IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
June 23, 2015
Lyle W. Cayce
Clerk

No. 14-20307

UNITED STATES OF AMERICA,

Plaintiff - Appellee

v.

MOHAMMAD JAMAL RASHID,

Defendant - Appellant

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:13-CR-579

Before JONES, SMITH, and COSTA, Circuit Judges.

PER CURIAM:*

Mohammad Jamal Rashid (Rashid) pled guilty to one count of receiving in interstate commerce and delivering or proffering for delivery, drugs that were misbranded, for pay or otherwise, with intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(c) and 333(a)(2). He also pled guilty to one count of conspiracy, inter alia, to import counterfeit goods. 18 U.S.C. § 371. The district court applied a two-level enhancement under U.S.S.G. § 2B5.3(b)(6)(A) and imposed a sentence of 27 months' imprisonment on both counts, to run

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

concurrently, as well as separate terms of supervised release on each conviction. Rashid appeals the application of the risk enhancement under § 2B5.3(b)(6). We find the evidence insufficient to support the district court's implicit finding under this guideline that Rashid's conduct created a risk of death or serious bodily injury. Accordingly, we VACATE Rashid's sentence and REMAND.

I.

Rashid entered into an agreement with Ashiq Ali Ghulan-Haider, also known as "Tina," and an individual known as Zalfiqar to import misbranded, counterfeit drug tablets from China into the United States. Specifically, Rashid agreed to receive at his home a package containing counterfeit drugs labeled as Viagra® and Cialis® tablets. In return for Rashid's cooperation, Tina agreed to forgive a $300 debt Rashid owed to him. The package, addressed to a false name at Rashid's address, was seized by United States Customs and Border Protection Officers. It contained 7,200 counterfeit and misbranded tablets of Viagra and Cialis. An undercover federal agent then delivered the seized package to Rashid's home, where Rashid purported to be the person whose name was listed on the package and told the agent that he had been expecting its arrival. After Rashid accepted the package, the agent detained him for questioning.

During questioning, Rashid detailed his agreement with Tina and Zulfiqar and agreed to cooperate with the investigation. Samples of the counterfeit tablets were sent to the Food and Drug Administration ("FDA"), Pfizer, and Eli Lilly for testing;[1] the tests confirmed that the tablets were counterfeit and misbranded. The packages of Viagra purported to contain

[1] Pfizer is the exclusive manufacturer and distributor of Viagra in the United States, and Eli Lilly is the exclusive manufacturer and distributor of Cialis in the United States.

100 milligrams of sildenafil citrate, but testing revealed that each tablet contained less than 100 milligrams of the ingredient. The Cialis tablets also contained sildenafil citrate, though the package claimed that the tablets contained 20 milligram of tadalafil, the active ingredient in Cialis.

After Rashid pled guilty, the probation officer determined a base level of eight for Rashid's offense, recommended several enhancements in the presentence report ("PSR"), including a two-level enhancement under U.S.S.G. § 2B5.3(b)(6)(A) for an offense that "involved a conscious or reckless risk of death or serious bodily injury," and calculated the advisory guidelines range at 33 to 41 months' imprisonment. Rashid objected to the enhancement under § 2B5.3(b)(6)(A) as unwarranted because the PSR contained no evidence that the tablets were capable of causing death or serious bodily injury. In an addendum to the PSR, the probation officer replied that "the offense, by its nature, and on the instant facts given the incorrect pharmaceutical ingredients in the tables, involves the conscious or reckless risk of death or serious bodily injury to prospective customers." The government submitted "victim impact statements" from Eli Lilly and Pfizer. Each company's statement included approximately one paragraph warning about the potential risks that drugs like Viagra or Cialis can pose.

At sentencing, the court overruled all of Rashid's objections, adopting the PSR and its addenda. The district judge made no specific findings regarding § 2B5.3(b)(6)(A), but stated only that "of course, these drugs could only be selected by a lawfully – by written prescription, and I think the response speaks for itself." The district judge also suggested the possibility that the counterfeit tablets also contained "fillers," such as "industrial stuff." Defense counsel objected to the suggestion as "wildly inappropriate" speculation, and the judge noted that he would not consider it when making his sentencing decision. The court imposed a sentence, slightly below the guidelines range, of

27 months' imprisonment on both counts concurrently. Rashid did not again object to the sentence, but filed a timely notice of appeal.

II.

We review a district court's application of the sentencing guidelines de novo, and its factual findings for clear error. *See United States v. Garcia-Guerrero*, 313 F.3d 892, 895 (5th Cir. 2002). Rashid challenges the district court's application of § 2B5.3(b)(6)(A), asserting that the evidence does not support the finding that the tablets he received were capable of causing death or serious bodily injury, nor does it support a finding that he was consciously aware of any risk of death or serious bodily injury, or that any such risk would have been obvious to a reasonable person.

The application of the § 2B5.3(b)(6)(A) risk enhancement is one of first impression in this court. U.S.S.G. § 2B5.3(b)(6), Criminal Infringement of Copyright or Trademark, provides:

> [i]f the offense involved (A) the conscious or reckless risk of death or serious bodily injury . . . increase by 2 levels."[2]

§ 2B5.3(b)(6). Rashid maintains that the enhancement was conjectural and thus clearly erroneous because the government did not show that the counterfeit tablets *in fact* posed a risk of death or serious bodily injury. He also challenges the implication that generalized statements about the dangers associated with counterfeit drugs can be sufficient to establish risk.

