

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

No. 08-4004

United States of America,

Appellee,

v.

Orlando Birbragher, also known as
Orlando Villarreal Birbragher,
also known as Orlando Villarreal,

Appellant.

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* Appeal from the United States
* District Court for the Northern
* District of Iowa.
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Submitted: November 20, 2009
Filed: April 26, 2010

Before WOLLMAN, JOHN R. GIBSON, and SHEPHERD, Circuit Judges.

SHEPHERD, Circuit Judge.

Orlando Birbragher conditionally pled guilty to conspiracy to distribute controlled substances, in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(D), 841(b)(1)(D)(2), 846, 856(a)(1), and 861(a)(1), and conspiracy to launder money from the drug conspiracy, in violation of 18 U.S.C. §§ 1956(a)(1)(A)(i), 1956(a)(1)(B)(i), 1956(h), and 1957. The district court¹ sentenced Birbragher to 35 months

¹The Honorable Linda R. Reade, Chief Judge, United States District Court for the Northern District of Iowa.

imprisonment to be followed by a two-year term of supervised release. The court also entered a preliminary forfeiture order of \$2,465,209.92.² Birbragher appeals the denial of his motion to dismiss the indictment, contending that the Controlled Substances Act (CSA), 21 U.S.C. §§ 801-971, is unconstitutionally vague as applied to him. Birbragher also challenges his sentence. We affirm the district court's denial of Birbragher's motion to dismiss the indictment and dismiss Birbragher's appeal of his sentence in accordance with his appeal waiver.

I.

Because Birbragher moves to dismiss the drug conspiracy charge on the ground that the CSA is unconstitutionally vague as applied to the allegations in the indictment, we consider the facts as alleged in the indictment. See United States v. Mazurie, 419 U.S. 544, 550 (1975) (“It is well established that vagueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand.”); see also United States v. Farm & Home Sav. Ass'n, 932 F.2d 1256, 1259 n.3 (8th Cir. 1991) (providing that, in considering a motion to dismiss an indictment, “we accept the government’s allegations as true, without reference to allegations outside the indicting document” (citing Boyce Motor Lines, Inc. v. United States, 342 U.S. 337, 343 & n.16 (1952))).

²In its Amended Preliminary Order of Forfeiture, the district court determined that \$3,784,023 represented the amount of money involved in the drug and money laundering conspiracy offenses. The court reduced the forfeiture amount to \$2,465,209.92 as a result of the civil forfeiture of Birbragher's personal property in the form of bank accounts and interest accrued on such accounts. The forfeiture amount is not fixed in that “[t]he United States [has agreed to] seek to amend [the] Preliminary Order of Forfeiture to credit [Birbragher] for the interest accrued on [the] accounts.” United States v. Birbragher, No. CR 07-1023, slip op. at 4 n.1 (N.D. Iowa June 29, 2009).

Between approximately January 2003 and May 20, 2004, Birbragher and Marshall Kanner were the principal owners and operators of Pharmacom International Corporation (“Pharmacom”), a company that used the internet to distribute prescription drugs, including Schedule III and IV controlled substances, for which a valid prescription is required.³ Pharmacom conducted these transactions through a website, www.buymeds.com, and other affiliated websites. Internet users logged onto one of these websites “and placed orders for prescription drugs.” (Indictment ¶ 13.) The individuals completed a short health history questionnaire and provided credit card payment information. Pharmacom did not verify the customers’ identities or require them to submit any medical records during this process.

Doctors, who had contracted with Pharmacom, reviewed “the prescription drug orders.” (*Id.*) Among the doctors Pharmacom hired were Armando Angulo, employed from July 2003 to February 2004, and Peter Lopez, employed from October 2003 to April 2004. Angulo was a Florida resident licensed to practice medicine in Florida. Lopez was not licensed to practice medicine anywhere in the United States. The doctors approved the orders without an in-person examination, and, generally, without reviewing any medical records. Occasionally, the doctors emailed or called a customer on the telephone. If the doctor “approve[d] a drug order,” Pharmacom “digitally affixed” the doctor’s electronic signature to a “prescription” created by its computers. (*Id.*)

Pharmacom contracted with pharmacies to fill the “approved ‘prescription’ orders.” (*Id.*) They were batched and downloaded from Pharmacom’s website by the pharmacies, who then filled and shipped them to customers throughout the United States. For example, Union Family Pharmacy (“Union Family”) of Dubuque, Iowa,

