

Filed: March 19, 1997

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 96-4536
(CR-91-378-HAR)

United States of America,

Plaintiff - Appellee,

versus

Robert Shulman,

Defendant - Appellant.

O R D E R

The Court amends its opinion filed February 27, 1997, as follows:

On page 6, third full paragraph, line 2 -- the phrase "the district held" is corrected to read "the district court held."

For the Court - By Direction

/s/ Patricia S. Connor

Clerk

UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

No. 96-4536

ROBERT SHULMAN,
Defendant-Appellant.

Appeal from the United States District Court
for the District of Maryland, at Baltimore.
John R. Hargrove, Senior District Judge.
(CR-91-378-HAR)

Argued: January 31, 1997

Decided: February 27, 1997

Before WILKINSON, Chief Judge, and WILLIAMS and
MICHAEL, Circuit Judges.

Affirmed by unpublished per curiam opinion.

COUNSEL

ARGUED: Mark Daryl Rasch, Bethesda, Maryland, for Appellant.
Lawrence McDade, Deputy Director, Office of Consumer Litigation,
UNITED STATES DEPARTMENT OF JUSTICE, Washington,
D.C., for Appellee. **ON BRIEF:** Lynne A. Battaglia, United States
Attorney, UNITED STATES DEPARTMENT OF JUSTICE, Wash-
ington, D.C., for Appellee.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

OPINION

PER CURIAM:

Robert Shulman appeals the sentence imposed by the district court following his plea of guilty to one count of conspiracy to defraud the United States, see 18 U.S.C.A. § 371 (West 1966 & Supp. 1996); one count of wire fraud, see 18 U.S.C.A. § 1343 (West Supp. 1996); two counts of making a false statement to the Food and Drug Administration (FDA), see 18 U.S.C.A. § 1001 (West Supp. 1996); and one count of obstructing an FDA investigation, see 18 U.S.C.A. § 1505 (West Supp. 1996).¹ He maintains that the district court erred in finding that the victims of his offenses suffered an economic loss in excess of \$80 million, resulting in the application of an 18-level enhancement to his base offense level under the Sentencing Guidelines. See U.S. Sentencing Guidelines Manual § 2F1.1(b)(1)(S) (1995). Because we conclude that the district court properly applied a fraud loss enhancement under U.S.S.G. § 2F1.1(b)(1), we affirm Shulman's sentence.

I.

Shulman was president, chief executive officer, chairman of the board of directors, and a major shareholder of Bolar Pharmaceutical Company, Inc., a manufacturer of generic drugs. As president and chief executive officer of the company, he was responsible for the overall management of Bolar and supervised the creation and testing of various generic drugs for which Bolar hoped to obtain marketing approval from the FDA. The several drugs that were the subject of his guilty plea were identified, for purposes of this appeal, as "cover-sheet" drugs and generic Dyazide.

¹ Shulman also pled guilty to one count of price-fixing in violation of the Sherman Act, see 15 U.S.C.A. § 1 (West Supp. 1996), which was charged separately. He received a 21-month concurrent sentence which he does not challenge.

A. "Coversheet" drugs

In March 1985, FDA investigators discovered that the company was manufacturing a number of generic drugs by formulas or processes not approved by the FDA. Once the FDA has approved the manufacture and marketing of a generic drug according to a certain formula, a manufacturer is required to seek FDA approval before making any modification to that formula, regardless of how insignificant the modification may be. See 21 C.F.R. § 314.70 (1996). Accordingly, the FDA required Bolar to halt the distribution of, and perform expensive bioequivalence studies² on, several generic drugs.

As a result of that expensive and disruptive episode, Shulman instructed Bolar employees to document future deviations from FDA-approved formulas or processes on "coversheets." When problems were encountered with making a product by the FDA-approved master formula, Shulman instructed Bolar employees to make changes in the ingredients or manufacturing process and then record the changes on the "coversheet." Bolar's production department maintained a copy of the coversheets to facilitate future production of the product, but the coversheets were hidden from FDA investigators. The batch production records kept pursuant to FDA regulations and made available to FDA investigators were completed by Bolar employees as if the approved master formula, rather than the coversheet formula, had been followed.

