

PUBLISH

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UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

PATRICK FISHER
Clerk

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

No. 96-4201

TIM THEM-Y-KOTRONAKIS,

Defendant - Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
(D. Ct. No. 86-486G)

Robert L. Booker, Booker & Associates, Salt Lake City, Utah, appearing for Defendant-Appellant.

Andrew Clark, Attorney, U.S. Department of Justice, Washington, DC (Eugene M. Thirolf, Director, and Jacqueline H. Eagle, Attorney, Office for Consumer Litigation, U.S. Department of Justice, Washington, DC, and David J. Horowitz, Associate Chief Counsel for Enforcement, Food and Drug Administration, Rockville, Maryland, on the brief), appearing for Plaintiff-Appellee.

Before TACHA, BRISCOE, and LUCERO, Circuit Judges.

TACHA, Circuit Judge.

Defendant Tim Theymy-Kotronakis ("Theymy") was convicted in the United

States District Court for the District of Utah of criminal contempt under 18 U.S.C. § 401(3) for violating a permanent injunction. Defendant now appeals that conviction. We exercise jurisdiction under 28 U.S.C. § 1291 and affirm.

BACKGROUND

They is a manufacturer of medical devices, the “Ster-O-Lizer” and the “AIDS Treating Machine,” which are subject to regulation under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. In 1986, the United States filed a civil seizure action under the FDCA against the Ster-O-Lizer devices, and later amended its complaint to seek injunctive relief as well. In 1989, the U.S. District Court for the District of Utah granted summary judgment for the government, finding that the seized Ster-O-Lizers were devices within the meaning of the FDCA, and further that they were adulterated and misbranded in violation of the FDCA. See United States v. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. 1159 (D. Utah 1989). The court condemned the devices and issued a permanent injunction against They. This 1989 injunction prohibits They from directly or indirectly “[i]ntroducing or causing the introduction into interstate commerce of any device, or holding for sale any device after shipment of one or more of its components in interstate commerce, unless and until,” among other things, the Food and Drug Administration (FDA) has notified They that he is in compliance with its current good manufacturing

practice regulations (CGMPs). United States v. 22 Rectangular [or] Cylindrical Finished Devices, No. C-86-0486G, Judgment and Decree of Condemnation and Injunction at ¶ IX.A (D. Utah Mar. 16, 1989) (“1989 Order”). The 1989 Order refers to the “Ster-O-Lizer” by name. In 1994, by consent of the parties, the court entered a new order that “supplements but does not supersede” the 1989 Order. The 1994 Order prohibits Theymy from “manufacturing, processing, labeling, packing, promoting, distributing, or holding for sale the AIDS Treating Machine or any other article of device intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . as set forth in 21 U.S.C. § 321(h), unless and until” Theymy has obtained from the FDA either premarket approval or an investigational device exemption. United States v. 22 Rectangular or Cylindrical Finished Devices, No. C-86-0486G, Consent Decree of Injunction Pending Final Resolution of Reserved Issues at ¶ III.B (D. Utah July 5, 1994) (“1994 Order”). It is undisputed that the defendant never received notification from the FDA that he was in compliance with the FDA’s CGMPs, that he did not receive premarket approval for the AIDS Testing Machine or any other device, and that he never obtained an investigational device exemption from the FDCA requirements for any of his products.

In June 1995, the government submitted a contempt petition alleging that Theymy had violated the terms of the 1989 and 1994 Orders. After a bench trial,

the district court concluded that They had committed criminal contempt by willfully disobeying the 1989 and 1994 Orders, in violation of 18 U.S.C.

§ 401(3). See United States v. 22 Rectangular or Cylindrical Finished Devices, 941 F. Supp. 1086, 1096 (D. Utah 1996).

DISCUSSION

They contends that the evidence presented by the government was insufficient to prove beyond a reasonable doubt that he had committed criminal contempt by violating the terms of the 1989 and 1994 Orders. When a criminal defendant appeals on the basis of insufficient evidence, we review the evidence de novo, viewing the facts in the light most favorable to the government to determine whether the evidence, together with the reasonable inferences to be drawn therefrom, convinces us that a reasonable factfinder could have found the appellant guilty of the crime charged beyond a reasonable doubt. See United States v. Voss, 82 F.3d 1521, 1524 (10th Cir.) (citations omitted), cert. denied, 117 S. Ct. 226 (1996). The record contains more than sufficient evidence to allow a reasonable factfinder to find that They violated the terms of the 1989 and 1994 Orders. Moreover, we find that he had notice of the orders and that his disobedience of the orders was willful. See Yates v. United States, 316 F.2d 718, 723 (10th Cir. 1963) (“[K]nowledge or notice of the order in question on the part of appellant and a willful disobedience of that order are essential elements of

criminal contempt.”).