³The Controlled Substances Act (CSA), 21 U.S.C. §§ 801-971, defines certain drugs as “controlled substances” and lists them within one of five established schedules, depending on potential for abuse and accepted medical use. 21 U.S.C. § 802(6).

filled “prescriptions” for Pharmacom from August 18, 2003, through September 12, 2003. Jack Huzl, a licensed pharmacist in Iowa and Colorado, owned and operated Union Family. Huzl hired Douglas Bouchey, a pharmacist licensed in Iowa and Michigan, to fill Pharmacom’s “prescriptions.” Union Family filled at least 4,195 “prescriptions” for Pharmacom and distributed at least 180,430 Schedule III and 53,310 Schedule IV dosage units. Union Family shipped the vast majority of these “prescriptions” to customers outside Iowa, even though Union Family was only registered as a pharmacy in Iowa.

Collectively, Pharmacom’s doctors and pharmacies authorized and filled more than 246,000 “prescriptions” for controlled substances, totaling over 12.5 million Schedule III dosage units and more than 1.9 million Schedule IV dosage units. Pharmacom’s customers paid in excess of \$40 million for these “prescriptions.” Pharmacom used the proceeds of this unlawful activity to pay contracting doctors approximately \$2.29 million for authorizing “prescriptions.” Pharmacom paid approximately \$2.26 million to the pharmacies for filling the orders. The funds deposited into the bank accounts of the doctors and the pharmacies allowed them to continue operating as critical members of the drug conspiracy. Pharmacom also paid approximately \$7.75 million to acquire the Schedule III and IV controlled substances; \$1.60 million for shipping costs; \$3.14 million for marketing costs, including internet advertising; and \$1.99 million to its employees to help operate its business. These financial transactions totaled approximately \$19 million.

Birbragher, along with Kanner, Huzl, Bouchey, Angulo, and Lopez (collectively “codefendants”), and others acting at their behest, shifted drug proceeds to shell corporations that they had created to conceal the nature, location, source, ownership and control of the proceeds. The shell corporations were almost all Florida corporations, with the exception of one corporation registered in the U.S. Virgin Islands. Pharmacom also sent money to various bank accounts or trust accounts controlled by or for the benefit of Birbragher’s relatives or Kanner’s relatives.

Birbragher, his codefendants, and others working at their behest, conducted at least 859 money-laundering transactions involving \$10,000 or more in drug proceeds.⁴

On November 7, 2007, Birbragher and his codefendants were charged in a 31-count indictment.⁵ Birbragher was charged in Count I, a drug conspiracy with multiple objects, and Count II, a multiple object conspiracy to launder money from the drug conspiracy alleged in Count I.

With regard to the drug conspiracy, the indictment alleges that between approximately January 2003 and May 20, 2004, “in the Northern District of Iowa and elsewhere,” Birbragher, his codefendants, and others conspired to violate the CSA, specifically, 21 U.S.C. § 846. (See Indictment ¶ 11.) The drug conspiracy had four objects:

- 1) To dispense and cause to be dispensed Schedule III controlled substances outside of the usual course of professional practice and

⁴These money-laundering transactions involved using the proceeds of the drug conspiracy to: pay individuals, who operated affiliate websites that funneled Internet drug customers to www.buymeds.com; pay medical doctors, or purported medical doctors, for authorizing “prescriptions” on behalf of Pharmacom; and pay pharmacies for filling “prescriptions” on behalf of Pharmacom. (Indictment ¶ 26.) In addition, the transactions included the transfer of drug conspiracy proceeds from Pharmacom bank accounts to: accounts controlled by Birbragher; accounts controlled by Kanner; and A.A., an original investor and officer of Pharmacom. (Id.) Finally, the transactions involved transferring proceeds of the drug conspiracy from bank accounts controlled by Pharmacom or Birbragher to: M.N. for the purchase of jewelry; pay private charter plane companies; purchase or lease vehicles; and purchase real estate, professional basketball tickets, coffee, landscaping, interior design services, and artwork; and pay investment company fees. (Id.)

⁵A superceding indictment was filed on August 6, 2008; however, the superceding indictment did not materially alter the substantive charges against Birbragher.

without legitimate medical purpose, in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(D); and

- 2) To dispense and cause to be dispensed Schedule IV controlled substances outside of the usual course of professional practice and without legitimate medical purpose, in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(D)(2);
- 3) To knowingly open, lease, rent, use, and maintain pharmacy fulfillment centers for the purpose of distributing Schedule III and Schedule IV controlled substances outside the usual course of professional practice and without legitimate medical purpose, in violation of Title 21, United States Code, Section 856(a)(1); and
- 4) To knowingly and intentionally employ, hire, persuade, induce, entice, and coerce [minors], to violate the drug laws by dispensing and causing to be dispensed Schedule III and Schedule IV controlled substances outside of the usual course of professional practice and without legitimate medical purpose, in violation of Title 21, United States Code, Section 861(a)(1).

