implication is consistent with the industry's position that the limited supply of blood tube holders during the 1990s made it infeasible to

discard reusable holders after each use. (App. at 312, 316, 323.); *supra*, pp. 11-12.[8]

OSHA's 1993 publication, *Most Frequently Asked Questions Concerning the Bloodborne Pathogens Standard* (Feb. 1, 1993), (App. at 12), (quoted in MetWest's Br. at 5), is to the same effect. (App. at 18.) These guidance documents do not support MetWest's position here, as MetWest does not invoke an exception under paragraph (d)(2)(vii)(A).

OSHA's March 9, 1993 standard interpretations letter, (App. at 31), also does not support MetWest's argument. The letter states that "the standard prohibits the recapping and/or removal of contaminated needles unless no alternative is feasible or it is required by a specific medical procedure." *Ibid.*

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[8] It is generally agreed (as MetWest acknowledged before the Commission) that, during the 1990s, single-use blood tube holders were not widely available. (App. at 312, 316, 323, 347, 356.) Indeed, there were not enough blood tube holders of any type then, single-use or reusable, for every blood tube holder to be discarded after a single use. (*Id.* at 312, 316, 323). Although MetWest now claims that reusable blood tube holders could have been used as single-use holders since the reusable devices could have been discarded after a single use, MetWest's Br. at 15, that position is inconsistent with the record, *see supra*, p. 12.

The letter notes that in some circumstances, removal of a contaminated needle from a phlebotomy collection device may be necessary, and states that the use of the questioner's particular type of reusable blood tube holder does not appear to violate the standard. (*Ibid.*) This statement is in line with the agency's prior guidance that reusable blood tube holders may be necessary on feasibility or medical necessity grounds.

Furthermore, contrary to MetWest's assertion, OSHA Instruction CPL 2-2.44D (Nov. 5, 1999), (App. at 34), does not acknowledge that the one-handed needle removal technique was a generally acceptable practice. MetWest Br. at 7. Instead, the instruction repeated the Secretary's consistent position that the removal provision generally prohibited this type of procedure but permitted it where the employer could demonstrate that one of the exceptions applied. (App. at 36-38).[9]

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[9] MetWest selectively quotes a passage from the instruction, discussing another provision of the standard, concerning sharps disposal, that the company claims shows the Secretary's general acceptance of the one-handed technique. MetWest's Br. at 7 (quoting App. at 38). The very next two sentences, which MetWest does not quote, however, say that

MetWest argues that OSHA permitted the removal of needles from reusable blood tube holders in the 1990s because these one-handed removals were not covered by the standard. MetWest claims that the record does not support the Commission's finding, (App. at 359), that these devices were permitted under the infeasibility exception because of a shortage of single-use holders. MetWest Br. at 14-17. MetWest does not dispute that a supply problem actually existed, but rather asserts that the lack of any OSHA meetings with employers, or findings in the preamble to the final rule, on the shortage of single-use blood tube holders shows that OSHA could not have based its acceptance of reusable holders on any such shortage. *Id.* at 14-15. MetWest also contends that the preamble's findings that the standard is technologically feasible and that many employers are close to full compliance with it further undermine the Commission's finding. *Id.* at 16-17.

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the general ban on needle removal applies and unless the Compliance Officer determines that one of the removal provision's exceptions is applicable, the employer should be cited under that provision. *Ibid.*

These arguments are without merit. MetWest's argument that one-handed removals are not covered by the removal provision are precluded by the plain language of that provision, which expressly allows for the use of a one-handed technique under an exception to the ban on removal of needles when the employer can demonstrate that no alternative is feasible. This requirement of demonstration reflects the agency's understanding that medical technology is not static. OSHA could not have made conclusive findings, in advance, on the circumstances in which removal is necessary. Moreover, there was no need to consult with employers about the supply of single-use blood tube holders at a time when it was generally understood (as MetWest acknowleged before the Commission) that single-use blood tube holders were not widely available (App. at 312, 316, 323, 347, 356).