I. Proper Construction of the Orders

Before addressing the sufficiency of the evidence, we must determine how the orders should be construed. They contend that the 1989 Order applies only to the Ster-O-Lizer and that the 1994 Order applies only to the AIDS Treating Machine. It is true that the first order refers to the Ster-O-Lizer by name and the second order refers to the AIDS Treating Machine by name. However, neither order is limited to just one product.

The 1989 Order prohibits the shipping, sale, or offering for sale of “the condemned articles [i.e., the Ster-O-Lizers] or any other articles of device” unless a Department of Health and Human Services representative releases them for sale. 1989 Order at ¶ VII.B.4 (emphasis added); see also id. at ¶ II (finding specifically that the Ster-O-Lizer is a device within the meaning of the FDCA). That order also prohibits They from introducing “any device” into interstate commerce, or holding for sale “any device” after shipment of one or more of its components in interstate commerce, until the FDA has informed him in writing that he is in compliance with the FDA’s CGMP. Id. at IX.A.4. Because the 1989 Order repeatedly specifies that it covers “any device,” They’s contentions that it covers only the Ster-O-Lizer are without merit.

Likewise, the terms of the 1994 Order are not limited to the AIDS Treating

Machine, but also cover any “device.” See 1994 Order at ¶ III.A (prohibiting They from conducting a clinical investigation of “the AIDS Treating Machine or any other article of device” without obtaining an exemption from the FDA (emphasis added)); id. at ¶ III.B (prohibiting They from “[m]anufacturing, processing, labeling, packing, promoting, distributing, or holding for sale the AIDS Treating Machine or any other article of device” (emphasis added)). Moreover, the 1994 Order clearly states that it is intended to supplement but not supersede the 1989 Order. Thus, They’s contentions that the 1994 Order is limited to the AIDS Treating Machine also is without merit. In short, the language of each order is broad enough to cover both the Ster-O-Lizer and the AIDS Treating Machine, regardless of whether those products are mentioned by name.

They also asserts that the term “device” is ambiguous. We disagree. Each order specifically refers to the statutory definition of “device” contained at 21 U.S.C. § 321. See 1989 Order at ¶ II (referring to 21 U.S.C. § 321(h)); 1994 Order at ¶ II (referring to 21 U.S.C. §§ 321(g), (h) and also to the regulatory definitions found at 21 C.F.R. §§ 201.128 and 801.4). Further, the 1994 Order specifically sets forth a definition of device, i.e., articles “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body

of man.” 1994 Order at ¶ II, III.B.

II. Evidence of Acts in Violation of the 1989 and 1994 Orders

A. Promoting and Holding for Sale the AIDS Treating Machine and Ster-O-Lizer

The injunction prohibits They from promoting or holding for sale the AIDS Treating Machine or any other article of device. The government introduced evidence that They had promoted the AIDS Treating Machine and both promoted and held for sale the Ster-O-Lizer within weeks of the entry of the 1994 Order.

1. Promotion of the AIDS Treating Machine

They sent at least two letters to different individuals promoting the AIDS Treating Machine. First, They sent a letter to Mr. Edward Cerullo in New York in which They claimed that the AIDS Treating Machine was a “multi-billion dollar making opportunity.” Appellee’s App. at 307 (letter dated 7/25/94). Second, in a letter to Fidel Castro of Cuba, They promised that his machine “will treat all the HIV-AIDS carriers and free them from the disease [sic].” Id. at 308 (letter dated 8/15/94).