This is in violation of Title 21, United States Code, Section 846.

(Indictment ¶ 11.)

As to the money laundering conspiracy, the indictment alleges that between approximately January 2003 and August 9, 2004, “in the Northern District of Iowa and elsewhere,” Birbragher, his codefendants, and others conspired to conduct, and attempt to conduct, financial transactions involving the proceeds of the Count I drug conspiracy (“the unlawful activity”), in violation in 18 U.S.C. § 1956(h). The money laundering conspiracy had three objects:

- 1) To conduct and attempt to conduct one or more financial transaction(s) which involved the proceeds of specified unlawful activity, that is the illegal dispensing of Schedule III and IV

controlled substances, in violation of Title 21, United States Code, Section 841(a)(1), knowing that the property involved in the financial transaction(s) represented the proceeds of unlawful activity, with the intent to promote the carrying on of the specified unlawful activity, in violation of Title 18, United States Code, Section 1956(a)(1)(A)(i);

- 2) To conduct and attempt to conduct one or more financial transaction(s) which involved the proceeds of specified unlawful activity, that is the illegal dispensing of Schedule III and IV controlled substances, in violation of Title 21, United States Code, Section 841(a)(1), knowing that the property involved in the financial transaction(s) represented the proceeds of unlawful activity, and knowing that the transactions were designed in whole or in part to conceal and disguise the nature, the source, the ownership, or the control of the proceeds of specified unlawful activity, in violation of Title 18, United States Code, Section 1956(a)(1)(B)(i); and
- 3) To knowingly engage and attempt to engage in one or more monetary transaction(s) of a value greater than \$10,000 derived from specified unlawful activity, that is, the illegal dispensing of Schedule III and IV controlled substances (a violation of Title 21, United States Code, Section 841(a)(1)), in violation of Title 18, United States Code, Section 1957.

(Indictment ¶ 22.)

Bouchev and Kanner moved to dismiss the indictment on the ground that the CSA was unconstitutionally vague as applied to them. Birbragher and Lopez joined the motions.⁶ The district court denied the motions to dismiss as to all of the defendants, concluding that the vagueness doctrine did not apply. Specifically, as to

⁶Huzl died shortly after the indictment was filed. Angulo is a fugitive whose last known location was Panama.

Birbragher and Kanner, the court observed that: (1) they were nonregistrants under the CSA,⁷ (2) courts have considered and rejected void for vagueness challenges to the application of the CSA to nonregistrants, (3) nonregistrants have been charged and convicted under the CSA for conduct similar to that alleged in the indictment, and (4) neither had offered precedent to the contrary or any reason to depart from that precedent.

Birbragher entered into a plea agreement which contained an appeal waiver provision. On August 5, 2008, Birbragher entered a conditional plea of guilty⁸ to the first two objects of the Count I drug conspiracy and the third object of the Count II money laundering conspiracy. The district court conducted Birbragher's sentencing hearing on December 17, 2008. Based on his offense, the court determined that Birbragher's advisory Guidelines range was 46 to 57 months. The court then granted the government's downward departure motion due to Birbragher's substantial assistance. See United States Sentencing Commission, Guidelines Manual, §5K1.1 (Nov. 2009) ("Upon motion of the government stating that the defendant has provided substantial assistance in the investigation or prosecution of another person who has committed an offense, the court may depart from the guidelines."). The government recommended a 5-10 percent reduction; however, the court reduced Birbragher's advisory Guidelines range by approximately 24 percent, resulting in a final advisory Guidelines range of 35 to 43 months. The court sentenced Birbragher to 35 months imprisonment to be followed by a 2-year term of supervised release. The court also

⁷"Every person who manufactures or distributes any controlled substance" must obtain a registration from the Attorney General. 21 U.S.C. § 822(a). Therefore, "nonregistrants" under the CSA include those who have not obtained such a registration.

⁸A defendant who wishes to preserve his right to appeal may enter a conditional plea of guilty, "reserving in writing the right to have an appellate court review an adverse determination of a specified pretrial motion." Fed. R. Crim. P. 11(a)(2).

entered a preliminary forfeiture order in the net amount of \$2,645,760.59. See infra note 2. Birbragher brings this appeal.

