

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Criminal No. 13-00273 (SRN/FLN)**

UNITED STATES OF AMERICA,)
)
 Plaintiff,)
)
 v.)
)
 MORAN OZ (2);)
 BABUBHAI PATEL (3);)
 LACHLAN SCOTT MCCONNELL (6);)
 ELIAS KARKALAS (8);)
 PRABHAKARA RAO TUMPATI (9);)
)
 Defendants.)
)

ORDER

Jacqueline Blaesi-Freed, Linda I. Marks, U.S. Department of Justice, Consumer Protection Branch, 450 5th St. NW, Ste. 6400, Washington, DC 20001, and Roger J. Gural, U.S. Department of Justice, Civil Division, P.O. Box 386, Washington, DC 20044, for the United States of America.

Joseph S. Friedberg, Joseph S. Friedberg, Chartered, 701 4th Ave. S., Ste. 300, Minneapolis, MN 55415, Robert D. Richman, P.O. Box 16643, St. Louis Park, MN 55416, for Defendant Moran Oz.

JaneAnne Murray, Murray Law LLC, 310 South Fourth Ave., Ste. 5010, Minneapolis, MN 55415 for Defendant Babubhai Patel.

Marie Celine Pacyga and Ryan M. Pacyga, Pacyga and Associates, PA, 333 South Seventh St., Ste. 2850, Minneapolis, MN 55402, for Defendant Lachlan Scott McConnell.

Daniel L. Gerdts, 247 Third Ave. S., Minneapolis, MN 55415, John C. Brink, 310 4th Ave. S., Ste. 1008, Minneapolis, MN 55415, for Defendant Elias Karkalas.

James E. Ostgard, Ostgard Law Office, P.O. Box 582536, Minneapolis, MN 55458, Paul Daniel Schneck, Paul Daniel Schneck, LTD, 222 South 9th St., Ste. 1600, Minneapolis, MN 55402, for Defendant Prabhakara Rao Tumpati.

SUSAN RICHARD NELSON, United States District Judge

This matter is before the Court on the Government's Motion in Limine to Exclude Evidence of Defendants' Mistaken Belief that Their Conduct was Lawful (Gov't's Mot.") [Doc. No. 699]. For the reasons set forth below, the Government's Motion is granted in part and denied in part.

I. BACKGROUND

Defendants are charged with a variety of offenses related to their involvement with an online pharmacy, RX Limited ("RXL"). (See Indict. [Doc. No. 5].) In relevant part, Defendants are charged with misbranding drugs in violation of the Food, Drug, and Cosmetics Act ("FDCA"), mail and wire fraud, distribution of a controlled substance in violation of the Controlled Substances Act ("CSA"), and related conspiracy charges. (See id.) Each of these charges requires that the Government prove that Defendants acted with knowledge or intent. See 21 U.S.C. § 841(h)(1); 21 U.S.C. § 333(a)(2); 18 U.S.C. §§ 1341, 1343.

The Government contends that none of these charges require it to prove that Defendants "knew they were violating the law[.]" or that they "specifically intended to violate the law." (Gov't's Mot. at 1, 3.) The Government therefore asks that the Court exclude any argument or testimony "attempting to establish defendants did not specifically know their actions violated the law." (Id. at 4.) Furthermore, the Government argues that the Court should exclude any evidence regarding Defendants' mistaken belief that Fioricet—one of the drugs Defendants allegedly distributed through

RXL—was not a controlled substance. (Id. at 7.) This Court previously held as a matter of law that Fioricet is a controlled substance under the CSA. United States v. Oz, No. 13-cr-00273 (SRN/JJK), 2016 WL 1183041, at *3–5 (D. Minn. Mar. 28, 2016).

Defendants concede that the Government “is not required to prove a defendant’s specific intent to violate the law.” (Defs.’ Mem. in Opp. at 1 [Doc. No. 726].) However, Defendants argue that the intent to defraud or mislead is the “gravamen of all these charges” and thus they should be allowed to put on a good faith defense—that is, present evidence that they lacked the required knowledge or intent to defraud because they acted with good intentions. (Id.) Additionally, Defendants contend that the Government must prove that they knew Fioricet was a controlled substance and thus Defendants should be allowed to present evidence that they did not believe that the drug was controlled. (See id. at 6.)

