FILED
United States Court of Appeals
Tenth Circuit

December 12, 2013

Elisabeth A. Shumaker
Clerk of Court

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

ZACHARY C. WILLIAMS,

Defendant - Appellant.

No. 12-6097
(D.C. No. 5:10-CR-00216-HE-1)
(W.D. Okla.)

ORDER AND JUDGMENT[*]

Before **BRISCOE,** Chief Judge, **KELLY** and **GORSUCH**, Circuit Judges.

Zachary Carl Williams appeals his conviction for conspiracy to misbrand prescription drugs in violation of 21 U.S.C. §§ 331(a), 331(k), 333(a), and 18 U.S.C. § 371. Williams raises five issues on appeal. In his first two issues he alleges the indictment was constructively amended in violation of his constitutional rights. In his third and fourth issues he alleges the jury was improperly instructed. Finally, Williams argues that he is entitled to tribal

[*] This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. It may be cited, however, for its persuasive value consistent with Fed. R. App. P. 32.1 and 10th Cir. R. 32.1.

sovereign immunity because his pharmacy operation was authorized by a license issued by the Ponca Tribe, a federally recognized tribe. Finding no error, we affirm Williams' conviction.

I

A. Factual Background

This case arises out of Williams' operation of White Eagle Pharmacy ("White Eagle") on the Ponca Tribe reservation. In February 2009, Williams appeared before the Ponca Tribe Business Committee, the tribe's governing body, to propose that his company operate a tribal-owned pharmacy on tribal land. In return, White Eagle would pay the Ponca Tribe fifty cents per prescription and hire tribal members as pharmacy employees. Williams suggested that the Committee pass a pharmacy act in order to issue pharmacy licenses, and he provided a proposed pharmacy act that he represented was similar to Oklahoma's Pharmacy Act. Williams also told the Committee that a licensed pharmacist would be on duty and physically present at White Eagle at all times.

On March 17, 2009, the Committee passed the Ponca Tribe Pharmacy Act. The Act prescribed that an "Advisory Board" would oversee enforcement of the Act and issue licenses. The Ponca Tribe never established an Advisory Board, however. On June 19, 2009, the Secretary Treasurer of the Business Committee met with Williams and gave Williams two licenses from the Ponca Tribe which purported to allow Williams to transfer prescription drugs from Seneca Cayuga

tribal land to Ponca tribal land.[1] Both licenses were issued to "White Eagle Rx," effective from June 19, 2009, to June 19, 2014. On June 19, 2009, the Ponca Tribe entered into a "Pharmacy Management and Administrative Services Agreement" with Williams' company, Abaci Holdings, LLC. Under this Agreement, the Ponca Tribe owned the White Eagle Pharmacy, and Abaci Holdings was slated to manage and operate the pharmacy.

White Eagle was not a walk-in pharmacy, but rather is described as a "fulfillment" pharmacy. White Eagle contracted with companies, such as Health Solutions Network, LLC ("Health Solutions"), to fill batch prescriptions. Health Solutions operated a website where customers from different states completed online questionnaires detailing their ailments. A doctor in Puerto Rico would then review the questionnaire and "prescribe" drugs solely on that basis. Drugs were prescribed without the prescribing doctor's physical examination of the patient, or even a conversation with the patient regarding the patient's ailments. Williams filled these online prescription drug orders without the presence or authorization of a licensed pharmacist. Williams simply had employees count pills into bottles and then ship the filled bottles to customers. White Eagle filled

[1] The first license granted its holders "the privilege of engaging in the sale of pharmaceutical products on Federal Trust Property held for the benefit of the Ponca Tribe of Indians of Oklahoma." Aplt. App. Vol. I at 87. The second license allowed "[i]mportation, exportation, wholesale, retail, and mail telephone order sales, compounding and manufacturer of pharmaceutical products." Id. Vol. III at 661.

up to 1,200 orders per day. The primary drugs ordered and shipped were Soma, Tramadol, and Fioricet, which are prescription pain relievers or muscle relaxers.