II.

Birbragher asserts that the CSA is unconstitutionally vague in violation of his Fifth Amendment right to due process of law as applied to his ownership and operation of Pharmacom from March 2003 through May 2004. We review de novo whether a penal statute, like the CSA, is void for vagueness under the Fifth Amendment. United States v. Orchard, 332 F.3d 1133, 1137 (8th Cir. 2003).

“The Fifth Amendment guarantees every citizen the right to due process. Stemming from this guarantee is the concept that vague statutes are void.” United States v. Washam, 312 F.3d 926, 929 (8th Cir. 2002) (citing Connally v. Gen. Constr. Co., 269 U.S. 385, 391 (1926)). The vagueness doctrine recognizes that “[a] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.” Id. (quoting Connally, 269 U.S. at 391). In other words, “[v]oid for vagueness simply means that criminal responsibility should not attach where one could not reasonably understand that his contemplated conduct is proscribed.” Id. (quoting United States v. Nat’l Dairy Prods. Corp., 372 U.S. 29, 32-33 (1963)); see also Grayned v. City of Rockford, 408 U.S. 104, 108 (1972) (“[L]aws [must] give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning.”). “To defeat [Birbragher’s] vagueness challenge, [the CSA] must pass a two-part test: The statute must first provide adequate notice of the proscribed conduct, and second, not lend itself to arbitrary enforcement.” United States v. Barraza, 576 F.3d 798, 806 (8th Cir. 2009) (quotation omitted).

A.

First, we consider whether the CSA provided Birbragher with adequate notice that the statute prohibited his ownership and operation of Pharmacom. Birbragher asserts that he lacked the requisite notice for two reasons: (1) when reading the CSA in 2003, it was unclear that the manner in which Pharmacom dispensed Schedule III and IV controlled substances was prohibited, and (2) the fact that Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the “Online Pharmacy Act”),⁹ 21 U.S.C. § 829(e), on October 15, 2008 (effective on April 15, 2009) establishes that, prior to the Online Pharmacy Act’s passage, it was unclear whether the CSA criminalized Birbragher’s ownership and operation of Pharmacom.

Here, individuals purchased Schedule III and IV drugs through Pharmacom. See 21 U.S.C. § 802(6). The CSA provides: “it shall be unlawful for any person knowingly or intentionally [to] distribute . . . a controlled substance.” 21 U.S.C. § 841. The CSA further criminalizes a conspiracy to violate § 841. Id. § 846. It is also unlawful to conspire to launder the proceeds of “specified unlawful activity,” which includes illegal distribution of controlled substances. 18 U.S.C. § 1956.

The CSA contains several exceptions to § 841’s broad prohibition on the distribution of controlled substances. The exception relevant here empowers the Attorney General to implement a registration process to authorize medical professionals, known as “registrants,” to dispense controlled substances such that every physician and pharmacy that distributes or dispenses any controlled substances must obtain a registration issued by the Attorney General. 21 U.S.C. § 822(a)-(b). Thus, the responsibility for the proper prescribing and dispensing of controlled

⁹“Ryan Haight . . . died at age eighteen in 2001 from an overdose of hydrocodone he obtained over the internet from a prescription [that was] issued unlawfully” United States v. Fuchs, No. 3:02-CR-369-P, 2005 WL 440429, at *1 (N.D. Tex. Feb. 23, 2005) (unpublished).

substances falls not only on the prescribing physician but also upon the pharmacist who fills the prescription. 21 C.F.R. §§ 1306.04(a), 1306.05(a). A controlled substance may be prescribed only “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” *Id.* § 1306.04(a). There are no statutory definitions of “legitimate medical purpose” or “usual course of professional practice.” However, case law provides that “[t]he term ‘professional practice’ refers to generally accepted medical practice[.]” *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (citing *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986)).

Section 841(a)(1) provides: “Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense a controlled substance.” 21 U.S.C. § 841(a)(1). In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court held that, despite registration, “physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice” because “only the lawful acts of registrants are exempted.” *Id.* at 124, 131. With respect to the evidence supporting the physician’s conviction for distributing methadone in violation of § 841, the Court determined:

The evidence presented at trial was sufficient for the jury to find that respondent’s conduct exceeded the bounds of “professional practice.” [H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale “pusher”—not as a physician.

Id. at 142-43 (footnote omitted).