2. Promotion and Holding for Sale of the Ster-O-Lizer

At about the same time that he was promoting the AIDS Treating Machine, They solicited Steve Nielsen of the General Medical Corporation in Richmond, Virginia, to act as the “exclusive sales agent” for the Ster-O-Lizer. Id. at 309

(letter dated 7/25/94). They also placed an ad in the Salt Lake Tribune seeking a salesman to work on commission and possibly become “national sales director.” Id. at 311 (ad dated 7/3/94). Joseph Cormier testified that he answered the ad, that They trained him to sell Ster-O-Lizers, and that They tried to sell him a Ster-O-Lizer. Cormier testified that he and They together visited the offices of several physicians in the Salt Lake City area, demonstrating, promoting, and attempting to sell the Ster-O-Lizers.

These facts constitute sufficient evidence that They promoted the AIDS Treating Machine and promoted and held for sale the Ster-O-Lizers in violation of the 1994 Order.

B. Sale and Shipment of Ster-O-Lizers in Interstate Commerce

The 1989 Order prohibits They from “[i]ntroducing or causing the introduction into interstate commerce of any device, or holding for sale any device after shipment of one or more of its components in interstate commerce” until the FDA informed They that he was in compliance with the FDA’s CGMPs. See 1989 Order at ¶ IX.A. It is undisputed that the FDA never notified They that he was in compliance with the CGMPs.

1. Sale and Shipment of the Ster-O-Lizer to Spain

In May 1995, They had an air freight company pick up a package containing a Ster-O-Lizer for delivery to an international freight forwarder. The

package was marked for shipment to Barcelona, Spain. The package, which was called to the FDA's attention by the international freight company and eventually seized by the U.S. Marshal, had an invoice showing a price of \$7,000. This attempted shipment to Spain violated the injunction for two reasons. First, it meant that They introduced the Ster-O-Lizer into interstate commerce. Second, it meant that he held the device for sale after shipment of one of its components in interstate commerce. (They concedes that gauges used in the Ster-O-Lizer came from a company in Ohio.)

They asserts that the shipment of the Ster-O-Lizer to Spain constituted foreign commerce, not interstate commerce, and thus does not violate the terms of the injunction. We agree with the district court that interstate commerce, for purposes of the FDCA, includes foreign commerce. The FDCA defines "interstate commerce" as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b)(1) (emphasis added); see also United States v. Food, 2,998 Cases, 64 F.3d 984, 992 (5th Cir. 1995) ("The plain words of the statute expansively define 'interstate commerce' to effectively include foreign commerce."). It is insignificant that the Ster-O-Lizer did not actually reach Spain. It is sufficient that They introduced the package into interstate commerce by having the package delivered to the international freight company, even though it did not reach its intended destination. Cf. Baltimore & O.S.W.R.

Co. v. Settle, 260 U.S. 166 (1922) (focusing on the intent with which railroad lumber shipment was made in order to determine whether it was intrastate or interstate in nature).

Even assuming that the injunction did not extend to shipments intended for foreign commerce, the shipment to Spain still would have violated the terms of the injunction. The injunction not only prohibits the introduction of nonconforming devices into interstate commerce, but also prohibits the sale of a nonconforming device whose components have been shipped in interstate commerce. As noted above, They admitted that the gauges on the Ster-O-Lizers had originated in Ohio and had been shipped in interstate commerce.

They next contends that his shipment to Spain was for research purposes and was not a sale. He points to a statutory provision permitting shipments of non-FDA approved devices to other countries. See 21 U.S.C. § 381(e). However, one must meet certain statutory prerequisites in order to be allowed to export devices under this provision, see id., and They has not demonstrated that his devices meet those prerequisites. Moreover, devices that fail to meet a requirement of section 360d or 360e (relating to performance standards and premarket approval) are not eligible for export under section 381(e), unless the FDA grants an exception. They has not shown that he has met the requirements of sections 360d and 360e, and the FDA has not granted him an exception.

The evidence, when viewed in the light most favorable to the government, also rebuts Theymy's assertion that his shipment of the Ster-O-Lizer to Spain was for research purposes. The box containing the Ster-O-Lizer had an invoice for \$7,000, indicating that it was a sale, not a loan for research purposes. Moreover, Theymy wrote a letter to his contact in Spain before the shipment was sent, explaining that he could buy a Ster-O-Lizer "by wiring directly to our Bank the sum of \$7,000.00." Appellee's App. at 318 (letter dated 5/4/95). Theymy has produced no evidence supporting his assertion that the shipment was for research purposes.

