PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 03-4184

UNITED STATES OF AMERICA

v.

JAMES C. FALLON,
Appellant

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Crim. No. 02-cr-00324)
District Judge: Hon. James T. Giles

Argued July 12, 2005[*]

Before: SLOVITER, McKEE and ROSENN,[**] Circuit Judges

(Filed: December 12, 2006)

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[*]The court en banc heard argument on November 1, 2005 on the issue raised by Fallon with respect to the applicability of the Sixth Amendment to the restitution order. The en banc opinion rejecting Fallon's argument was filed February 15, 2006. Fallon and the defendants in the other cases raising the same issue filed a petition for a writ of certiorari before the Supreme Court of the United States, which denied the petition on November 27, 2006.

[**]Judge Rosenn heard oral argument on this case both before the panel and before the en banc court on November 1, 2005, but passed away on February 7, 2006.

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OPINION OF THE COURT

SLOVITER, Circuit Judge.

Appellant James C. Fallon was convicted by a jury of one count of wire fraud and three counts of mail fraud in the United States District Court for the Eastern District of Pennsylvania. This is an appeal of the District Court's judgment of conviction

and sentence entered on October 16, 2003.[1]

I.

Fallon was the president of Derma Genesis, a company which manufactured and distributed microdermabradors under the name "Derma Peel."[2] Dermabradors are classified by the Food, Drug, and Cosmetic Act ("FDCA") as class I medical devices (a device which carries the lowest amount of medical risk). See generally 21 U.S.C. § 360c(a). Prior to February 18, 1998, manufacturers who wished to market a Class I device were required to first obtain a 510(k) letter from the Food and Drug Administration, indicating that the device was substantially equivalent to an existing device previously approved for distribution. See generally 21 U.S.C. § 360(k).[3]

In November 1997, the FDA received notice that Fallon was marketing Derma Peel without obtaining the requisite clearance from the FDA. By letter dated November 4, 1997, a representative of the FDA informed Fallon that this practice was prohibited; Fallon acknowledged receipt of the letter and filed a formal clearance application on November 19, 1997. On that date, the FDA assigned a unique computer-generated number to his application, and sent Fallon a letter instructing him to use the number on all future correspondence.

In January 1998, prior to obtaining 510(k) approval from the FDA, Fallon met with a group of medical-device salesman in

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[1]The District Court had jurisdiction under 18 U.S.C. § 3231; we have jurisdiction under 28 U.S.C. § 1291 and 18 U.S.C. § 3742(a).

[2] Dermabradors are motor-driven devices that force abrasive crystals over the surface of the skin and vacuum away exfoliated skin.

[3]The reference to a 510(k) letter is to § 510(k) of the Food, Drug, and Cosmetic Act which is codified as 21 U.S.C. § 360(k). Because it is generally referred to in the industry as a 510(k) letter, it will be referred to in that manner in this opinion.

an effort to promote the Derma Peel. In attendance was Michael Coffelt, director of medical sales for a company in the process of merging with American Business Leasing ("ABL"). Coffelt was impressed with Fallon's presentation and recommended to ABL that it enter into a vendor agreement with Derma Genesis, whereby ABL would buy Derma Peel devices and lease them to interested doctors.

ABL's credit personnel were reluctant to do business with Derma Genesis because Fallon had previously filed for bankruptcy protection, Derma Genesis was a start-up company with an unproven track record and unproven equipment, and because Fallon failed to provide certain requested tax and social security information. Coffelt, however, lobbied ABL to re-consider its decision.