In addition to its holding concerning physicians, the Moore Court observed, “By its terms, § 841 reaches ‘any person.’” Id. at 131; see also United States v. Johnson, 831 F.2d 124, 127 (6th Cir. 1987) (“[T]he basic proscription in section 841 applies to ‘any person’ . . .”). It follows that § 841 applies to nonregistrants. The Sixth Circuit expressly addressed this issue in Johnson. There, the defendant, who was not a licensed physician, oversaw the administration of a medical center where prescriptions for controlled substances were illegally dispensed and was convicted of 10 counts of distribution of controlled substances and 2 counts of aiding and abetting. 831 F.2d at 126 (citing 21 U.S.C. §§ 2, 841(a)). On appeal, he contended that, as a nonphysician, he could not “be lawfully convicted under section 841 for issuing bogus prescriptions.” Id. at 128. The Sixth Circuit observed,

We are not persuaded by this argument. Essentially, [the defendant] is contending that he does not fit within the category of physicians which, under Moore, were excluded from the exception for practitioners registered under section 822. Proceeding from this assumption, [the defendant] then reaches the dubious conclusion that he is not subject to the general rule. The weakness of this argument is apparent. Obviously, the Supreme Court’s pronouncements in Moore are not directly applicable to [the defendant] since he was never a licensed practitioner, and therefore, never eligible for the exception contained in the first sentence of section 841. Thus, [the administrator of a medical center] falls within the general rule which applies to “any person.”

Id.; see also United States v. Mahar, 801 F.2d 1477, 1480, 1487 (6th Cir. 1986) (rejecting challenge to the sufficiency of the evidence to convict medical clinic owner/president/manager under CSA for drug conspiracy); Vamos, 797 F.2d at 1148, 1151-54 (affirming nurse/office manager’s conviction for aiding and abetting the distribution of controlled substances outside the scope of professional medical practice under the CSA); United States v. Albert, 675 F.2d 712, 715-16 (5th Cir. 1982) (rejecting physician’s argument that his conviction for conspiracy to dispense controlled substances in violation of the CSA should be reversed because his

coconspirators were nonphysicians); United States v. Hicks, 529 F.2d 841, 844 (5th Cir. 1976) (per curiam) (rejecting security guard's argument that, as a matter of law, he was exempt from prosecution under § 841 because as a nonphysician he was legally incapable of dispensing); United States v. Green, 511 F.2d 1062, 1070-71 (7th Cir. 1975) (rejecting challenge of the defendant, owner of a building that housed a medical center and pharmacy involved in prescription sales operation, to the sufficiency of the evidence supporting his conviction for conspiracy with physician and pharmacist to violate § 841(a)); United States v. Prejean, 429 F. Supp. 2d 782, 787, 804 (E.D. La. 2006) (rejecting argument of defendant, the owner of three pain management clinics and two pharmacies, that indictment should be dismissed because it failed to state a violation of § 841 because the statute could not be applied to nonphysician/nonregistrant); United States v. Lovin, No. 07cr2016-IEG, 2008 WL 4492616, at *4 (S.D. Cal. Sept. 29, 2008) (unpublished) ("Courts have upheld convictions of non-practitioners for conspiring to distribute, or aiding and abetting the distribution of controlled substances based upon prescriptions issued outside the course of medical practice."). Thus, it is well settled that § 841 applies to Birbragher, as the owner and operator of a company involved in an alleged conspiracy with doctors and pharmacists to distribute controlled substances outside the scope of their professional practice.

Furthermore, the fact that the nonregistrant in this case engaged in a drug conspiracy in violation of § 841 via the internet is immaterial. The Fifth and Tenth Circuits, and two district courts, have approved the application of § 841 to the operation of internet pharmacies. See United States v. Fuchs, 467 F.3d 889, 908-09 (5th Cir. 2006) (rejecting sufficiency of the evidence challenge to drug conspiracy conviction of pharmacist who had set up internet pharmacy); United States v. Nelson, 383 F.3d 1227, 1228-30 (10th Cir. 2004) (rejecting sufficiency of the evidence challenge to drug conspiracy conviction of physician who had issued prescriptions for internet pharmacy); United States v. Quinones, 536 F. Supp. 2d 267, 268-73 (E.D.N.Y. 2008) (denying motion to dismiss indictment charging creators/operators

of websites with distribution of controlled substances, conspiracy with medical professionals to distribute controlled substances, and money laundering on the ground that the acts committed were not prohibited by section 841 of the CSA); United States v. Hernandez, No. 07-60027-CR, 2007 WL 2915854, at *1-11 (S.D. Fla. Oct. 4, 2007) (unpublished) (denying motion to dismiss indictment charging physicians, business owners, and corporations with conspiracy to distribute controlled substances in connection with sales over the internet).