2. Sale and Shipment of Ster-O-Lizer to Greece

Theymy also sent a "reconditioned" Ster-O-Lizer to a hospital in Greece. This action, like the shipment of the Ster-O-Lizer to Spain, violates the 1989 Order's prohibition of the shipment of the Ster-O-Lizer or any other device in interstate commerce. The action also appears to be a sale in violation of the 1989 Order's prohibition after the shipment of a component in interstate commerce. Although Theymy claimed on the invoice that the shipment was a donation, the invoice indicated a price of \$1,000.

In sum, we find that Theymy's activities promoting both the AIDS Treating Machine and the Ster-O-Lizer, and his two sales and shipments of Ster-O-Lizers to foreign countries, violated the explicit terms of the 1989 and 1994 Orders.

III. Notice

Knowledge or notice of the relevant court order is an essential element of the crime of contempt. See Yates, 316 F.2d at 723. We find that They had the requisite knowledge or notice.

On two occasions, They received copies of the injunction from FDA inspectors and had the terms of the injunction explained to him. On each occasion, he signed an affidavit indicating his awareness and understanding of the terms of the 1989 and 1994 Orders. FDA investigators first visited his facilities in September, 1993, after the entry of the original 1989 Order but before the 1994 Order. At that time, They signed an affidavit that stated that FDA investigators

provided me with a copy of the Judgment and Decree of Condemnation and Injunction [i.e., the 1989 Order] which states that I have been perpetually restrained and enjoined from directly or indirectly doing any introducing or causing the introduction into interstate commerce of any device, or holding for sale any device after shipment of one or more of its components in interstate commerce. Investigator Moore explained this judgment to me. I understand the Judgment and Decree of Condemnation and Injunction for which I am named. I further understand that until I comply with the requirements of the Judgment and Decree (sect. IX A & B), I may not manufacture, sell or distribute any medical device as defined.

Appellee's App. at 303.

In November, 1994, FDA inspectors again visited and provided They with a copy of the injunction, this time including the 1994 Order, and explained the injunction to him. They again signed an affidavit, affirming that he had been

provided with copies of the 1989 and 1994 Orders. In this affidavit, They stated:

I understand that the injunction restrains and enjoins me from manufacturing, selling or distributing any medical devices until I have complied with the Food, Drug and Cosmetic Act and until I have complied with the requirements as stated in the injunction.

Id. at 310 (affidavit dated 11/18/94).

Each typed affidavit contains handwritten changes, indicating that They read the affidavits carefully before signing them. These affidavits demonstrate that They understood the restrictions placed upon him by the orders. Therefore, we reject his claim of lack of notice.

IV. Willfulness

Finally, They argues that if he did violate the orders, his violation was not willful. See Yates, 316 F.2d at 723 (noting that willfulness is an essential element of criminal contempt). We reject his claim.

In the context of criminal contempt, willfulness is defined “as a volitional act done by one who knows or should reasonably be aware that his conduct is wrongful.” United States v. Greyhound Corp., 508 F.2d 529, 531-32 (7th Cir. 1974). They knew of both the 1989 and the 1994 Orders, and he twice affirmed to FDA inspectors that he understood what the orders required. The terms of both orders are clear, and they refer to the Ster-O-Lizer and AIDS Treating Machine by name. The orders clearly prohibit They from manufacturing, promoting,

distributing, introducing into interstate commerce, or holding for sale the Ster-O-Lizers, the AIDS Treating Machine, or any other device unless certain conditions were met. It is undisputed that none of those conditions was met. Yet, They repeatedly undertook to promote, sell, and ship his products. He even told Mr. Cormier that the injunction did not pertain to him, and he boasted to a potential customer that he could commence human trials of the AIDS Treating Machine “without the FDA being able to stop me.” Under these circumstances, a rational factfinder reasonably could infer that They’s violation of the injunction was willful. Viewing these facts and the reasonable inferences to be drawn therefrom in the light most favorable to the government, They’s claims that he did not intend to violate the orders are unpersuasive.

CONCLUSION

We find that there was sufficient evidence to prove beyond a reasonable doubt that They repeatedly violated the terms of the 1989 and 1994 Orders, and that he did so wilfully and with notice of the orders. We AFFIRM his conviction for criminal contempt and DENY the motion for leave to file an additional opening brief.