On February 9, 1998, Fallon faxed to ABL, among other things, a purported 510(k) clearance letter on FDA letterhead. The government's evidence at trial demonstrated definitively that the letter was a fabrication. The November 4, 1997 date stamp of the letter was lifted from an earlier FDA correspondence to Fallon, which cautioned him not to market Derma Peel until he had obtained prior FDA clearance. Further, although the letter was purportedly signed by Consumer Safety Officer "Margaret Shuppers," FDA's records reveal that there has never been an FDA employee by that name. Finally, the letter bore Fallon's unique 510(k) application number, even though that number was not assigned to him until November 19, 1997, two weeks after the November 4 date stamp.[4]

In February of 1998, Alan Frankel, president of ABL,

[4] By letter dated December 10, 1998, the FDA advised Fallon that as of February 19, 1998 (ten days after Fallon faxed the fabricated 510(k) clearance letter to ABL), his product had been exempted from the pre-clearance requirement by virtue of Food and Drug Administration Modernization Act of 1997.

authorized the company to enter into a relationship with Fallon.[5] Over the next several months, ABL purchased 70 microdermabradors from Derma Genesis which it planned to lease to physicians. ABL's relationship with Derma Genesis ended in October 1998, after ABL determined that the value of the devices had dropped significantly over the course of the year and that an abnormally high percentage of doctors were behind on their lease payments.

On June 4, 2002, Fallon was indicted by a grand jury and charged with one count of wire fraud, in violation of 18 U.S.C. § 1341, and four counts of mail fraud, in violation of 18 U.S.C. § 1343. A superseding indictment was returned on October 1, 2002, adding one count of witness tampering in violation of 18 U.S.C. § 1512. The basis for the fraud charges was the fabricated FDA clearance letter.

At trial, Frankel testified that ABL had a policy of requiring FDA clearance from medical device manufacturers which he claimed he had brought with him from his prior employer, Capelco Leasing. He further testified that he explicitly required Fallon to produce a 510(k) clearance letter as a condition to doing business with Derma Genesis. He stated that documentary proof of this statement was lost at the time of trial.

Fallon attempted to rebut Frankel's testimony through the testimony of Michael Coffelt and Joseph Nachbin. Coffelt testified that in his fifteen years experience in the medical leasing business, he had never requested nor seen an FDA clearance letter prior to this case.

Nachbin, a former Vice President and Chief Operating

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[5] The record reveals some support for Fallon's contention that ABL was doing business with Derma Genesis even before ABL received the fabricated 510(k) letter. On February 5, 1998 (four days before receiving the fabricated 510(k)), ABL approved a lease of Fallon's product to Dr. William Green.

Officer at Capelco, was proffered as a fact witness[6] to testify to the customs and practices of the medical leasing industry,[7] and to rebut Frankel's assertion that Capelco had a policy of requiring FDA clearance before entering into leasing relationships with medical device suppliers. Before allowing Nachbin to testify at trial, the District Court made an in limine inquiry into his testimony outside the jury's presence.

Although the Court allowed Nachbin to testify to his personal experience at Capelco, it prohibited him from offering testimony on the custom and practice of the medical leasing industry, stating that:

> I will not permit him to testify as to [the] industry, because he does not speak for an[d] cannot speak for the entire industry. And, beyond that, he cannot say that a particular company could not have, for a particular product or particular circumstances presented by the manufacturer, required a 510(k) clearance letter. And, he can't say what was, in fact, done by this particular leasing company.

App. at 867.

At the conclusion of trial the District Court dismissed Count Six (witness tampering) for insufficient evidence. The

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[6] Nachbin was originally offered as an expert witness to testify as to custom and practice. For reasons not entirely clear from the record, on May 12, 2003, Fallon apparently withdrew Nachbin as an expert witness and proffered him instead as a fact witness.

[7] Nachbin has thirty-two years' experience in the medical leasing industry. At the time of trial, Nachbin was a principal of the Alta Group, a consulting group to the equipment leasing and financing industry, had been on the board of directors of the Equipment Leasing Association, and was the author of several articles in Leasing Monitor Magazine.

jury then returned a verdict of guilty on Count One (wire fraud) and on Counts Two through Four (mail fraud). Fallon was found not guilty on Count Five (mail fraud). On October 14, 2003, Fallon was sentenced to a term of imprisonment of twelve months and one day to be followed by a thirty-six month term of supervised release, a fine of $1,000, and restitution in the amount of $55,235.86.