Birbragher was not indicted because his business, Pharmacom, utilized the internet to distribute controlled substances. Rather, he was prosecuted for conspiring with doctors and pharmacists to distribute controlled substances in a manner which the government alleges is outside the usual course of professional practice. See Quinones, 536 F. Supp. 2d at 271 (“[N]on-registrants can be prosecuted for conspiring with or aiding and abetting registrants . . . regardless of the means used to carry out the distribution: If the means are within the usual scope of professional practice, they are legal; if they are outside that scope, they are illegal.”). Specifically, Birbragher was prosecuted because of the manner in which Pharmacom allegedly operated in that:

Contracting doctors issued “prescriptions” for controlled substances:

- (1) based on “a short health history questionnaire,” where “[t]he customers’ identities were not verified, nor were customers required to submit any medical records, as part of the ordering process[.]”
- (2) “without examining any of the customers, and in the vast majority of cases, without reviewing any medical records[.]” and
- (3) “[t]he only contact the doctors had with the customers, if any contact occurred at all, was the occasional brief telephone call or an exchange of e-mails.”

Contracting pharmacies filled “prescriptions” for controlled substances:

- (1) “shipp[ing] the controlled substance ‘prescriptions’ to customers throughout the United States,”
- (2) “without contacting the customers or the doctors who had approved, or purportedly approved, the prescription drug orders.”

(Indictment ¶ 13.) The Tenth Circuit recently rejected a vagueness challenge to the CSA by a pharmacist in a similar fact situation. See United States v. Lovern, 590 F.3d 1095 (10th Cir. 2009). The court stated:

Mr. Lovern was a pharmacist with decades of experience. According to his own testimony, Mr. Lovern understood that he had a legal duty to ensure he filled only those prescriptions issued in the usual course of medical practice. He understood as well that a patient-physician relationship, including a physical examination, usually precedes a prescription in contemporary medical practice. And he knew that the prescriptions he filled at [the pharmacy] were issued after a customer filled in an online questionnaire with no follow-up physical examination or consultation with a physician. A reasonable jury could find that Mr. Lovern knowingly filled prescriptions issued outside the usual course of medical practice, something Mr. Lovern admitted he could not do lawfully. On this record, we cannot say that Mr. Lovern was the unwitting victim of a law he didn’t understand.

Id. at 1103.

A reasonable person reading § 841(a)(1) is on notice that distributing controlled substances violates the CSA unless such distribution fits within an exception. Such a person is also on notice that the “prescription exception” of § 1306.04 does not apply to “prescriptions” issued and/or filled outside the usual course of professional practice. Furthermore, we note that Birbragher has not cited any authority, and we find none, that either the CSA or 21 C.F.R. § 1306.04 fails to provide adequate notice of what conduct is prohibited. Cf. United States v. DeBoer, 966 F.2d 1066, 1068-69

(6th Cir. 1992) (“[T]he language in § 841(a)(1) and 21 C.F.R. § 1306.04(a) clearly defines the pharmacist’s responsibilities that give rise to conduct that constitutes an unlawful distribution of a prescription drug.”); United States v. Rosenberg, 515 F.2d 190, 197 (9th Cir. 1975) (“The language [‘in the course of professional practice’] clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes.”); United States v. Collier, 478 F.2d 268, 270-72 (5th Cir. 1973) (rejecting argument that § 841(a), as applied to physicians, is unconstitutionally vague). In sum, Birbragher had adequate notice that the distribution of controlled substances outside the course of professional practice violated the CSA regardless of the means of distribution.

B.

Next, we ask whether § 841(a)(1) of the CSA allows for arbitrary enforcement. “Congress must provide minimal requirements to guide law enforcement” Washam, 312 F.3d at 931. The Supreme Court has identified this inquiry as “the more important aspect of the vagueness doctrine” because “[w]here the legislature fails to provide such minimal guidelines, a criminal statute may permit ‘a standardless sweep [that] allows policemen, prosecutors, and juries to pursue their personal predilections.’” Kolender v. Lawson, 461 U.S. 352, 358 (1983) (quoting Smith v. Goguen, 415 U.S. 566, 575 (1974)). Furthermore,

It would certainly be dangerous if the legislature could set a net large enough to catch all possible offenders, and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large. This would, to some extent, substitute the judicial for the legislative department of the government.