B. Procedural Background

Although Williams was initially indicted on seven counts on July 7, 2010, the grand jury subsequently issued a superseding indictment on December 8, 2010, charging Williams with the following six counts: Count 1 charged conspiracy to distribute Fioricet,[2] a controlled substance, in violation of 21 U.S.C. §§ 841(h)(1), 846; Count 2 charged conspiracy to misbrand the prescription drugs Fioricet, Soma, and Tramadol, in violation of 21 U.S.C. §§ 331(a), 331(k), 333(a), and 18 U.S.C. § 371; and Counts 3 through 6 charged distribution and aiding and abetting distribution of Fioricet via Fed-Ex shipment, in violation of 21 U.S.C. § 841(a) and 18 U.S.C. § 2.

Williams filed a motion to dismiss. He argued that the district court lacked subject matter jurisdiction to prosecute federal crimes committed in Indian Country, and that he was immune from suit under tribal sovereign immunity. Williams also asserted broad international human rights and aboriginal rights arguments. After conducting a hearing on Williams' motion, the district court denied the motion.

A jury subsequently found Williams guilty on Count 2 of the superseding

[2] Fioricet contains butalbital, a Schedule III controlled substance, acetaminophen (the active ingredient in Tylenol), and caffeine.

indictment (conspiracy to distribute misbranded drugs in violation of the Food, Drug, and Cosmetic Act), and not guilty on the remaining counts. The district court sentenced Williams to a term of thirty-seven months' imprisonment followed by two years of supervised release.

C. Statutory and Regulatory Background

1. The Food, Drug, and Cosmetic Act

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, outlaws drug misbranding. Under 21 U.S.C. § 331, it is unlawful to introduce, deliver, or receive in interstate commerce misbranded drugs.[3] Under 21 U.S.C. § 352(f), a drug is "misbranded" if it does not bear "adequate directions for use." FDA regulations define "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. The "intended use" of the drug is the "objective intent of the person legally responsible for the labeling of the drug," and may be determined for example, by labeling claims, advertising matter, or oral or written statements

[3] Different subsections of § 331 prohibit misbranding at different points of interstate commerce. Section § 331(a) makes it unlawful to "introduc[e] or deliver[] for introduction into interstate commerce . . . any drug . . . that is . . . misbranded." 21 U.S.C. § 331(a). Section 331(b) prohibits misbranding drugs while "in interstate commerce," and § 331(c) prohibits receiving misbranded drugs in interstate commerce. Id. § 331(b), (c). Section 331(k) fills any gap left by the prior subsections and prohibits "the doing of any . . . act with respect to . . . a drug . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being . . . misbranded." Id. § 331(k).

by such persons or their representatives." 21 C.F.R. § 201.128. Here, the individual labeling the drugs shipped from White Eagle was Williams. The prescription drugs he was labeling and shipping, however, were "not safe for use except under the supervision of a practitioner." 21 U.S.C. § 353(b)(1)(A). Therefore, prescription drugs can never bear "adequate directions for use" under FDA's interpretation, and thus are presumptively misbranded. E.g., United States v. Evers, 643 F.2d 1043, 1051 (5th Cir. 1981); United States v. An Article of Device, 731 F.2d 1253, 1261 (7th Cir. 1984) ("Although this regulatory arrangement may seem strange insofar as it makes prescription devices presumptively misbranded, the device is not contrary to either the letter or intent of the statute.").

Prescription drugs can avoid the misbranding prohibition in two ways. First, § 352(f) states that "where any requirement of [adequate directions for use] . . . is not necessary for the protection of the public health, the [FDA] shall promulgate regulations exempting such drug" from § 352(f)'s requirement. 21 U.S.C. § 352(f). Pursuant to this language, the FDA enacted Subpart D, "Exemptions from Adequate Directions for Use." See 21 C.F.R. Pt. 201. Under 21 C.F.R. § 201.100, prescription drugs that are "[i]n the possession of a . . . clinic pharmacy . . . regularly and lawfully engaged in dispensing prescription drugs" and that satisfy the labeling requirements of § 201.100(b) are exempt from the "adequate directions for use" requirement. Id. § 201.100(a)(1)(ii), (b).