MetWest's arguments about the preamble's findings of technological feasibility and many employers' near compliance with the standard also do not refute the Commission's finding on the infeasibility exception. The preamble's feasibility analysis determined whether technology was available to make

compliance with the standard as a whole generally feasible. The finding of general feasibility is not inconsistent with the recognition that, under specific provisions of the standard, feasibility problems may exist for certain devices and procedures, and the removal provision expressly provides for such problems. *See United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1270 (D.C. Cir. 1980) (feasibility of a standard does not mean that it is feasible for all firms at all times in all jobs). Similarly, the preamble's finding that many employer are close to full compliance with the standard does not support MetWest's argument because such compliance includes qualifying for the provision's exceptions, including the inability to obtain single-use blood tube holders where there is a shortage of such devices – the very condition that MetWest claims that OSHA did not accept in the preamble.

2. Contrary to MetWest's claim, OSHA instruction CPL 2-2.69 (Nov. 27, 2001), (App. at 104) did not represent a change in the agency's interpretation of the standard. MetWest Br. at 9. The directive restated the Secretary's position that "removing contaminated needles is prohibited as

a general practice," but may be necessary in certain circumstances. (App. at 105.) In the directive, however, the Secretary indicated that, unlike in her prior policy of declining to take issue with the applicability of the exceptions, she would now require employers to demonstrate, on a case-by-case basis, that an exception applies. Thus, under the directive, a needle must be immediately discarded after use unless the employer demonstrates the existence of circumstances necessitating removal. (*Ibid.*)

In a subsequent document, OSHA explained the basis for requiring employers to demonstrate the infeasibility of alternatives to removal. OSHA Safety and Health Information Bulletin (SHIB) (October 15, 2003). (App. at 122.) The SHIB observed that single-use holders ("safety-engineered medical devices") have become more available, (*ibid.*), and that accordingly, feasibility would be established only in "very rare situations," where the employer can demonstrate an inability to purchase such devices because of a supply shortage. (*Id.* at 124.)

3. MetWest further asserts that *Union Tank Car Co.*, 18 BNA OSHC 1067 (No. 96-0563, 1997), where the Review

Commission found that the Secretary could not change a long-standing interpretation of a standard without an adequate explanation and rule-making, shows that APA rule-making requirements should have been applied here. MetWest's Br. at 22-23. MetWest also alleges that the Secretary's change in her position without rule-making unfairly surprised the regulated community. *Id.* at 23.

MetWest's reliance on *Union Tank Car Co.*, 18 BNA OSHC 1067 (No. 96-0563, 1997), is misplaced. That case involved the Secretary's change in her long-standing interpretation of a an ambiguous provision of a standard and her failure to elaborate the policy concerns that led to the change. *Id.* at 1069. Here, by contrast, the basis for the cited violation is the plain meaning of the removal provision, and the Secretary has consistently applied the provision in accordance with its plain meaning. (App. at 359-60.) The Secretary has not changed her interpretation that the standard prohibits removal of needles by any means unless the employer demonstrates that an exception applies. While the Secretary now enforces the standard more stringently in light of changed conditions, this

change in enforcement policy does not require rule-making or detailed explanation. *Hudson v. FAA*, 192 F.3d 1031, 1036-37 (D. C. Cir. 1999). In any case, the Secretary has adequately explained the basis for the new policy. S*ee supra*, pp. 35-36. Thus, *Union Tank Car* is completely inapplicable here.[10]

In sum, the Secretary's guidance documents have consistently indicated that the removal of a needle from a reusable blood tube holder is permitted only if such removal is necessary on feasibility or medical necessity grounds. The only difference between the agency's current guidance materials and those issued immediately following promulgation of the standard is that because of the ready availability of safer single-use devices, OSHA now enforces the exceptions more stringently. MetWest does not invoke an exception under paragraph (d)(2)(vii)(A); rather the company

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[10] MetWest cites no evidence that it, or any other employer, was prejudiced by the Secretary's change in enforcement policy. Since MetWest was not cited until March 1, 2004, (App. at 185), more than two years after the Secretary announced her stricter enforcement policy, (App. at 104), and after three OSHA publications, posted on the agency's Web site, notified the regulated community of that policy change, (App. 104, 119, 122), MetWest cannot plausibly argue that it lacked fair notice of the change.

claims that the paragraph does not apply to one-handed needle removal techniques. As we have shown, MetWest's argument is contrary to the standard's plain terms.