II. DISCUSSION

Ignorance of—or a mistaken understanding about—the law is not a defense to criminal prosecution. Cheek v. United States, 498 U.S. 192, 199 (1991). The FDCA, CSA, and mail and wire fraud statutes do not require that the Government prove that Defendants knew of—or intended to violate—those laws when they engaged in their allegedly offending behavior. See United States v. Carlson, 810 F.3d 544, 554 (8th Cir. 2016), cert. denied sub nom. Gellerman v. United States, 137 S. Ct. 102 (2016), and cert. denied, 137 S. Ct. 291 (2016) (FDCA); United States v. Ansaldi, 372 F.3d 118, 128 (2d Cir. 2004) (CSA); United States v. Tucker, 137 F.3d 1016, 1036 (8th Cir. 1998) (mail fraud).

A. The FDCA Charges and Evidence Related to Intent

The Government argues that it need only prove that Defendants understood the nature of their alleged misbranding fraud and not that Defendants were familiar with the misbranding provisions of the FDCA. (Gov't's Mot. at 3–4.) It concedes that Defendants “are entitled to argue they lacked the requisite intent for the misbranding charges—for example by asserting that they, in good faith, believed the prescriptions being issued were valid prescriptions[,]” but contends that Defendants “cannot escape culpability by baldly asserting that they did not know what the [FDCA] required.” (*Id.* at 4.) Defendants argue that they intend to present evidence about their good faith belief that the underlying prescriptions were valid and that this is “one and the same as saying [they] did not specifically know what the [FDCA] required or that his actions violated the law.” (Defs.’ Mem. in Opp. at 2.)

Defendants may present evidence that they genuinely believed the prescriptions at issue in this case were properly issued and obtained. *See United States v. Brown*, 478 F.3d 926, 928 (8th Cir. 2007) (describing a good faith defense as challenging the mens rea element of a fraud crime based on evidence that the defendant acted with good intentions and thus lacked the intent to mislead or defraud). What Defendants may not do is argue that they were unaware of the FDCA’s prescription requirement, or that they believed they were in compliance with that law. *See United States v. Carozza*, 608 F. App’x 532, 535–36 (9th Cir. 2015), *cert. denied*, 136 S. Ct. 1162 (2016) (“The district court did not err by instructing the jury that Defendants’ belief that they were in compliance with the law or that the government lacked the authority to enforce the law in

a particular way was not, standing alone, a defense. Defendants’ beliefs about the law as written were irrelevant, as the precise issue for the jury’s consideration was whether Defendants believed that their physicians were issuing prescriptions in the usual course of professional practice and for a legitimate medical purpose.”); United States v. Smith, 573 F.3d 639, 652 (8th Cir. 2009) (describing a “valid prescription” under the FDCA as “one issued in the usual course of professional practice and for a legitimate medical purpose,” meaning there is a bona fide physician–patient relationship (quotations omitted)). The issue for the jury is whether Defendants believed that the prescriptions were issued in the usual course of professional practice and for a legitimate medical purpose; thus, testimony on this subject is admissible while evidence regarding Defendants’ subjective beliefs about—or awareness of—the FDCA is not.

B. The CSA Charges and Evidence Related to Intent

The Government argues that the CSA “only requires that [it] prove the defendants knowingly distributed Fioricet, not that the defendants knew Fioricet was a controlled substance.” (Gov’t’s Mot. at 4.) It relies heavily on McFadden v. United States, 135 S. Ct. 2298 (2015), to support its contention that “the government can prove *either* that defendant did not know what substance he was dealing with, but knew that it was controlled, *or* that defendant knew the precise substance he was dealing with, even if he did not know it was controlled.” (Id. at 6 (emphasis original).) Defendants argue that McFadden is inapposite because it dealt with the mens rea standard in so-called analogue drug cases and because Fioricet is distinct from “well-known” controlled substances like heroin. (See Defs.’ Mem. in Opp. at 3–6, 9–10.) Defendants argue that the Government

must prove that they in fact knew Fioricet was a controlled substance. (See id. at 6, 10.) The Court agrees with Defendants, subject to one important caveat, as explained below.