Second, 21 U.S.C. § 353(b)(2) exempts "[a]ny drug dispensed by filling or refilling a . . . prescription of a practitioner licensed by law to administer such drug" if basic labeling requirements are met. Id. Consequently, dispensing a prescription drug without a prescription constitutes misbranding. E.g., United States v. Mitcheltree, 940 F.2d 1329, 1348 (10th Cir. 1991) (citing United States v. Bradshaw, 840 F.2d 871, 872 n.2 (11th Cir. 1988)); United States v. Goldberg, 538 F.3d 280, 288 (3d Cir. 2008).

2. The Controlled Substances Act

The Controlled Substances Act ("CSA") classifies and regulates controlled substances. See 21 U.S.C. § 812; 21 C.F.R. §§ 1308.11-15. If controlled substances are distributed for medical uses through an online pharmacy, the online pharmacy is required to be licensed "in each State from which it, and in each State to which it, delivers . . . controlled substances by means of the internet." 21 U.S.C. § 831(b). Section 841(h) renders it "unlawful for any person to knowingly or intentionally . . . deliver, distribute, or dispense a controlled substance by means of the Internet," unless that person is a registered person acting pursuant to a valid prescription. See 21 U.S.C. §§ 822, 829(e), 841(h)(1)(A), (h)(4). A "valid prescription" is one issued by "a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 21 U.S.C. § 829(e)(2).

II

A. Constructive Amendment of Indictment

In his first two arguments, Williams asserts that the evidence at trial and the jury instructions constructively amended the superseding indictment by "eliminating the requirement 'that the labeling bear adequate directions for use' in accordance with 21 U.S.C. § 352(f)(1)." Aplt. Br. at 18. Ordinarily, "[w]e review *de novo* the question whether the district court proceedings constructively amended the indictment." United States v. Farr, 536 F.3d 1174, 1179 (10th Cir. 2008). Because Williams did not raise this objection before the district court, however, we review his constructive amendment argument for plain error. See United States v. Brown, 400 F.3d 1242, 1253 (10th Cir. 2005).[4] "Under the plain error standard, we may reverse only if a defendant demonstrates (1) error (2) that is plain, (3) that prejudices his substantial rights, and (4) that seriously affects the fairness, integrity, or public reputation of judicial proceedings." United States v. Mendiola, 696 F.3d 1033, 1036 (10th Cir. 2012) (quotation omitted). "Because all four requirements must be met, the failure of any one will foreclose relief and the others need not be addressed." United States v. Gantt, 679 F.3d 1240, 1246

[4] In his opening brief, Williams states that the alleged constructive amendment of the superseding indictment is a "per se violation of Mr. Williams's Fifth Amendment rights." Aplt. Br. at 18. In Brown, this Court clarified the "uncertainty" in Tenth Circuit precedent regarding whether an unobjected-to constructive amendment is reversible per se or reversible only when it constitutes plain error. We concluded that a defendant must show plain error when he fails to raise the argument before the district court. 400 F.3d at 1253 n.6.

(10th Cir. 2012).

The Constitution protects defendants from being tried on charges that are not contained in the charging document. U.S. Const. amend. V; Stirone v. United States, 361 U.S. 212, 217 (1960). "'To constitute a constructive amendment, the district court proceedings must modify an essential element of the offense or raise the possibility the defendant was convicted of an offense other than that charged in the indictment.'" United States v. DeChristopher, 695 F.3d 1082, 1095 (10th Cir. 2012) (quoting United States v. Hien Van Tieu, 279 F.3d 917, 921 (10th Cir. 2002)).

Count 2 of the superseding indictment stated:

> A drug is misbranded if its labeling does not bear adequate directions for use. Prescription drugs fail to bear adequate directions for use and are misbranded unless they meet all regulatory requirements, including the requirement that the drugs are in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in the dispensing of prescription drugs and dispensed pursuant to a valid prescription.

Aplt. App. Vol. I at 261.

The district court instructed the jury that:

> Federal law provides that prescription drugs, such as Fioricet, Soma and Tramadol, are misbranded if they are not in the possession of a retail pharmacy regularly and lawfully engaged in the dispensing of prescription drugs, or if the drugs are not dispensed pursuant to a valid prescription.

Id. Vol. IV at 866.