Fallon filed a timely notice of appeal.

II.

Fallon argues that 1) The District Court committed reversible error by precluding him from eliciting Nachbin's testimony regarding the custom and practice of the medical leasing industry; and 2) the Court erred with respect to its order of restitution by adopting an unlimited theory of "but for" causation.[8]

A. Exclusion of Nachbin's Custom and Practice Testimony

We review a district court's decision to admit or exclude testimony for abuse of discretion. See United States v. Pelullo, 964 F.2d 193, 199 (3d Cir. 1992). To the extent that these rulings are based on an interpretation of the Federal Rules of Evidence, however, our review is plenary. Id.

The critical issue at Fallon's trial was the materiality of the fabricated 510(k) letter. The jury was instructed, as part of the mail fraud counts, that:

> [t]he Government has to prove . . . that the scheme to defraud employed false material misrepresentations. False embraces the concept that there was a fake FDA letter. Material means

[8] Falon's third argument, that the District Court violated his Sixth Amendment rights by ordering restitution on the basis of facts that were not found by the jury beyond a reasonable doubt was rejected by the en banc court. See supra note *.

> that the statement would have a natural tendency to influence or is capable of influencing the decision of a person or entity to which it is addressed. That it would have the tendency and is capable of influencing or causing another person to rely upon it, to act because of it.

App. at 1013a; see also Neder v. United States, 527 U.S. 1, 16 (1999).

Fallon sought to introduce Nachbin's testimony regarding the custom and practice of the industry to rebut Frankel's assertions that ABL had a policy of requiring FDA clearance from device manufacturers (which he had brought from Capelco), and that he himself relied upon the fabricated 510(k) letter in entering into the business relationship with Derma Genesis.

This court has consistently allowed "testimony concerning business customs and practices." United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991) (citation omitted) (providing that such evidence is relevant "both to explain the practice of the industry in which this prosecution arose and to establish what someone with Leo's extended background in the industry probably would know"); First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981) (per curiam) (permitting admission of evidence of customs and practices in the banking industry); see also Marx & Co., Inc. v. Diners' Club, Inc., 550 F.2d 505, 509 (2d Cir. 1977) ("Testimony concerning the ordinary practices of those engaged in the securities business is admissible under the same theory as testimony concerning the ordinary practices of physicians or concerning other trade customs[.]"). Contrary to the District Court's understanding, a witness need not represent an entire industry in order to have sufficient knowledge of that industry's customs and practices so as to render substantial assistance to the jury. See, e.g., Leo, 941 F.2d at 196-97. Thus, we find the District Court's exclusion of Nachbin's custom and practice testimony was erroneous as a matter of law.

We will not, however, grant Fallon a new trial because we

find this error harmless.[9] As stated in Chapman v. California, 386 U.S. 18, 24 (1967), an error is harmless if the record demonstrates "beyond a reasonable doubt that the error complained of did not contribute to the verdict obtained." See also Fed. R. Crim. P. 52(a).[10] As the Supreme Court has stated, an "otherwise valid conviction should not be set aside if the reviewing court may confidently say, on the whole record, that the . . . error was harmless beyond a reasonable doubt." Delaware v. Van Arsdall, 475 U.S. 673, 681 (1986).

Notwithstanding the District Court's decision prohibiting Nachbin from testifying to the custom and practice of the industry, the Court did permit Nachbin to testify to the more pertinent issue of whether Capelco had a practice of requiring FDA clearance from device manufacturers during the time period when Frankel was employed at the company. Thus, to the extent that Fallon sought to impeach Frankel's testimony, Nachbin's more specific and relevant testimony was heard by the jury. Furthermore, the jury did hear general testimony regarding custom and practice of the leasing industry from Coffelt, who testified that in his fifteen years' experience of bringing new products to market, he had never requested a manufacturer to produce a clearance letter nor had he even seen such a letter prior to this case.[11]

We therefore conclude that although the District Court's decision prohibiting Nachbin from testifying as to industry

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[9] Fallon properly preserved this error at trial.

