IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

UNITED STATES OF AMERICA,	)	
	)	
Appellee,	)	
	)	
v.	)	**Case No. 12-6097**
	)	
ZACHARY CARL WILLIAMS,	)	
	)	
Appellant.	)	
	)	

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

THE HONORABLE JOE HEATON
DISTRICT JUDGE
5:10-CR-00216-HE-1

REPLY BRIEF OF APPELLANT
ORAL ARGUMENT IS REQUESTED

Respectfully Submitted,

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TABLE OF AUTHORITIES

IN THE UNITED STATES COURT OF APPEALS
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United States of America,	**) APPEAL CASE NO.: 12-6097**
Plaintiff/Appellee,	**)**
	) District Court Case No.: 5:10-CR-00216-HE-1
	) Western District of Oklahoma
vs.	**)**
	)
Zachary Carl Williams,	**)**
Defendant/Appellant.	**)**

REPLY BRIEF OF APPELLANT

Comes now, Appellant, Zachary Carl Williams, by and through counsel Michael S. Johnson, with his Reply to the Government's Brief filed on January 21, 2013, and would reply as follows:

PROPOSITION ONE

THE GOVERNMENT'S BRIEF FAILS TO ADDRESS WHAT EVIDENCE WAS PRESENTED AT THE TRIAL ON THE MERITS WHICH WOULD SHOW THAT APPELLANT DID NOT PROVIDE "ADEQUATE DIRECTIONS FOR USE"

The Government opines in their brief that the district court was correct in not instructing in the jury on "adequate directions for use" since it is impossible for prescription drugs to have adequate directions for use for a layman. See Appellee's Brief, page 20. This opinion is based upon the Government's superficial reading of ***United States v. Evers***, 643, F.2d 1043 (5th Cir. 1981), and a misunderstanding of the

different labeling requirements which are required depending on where the drugs are in the stream of commerce.

Evers held that a **doctor** could not be guilty of failing to provide his patients with "adequate directions for use" of prescription drugs, because prescription drugs, by definition, can only be used under a physician's supervision. ***Evers***, at 643 F.2d at 1050 - 1051. "Adequate directions for use" are defined as directions under which the layman can use a drug safely and for the purpose it was intended. See 21 CFR § 201.5, and ***Evers*** at 1050. The "intended use" of a drug is the objective intent of the person legally responsible for the labeling of the drug and may be determined by example by labeling claims, advertising matter or oral or written statements by such persons or their representatives. ***Id***. at 1051.

Additionally, labeling requirements, i.e. "adequate directions for use," are different depending on where the drugs are in the stream of commerce. 21 U.S.C. § 331(a)(b)(c)&(k) provide protection from misbranding from the time the product enters the stream of commerce until it reaches the ultimate consumer. See ***United States v. Sullivan***, 332 U.S. 689, 68 S.Ct. 231, 92 L.Ed. 297 (1948). The adequate directions for use under 21 U.S.C. § 352(f)(1) depends on where the product is in the commerce stream. ***Evers*** at 1050.

In the Superceding Indictment the Government alleged that Appellant held for sale misbranded drugs after shipment in interstate commerce, 21 U.S.C. § 331(k) and

introduced misbranded drugs into interstate commerce in violation of 21 U.S.C. § 331(a). Each of these two phases of the commerce stream have different labeling requirements, i.e. "adequate directions for use." The Government presented no evidence concerning these standards at the trial on the merits. Instead, the Government in its requested jury instruction and with the instruction given by the court no longer alleged "adequate direction for use" but rather that Appellant failed to have an exemption under 21 CFR § 201.100. This is not the only exemption which could have alleviated the necessity for "adequate directions of use." Under 21 CFR § 201.115 a prescription drug is not considered misbranding if the drug is in the possession of someone who can lawfully engage in the dispensing of drugs and the label contains *inter alia* the statement "Rx only," the recommended dosage, the route of administration, the amount of each active ingredient, the names of the inactive ingredients (if the drug is for oral use), and the lot or control number.

Additionally, under 21 U.S.C. § 353(b)(2) any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirement of 21 U.S.C. § 352 if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and if stated in the prescription the name of the patient and directions for use and cautionary statement, if any, contained in such prescription.