II. *The Needlestick Safety and Prevention Act Does Not Prohibit the Secretary from Enforcing the Removal Provision's Ban on the Use of Reusable Blood Tube Holders.*

A. This issue involves the interpretation of a statute that the Secretary administers. Questions of textual interpretation are issues of law and are decided *de novo*. *Yousuf v. Samantar*, 451 F.3d 248, 251 (D.C. Cir. 2006). If the intent of Congress on the precise question at issue is clear, that intent must be given effect. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984). If, however, the statute is silent or ambiguous, with respect to the specific issue, considerable weight should be given to the agency's construction as long as it is reasonable. *Id.* at 843-44. To the extent that there are nontextual issues, as noted earlier, they are reviewed under a standard that is highly deferential to the Commission's findings. *See supra*, pp. 22-23.

MetWest argues that the Needlestick Safety and Prevention Act (Needlestick Act), Pub. L. No. 106-430, 114 Stat. 1901 (2000), MetWest's Br., Add. at 18, tacitly approved the Secretary's contemporaneous interpretation that the removal provision permits the use of reusable blood tube holders. MetWest's Br. at 26-27. MetWest also asserts that the Secretary's ban on the use of these holders violates the Act's requirement that employers select a safer medical device. *Id.* at 27-28. MetWest further contends that, in selecting its Pronto reusable blood tube holder, it complied with this requirement by selecting a safer device than the single-use blood tube holder that OSHA requires. *Id.* at 28-29. As shown below, none of these arguments has merit.

There is no basis for MetWest's reading that the Needlestick Act ratifies OSHA's contemporaneous enforcement policy of permitting reusable blood tube holders under the exceptions clause of the removal provision. In the first place, the Needlestick Act provision in question simply requires employers to consider annually the implementation of commercially available and safer medical devices. Needlestick

Act, § 3(4), 114 Stat. at 1903, MetWest's Br., Add. at 20. As the legislative history of the Needlestick Act reveals, this annual review requirement is no different from what the Secretary had already administratively required employers to do for years:

> Through the mandatory exercise of the annual review of the ECP [exposure control plan], employers are required to evaluate workplace explosures to bloodborne hazards and make changes to their ECP which include the consideration and implementation of new technology – safer medical devices and safe work practices – where feasible. This requirement was stated in the preamble to the standard in 1991, and also reiterated in the 1992 compliance directive.

OSHA's Compliance Directive on Bloodborne Pathogens and the Prevention of Needlestick Injuries, Hearings on H.R. 5178 Before the Subcomm. on Workforce Protections of the House Education and the Workforce Comm., 106th Cong. (2000) (statement of Charles L. Jeffress, Assistant Secretary, OSHA), MetWest's Br., Add. at 26. The statutory codification of an existing administrative requirement cannot reasonably be read as precluding the Secretary's enforcement of the specific requirements of the removal provision. (App. at 351.)

Second, MetWest's argument presumes that in the 1990s OSHA *interpreted* the removal provision to permit use of reusable blood tube holders, and that, in the Needlestick Act, Congress tacitly approved that interpretation. In fact, the only "interpretation" of the removal provision that OSHA has made, from the 1990s to the present, has been to follow the provision's plain meaning, which bans removal of contaminated needles, except where the employer can demonstrate that no alternative is feasible or removal is medically necessary. Tacit approval of the plain meaning of the removal provision would prohibit, not permit, the use of reusable blood tube holders. As the Commission found, OSHA permitted the use of such devices under the exceptions clause of the removal provision as a matter of enforcement policy. (App. at 360.) There is no basis for reading the Act as prohibiting the Secretary from enforcing the removal provision's ban on the use of reusable blood tube holders.[11]