Williams claims that the government "failed to present any evidence

through its witnesses and exhibits that there were not adequate directions for use on labels affixed to the bottles at White Eagle," which he argues was "the key provision and element under which [he] was charged in the superseding indictment in Count Two." Aplt. Br. at 17-18. Williams further argues:

> If the drug labeling fails to have 'adequate directions of use' pursuant to 21 U.S.C. § 352(f)(1), then it would not be misbranded if it meets [21 C.F.R. § 201.100's] exception. Because the government failed to present any evidence that the prescriptions that left White Eagle Rx did not contain "adequate directions for use," the necessity of this exemption was not triggered.

Aplt. Br. at 19 (emphases added).[5]

Simply put, Williams misunderstands the FDCA. Under FDA's definition, prescription drugs can never satisfy the "adequate directions for use" requirement under § 352(f) because they are unsafe for use by laymen. Accordingly, there was no need for the district court to instruct the jury on the meaning of "adequate directions for use," nor for the government to introduce evidence that no "adequate directions for use" were on the drug labels here. As prescription drugs are presumptively misbranded, criminal liability can only be avoided if one of the exceptions to § 352(f) apply, i.e., the prescription drug is in the possession of a

[5] Williams also states that "'[a]dequate directions for use' under 21 U.S.C. § 352(f)(1) depends on where the product is in the commerce stream." Aplt. Br. at 19. As support, he cites Evers, 643 F.2d at 1049-50, and 21 C.F.R. § 201.5. Neither supports this proposition, however. Section 331 only establishes liability for misbranding and does not mandate label requirements. Whether the label provides "adequate directions for use" is determined by § 352(f) and its exceptions, not by § 331.

clinic pharmacy that regularly and lawfully engages in the dispensing of prescription drugs, and its labeling satisfies the labeling requirements of 21 C.F.R. § 201.100(b); or the prescription drug is dispensed by filling or refilling a prescription of a practitioner licensed by law to administer such drug, and the labeling requirements of 21 C.F.R. § 201.100(b) are met. In this case, the jury did not need to reach the "directions for use" question because neither Williams nor White Eagle were licensed to lawfully dispense prescription drugs. The superseding indictment set out the applicable law regarding the misbranding of prescription drugs. The trial evidence and the subsequent instruction to the jury on Count 2 were properly focused on the proofs necessary to sustain a conviction on Count 2. Accordingly, "the crime and the elements of the offense that sustain [Williams'] conviction [for misbranding] are fully and clearly set out in the indictment." United States v. Miller, 471 U.S. 130, 136 (1985). Williams has not shown error.

B. Jury Instruction on Count 1

Williams next argues that the district court made two errors in its jury instruction. We review *de novo* legal objections to the jury instructions, and view the record and instructions as a whole to determine if they "fairly, adequately and correctly state the governing law and provide the jury with an ample understanding of the applicable principles of law and factual issues confronting them." United States v. Jones, 468 F.3d 704, 710 (10th Cir. 2006) (quoting

United States v. Denny, 939 F.2d 1449, 1454 (10th Cir. 1991)). We review for abuse of discretion "the district court's decision to give or to refuse a particular jury instruction," as well as "a district court's shaping or phrasing of a particular jury instruction." United States v. Bedford, 536 F.3d 1148, 1152 (10th Cir. 2008). However, when the defendant fails to object to an instruction, we review for plain error.

Williams alleges two errors in the court's instruction on Count 1: 1) the district court instructed that a "valid prescription" required at least one in-person meeting between the doctor and patient; and 2) the district court instructed that White Eagle was an online pharmacy. Although the jury acquitted Williams on Count 1, he nevertheless asserts that the alleged errors in the instruction on Count 1 warrant reversal of his conviction on Count 2 as alternative-theory error and because the instructions as a whole misled the jury. See Aplt. Br. at 25 ("[I]t is impossible to ascertain which description of valid prescription . . . the jury used as a basis for finding Williams guilty, or if they even used this definition at all."); id. at 28 ("[T]he jury was left with the impression based on the instruction that White Eagle Rx['s] license was not valid because they were not licensed by the State.").