The Government alleged in the Superceding Indictment specifically that the Appellant had failed to provide "adequate directions for use." The Government then defined in the Indictment that prescription drugs failed 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 clinical pharmacy regularly and lawfully engaged in the dispensing of prescription drugs and dispensed pursuant to a valid prescription. See AA, Vol I, 261-262. As shown above these are not the only exemptions. At trial, the Government failed to present any evidence that the labeling did not bear "adequate directions for use." This was the conduct that was charged in the Indictment. Specifically, the Government requested and the court obliged in instructing the jury:

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

See AA, Vol IV, 862.

This instruction did not require the jury to find that the Appellant had failed to provide "adequate directions for use" which is the conduct charged in the Indictment. Furthermore, although there are various manners and regulations regarding exemptions depending on where the drugs are in the commerce stream, the Government failed again to present any evidence of what those requirements and

regulations were. Instead, they relied solely on the definition in the jury instruction that stated "are misbranded if they are not in 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." AA, Vol IV, 62. This jury instruction, which was requested by the Government, constructively amended the Indictment and broadened the basis by which Appellant could have been convicted. Instead of proving that Appellant had not provided "adequate directions for use," the Government focused on the fact that Appellant did not have an exemption to adequate directions for use. This is a Constructive Amendment to the Indictment.

Appellee's Brief alleges that because Appellant failed to raise his constructive amendment argument in the District Court that this Court will review under plain error. Appellee's Brief, page 19. The courts review de novo whether jury instructions constructively amend the indictment. ***United States v. Springer***, 625 F.3d 1305, 1307 (10th Cir. 2010).

PROPOSITION TWO

THE GOVERNMENT FAILED TO ADDRESS WHETHER THE CONFLICTING DEFINITIONS OF THE TERM "VALID PRESCRIPTION" AND THE ERRONEOUS INSTRUCTION THAT WHITE EAGLE RX WAS AN ONLINE PHARMACY DID NOT INFLUENCE THE JURY IN FINDING APPELLANT GUILTY ON COUNT 2 OF THE INDICTMENT

The Government opines that since the jury was able to acquit the Appellant on Count 1 and convicted him on Count 2, that the jury clearly must have understood the instruction. Appellee's Brief, page 25. This is impossible to determine based on the conflicting definitions of the term "valid prescription" as used in two separate jury instructions and also the erroneous instruction that White Eagle Rx was an online pharmacy.

The conflicting definitions given by the court in the jury instructions regarding the term "valid prescription" was specifically objected to at the jury instruction conference. See AA, Vol VII, 1806 - 1808. The stated objection was "Health Solutions Network would object to the definition of valid prescription and practice of telemedicine as they are defined by Section 829". . . . This objection was joined by counsel for the Appellant. AA, Vol VII, 1808. Furthermore, counsel for the Appellant objected to the definition of White Eagle Rx as an online pharmacy. AA, Vol VII, 1805. Specifically the stated objection was "you have heard evidence . . . that what the court is doing is instructing as a matter of law that the Ponca issued license is not valid, and we believe that would be a factual question, not a legal

determination by the court." AA, Vol VII, 1806. This objection was overruled by the court. ***Id***.

One of the grounds that the jury could have convicted the Appellant on Count 2, as instructed, was that the drugs were not dispensed pursuant to a "valid prescription." AA, Vol IV, 866. Unfortunately, the court gave two conflicting definitions of the term "valid prescription," the first one being erroneous as a matter of law. Nothing in the first jury instruction limited the term "valid prescription" solely to Court 1. AA, Vol IV, 862. Specifically, the first jury instruction stated:

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

AA, Vol IV, 862.

Additionally, on the subsequent instruction for Count 2, the court instructed the jury as follows:

> "In this regard the term "valid prescription" means a prescription that is issued for a legitimate medical purpose and 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."

AA, Vol IV, 866.

These terms are in direct conflict with one another and the first definition in Count 1 is an erroneous statement as a matter of law based on the facts of this case. Counsel is not contesting the finding of the court that Fiorcet is a controlled

substance as alleged by the Government in their brief. See Appellee's Brief, page 22. Fiorcet is an exempted controlled substance and has been exempted from complying with 21 U.S.C. § 829. AA, Vol 1, 53, 21 U.S.C. § 811(g), et. seq., 21 CFR 1308.32.