United States v. Reese, 92 U.S. 214, 221 (1875).

Section 841(a)(1) broadly prohibits the distribution of controlled substances. Section 822 provides an exception for physicians and pharmacies who obtain a registration from the Attorney General in order to prescribe and dispense controlled substances. Pursuant to § 1306.04(a), a controlled substance may only be prescribed and dispensed “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” The provisions of the CSA at issue here, and its accompanying regulation, are sufficiently clear that the speculative danger of arbitrary enforcement does not render it void for vagueness. See DeBoer, 966 F.2d at 1068-69; Rosenberg, 515 F.2d at 197-98; Collier, 478 F.2d at 272; see also Quinones, 536 F. Supp. 2d at 274 (“By its terms, § 841(a)(1) creates a sweeping prohibition on distribution of controlled substances, subject to a relatively narrow exception for distribution within the usual scope of professional practice. That latter phrase has an objective meaning that prevents arbitrary prosecution and conviction: Neither the government nor the jury is free to impose its own subjective views about what is and is not appropriate; rather, the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the circumstances.”).

C.

Finally, Birbragher argues that the fact that Congress passed the Online Pharmacy Act after he engaged in the actions giving rise to the indictment establishes that the CSA, as it existed prior to the Online Pharmacy Act, was unclear as to whether it prohibited such conduct. Birbragher specifically relies on Senator Leahy’s comments with regard to the Online Pharmacy Act.

The Online Pharmacy Act prohibits the delivery, distribution, or dispensing of a controlled substance that is a prescription drug over the internet without a “valid prescription” and defines “valid prescription” as a prescription issued by “a practitioner who has conducted at least 1 in-person medical evaluation of [a] patient.”

21 U.S.C. § 829(e)(1)-(2)(A)(i). Discussing the Online Pharmacy Act, Senator Leahy stated:

I hope this bill will help reduce the prevalence of rogue online pharmacies in our society. We are a nation in the midst of a technological revolution. In the digital age, the Internet has provided Americans with better access to convenient and more affordable medicine. Unfortunately, the prevalence of rogue online pharmacies has also made the Internet an increasing source for the sale of dangerous controlled substances without a licensed medical practitioner's valid prescription. Online drug traffickers have used evolving tactics to evade detection by law enforcement and circumvent the proper constraints of doctors and pharmacists.

154 Cong. Rec. S10184-03 (2008).

We find Birbragher's reliance on the Online Pharmacy Act and Senator Leahy's statement misplaced. "[S]tatutes are construed by the courts with reference to the circumstances existing at the time of the passage." United States v. Wise, 370 U.S. 405, 411 (1962); see Quinones, 536 F. Supp. 2d at 273 ("[I]t may well be that Congress intended the [Online Pharmacy Act] to proscribe, by a clear-cut, *per se* rule, the distribution of controlled substances over the Internet without a face-to-face meeting between patient and doctor; it does not follow that the same conduct is not within the embrace of the current prohibition of distribution outside the usual scope of professional practice."); Lovin, 2008 WL 4492616, at *5 ("The fact that the Senate has passed a bill which would amend the CSA to explicitly prohibit the conduct at issue in this case does not invalidate the government's prosecution of defendants under the existing provisions of the CSA."). As the preceding analysis demonstrates, the CSA, as it existed when Birbragher engaged in the conduct alleged in the indictment, was not unconstitutionally vague as applied to Birbragher's ownership and operation of Pharmacom. Therefore, we reject Birbragher's vagueness challenge.

III.

Birbragher next challenges his sentence, asserting that the district court erred by giving undue weight to the government's § 5K1.1 substantial assistance downward departure recommendation. Specifically, Birbragher asserts that the court incorrectly believed, as a result of the plea agreement, that it was required to follow the government's reasoning for its "low request," a 5-10 percent reduction. (Appellant Br. 32.) The government responds that the appeal waiver contained in Birbragher's signed plea agreement warrants dismissal of this portion of the appeal. "Whether a valid waiver of appellate rights occurred is a question of law that we will review de novo." United States v. Sisco, 576 F.3d 791, 795 (8th Cir. 2009).

"A plea agreement is essentially a contract between the government and the defendant. A defendant may waive his appellate rights pursuant to that agreement." Id. (citation omitted).

