NONPRECEDENTIAL DISPOSITION
To be cited only in accordance with Fed. R. App. P. 32.1

United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

Submitted June 30, 2016*
Decided July 5, 2016

Before

WILLIAM J. BAUER, *Circuit Judge*

JOEL M. FLAUM, *Circuit Judge*

MICHAEL S. KANNE, *Circuit Judge*

No. 16-1289

UNITED STATES OF AMERICA, *Plaintiff-Appellee*,	Appeal from the United States District Court for the Eastern District of Wisconsin.
v.	No. 10-CR-253
CONRAD E. LEBEAU, *Defendant-Appellant*.	C.N. Clevert, Jr., *Judge*.

O R D E R

Conrad LeBeau pleaded guilty to selling a drug not approved by the Food and Drug Administration. As a part of a conditional plea agreement, he reserved the right to appeal rulings on pretrial motions in which he unsuccessfully sought to dismiss the charges. He had argued that his product was not a "drug," obtaining FDA approval was impossible, and the prosecution violated his right to free speech. Because the district court correctly rejected all three arguments as legally baseless, we affirm.

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* After examining the briefs and the record, we have concluded that oral argument is unnecessary. Thus the appeal is submitted on the briefs and the record. *See* FED. R. APP. P. 34(a)(2)(C).

In an information, the government alleged that LeBeau and his company peddled products that he touted would alleviate illnesses. He advertised that four products—"SPK Spiro-Kete," "Saccharmyces Boulardii," "Perfect Colon Formula #1," and "LeBeau's Cold and Flu Tonic"—could treat or mitigate certain food allergies, Lyme disease, colds, influenza, and H1N1 flu. The government charged LeBeau and his company, Vital Health Products, Ltd., with four misdemeanor counts of introducing into interstate commerce these new drugs without FDA approval, in violation of the Federal Food, Drug, and Cosmetic Act, *see* 21 U.S.C. §§ 331(d), 355.

Consenting to proceed before a magistrate judge, LeBeau initially pleaded not guilty to the charges and moved to dismiss them. Among other contentions, he raised three arguments. First, he argued, Congress did not intend the definition of a "drug" under 21 U.S.C. § 321(g) to cover products consisting of natural substances, such as his, which should be deemed foods or dietary supplements. Second, it was impossible, he thought, to obtain FDA approval for his products because, according to him, the application requirements for new drugs in 21 U.S.C. § 355(b) mandate a patent, and natural substances are not patentable. Finally he contended that §§ 331 and 355 of the Act violate his First Amendment right to commercial speech by proscribing truthful claims about his products.

The magistrate judge denied LeBeau's motions. He first concluded that the Act defines "drug" to encompass natural substances such as foods and herbs, and not just patentable, artificial substances, when the seller has "intended [them] for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). The judge also rejected LeBeau's argument that it was impossible to comply with 21 U.S.C. § 355 without obtaining a patent because § 355 does not require a patent; it requires only that he provide information about relevant patents, if any. As for LeBeau's First Amendment challenge, the judge observed that the government merely offered his statements as evidence of how he intended buyers to use the products that he sold. This evidentiary use of speech, the judge pointed out, does not violate the First Amendment, *see Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993).

Following the denial of his motions, LeBeau pleaded guilty to one of the counts in the information. In his plea agreement and plea colloquy, LeBeau admitted that he promoted on his website the sale of Perfect Colon Formula #1; that he made "disease claims" about the formula by asserting that it "reduces food allergies"; that the product was a drug requiring FDA approval; that the FDA had not approved its sale; and that he

therefore violated the Act. He reserved, however, the right to appeal the magistrate judge's decisions on his pretrial motions. *See* FED. R. CRIM. P. 11(a)(2).

The magistrate judge rejected LeBeau's later attempt to withdraw this plea. A few days before sentencing, LeBeau told the judge that he was not guilty. He signed the plea agreement, he continued, only because he had difficulty finding experts to testify, the government had opposed his evidence of the health claims that he had made, and the case stressed him. He also disputed the factual basis for guilt. He argued that his hype that Perfect Colon Formula #1 "reduces food allergies" was not a claim that the product was "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and therefore was not a drug that required FDA approval. His true intent, he clarified, was to sell a product that "reduces food sensitivities" or "intolerances," not "diseases." Treating LeBeau's filing as a motion to withdraw his guilty plea, the magistrate judge denied it. *See* FED. R. CRIM. P. 11(d)(2)(B). The transcript of the plea colloquy, the judge explained, demonstrated that LeBeau knew all of the implications of the plea, and that he pleaded guilty voluntarily, knowingly, and intelligently. The magistrate judge sentenced him to one year of probation and a $100 fine.

