

**PUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

UNITED STATES OF AMERICA,

Plaintiff-Appellee.

v.

No. 95-5600

JAY MARCUS,

Defendant-Appellant.

Appeal from the United States District Court  
for the District of Maryland, at Baltimore.  
Herbert N. Maletz, Senior Judge, sitting by designation.  
(CR-93-286-PJM)

Argued: March 8, 1996

Decided: May 3, 1996

Before WIDENER, WILKINS, and MICHAEL, Circuit Judges.

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Affirmed by published opinion. Judge Wilkins wrote the opinion, in  
which Judge Widener and Judge Michael joined.

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**COUNSEL**

**ARGUED:** William James Murphy, MURPHY & SHAFFER, Baltimore, Maryland, for Appellant. Susan Leslie Strawn, Office of Consumer Litigation, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON BRIEF:** John J. Connolly, MURPHY & SHAFFER, Baltimore, Maryland, for Appellant. Lynne A. Battaglia, United States Attorney, Maury S. Epner, Assistant United States Attorney, Lawrence C. McDade, Deputy Director,

**OPINION**

WILKINS, Circuit Judge:

Jay Marcus 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). He maintains that the lower court erred in finding that the victims of his offense suffered an economic loss in excess of \$10 million, resulting in the application of a 15-level enhancement to his base offense level pursuant to United States Sentencing Commission, Guidelines Manual, § 2F1.1(b)(1)(P) (Nov. 1992). We affirm.

I.

Marcus was president and chief executive officer of Halsey Drug Company, Inc., a manufacturer of generic drugs. After obtaining approval from the United States Food and Drug Administration (FDA) to manufacture and market quinidine gluconate (a time-released medication used in the treatment of certain cardiac arrhythmias) pursuant to an FDA-approved formula and process, Halsey began to "scale up" operations. This procedure involved increasing the amount of the drug that was produced from the relatively small quantities prepared during testing to larger production-sized batches. However, problems with dissolution tests<sup>1</sup> performed on the quinidine gluconate manufactured in these larger amounts led Halsey employees to modify the approved formula by adding two inactive ingredients, or excipients--magnesium stearate and stearic acid. This change in formulation did not result in any modification of the active ingredients of the drug.

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<sup>1</sup> Regulations prescribing good manufacturing practices for production and process controls require testing of the time and rate of dissolution of drug products from each batch during the manufacturing process to assure the uniformity and integrity of the drugs. See 21 C.F.R. § 211.110(a)(4) (1995).

Marcus was not initially aware of the modification, but when he learned of it, he elected not to inform the FDA or to seek approval for the revision for fear that the FDA would consider the change to be significant and require additional bioequivalence testing,<sup>2</sup> likely resulting in a long and expensive delay in marketing. It was undisputed that Halsey's gross sales from the quinidine gluconate manufactured in accordance with the unapproved formula exceeded \$10 million.

Marcus reached an agreement with the Government under which he would plead guilty to one count of conspiracy to defraud the United States. The parties stipulated to the material facts and agreed, in the main, to the appropriate application of the sentencing guidelines. However, the parties reserved the right to present differing views on the proper application of the loss enhancement provision of § 2F1.1(b)(1)--the Government taking the position that Marcus' offense level should be increased by 15 levels based on a loss in excess of \$10 million and Marcus arguing that a loss enhancement of far less was appropriate.

During the initial sentencing hearing, the district court held that the amount of Halsey's gross sales was the appropriate measure of loss under § 2F1.1(b)(1) and imposed the 15-level enhancement to Marcus' base offense level. 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 determined that Marcus' guideline range was 41-51 months imprisonment and imposed a sentence at the low end of this range.

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<sup>2</sup> When submitting an abbreviated new drug application seeking FDA approval to market a generic drug, an applicant must demonstrate, *inter alia*, that the drug formulation that it proposes to use is bioequivalent to the name-brand drug. See 21 C.F.R. § 314.94(a)(7) (1995). 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) (1995) (emphasis omitted).