[W]hen reviewing a purported waiver, we must confirm that the appeal falls within the scope of the waiver and that both the waiver and plea agreement were entered into knowingly and voluntarily. But, we will not enforce a waiver that results in a miscarriage of justice. The burden of proof is on the government to prove that a plea agreement clearly and unambiguously waives a defendant's right to appeal. Any ambiguities in the agreement are construed against the government.

Id. (quotations and citations omitted).

Birbragher entered into a plea agreement containing the following provision:

APPEAL WAIVER

After conferring with his attorney and after being advised of his appeal rights, the defendant knowingly and voluntarily waives his right to

appeal his conviction and the sentence imposed (except as expressly reserved in paragraph 1 of this agreement). The defendant also waives his right to file post-conviction relief actions, including actions pursuant to 18 U.S.C. § 3582(c)(2) and 28 U.S.C §§ 2255 and 2241, coram nobis actions and motions to reconsider or reduce his sentence. The defendant retains his right to appeal or contest his sentence in the following limited circumstances: (1) if the sentence is not in accordance with this plea agreement; (2) if the sentence imposed exceeds the maximum statutory penalty; (3) if the sentence is unconstitutionally defective. Further, after being fully advised of the implications, the defendant knowingly and voluntarily waives his right to file post-conviction relief actions, including actions pursuant to 18 U.S.C. § 3582(c)(2) and 28 U.S.C. §§ 2255 and 2241 and coram nobis actions. This waiver does not, however, prevent him from challenging the effectiveness of his attorney after conviction and sentencing. Defendant does not have any complaints at this time about the effectiveness of his attorney. The waivers set out above relate to any issues which now exist or which may arise in the future. The defendant agrees to these waivers in order to cause the government to accept the provisions and stipulations of this plea agreement, to avoid trial, and to have his case finally concluded. The defendant understands that at the conclusion of his sentencing hearing, the court will note that the defendant's appeal rights are limited by this waiver. No assurances or promises have been made by any party as to what the defendant's ultimate sentence will be.

(App. 24-25.) Paragraph 1 of the plea agreement, incorporated by reference into the explicit appeal waiver, contained, in relevant part, the following language:

The United States consents to this being a conditional plea of guilty made pursuant to Federal Rule of Criminal Procedure 11(a)(2). The United States and the defendant agree that at the time the defendant pleads guilty, the defendant will provide the United States and the court with a written reservation of the right to appeal from any adverse determination of the defendant's motion to dismiss based on vagueness of the statutes filed at Dockets 100, 102, . . . 105[, 207, 210, and 248]. This written reservation will be filed with the Court at the time the guilty plea is entered in order to make this plea conditional. If the defendant

fails to file this written reservation at the time he enters his guilty plea in accordance with Federal Rule of Criminal Procedure 11(a)(2), the defendant understands and agrees his plea of guilty will be unconditional. If the Court does not approve the entry of this conditional plea, the defendant and the United States shall not be bound by this agreement.

(Id. at 2 (emphasis omitted).)

Under Sisco, this court will enforce an appeal waiver if: (1) the record indicates that the defendant entered into the agreement and the waiver knowingly and voluntarily; (2) the appeal falls within the scope of the waiver; and (3) enforcing the waiver would not result in a miscarriage of justice. 576 F.3d at 795. Here, each requirement is met. Although Birbragher does not even argue that any of these requirements are lacking, we conclude that each is met. First, there is no indication in the record of a lack of voluntariness. Second, Birbragher's challenge to his sentence falls within the scope of the appeal waiver. Birbragher retained his right to appeal his sentence only if it was not in accordance with the plea agreement, his sentence exceeded the maximum statutory penalty, or his sentence was unconstitutionally defective. Finally, we find no miscarriage of justice in enforcing Birbragher's appeal waiver. Therefore, we enforce Birbragher's waiver of his right to appeal and decline to address the merits of his claim.¹⁰

IV.

For the reasons stated above, we affirm the judgment of the district court in Birbragher's appeal of the denial of his motion to dismiss the indictment, and we dismiss Birbragher's appeal of his sentence based on the waiver.

¹⁰We note that section 5K1.1 provides that a district court may "tak[e] into consideration the government's evaluation of the assistance rendered[.]" USSG §5K1.1(a)(1). Furthermore, Birbragher has not offered any record support for the notion that the district court believed it was constrained by the government's recommendation. On the contrary, the district court actually exceeded the government's reduction recommendation of 5-10 percent, reducing Birbragher's advisory Guidelines range by approximately 24 percent.