1. Final Judgment Rule

Initially, the government contends that Williams cannot raise this issue because he "was neither convicted nor sentenced on Count 1." Aplee. Br. at 23.

A criminal case is final "when it terminates the litigation between the parties on the merits and leaves nothing to be done but to enforce by execution what has been determined." Berman v. United States, 302 U.S. 211, 212-13 (1937). "Final judgment in a criminal case means sentence." Id. at 212. Accordingly, the government correctly states that "[i]n a criminal case the rule prohibits appellate review until conviction and imposition of sentence." Flanagan v. United States, 465 U.S. 259, 263 (1984). But we have that final judgment here.

Although Williams was acquitted on Count 1, he may still challenge the instruction as it relates to his conviction on Count 2. Once the district court enters final judgment, an appeal from that judgment may include the majority of the district court's rulings that preceded the final judgment. Id. ("This final judgment rule requires that a party must ordinarily raise all claims of error in a single appeal following final judgment on the merits.") (quotation omitted). The cases cited by the government do not lead us to a different conclusion, as they regard interlocutory appeals. Here, Williams directly appeals his conviction after being sentenced. Accordingly, we have jurisdiction pursuant to 28 U.S.C. § 1291, to address what, if any, effect the instruction on Count 1 had upon Williams' conviction on Count 2.

2. Definition of Valid Prescription

Williams claims the definition of "valid prescription" in the instruction on Count 1 was wrong. He agrees that the district court correctly defined "valid

prescription" in its Count 2 instruction, but he argues that "it is impossible to ascertain" which definition the jury relied on when convicting him on Count 2. Aplt. Br. at 25. As Williams did not raise this specific objection before the district court,[6] we review Williams' challenge to the Count 1 instruction for plain error. United States v. Bader, 678 F.3d 858, 867 (10th Cir. 2012); United States v. Zapata, 546 F.3d 1179, 1190 (10th Cir. 2008).

The instruction for Count 1 stated in relevant part:

> The indictment alleges that the defendants conspired to distribute a controlled substance contrary to law. The applicable law, 21 U.S.C. § 841(h), makes it a crime to distribute a controlled substance, such as Fioricet, unless certain requirements are met. In the case of an online pharmacy, those requirements include that the drug be dispensed pursuant to a valid prescription and that the pharmacy comply with applicable state licensing requirements.

---

[6] In his opening brief, Williams states that his counsel joined in co-defendant Health Solutions' objection to the definition of "valid prescription." See Aplt. Br. at 21-22. His citations to the record do not support his contention, however. At the jury instruction conference, Health Solutions' counsel objected to the definition of "valid prescription" because it disagreed with the district court's conclusion that Fioricet was not exempted from the criminal provisions of the CSA. Aplt. App. Vol. VII at 1806-07. Health Solutions' counsel asked that the definition for "practice of telemedicine" be removed from the instructions, and Williams joined in that request. Id. at 1808. Williams then objected to the district court's Count 1 instruction, arguing that "what constitutes a valid prescription . . . would be a question of fact, not law for the Court." Id. at 1808-09. Williams' citations do not support his assertion that he specifically objected to the inclusion of the "in-person" requirement in the definition of "valid prescription." Reply Br. at 6 (citing Aplt. App. Vol. VII at 1806-08); see 10th Cir. R. 28.2(C)(3)(b) ("Briefs must cite the precise reference in the record where a required objection was made and ruled on [when] based on . . . the giving of or refusal to give a particular jury instruction.").

> As applicable to the circumstances of this case, a "valid prescription" is one that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient.

Aplt. App. Vol. IV at 862 (emphasis added).

The instruction for Count 2 stated:

> The indictment alleges the purpose of the conspiracy charged in Count 2 was to hold misbranded drugs for sale after shipment in interstate commerce and to introduce misbranded drugs into interstate commerce with the intent to defraud and mislead, contrary to 21 U.S.C. §§ 331 and 333. The drugs the defendants are charged with misbranding are Fioricet, Soma and Tramadol. This instruction will explain the underlying offense of misbranding.
>
> Federal law provides that prescription drugs, such as Fioricet, Soma and Tramadol, are misbranded if they are not in the possession of a retail pharmacy regularly and lawfully engaged in the dispensing of prescription drugs, or if the drugs are not dispensed pursuant to a valid prescription. In this regard the term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner. The usual course of medical practice refers to a standard of medical practice generally recognized and accepted in the United States.
>
> . . . .