While Marcus' appeal of his sentence was pending before this court, we issued our decision in United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995). In light of Chatterji, we granted Marcus' unopposed motion to remand for reconsideration. On remand, the Government continued to maintain that the gain to Halsey was an appropriate measure of the consumers' economic loss, pointing to the factual differences underlying this case and Chatterji. Declining to hear testimony from the parties as to the safety and efficacy of the altered quinidine gluconate, the district court agreed with the Government that Chatterji did not dictate the conclusion that Halsey's gross sales were not an appropriate measure of loss. Instead, it reasoned that unlike Chatterji, the change in formula undertaken by Halsey had rendered the quinidine gluconate something other than what it purported to be because the altered formula had not been approved by the FDA and was of unknown safety and efficacy. Under these circumstances, the court concluded, the drug was worthless, and accordingly Halsey's gross sales of the drug were the appropriate measure of loss. The lower court, therefore, reaffirmed the sentence it had previously imposed. Marcus again appeals, asserting that the economic loss calculation was erroneous.

## II.

Recognizing that federal fraud statutes are broadly written and apply to a large range of conduct of varying severity, the United States Sentencing Commission designed § 2F1.1 "to apply to a wide variety of fraud cases." U.S.S.G. § 2F1.1, comment. (backg'd.). Because empirical analysis by the Commission demonstrated that under preguideline practice the amount of the loss and the nature of the conduct--i.e., whether the offense consisted of an isolated crime of opportunity as opposed to one that was sophisticated or repeated--were considered the two most significant factors in determining the length of the sentence imposed, the Commission formulated the fraud guideline around these two factors. Id.

With respect to the amount of the loss, § 2F1.1(b)(1) provides for increases in a defendant's base offense level corresponding to the amount of economic loss suffered by victims of the defendant's relevant criminal conduct. See U.S.S.G. § 2F1.1(b)(1). A determination of the amount of the loss suffered focuses, as it does in theft cases, on

"the value of the money, property, or services unlawfully taken." Id., comment. (n.7). In general, "[l]oss under § 2F1.1(b)(1) is the actual, probable, or intended loss to the victims." Chatterji, 46 F.3d at 1340. We have recognized, though, that in some instances gain may prove to be an appropriate alternative measure of loss. Id. It is not, however, a proxy for loss if there is none. Id. Thus, gain, measured either by gross sales or by some other gauge, does not support a loss enhancement under § 2F1.1(b)(1) if there was no actual, probable, or intended loss to the victims. Id.

Marcus maintains that the district court improperly substituted Halsey's gain as a proxy for loss without any factual showing that this was an appropriate measure of some actual, probable, or intended loss to the consumers who purchased Halsey's quinidine gluconate. Further, he asserts that the consumers suffered no loss because the drug Halsey marketed was exactly what it purported to be--a safe, effective, FDA-approved generic drug.

In Chatterji, this court addressed an argument similar to that raised by Marcus. In seeking approval to manufacture vancomycin, an injectable antibiotic, Chatterji submitted records to the FDA purporting to show the results of three separate batch tests when in fact three separate tests had not been performed. Id. at 1339. Additionally, he failed to report to the FDA as required that he had directed that the amount of an inert antioxidant in another drug his company manufactured, ritodrine hydrochloride, be increased above the amount specified in the FDA-approved formula. Id. In sentencing Chatterji, the district court concluded that the effect of his regulatory fraud was to invalidate the FDA approval to market the drugs. Id. at 1340. Consequently, it found that because they lacked FDA approval, the drugs were without value to the consumers who purchased them. Id. Under this theory, the entire amount paid by consumers--i.e., the manufacturer's gross sales--constituted the appropriate measure of loss. Id. Accordingly, the sentencing court applied a loss enhancement pursuant to § 2F1.1(b)(1), calculating the amount of the loss as the gross sales of the two drugs. Id.