Bolar filed supplemental abbreviated new drug applications (ANDAs) requesting approval of the changes and, as respective FDA approvals were received, discontinued the coversheet practice on a

² When submitting an abbreviated new drug application (ANDA) seeking FDA approval to market a generic drug, an applicant must demonstrate that the generic formulation is bioequivalent to the name-brand drug. See 21 C.F.R. § 314.94(a)(7) (1996). Generally speaking, "[b]ioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e) (1996) (emphasis omitted).

product-by-product basis. Six supplemental ANDAs (relating to six coversheet drugs) were never approved by the FDA, and formed the basis for the indictment and the guilty plea. The Government contends, and on appeal Shulman apparently concedes, that Bolar received approximately \$70 million in revenue from the six remaining drugs manufactured under the coversheet scheme.

B. Generic Dyazide

In 1987, Bolar submitted an ANDA to the FDA in an attempt to obtain approval to market triamterene-hydrochlorothiazide, the generic version of the name-brand drug Dyazide used to treat hypertension. To gain approval, FDA regulations required the submission of a bioequivalence study. *See* 21 C.F.R. § 314.94(a)(7) (1996). Accordingly, in January 1987, the FDA instructed Bolar to supply samples of both generic Dyazide and name-brand Dyazide for bioequivalency testing at Pharmakinetik Laboratories in Baltimore, Maryland. Because Bolar had experienced difficulty in maintaining the stability of its generic Dyazide, Jacob Rivers, Bolar's vice-president, substituted brand-name Dyazide in Bolar capsules for the FDA to test. As a result, the FDA, believing that it was testing Bolar's generic Dyazide, tested name-brand Dyazide against itself. Not surprisingly, the FDA approved Bolar's ANDA for generic Dyazide in August 1987, and sales began immediately.

In June 1989, Pharmakinetik Laboratories informed Shulman that it had discovered the fraudulent substitution in the bioequivalence study. Immediately, Shulman began aggressively campaigning to cover up the facts about the bioequivalence study's false samples. He flew to Baltimore with Rivers and met with Pharmakinetik Laboratories' chief scientific officer, Mark Perkal, in an attempt to conceal the fraudulent study. After Perkal stated that he had to consult with his rabbi in New York City before taking such serious action, Shulman, Rivers, and Perkal flew to New York where Perkal met with his rabbi and ultimately agreed to participate in the cover-up. The next day, Shulman had samples of the name-brand Dyazide used in the bioequivalence study removed from Pharmakinetik Laboratories' offices, and had them replaced with samples of Bolar-manufactured product. FDA investigators arrived at Pharmakinetik Laboratories two days later.

Despite Shulman's herculean efforts, the elaborate cover-up unraveled in January 1990. At that time, Bolar stopped selling generic Dyazide. During the time Bolar sold generic Dyazide, the company earned approximately \$142 million in gross sales of the drug. From June 1989, the date Shulman admits he learned that the FDA approval had been fraudulently obtained, until January 1990 when Bolar stopped selling the drug, the company earned approximately \$34 million in generic Dyazide sales.

C.

On November 7, 1991, Shulman pled guilty to one count of conspiring to defraud the United States, one count of wire fraud, two counts of making a false statement to the FDA, and one count of obstructing an FDA investigation. Although the plea agreement between Shulman and the Government stipulated to the appropriate application of the sentencing guidelines, the parties reserved the right to contest the proper application of the loss enhancement provision § 2F1.1(b)(1) -- the Government taking the position that Shulman's offense level should be increased by eighteen levels based on a loss in excess of \$80 million, and Shulman arguing that a loss enhancement of far less was appropriate.