[11] Indeed, the Needlestick Act's requirement that employers consider and implement *commercially available* safer medical devices, Needlestick Act, Pub. L. No. 106-430, § 3(4)(B), 114 Stat. 1901, 1903 (2000), MetWest's Br., Add. at 20, is

B. MetWest also contends that, in selecting its reusable blood tube holder, it complied with the Needlestick Act by selecting a reusable blood tube holder, a safer device than the single-use blood tube holder that the Secretary requires. MetWest's Br. at 28-29. This contention is unfounded. There is nothing in the Needlestick Act that permits employers to ignore the specific requirements of the removal provision, and employers may not substitute their own judgment for the express requirements of an OSHA standard. *Fluor Daniel v. Occupational Safety & Health Review Comm'n*, 295 F.3d 1232, 1240 (11th Cir. 2002).

If MetWest really believed that its reusable blood tube holder was safer than a single-use device, the company could have applied for a variance from the standard. OSH Act, 29

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consistent with OSHA's rationale for enforcing the removal provision less strictly when single-use blood tube holders were scarce and more strictly when such devices were widely available. The legislative history makes this point even more explicit: "the requirement in this legislation for the consideration and implementation of safer medical devices is hinged upon the 'appropriateness' and the 'commercial availability' of such devices." Cong. Rec. E 1513 (daily ed. Sept. 18, 2000) (statement of Rep. Ballenger), MetWest's Br., Add. at 29; 146 Cong. Rec. S11043 (2000); MetWest's Br., Add. at 32.

U.S.C. § 655(d). Since MetWest did not do so or contend that requesting a variance would have been futile, (App. at 352), the company cannot excuse its violation of the removal provision by arguing that its medical device was safer and that therefore the Needlestick Act required the company to commit the violation.

In any event, MetWest has not proved that the reusable blood tube holder is safer than the single-use holder. MetWest's parent company, Quest Diagnostics, operates about 400 patient service centers in California that use the single-use blood tube holder, and MetWest's own witness conceded there is no meaningful statistical difference between the rate of needle stick injuries at those facilities and the rate of such injuries at Quest facilities, such as MetWest, that use reusable devices. (App. at 263-64, 339-41, 348).[12]

The record also contains studies showing that the reusable holders are more dangerous than single-use holders

[12] Since the ALJ found that MetWest's needlestick records were incomplete and that the company failed to show that those records were statistically significant, (App. at 351), it is likely that the company understated the rate of needle stick injuries at its facility.

(App. at 100, 158-62, 166-67). Based in part on these and other studies, the Secretary has repeatedly found that blood tube holders shoud not be reused. Preamble to the Final Rule, 56 Fed. Reg. 64,004, 64,118 (1991); (App. at 105, 119-20, 122-24.) Therefore, MetWest has not established that its reusable blood tube holder is a safer medical device.

CONCLUSION

For these reasons, the court should affirm the Commission's final order affirming the violation of 29 C.F.R. § 1910.1030(d)(2)(vii)(A) and assessing a penalty of $1,875.

Respectfully submitted.

GREGORY F. JACOB
Solicitor of Labor

JOSEPH M. WOODWARD
Associate Solicitor for
Occupational Safety and Health

CHARLES F. JAMES
Counsel for Appellate Litigation

/s/_____
SCOTT GLABMAN
Senior Appellate Attorney
U.S. Department of Labor
200 Constitution Ave., N.W.
Washington, D.C. 20210
(202) 693-5493

JULY 2008

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Elizabeth L. Ash, Esq.
EAsh@seyfarth.com

Brent I. Clark, Esq.
bclark@seyfarth.com

James L. Curtis, Esq.
jcurtis@seyfarth.com

/s/_____
SCOTT GLABMAN
Attorney for the Department of Labor