[10] Rule 52(a) of the Federal Rules of Criminal Procedure, which governs direct appeals from judgments of conviction in the federal system, provides that "[a]ny error, defect, irregularity, or variance that does not affect substantial rights must be disregarded."

[11] Coffelt further testified FDA clearance letters were not customary because leasing companies, such as ABL, make no representations regarding the equipment they lease. Instead, the lessee assumes the equipment at his or her own risk.

custom and practice was error, this error was harmless, and a new trial is not warranted.

B. The District Court's Calculation of Restitution

As part of his sentence, Fallon was ordered to pay restitution in the amount of $55,235.86. The District Court calculated this figure by crediting ABL's statement that it had approximately $125,000 in unpaid lease payments on Derma Peel accounts. The court subtracted approximately $30,000 for lease payments that had in fact been paid, and subtracted another $40,000 was for the residual value of the Derma Peel devices now owned by ABL. In making its calculations, the Court stated:

> I credited the testimony of ABL that it would not have dealt with Mr. Fallon, but for the representations made to it . . . that it was [a] cleared device. . . . And therefore having launched itself based upon Mr. Fallon's misrepresentation, whatever was not collected under those contracts becomes part of the loss to the victim.

App. at 1087a-88a.

Fallon contends that the District Court erred by adopting a theory of unlimited "but for" causation by which he was ordered to pay restitution for any lease payments that ABL did not receive, regardless of the doctors' reasons for not making them. For instance, one doctor had passed away while his lease was still active; ABL could not enforce the lease against his heirs, and the company charged Fallon with a loss of $11,562.06. Another doctor filed for bankruptcy during the course of his lease. Nonetheless, ABL charged Fallon with causing a loss of $ 22,219.89. In addition, Fallon notes that the District Court failed to credit any profit that ABL may have made by leasing Fallon's product. Thus, Fallon argues, ABL may not have experienced any loss whatsoever with respect to the lease transaction; rather, it may merely have earned a lesser profit than it had originally anticipated.

We "review a restitution order under a bifurcated standard: plenary review as to whether restitution is permitted by law, and abuse of discretion as to the appropriateness of the particular award." United States v. Quillen, 335 F.3d 219, 221 (3d Cir. 2003) (internal quotation and citations omitted). Because Fallon challenges the legality of the restitution order, our review is plenary.

The Mandatory Victims Restitution Act ("MVRA") provides that:

> (a)(1) Notwithstanding any other provision of law, when sentencing a defendant convicted of an offense described in subsection (c), the court shall order, in addition to . . . any other penalty authorized by law, that the defendant make restitution to the victim of the offense . . . .
>
> (2) For the purposes of this section, the term "victim" means a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern . . . .

18 U.S.C. § 3663A. By the statute's explicit terms, loss can only be paid to victims who are "directly and proximately harmed." Id.

Thus, this court, as well as others, has repeatedly recognized that under the MVRA "restitution must be . . . 'based upon losses directly resulting from [the defendant's criminal] conduct.'" Quillen, 335 F.3d at 222 (quoting Gov't of V.I. v. Davis, 43 F.3d 41, 45 (3d Cir. 1994)).[12] The First Circuit has

[12] For scheme-based crimes such as wire fraud and mail fraud, see, e.g., United States v. Dobson, 419 F.3d 231 (3d Cir.

adopted the following two-prong test:

> First: Restitution should not be ordered in respect to a loss which would have occurred regardless of

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2005), the term "victim" is broadly defined by the MVRA. See 18 U.S.C. § 3663A (stating that the "in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, [the term victim means] any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern. . . .").