During the initial sentencing hearing, the district court determined that the amount of Bolar's sales of coversheet drugs and generic Dyazide was the appropriate measure of loss under U.S.S.G. § 2F1.1(b)(1). It accepted the Government's argument that economic gain to the manufacturer was the proper measure of loss on the theory that because the drug did not meet FDA specifications, it had no value. Relying on this finding, the district court sentenced Shulman to 60 months imprisonment and fined him \$1,250,000. Shulman did not appeal.

In 1995, Shulman filed a motion to vacate his sentence under 28 U.S.C.A. § 2255 (West 1994), arguing that the district court violated Federal Rule of Criminal Procedure 32(c)(5) by failing to inform him of his right to appeal. After the district court denied Shulman's § 2255 motion, he appealed. In an unpublished opinion, we vacated the district court's order denying his motion and remanded the case for resentencing. See United States v. Shulman, No. 95-5603, 1996 WL

245269, *1 (4th Cir. May 13, 1996) (per curiam) (stating that the "government concedes that the district court failed to inform Shulman at sentencing that he had the right to appeal his sentence" and "that a failure to advise a defendant of his right to appeal is per se reversible error requiring resentencing").

At resentencing, Shulman argued that no losses were suffered by Bolar customers because both the coversheet drugs and the generic Dyazide were bioequivalent to FDA-approved drugs. Alternatively, he argued that his actions resulted in a monetary loss of much less than \$80 million. According to Shulman, Bolar received only \$36.5 million from drugs manufactured under the coversheet scheme, not \$70 million. In addition, he argued that only \$34 million of generic Dyazide sales should be attributed to him, not the \$142 million in total sales of the drug, because Bolar sold only \$34 million of generic Dyazide after he learned that FDA approval of the drug had been fraudulently obtained.

The district court rejected Shulman's arguments and concluded that his fraudulent conduct caused a loss of more than \$80 million to customers of Bolar. Specifically, the district court found that Shulman ran the conspiracy to evade FDA regulations from the very beginning, that he was the moving force behind it, that he was a very active president "who controlled every facet of the company from start to finish" (J.A. at 268), that all decisions were approved by him, and that his motive was to get drugs on the market faster than anyone else in order to make millions of dollars. In addition, the district court expressly determined that Shulman knew or should have known about the generic Dyazide fraud in August 1987 when the drug went on the market, in light of his control of the company and his "conduct to cover it up." (J.A. at 267.)

Finding that generic Dyazide sales by Bolar exceeded \$124 million, the district court held that "the amount of money, 124 million dollars, is a loss, not only a loss to the consumer, but it is a loss to his competitors" (J.A. at 269.) In addition, the district court made the following findings:

[The "coversheet" drugs] had no, absolutely no bioequivalency testing at all, you just throw together a formula, no

testing whatsoever and put it there, shove it into the Food and Drug Administration; and then before they even approve it, you go out and sell it then. That comes up to some -- I think you have been listed at 36 million.

(J.A. at 269.) Considering these losses together, the district court imposed an 18-level enhancement to Shulman's base offense level under U.S.S.G. § 2F1.1(b)(1)(S). The district court made several other adjustments to reach a final adjusted offense level of 25.³ That offense level, combined with a Criminal History Category I, resulted in a guideline range of 57-71 months imprisonment. The district court resentenced Shulman to 60 months imprisonment and reimposed a \$1,250,000 fine.

II.

The Sentencing Guidelines provide a base offense level of six for crimes involving fraud or deceit, see U.S.S.G. § 2F1.1, and then incrementally increase the offense level according to the amount of loss suffered as a result of the fraud, see U.S.S.G. § 2F1.1(b)(1)(A)-(S). We review the district court's application of the Sentencing Guidelines under a "due deference" standard, examining factual determinations for clear error and legal conclusions de novo. See 18 U.S.C.A. § 3742(e); United States v. Daughtrey, 874 F.2d 213, 217-18 (4th Cir. 1989). Because the district court's determination of the amount of loss is a factual one, we will vacate Shulman's sentence only if the district court's fraud loss determination was clearly erroneous. See United States v. Castner, 50 F.3d 1267, 1274 (4th Cir. 1995) (citing United States v. West, 2 F.3d 66, 71 (4th Cir. 1993)).