We rejected the Government's argument that Chatterji's fraudulent conduct voided FDA approval for the drugs ab initio, rendering the drugs without value to consumers. Id. at 1341. Recognizing that statu-

tory and regulatory provisions required the FDA to withdraw its approval in the event that it found that a false statement of material fact had been made, and refusing to render these provisions superfluous, we held that although Chatterji had not performed one of the batch tests for vancomycin and had failed to report the increase of an inert antioxidant in ritodrine, the marketed drugs did not lack FDA approval. Id. Moreover, we determined that the record would not support a conclusion that consumers of the drugs had suffered any economic loss, because the drugs "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. In differentiating the facts before the court from ones in which a product would not be considered to be exactly what it purported to be, we emphasized that it was undisputed that the "vancomycin performed according to FDA specifications" and "that the safety and therapeutic value of the ritodrine were not affected by the addition of . . . only 2.3% more of an inert inactive ingredient than allowed under the FDA-approved formula that was intended to ensure that the drug would retain full potency over the course of its shelf life." Id. And, finally, we explained that there was no question that had a third batch of vancomycin been separately tested and reported and had a request for approval of the insignificant formula change to ritodrine been requested, the FDA would have granted approval. Id. We concluded:

In sum, 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 it is represented to be. We have little doubt that economic loss would exist in such situations. But, when a drug possesses FDA approval, poses no threat to the health and well-being of the consumer, and meets all of the goals of FDA requirements for safety and efficiency, there can be no actual, monetary loss attributable to the regulatory fraud by which FDA approval was obtained. Economic gain to the manufacturer therefore is not the appropriate measure of loss in such a situation.

Id. at 1342.

Marcus contends that as in Chatterji, the addition of unapproved excipient ingredients to the Halsey drug produced no economic loss to consumers because it was exactly what it purported to be--quinidine gluconate possessing FDA approval, posing no threat to the health and well-being of the consumer, and meeting all of the goals of FDA requirements for safety and efficiency. The gist of Marcus' argument is that, just as in Chatterji, the active ingredients in the quinidine gluconate were not changed and the addition of the two unapproved excipient ingredients had no effect on the actual therapeutic performance of the drug.

Marcus, however, fails to grasp the critical difference between the formula change at issue in Chatterji and the one at issue here. 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. Here, however, Marcus stipulated that the reason for the modification to the formula was the problem experienced by the quinidine gluconate in passing dissolution tests, a problem bearing on the therapeutic value of a time-released drug. Further, Marcus conceded that the modification would have been viewed by the FDA as significant enough to require additional bioequivalence testing--testing that would not have been necessary if there had been no possibility that the change could have affected the safety or therapeutic value of the drug.

This distinction is 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. Thus, even if further testing of the quinidine gluconate would have shown that the modified formula was bioequivalent to the name-brand drug, Marcus had no way of knowing that the drug was safe and effective without conducting that additional testing. Consequently, the modification to the FDA-approved formula undertaken by Halsey undoubtedly had an unknown effect on the safety and effi-

cacy of the drug; and, as such, consumers did not receive that for which they bargained--an FDA-approved drug of known safety and efficiency.<sup>3</sup> Cf. United States v. Castner, 50 F.3d 1267, 1276 & n.8 (4th Cir. 1995) (distinguishing Chatterji and holding that the Navy suffered actual loss when defendant supplied parts that did not meet bargained-for specifications even though it was claimed that the parts supplied actually performed as well as those that did meet the specifications).

Because we did not address in Chatterji a situation in which a modification to an FDA-approved formula posed the potential to affect the safety, therapeutic value, or bioequivalence of the drug, we conclude that the facts presented here are distinguishable from those at issue in Chatterji. The marketing of a drug employing an unapproved and untested formula, when the modification presents the potential to affect the safety, therapeutic value, or bioequivalence of the drug, renders the drug of unknown efficacy and safety; the sale of a drug represented to possess FDA approval under those circumstances does not provide consumers with the benefit of their bargain. In other words, such a change prevents the drug from being that which it purports to be. Given the unchallenged finding that consumers would not purchase a drug of unknown safety and efficacy at any price, the district court correctly concluded that Halsey's gross sales were the appropriate measure of the actual loss suffered by consumers of the quinidine gluconate under such facts. Accordingly, we affirm.

#### AFFIRMED

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<sup>3</sup> Because we conclude that irrespective of whether the quinidine gluconate manufactured by Halsey was actually safe and effective, customers suffered a loss by not receiving a drug of known safety and efficacy, we need not address Marcus' argument that the district court erred in failing to entertain testimony on this issue.