The Government's brief failed to address whether or not this instruction was prejudicial, and whether or not the jury made its verdict solely on the definition given for Count 2. Instead the Government in its response opined that the Appellant could not base an appeal on a jury instruction given on a count for which he was acquitted. Because of the conflicting jury instructions, it is impossible to determine whether the verdict rested on a valid ground. ***Zant v. Stephens***, 462 U.S. 862, 881, 103 S.Ct. 2733, 77 L.Ed. 2d 35 (1999).

Additionally, because of the erroneous instructing of the jury that White Eagle Rx was an online pharmacy the jury was left with the impression that White Eagle Rx was not lawfully engaged in the dispensing of prescription drugs, one of the standards of which the jury could have found the Appellant guilty in Count 2. This should have been a factual determination which was left to the jury to make; however, by instructing the jury as such, the court as a matter of law, instructed the jury that the license was not valid. This was an erroneous instruction that invaded the province of the jury and although it did not directly relate to Count 2 by the heading placed on the jury instruction, it definitely was one of the issues that was litigated at trial and could have been used as a basis for conviction against the Appellant.

An instructional error on one of two independent alternative grounds for conviction requires a conviction to be set aside unless the court can be assured that the jury did in fact rely on the valid ground or unless the jury necessarily made the finding required to support a conviction on the valid ground. ***United States v. Holland***, 116 F.3d 1353, 1358 (10th Cir. 1997). ***Bousley v. United States***, 523 U.S. 613, 118 S.Ct. 1604, 140 L.Ed. 2d 828 (1998). A faulty jury instruction requires reversal when (1) we have substantial doubt whether the instruction, considered as a whole, properly guided the jury in its deliberations; and (2) when a deficient jury instruction was prejudicial. ***Townsend v. Lumbermen's Mut. Cas. Co.***, 294 F.3d 1232, 1242 (10th Cir. 2002). The inquiry is not whether the instruction was completely faultless but whether the jury was misled in any way. ***Coleman v. B-G Maint. Mgmt. Colo., Inc.***, 108 F.3d 1199, 1202 (10th Cir. 1997). In cases where the District Court has given a legally erroneous jury instruction and where the jury might have based its verdict thereon, prejudice exists, and reversal is required. See ***Adams-Arapaho Joint School District No. 28-J v. Continental Ins. Co.***, 891 F.2d 772, 779-780 (10th Cir. 1989). Because the court instructed the jury erroneously on the term "valid prescription," and because the court instructed erroneously that White Eagle Rx was an online pharmacy and as a matter of law did not have a valid license issued by the State, it is highly likely that the jury might have based its verdict thereon. As such, prejudice exists and reversal is required.

Wherefore, for the above-stated reasons, the Appellant has replied to the Government's Brief filed on January 21, 2013. Appellant requests that this Court reverse the judgment and sentence on Count 2 issued for the Appellant because of the error.

STATEMENT REGARDING ORAL ARGUMENT

Counsel requests oral argument since this matter has raised several issues of first impression with the Court.

Respectfully submitted,
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CERTIFICATE OF COMPLIANCE

As required by Fed. R. App. P. 32(a)(7)(C), I certify that this brief is proportionally spaced and contains 2,770 words.

X I relied on my word processor to obtain the count and it is Word Perfect 5.0.

I certify that the information on this form is true and correct to the best of my knowledge and belief formed after a reasonable inquiry.

/s/ Michael S. Johnson
Michael S. Johnson

CERTIFICATE OF SERVICE

__X__ I hereby certify that on Monday, February 11, 2013, I electronically transmitted the attached document to the Clerk of Court using the CM/ECF System for filing and transmittal of a Notice Electronic Filing to the following CM/ECF Registrants:

Assistant United States Attorney
210 West Park Avenue, Suite 400
Oklahoma City, Oklahoma 73102

/s/Michael S. Johnson
Michael S. Johnson

CERTIFICATE OF DIGITAL SUBMISSION

I certify that on Monday, February 11, 2013, I digitally submitted the within and foregoing instrument in PDF format to this Court through ECF Live, and further state that:

1. There were no redactions necessary.

2. The digital submissions have been scanned for viruses with Vipre Anti Virus Program, updated on February 11, 2013, and are free from viruses.

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