Shulman challenges the district court's loss calculation. First, he

³ The district court appropriately increased Shulman's offense level by two for more than minimal planning, see U.S.S.G. § 2F1.1(b)(2)(A); by four because he was an organizer or leader of the criminal activity, see U.S.S.G. § 3B1.1(a); and by two for obstruction of justice, see U.S.S.G. § 3C1.1. It reduced Shulman's offense level by three for acceptance of responsibility. See U.S.S.G. § 3E1.1. And, the district court acquiesced in the Government's motion for a 4-level downward departure to reflect Shulman's substantial assistance. See U.S.S.G. § 5K1.1.

argues that United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995), not United States v. Marcus, 82 F.3d 606 (4th Cir. 1996), is controlling. In Chatterji, the defendant, Dulal Chatterji, pled guilty to fraudulent conduct involving two products manufactured by Quad Pharmaceutical -- vancomycin and ritodrine hydrochloride. See Chatterji, 46 F.3d at 1339-40. In order to save time and money in the production of vancomycin, Chatterji prepared fewer research and development lots for stability testing than required by the FDA. The fraud thus resulted in FDA approval based on two valid lots of vancomycin, rather than the required three lots. See id. at 1338-39. The Chatterji court noted, however, that repeated tests of vancomycin produced by Quad after fraudulently obtaining FDA approval "revealed that in every instance the drug met all FDA requirements for safety and effectiveness." Id. at 1339. In addition, Chatterji directed the addition of slightly more of an inert ingredient in the production of ritodrine than was called for in the approved formula. The Chatterji court stated that the "minor formula change did not render Quad's ritodrine less effective or pose any danger to consumers who used the drug." Id. Thus, the Chatterji court held that "Quad's products were exactly what they purported to be: vancomycin and ritodrine, approved by the FDA, manufactured in a certain strength and dosage, and producing the specified therapeutic benefits that FDA requirements were intended to ensure." Id. at 1341. "In sum," the Chatterji court stated, "this is not a situation in which a drug with fraudulently-obtained FDA approval harms consumers, fails to produce its intended effects, or is something less than its is represented to be." Id. at 1342. Consequently, the Chatterji court reversed the district court's loss calculation and held that the government had failed to show consumer loss resulting from Chatterji's fraud on the FDA.

In Marcus, 82 F.3d at 606, we addressed another fraud-on-the-FDA scenario. There, we found that the drugs sold by Halsey Drug Company as a result of the defendant's fraud were not approved by the FDA, not tested for safety and efficacy, and, therefore, were altogether "something less than [they] were represented to be." Id. at 609-10 (quoting Chatterji, 46 F.3d at 1341). We stated that there was a

critical difference between the formula change at issue in Chatterji and the one at issue [in Marcus]. In Chatterji, the modification of the formula for ritodrine was merely an

insignificant change that implicated only the shelf life of the drug; it was undisputed that the modification in no way could have affected the bioequivalence of the drug and thereby its safety or therapeutic value.

Id. at 610. In Marcus, however, the defendant stipulated that the reason for the change in the formula was the problem the drug had in passing dissolution tests -- a problem bearing on the therapeutic value of the drug. See id. In addition, the defendant in Marcus (in contrast to the defendant in Chatterji) conceded that the modification to the formula would have been viewed by the FDA as significant, requiring additional (and expensive) bioequivalence testing. See id.

In Marcus, we characterized the distinction between the Chatterji and Marcus factual scenarios as "pivotal":

Since the modification to the formula for ritodrine in Chatterji had no potential to affect the bioequivalence or therapeutic value of the drug, not only was the ritodrine actually safe and effective, but it also was known to be safe and effective when marketed. Marcus, on the other hand, agreed that the change in the formula for quinidine gluconate posed the potential to affect the bioequivalence of the drug. Accordingly, the drug was of unknown safety and efficacy.