The 2011 Guidelines define a "serious bodily injury" as an "injury involving extreme physical pain or the protracted impairment of a function of a bodily member, organ, or mental faculty; or requiring medical intervention

[2] The PSR used the 2011 edition of the Guidelines. In November 2013, the Guidelines were amended and the risk enhancement provision was renumbered § 2B5.3(b)(6)(A). For the purposes of simplicity, all citations in this opinion will be to the provision as designated under the current Guidelines.

such as surgery, hospitalization, or physical rehabilitation." U.S.S.G. § 1B1.1, comment n.1(L). At sentencing, the district court did not explain why Rashid's conduct created a risk of serious injury sufficient to justify the risk enhancement, saying only that the presence of counterfeit Viagra and Cialis "speaks for itself." This finding is premised on a belief that counterfeit drugs are *per se* risky and pose an inherent risk of serious bodily injury. With regard to the application of sentence enhancements, however, this court has emphasized that bright-line tests are not necessarily appropriate. *See United States v. Bailon*, 444 F. App'x 55, 61 (5th Cir. 2011) ("[A] single, bright-line test is not necessarily appropriate for a guideline that must be applied to a wide variety of factual settings.") (quoting *Zuniga-Amezquita*, 468 F.3d 886, 889 (5th Cir. 2006)). Because § 2B5.3(b)(6) may apply to innumerable counterfeit drugs, it is best defined through careful application to the specific facts of a case. *See Bailon*, 444 F.App'x at 61 (refusing to adopt a blanket rule that giving any drug to a minor who is not one's child carries an inherent risk of serious bodily injury). Relevant factors a district court may consider in cases involving counterfeit drugs may include the nature of the particular drug involved, all of its active and inactive ingredients, the intended uses, the individuals for whom the drug is designed, and the FDA-issued warnings about the drug.

In *Zhou*, for example, the Tenth Circuit held the enhancement was proper where the defendant's production and distribution of counterfeit Alli®, a weight loss drug, created the risk of serious bodily injury. *United States v. Zhou*, 717 F.3d 1139 (10th Cir. 2012). The risk of injury was established by FDA alerts "describing the serious health risks posed generally by drugs containing Sibutramine . . . and warnings specifically addressing the health risks of the counterfeit Alli [the defendant] was producing and distributing." *Zhou*, 717 F.3d 1139, 1151-52. Specifically, there was evidence in *Zhou* that individuals taking counterfeit Alli "may have been taking three times the usual

daily dose . . . . [Those doses cause] anxiety, nausea, heart palpitations, tachycardia (a racing heart), insomnia and small increases in blood pressure in healthy people. In those with a history of cardiovascular disease, it could lead to elevated blood pressure, stroke, or heart attack." *Zhou*, 717 F.3d at 1152 n.5. Notably, the inquiry in *Zhou* was not whether the particular risk was inherent in all counterfeit drugs, nor was it limited to the question of whether the defendant's specific counterfeit drugs posed the requisite risk. Instead, the court focused on whether the type of drug was generally associated with such risk and if so, whether counterfeiting the drug compounded the likelihood of the risk.

In this case, the PSR relied only on general statements regarding the importance of FDA oversight and the government's "victim impact statements" provided on behalf of Pfizer and Eli Lilly. The PSR noted, without further explanation, that "the offense, by its nature, and on the instant facts given the incorrect pharmaceutical ingredients in the tablets, involves the conscious or reckless risk of death or serious bodily injury to prospective customers." The "victim impact statements" from Eli Lilly and Pfizer were equally vague. Each company's statement includes only one paragraph that mentions potential health concerns associated with the drugs. Indeed, the extent of the warnings contained in Pfizer's statement are as follows:

> Pharmaceutical drugs like VIAGRA® are substances that must be carefully handled and transported in specific ways and under specific conditions. When the supply chain is compromised or counterfeit drugs are sold patients may receive drugs that are ineffective or unsafe.

Similarly, Eli Lilly's statement declares that:

> Counterfeit drugs pose an inherent risk of death or serious bodily injury. Approved pharmaceutical manufacturers are subject to FDA oversight and inspection of their manufacturing processes as

> well as strict packaging and labeling requirements . . . . Lilly's manufacturing processes are tightly controlled in order to prevent inadvertent or knowing adulteration of its pharmaceutical products. Offenses involving counterfeit drugs circumvent these processes and pose a grave threat to public health and safety.

Unlike in *Zhou*, where the FDA had issued warnings about the dangers of ingesting Alli and counterfeit Alli products, none of the evidence here suggests that a similar danger of serious bodily injury or death is associated with Viagra, Cialis, or their counterfeit counterparts.

To justify applying the § 2B5.3(b)(6) enhancement for a counterfeit drug offense, the government must provide at least some evidence that the particular drug or the particular counterfeit version poses a threat of serious bodily injury or death. Without more, generalized statements about the safety concerns associated with counterfeit drugs are insufficient to support a two-level increase under § 2B5.3(b)(6)(A). *See Zhou*, 717 F.3d at 1152.

Neither the PSR nor the "victim impact statements" support a finding that drugs like Viagra, Cialis, and their counterfeits, are associated with an increased risk of death or serious bodily injury. The district court's application of the enhancement provision under § 2B5.3(b)(6) was error. The record is unclear as to whether the district court would have imposed the same sentence under the lower advisory guidelines range calculated without reference to this enhancement. Because there is a possibility that Rashid's sentence was influenced by the erroneous guidelines calculation, the error is not harmless.[3] Accordingly, we **VACATE** Rashid's sentence and **REMAND** for resentencing consistent with this opinion.

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[3] Having concluded that the application of the enhancement was error based on the analysis of risk, we need not reach Rashid's additional arguments discussing his subjective awareness of the risk or the contention that the risk would have been obvious to a reasonable person.