Appealing to the district judge, *see* 18 U.S.C. § 3402, LeBeau reiterated the arguments from his motion to dismiss, and the district judge affirmed. In rejecting the argument about the definition of a "drug" under the Act, the judge stressed that 21 U.S.C. § 321(g)(1), includes natural substances when the seller intends them to treat diseases, as LeBeau did. Nor was the judge swayed by LeBeau's "impossibility" argument: A patent is not required for FDA approval of a new drug. Finally, the judge concluded that the prosecution did not penalize commercial speech. The government used his statements about his product's qualities only as evidence of the item's intended use, which showed that it qualified as a "drug" under the Act. And in any event, LeBeau had not shown that his asserted speech concerned a lawful activity or that the regulation is more extensive than necessary to serve its substantial interest in drug regulation.

On appeal to this court, LeBeau begins by discussing what he sees as defects in his guilty plea. (Oddly, though, he concludes by stating that he is "not asking for a dismissal of the Plea Agreement.") He appears to argue, first, that his plea is involuntary because he felt pressured to accept the bargain in light of the potential maximum penalties he faced and the stress that the case created. Second, he repeats that the government's factual proffer was insufficient to support a conviction because when he advertised that his product "reduces food allergies," he did not intend to claim that it treated a "disease" and therefore he did not sell a "drug."

We assume that LeBeau is contesting the district court's refusal to allow him to withdraw his guilty plea, but reject the challenge. We review a decision to deny a request to withdraw a plea for an abuse of discretion. *See United States v. Redmond*, 667 F.3d 863, 870 (7th Cir. 2012). The district court here reasonably turned away both of LeBeau's arguments. First, LeBeau acknowledged during the plea colloquy that he understood the plea deal and was free to decline it. Therefore the court permissibly disbelieved that LeBeau was coerced into it. *See United States v. Collins*, 796 F.3d 829, 834 (7th Cir. 2015); *United States v. Weathington*, 507 F.3d 1068, 1073 (7th Cir. 2007). Second, the court reasonably rejected LeBeau's belated assertion that he intended his product to treat only food "insensitivities," not "diseases." The assertion is contradicted by his concession to the government after it proffered its case at the plea colloquy. The proffer included the fact that LeBeau advertised that his product "reduces food allergies" and that this assertion was a "disease claim." LeBeau conceded that the proffer was "substantially correct." Moreover "subjective claims of intent" do not control how a court decides a product's intended use. A court may infer the intended use from objective sources, such as the promotional materials that the government referred to in its proffer. *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977); *see United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995).

LeBeau next argues, unpersuasively, that the district court erred for a different reason in concluding that his product, a natural substance, is a "drug" under 21 U.S.C. § 321(g)(1). He believes that interpreting the term to include natural goods contradicts the intent of Congress, as evidenced by the congressional record of legislation that preceded the Act, the Pure Food Act of 1906. But the district court correctly noted that it was not necessary to review these documents. Under the succeeding law, 21 U.S.C. § 321(g)(1)(B), "drug" encompasses any material, even foods and other naturally occurring substances, that (as the government proffered in this case) LeBeau "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." *See Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983); *Nat'l Nutritional Foods Ass'n*, 557 F.2d at 334. LeBeau's product therefore qualifies.

LeBeau next revives his defense that obtaining FDA approval was impossible because FDA approval requires a patent and he sold non-patentable goods. But the district judge rightly observed that LeBeau's argument is meritless: The text of 21 U.S.C. § 355(b) provides that an applicant seeking FDA approval need only file "the patent number and expiration date of any patent" applicable to the drug for which the applicant seeks approval. Thus LeBeau needed only to disclose information about a patent if a patent existed; the Act did not obligate him to obtain a patent.

Finally, LeBeau again contends that the Act impermissibly burdens speech by forbidding claims about the health benefits of his product. But as the district judge rightly pointed out, the government is not prosecuting LeBeau for having made claims about his products. Rather, it is prosecuting LeBeau for his *acts*—his attempt to profit from the sale of a product—which he represented to have palliative properties—without having received approval to do so. The prosecutor used LeBeau's statements only to show how he intended consumers to use his product, and thus, whether the product is a drug under 21 U.S.C. § 321(g)(1). And this "evidentiary use of speech to establish the elements of a crime or to prove motive or intent" does not violate the First Amendment. *Mitchell*, 508 U.S. at 489; *see Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) ("[I]t is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that Whitaker's proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug."). Because LeBeau's statements promoted the unlawful sale of an unapproved drug, they were not entitled to protection. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *United States v. Caputo*, 517 F.3d 935, 940–41 (7th Cir. 2008).

AFFIRMED.