Id. Accordingly, we held in Marcus that "consumers did not receive that for which they bargained -- an FDA-approved drug of known safety and efficiency." Id. (citing Castner, 50 F.3d at 1276 & n.8). Because consumers would not purchase a drug of unknown efficacy and safety, gross sales of the drug were the appropriate measure of fraud loss. See id.

Here, Shulman concedes that "[a]ll but the most minor modifications of FDA approved formulas have the potential to affect the bioequivalences of the drug" (Appellant's Br. at 8), but then claims that the safety and efficacy (and bioequivalence) of the "coversheet" drugs was known because "[i]n each case where a change was made Bolar performed both dissolution testing and a dissolution profile of the new drug to ensure that the active ingredient dissolved in vitro at the same

rate as that of the innovator," (Appellant's Br. at 12). Thus, Shulman argues, the bioequivalence of the "coversheet" drugs was known (by Bolar, not the FDA) at the time Bolar marketed them, just as the bioequivalence of the ritodrine in Chatterji was known at the time it was marketed. As in Chatterji, Shulman argues, consumers were not defrauded and no loss occurred because they got what they paid for -- generic drugs bioequivalent to brand-name drugs.

Shulman's claim that "[e]very cover sheet drug sold passed these required tests prior to sale" (J.A. at 33), however, is not supported in the record. We are unable to say, as the Chatterji court did, that testing of the coversheet drugs conducted after FDA approval was fraudulently obtained "revealed that in every instance the drug met all FDA requirements for safety and effectiveness." Chatterji, 46 F.3d at 1339. Indeed, we are unable to say after reviewing the record whether any such tests were even conducted. Thus, we conclude that the "coversheet" drugs sold were of unknown bioequivalence. As a result, "consumers did not receive that for which they bargained-- an FDA-approved drug of known safety and efficiency." Marcus, 82 F.3d at 610. Accordingly, under Marcus, gross sales of the coversheet drugs -- which the district court found to total \$36 million⁴ -- is the proper measure of fraud loss. See id.

With respect to the Dyazide, it is undisputed that FDA-approval was obtained fraudulently. Shulman contends, however, that no loss occurred because "[s]hortly after approval Bolar commissioned an independent clinical study to compare its product with that of the innovator, SmithKline. This study was not required to be performed

⁴ Evidently, the district court accepted Shulman's argument that Bolar received \$36.5 million in revenue from drugs manufactured under the coversheet scheme -- not \$70 million as the Government contended. We note that on appeal, Shulman concedes that Bolar received \$70 million in revenue from coversheet drugs. (Appellant's Reply Br. at 4-5 (stating that "the gross sales of cover sheet drugs were, in fact, \$70 million").) Because we conclude that the total amount of loss resulting from Shulman's fraud far exceeded \$80 million as is required for the maximum 18-level enhancement under U.S.S.G. § 2F1.1(b)(1)(S), the district court's error in underestimating the amount of loss resulting from the coversheet fraud is unimportant.

by the FDA, and far exceeded the FDA requirements to demonstrate bioequivalence of Bolar's Dyazide." (Appellant's Br. at 17.) Again, however, the record does not support Shulman's contention that post-fraud tests confirmed the bioequivalence of the drug. Thus, as with the coversheet drugs, we conclude that the generic Dyazide was of unknown bioequivalence. Under Marcus, gross sales of the generic Dyazide -- which the district court found totalled \$124 million⁵ -- is the proper measure of fraud loss. See Marcus, 82 F.3d at 610.

Shulman also argues that the district court erred in determining that the substitution by Rivers of brand-name Dyazide for Bolar generic Dyazide in the bioequivalence study was a "reasonably foreseeable" act in furtherance of the conspiracy to submit false data to FDA. He contends that only \$34 million in generic Dyazide sales were reasonably foreseeable to him.