Id. at 866 (emphasis added).

Williams argues that the instruction for Count 1 modified its definition of "valid prescription" with "[a]s applicable to the circumstances of this case," which confused the jury about whether Count 1's definition of "valid prescription" applied to all counts.

Reading the instructions as a whole, we conclude the district court did not err. Even if we assume, arguendo, that Count 1's definition of "valid

prescription" was erroneous, the language in Count 2 and the related general instructions remedied any possible confusion. Count 2 clarified that "[i]n this regard the term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner," eliminating any confusion caused by the case-wide modifier in Count 1. Further, the district court instructed the jury to "consider[] separately" "each count of the indictment" in its general instructions to the jury. Aplt. App. Vol. IV at 841. The district court's instruction defining "valid prescription" in Count 1 was not plain error as regards Count 2. See United States v. Berry, 717 F.3d 823, 832 (10th Cir. 2013) ("We presume jurors attend closely to the language of the instructions in a criminal case and follow the instructions given them." (quotation omitted)); United States v. Pennett, 496 F.2d 293, 296 (10th Cir. 1974) ("We will not impute to juries the inability to correctly understand the totality" of the jury instructions).

Williams' alternative-theory argument is also unpersuasive. Williams describes Count 1 and Count 2 instructions as "two independent alternative grounds for conviction." See Aplt. Reply Br. at 9. Williams misapplies the term. Count 1 instructed the jury on the meaning of "valid prescription" under the CSA. Count 2 instructed the jury on the meaning of "valid prescription" under the FDCA. Count 1 and Count 2 alleged violations of different federal crimes, under different criminal statutes, not alternate theories of guilt for conviction under the

same statute. The alternative-theory doctrine does not apply here.

3. Online Pharmacy

Williams next argues that the district court erred in its Count 1 instruction by describing White Eagle as an online pharmacy. Because Williams did not object to this instruction, he again must show plain error.[7] "The proper inquiry is not whether the instruction could have been applied in an unconstitutional manner, but whether there is a reasonable likelihood that the jury did so apply it." Jones, 468 F.3d at 710 (citations and quotations omitted).

Under the CSA, online pharmacies must comply with licensing laws of both the state in which they operate and all states to which they deliver drugs. 21 U.S.C. § 831(b). An online pharmacy is defined as "a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A); see also 21 U.S.C. § 802(52)(B) (listing exceptions to definition).

On Count 1, the district court instructed that

> With respect to the requirement that the online pharmacy

[7] In his reply brief, Williams asserts that he objected to the district court's inclusion of "online pharmacy" in its Count 1 instruction. Aplt. Reply Br. at 6 (citing Aplt. App. Vol. VII at 1805). However, Williams objected to the Count 1 instruction because "the Court . . . is instructing as a matter of law that the Ponca-issued license is not valid," which he believed was "a factual question, not a legal determination by the Court." He did not object to the district court's instruction that White Eagle was an online pharmacy. Aplt. App. Vol. VII at 1805-06.

> comply with applicable state licensing requirements, you are instructed that an online pharmacy must comply with the licensing laws of each State from which, and each State to which, it delivers, distributes or dispenses controlled substances by means of the internet. You have heard evidence relating to a purported license issued by the Ponca Tribe of Oklahoma. An Indian tribe is not a State, and you are instructed that a license from an Indian tribe, even if otherwise valid, does not satisfy the requirement of compliance with the licensing requirements of the pertinent state. You may, however, consider such evidence as to a tribal license as it bears on the issue of a defendant's knowledge or intent.

Aplt. App. Vol. IV at 862.

