

MAR 18 2011

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

VINOD CHANDRASHEKM
PATWARDHAN,

Defendant - Appellant.

No. 09-50487

D.C. No. 5:08-cr-00172-VAP-1

MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Virginia A. Phillips, District Judge, Presiding

Argued and Submitted February 8, 2011
Pasadena, California

Before: PREGERSON, WARDLAW, and BEA, Circuit Judges.

Vinod C. Patwardhan appeals his conviction following a jury trial for (1) conspiracy, 18 U.S.C. § 371, (2) introducing misbranded drugs into interstate commerce with intent to defraud or mislead, 21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1), (3) smuggling goods into the United States, 18 U.S.C. § 545, (4)

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

aiding and abetting smuggling, 18 U.S.C. § 2(a), (b), and (5) criminal forfeiture, 18 U.S.C. §§ 981(a)(1)(C), 982(a)(2)(B), 21 U.S.C. § 853(p), 28 U.S.C. §§ 853(p), 2461(c). We have jurisdiction under 28 U.S.C. § 1291, and we affirm.¹

I. Conviction of Introducing Misbranded Drugs into Interstate Commerce

Patwardhan was convicted of introducing misbranded drugs into interstate commerce with intent to defraud or mislead. 21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1). We reject Patwardhan’s argument that he cannot be convicted of these charges.

Under the relevant statutory scheme, prescription drugs are per se misbranded. *See* 21 C.F.R. § 201.5; *see also Evers v. United States*, 643 F.2d 1043, 1051 (5th Cir. 1981) (accepting the FDA’s assertion that “since a prescription drug by definition can be used only under a physician’s supervision . . . it is impossible to provide ‘adequate directions for use’ to a layman”) (citing *United States v. Articles of Drug*, 625 F.2d 665, 673-75 (5th Cir. 1980)).

Prescription drugs legally flow through interstate commerce only when they fall

¹Because the parties are familiar with the facts of the case, we repeat them here only to the extent necessary to explain our decision.

under one of two exceptions.² See 21 C.F.R. §§ 201.100, 201.115; 21 U.S.C. § 353(b)(2); see also *Evers*, 643 F.2d at 1051.

Patwardhan does not argue, nor does an independent review of the record support the conclusion, that the non-FDA approved foreign medicine he brought into the United States for later distribution to his patients qualifies for either exception. Thus, Patwardhan can be convicted of introducing misbranded drugs

²Exception 1: Under 21 C.F.R. §§ 201.100, 201.115, a prescription drug is not considered misbranded if the drug is in the possession of someone who can lawfully engage in the dispensing of drugs, and the label contains, *inter alia*, the statement “Rx only,” the recommended dosage, the route of administration, the amount of each active ingredient, the names of inactive ingredients (if the drug is for oral use), and a lot or control number.

Exception 2: Under 21 U.S.C. § 353(b)(2), “[a]ny drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of [21 U.S.C. § 352]. . . if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filing, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statement, if any, contained in such prescription.”

into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1).³

Further, there was sufficient evidence presented at trial, viewed in the light most favorable to the prosecution, for ““*any* rational trier of fact [to find] . . . beyond a reasonable doubt”” that Patwardhan acted with the intent to defraud or mislead. *United States v. Nevils*, 598 F.3d 1158, 1161 (9th Cir. 2010) (quoting *Jackson v. Virginia*, 443 U.S. 307, 319 (1979) (emphasis in original)). Patwardhan told his staff not to give patients foreign medicine for at-home use after a patient’s mother expressed concern about one label, which was written in Hindi. Patwardhan never informed his patients that the drugs administered to them during in-office treatments were not FDA-approved. To the contrary, the IV bags used to administer the foreign medicine contained only the names of the FDA-approved counterparts. Additionally, there was evidence that Patwardhan’s staff hid foreign medicine during an audit, and used the codes corresponding to the FDA-approved

³Patwardhan relies on the Fifth Circuit’s decision in *Evers*, 643 F.2d 1043, to argue that it is legally impossible for a physician who administers prescription medicine to his patients to be convicted under the misbranding statute. His reliance is misplaced. *Evers* was charged under a different provision, section 331(k), which prohibits causing a drug to become misbranded while held after shipment in interstate commerce. In contrast, Patwardhan was charged with introducing misbranded drugs into interstate commerce under section 331(a).

drugs, not the foreign medicines that had actually been used, when billing Medicare for reimbursement.

II. Expert Testimony

We also conclude that the district court's mid-trial ruling excluding the testimony of expert witness Patrick Egan after that testimony was referenced in the defense opening statement does not warrant a new trial. "Evidentiary rulings will be reversed for abuse of discretion only if such nonconstitutional error more likely than not affected the verdict." *U.S. v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). Patwardhan, however, has not demonstrated that he was prejudiced by the district court's ruling.

Overwhelming evidence supported the guilty verdict, and thus the district court's ruling did not affect the outcome of the trial. *See id.* Moreover, *United States v. Gonzalez-Maldonado*, 115 F.3d 9 (1st Cir. 1997), upon which Patwardhan relies to argue that he suffered prejudice as a result of the district court's mid-trial ruling, is distinguishable. In *Gonzalez-Maldonado*, the district court's mid-trial ruling prevented the defense from introducing important impeachment testimony of the prosecution's key witness, testimony that defense counsel had promised in his opening statement the jury would hear. In contrast, Egan's testimony was not

critical to Patwardhan's defense, because Patwardhan never suggested that he was confused by the particular laws Egan was going to address. Defense counsel mentioned Egan only briefly in his opening statement, and the district court prohibited the prosecution from arguing that defense counsel had broken its promise by failing to introduce Egan's testimony. Thus, Patwardhan has not demonstrated that the district court's mid-trial decision to exclude Egan's testimony prejudiced him as to require a new trial.

AFFIRMED.