To calculate the amount of loss under U.S.S.G. § 2F1.1(b)(1) correctly, district courts must first apply the principles of relevant conduct.⁶ Cf. United States v. Irvin, 2 F.3d 72, 78 (4th Cir. 1993) (holding that

⁵ On appeal, Shulman did not dispute that sales of generic Dyazide actually totalled \$142 million. Apparently the district court transposed the numbers in coming up with a total of \$124 million. The district court's error in this respect is irrelevant. See U.S.S.G. § 2F1.1(b)(1)(S) (fraud involving loss in excess of \$80 million).

⁶ The relevant conduct provision of the Sentencing Guidelines, § 1B1.3, provides that specific offense characteristics, i.e., the loss amount that should be attributed a defendant under § 2F1.1, is to be determined on the basis of the following:

(1)(A) all acts and omissions committed, aided, abetted, counseled, commanded, induced, procured, or willfully caused by the defendant; and

(B) in the case of a jointly undertaken criminal activity . . . all reasonably foreseeable acts and omissions of others in furtherance of the jointly undertaken criminal activity,

that occurred during the commission of the offense of conviction, in preparation for that offense, or in the course of attempting to avoid detection or responsibility for that offense.

U.S.S.G. § 1B1.3(a)(1)(A)-(B).

district courts must apply relevant conduct principles in determining the quantity of narcotics properly attributable to each coconspirator); United States v. Gilliam, 987 F.2d 1009, 1012-13 (4th Cir. 1993) (stating that "in order to attribute to a defendant for sentencing purposes the acts of others in jointly-undertaken criminal activity, those acts must have been within the scope of the defendant's agreement and must have been reasonably foreseeable to the defendant"). The district court's determination regarding the "reasonable foreseeability" of acts of coconspirators is a factual question that we will overturn only if clearly erroneous. See United States v. Vinson, 886 F.2d 740, 742 (4th Cir. 1989). At sentencing, a district court need support its findings of fact only by a preponderance of the evidence. See United States v. Morgan, 942 F.2d 243, 246 (4th Cir. 1991).

The district court considered the rather broad conspiracy to which Shulman pled guilty and made specific factual findings concerning Shulman's role in (and control of) the conspiracy. Specifically, the district court determined that Shulman either knew or should have

had knowledge of exactly what was going on and some subordinate substituted brand names, such as in the case we have, then I think he had knowledge of that or he should have known that this was a part of the game that he was playing with the Food and Drug Administration.

(J.A. at 266-67.) As a result, the district court attributed the entire loss resulting from the Dyazide fraud to Shulman, not just the "34 million which was sold after [he was] notified -- at least he alleged that he was notified that there was a problem." (J.A. at 268.) After reviewing the parties' briefs, the record, and after hearing argument on this issue, we conclude that the district court was not clearly erroneous in determining by a preponderance of the evidence that the total gross sales of generic Dyazide were reasonably foreseeable to Shulman and should be attributed to him as fraud loss under principles of relevant conduct.

III.

Based on the foregoing, we conclude that the district court did not clearly err in determining that Shulman was responsible for fraud loss

totalling \$36 million relating to the coversheet drugs, and fraud loss totalling \$124 million relating to the generic Dyazide. As a result, we conclude that the district court properly increased Shulman's base offense level by eighteen levels under U.S.S.G. § 2F1.1(b)(1)(S) for fraud in excess of \$80 million. Accordingly, we affirm the sentence imposed by the district court.⁷

AFFIRMED

⁷ Shulman also argues that the district court deprived him of due process by considering at sentencing "unsupported, hearsay and inaccurate `facts' nowhere found in the record." (Appellant's Br. at 44.) After reviewing the parties' briefs and the transcript of sentencing, and after hearing argument on this issue, we conclude that Appellant's contentions on this issue are without merit.