Williams argues it was error to require White Eagle, as the alleged online pharmacy at issue, to comply with state licensing requirements because White Eagle did not have its own website or advertise through the internet. The CSA's definition of "online pharmacy" is broader than Williams realizes, however. Section 802(52) states that "a person, entity, or Internet site" qualifies as an online pharmacy if "the person, entity or Internet site . . . knowingly or intentionally" delivers or attempts to deliver a controlled substance via the internet. Accordingly, the plain language of the definition of "online pharmacy" does not require an online website because § 802(52) plainly includes "a person" or an "entity" as also qualifying as an online pharmacy if the "person" or "entity" knowingly or intentionally delivers or attempts to deliver a controlled substance via the internet. See United States v. Williams, 376 F.3d 1048, 1052 (10th Cir. 2004) ("In ascertaining the plain meaning of a statute, this court must look to the particular statutory language at issue, as well as the language and design of the

statute as a whole.").

Further, § 841(h) provides examples of conduct that would violate the CSA, including "serving as an agent, intermediary or other entity that causes the Internet to be used to bring together a buyer and seller" and "offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire." 21 U.S.C. § 841(h)(2)(C), (D). White Eagle filled prescriptions for customers who obtained their prescriptions from Health Solutions by online questionnaires, thereby falling within the prohibition set forth in 21 U.S.C. § 841(h)(2)(C), (D). The district court did not err in concluding that White Eagle qualified as an online pharmacy.

Williams also argues that the district court's Count 1 instruction stated "as a matter of law [that White Eagle] did not have a valid license issued by the State." Aplt. Reply Br. at 9. Williams argues that White Eagle "was not required to be licensed by the State of Oklahoma (or any state) because it was not located in any state." Aplt. Br. at 27. Because White Eagle complied with the Ponca Pharmacy Act, he argues, it was exempt from registering with the Secretary of Health and Human Services under the FDCA. He argues the jury may have relied on the district court's erroneous instruction on Count 1 to find him guilty of misbranding because White Eagle was not " lawfully engaged in the dispensing of prescription drugs." Id. at 28.

The instruction on Count 1 did not state that White Eagle did not have a

valid license. Rather, the instruction clarified that online pharmacies are still required to obtain licenses from the states in which they operate and to which they deliver, even if they are licensed by a tribe. Aplt. App. Vol. IV at 862. Assuming, arguendo that Williams' argument has merit, the CSA still requires online pharmacies comply with state licensing laws for all states into which the pharmacy delivers prescription drugs. Williams has not pointed to any evidence from which a jury could conclude that he was licensed in all of the states to which White Eagle delivered prescription drugs. He has not shown clear error.

C. Tribal Sovereign Immunity

Finally, Williams argues that he is immune from federal prosecution because "the Ponca Tribe of Oklahoma has the authority and did validly issue White Eagle Rx a pharmacy license." Aplt. Br. at 29. "We review de novo a district court's denial of a motion to dismiss based on tribal sovereign immunity." Miner Elec., Inc. v. Muscogee (Creek) Nation, 505 F.3d 1007, 1009 (10th Cir. 2007).

Williams does not explain how tribal sovereign immunity would provide him with immunity from federal criminal prosecution. Although he argued in the district court that he was immune because he was acting as an agent of the Ponca Tribe, Williams failed to flesh out this argument on appeal. As the government points out, we have previously declined to address "perfunctory" appellate arguments that "fail to frame and develop an issue." Murrell v. Shalala, 43 F.3d

1388, 1389 n.2 (10th Cir. 1994).

Williams was charged with and convicted of a crime in violation of a generally applicable federal statute. Williams does not argue that the FDCA is not applicable to him, but rather that he is immune from prosecution. However, he does not explain how the site of the pharmacy, the issuance of a tribal pharmacy license, or the Ponca Tribe's alleged regulatory authority over the pharmacy would bar his federal criminal prosecution.[8]

AFFIRMED.

Entered for the Court

Mary Beck Briscoe
Chief Judge

[8] This court has already essentially rejected Williams' argument by dismissing his co-defendants' interlocutory appeal of the district court's denial of their motion to dismiss based in part on sovereign immunity because "the defendants [did] not demonstrate[] a colorable claim that their cases fall outside the general rule that they are subject to general federal criminal statutes." United States v. Fels, No. 11-6253 (10th Cir. Oct. 26, 2011), ECF 9913670; United States v. Drew, No. 11-6254 (10th Cir. Oct. 26, 2011), ECF 9913670.