Several courts have interpreted this language to hold that restitution: 1) may be ordered to a victim not named in the indictment, provided that the victim was "directly harmed by the defendant's criminal conduct in the course of a scheme or conspiracy." United States v. Henoud, 81 F.3d 484, 489 (4th Cir. 1996); see also United States v. Kones, 77 F.3d 66, 70 (3d Cir. 1996); 2) may be ordered for losses which result from acts or conduct related to the scheme, but for which the defendant was not convicted; cf. United States v. Lawrence, 189 F.3d 838, 846 (9th Cir. 1999); United States v. Hensley, 91 F.3d 274, 277 (1st Cir. 1996); or 3) may be ordered for losses of a common scheme, even though the loss was caused by conduct occurring outside the statute of limitations. See United States v. Dickerson, 370 F.3d 1330, 1342 (11th Cir. 2004).

Nonetheless, despite Congress' clear intent to broaden the district court's authority to grant restitution for crimes involving a scheme or conspiracy, we are unaware of any cases holding that the definition of "victim" for scheme-based crimes diminishes the requirement that losses be "directly" caused by the defendant's actions. See, e.g., Dickerson, 370 F.3d at 1342-43 ("The district court must find that the victims' losses resulted 'directly' from the defendant's conduct in the course of the scheme."); Kones, 77 F.3d at 70 (holding the "harm to the victim [must be] closely related to the scheme, rather than tangentially linked"). Thus, even for scheme or conspiracy based crimes, the government bears the burden of showing that the loss suffered was "directly" caused by defendants' actions.

> the defendant's conduct. . . .
>
> Second: Even if but for causation is acceptable in theory, limitless but for causation is not. Restitution should not lie if the conduct underlying the offense of conviction is too far removed, either factually or temporally, from the loss.

United States v. Vaknin, 112 F.3d 579, 589 (1st Cir. 1997).

In the present case, the Court found by a preponderance of the evidence that ABL would not have entered into the leasing arrangement with Fallon but for the fabricated 510(k) FDA clearance letter. We believe that where, as here, the government demonstrates that a business transaction was consummated due to fraud by the defendant, a commonsense, but rebuttable inference arises that subsequent losses suffered by the victim of the fraud are sufficiently linked to the underlying fraud to support an award of restitution. Cf. Vaknin, 112 F.3d at 590. We conclude, however, that Fallon presented the District Court with sufficient evidence to rebut certain portions of the Court's restitution award. As noted, approximately $34,000 of the District Court's $55,235.86 restitution judgment can be attributed to lease payments missed by two doctors, one dead and one who filed for bankruptcy. The government failed to present evidence that either of these nonpayments was directly related to the fraud.

The government argues, however, that the District Court's restitution order was appropriate because ABL was unable to enforce any of its lease agreements related to the Derma Peel. It explains that because the various leases were entered into after each doctor was assured that the device had received FDA clearance, the doctors could assert defenses of fraudulent inducement. In support of its argument, the government relies on the testimony of ABL's in-house counsel that one doctor raised such a defense in a telephone conversation.

The government is correct that the District Court should consider the enforceability of the outstanding lease contracts

when calculating the appropriate amount of restitution. However, whether the doctors may have colorable fraudulent inducement claims is far from certain. See In re Allegheny Int'l, Inc., 954 F.2d 167, 178 (3d Cir. 1992) (setting forth the common law elements of fraudulent inducement). On February 19, 1998, prior to the start date of any of the leases, Derma Peel was exempted from all pre-clearance requirements by the Food and Drug Administration Modernization Act of 1997.

Finally, the record shows only one incident where a doctor raised (informally) the defense of fraudulent inducement. Even assuming that a fraudulent inducement defense is colorable under these facts, several doctors defaulted for reasons completely unrelated to the representations made regarding Fallon's product (i.e., death or bankruptcy). Thus, the government's blanket argument supporting the present restitution order cannot be sustained.

Accordingly, we will vacate the restitution order and remand to the District Court for a new restitution hearing.[13]

III.

For the reasons given above, we will affirm Fallon's judgment of conviction and sentence and vacate the District Court's restitution order and remand for further proceedings consistent with our opinion.

[13] Fallon has served his sentence of incarceration and is on supervised release. He has been permitted to work so that he can accumulate funds necessary to pay restitution. It is therefore requested that the District Court schedule a restitution hearing as promptly as possible.