The CSA requires that the Government prove Defendants “knowingly or intentionally” dispensed or distributed a controlled substance. 21 U.S.C. § 841(a), (h)(1). As part of this burden, the Government must establish that Defendants had “actual knowledge” that the substance they dispensed was a controlled substance, or were deliberately or willfully ignorant to that fact.¹ See United States v. Honea, 660 F.3d 318, 328 (8th Cir. 2011). Actual knowledge requires that the Government prove that Defendants knew they were dealing with a controlled substance, although it need not prove that they knew precisely what the substance was, or that it was specifically listed as a controlled substance. See United States v. Anderson, 747 F.3d 51, 61 (2d Cir. 2014) (“As to intentional possession and distribution of a controlled substance, the government must, of course, prove that the defendant knew he was dealing with a controlled substance.” (quotations omitted)); United States v. Abdulle, 564 F.3d 119, 125 (2d Cir. 2009) (“Although [the CSA] makes it unlawful for a defendant ‘knowingly or intentionally’ to manufacture, distribute, or dispense . . . a controlled substance, the law is settled that a defendant need not know the exact nature of a drug in his possession to violate [the CSA]; it is sufficient that he be aware that he possesses some controlled substance.” (quotations omitted)); United States v. Walia, No. 14-CR-213 MKB, 2014

¹ Deliberate ignorance, sometimes referred to as willful blindness, is where “the defendant was presented with facts that put her on notice that criminal activity was particularly likely and yet she intentionally failed to investigate those facts.” United States v. Katz, 445 F.3d 1023, 1031 (8th Cir. 2006) (quotations omitted).

WL 3734522, at *3 (E.D.N.Y. July 25, 2014) (“[T]he government need only prove that Defendant knew that the substance in question was a controlled substance or ‘illegal drug,’ that is, a substance proscribed under federal drug laws, but need not prove, as the Court understands Defendant to argue, that the Defendant knew that the substance in question was on the list of federally controlled substances.”).

McFadden examined the scienter requirement for prosecutions dealing with so-called analogue drugs—those being drugs engineered to mimic the physiological effects of substances specifically listed as controlled on the federal schedules, but which have slightly different chemical compositions than the listed substances. See 135 S. Ct. at 2302. The Controlled Substances Analogue Act (21 U.S.C. § 802 *et. seq.*) refers to the CSA for its scienter standard. See 21 U.S.C. § 813. The Supreme Court explained:

That knowledge requirement can be established in two ways. First, it can be established by evidence that a defendant knew that the substance with which he was dealing is some controlled substance—that is, one actually listed on the federal drug schedules or treated as such by operation of the Analogue Act—regardless of whether he knew the particular identity of the substance. Second, it can be established by evidence that the defendant knew the specific analogue he was dealing with, even if he did not know its legal status as an analogue. The Analogue Act defines a controlled substance analogue by its features, as a substance “the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II”; “which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than” the effect of a controlled substance in schedule I or II; or which is represented or intended to have that effect with respect to a particular person. § 802(32)(A). A defendant who possesses a substance *with knowledge of those features* knows all of the facts that make his conduct illegal, just as a defendant who knows he possesses heroin knows all of the facts that make his conduct illegal. A defendant need not know of the existence of the Analogue Act to know that he was dealing with “a controlled substance.”

McFadden, 135 S. Ct. at 2305 (emphasis added).

In a concurrence, Chief Justice Roberts joined in the Court’s opinion, except to the extent it concluded that the mens rea requirement was met where the government proved merely that a defendant knew the identity of the substance he possessed. Id. at 2307 (Roberts, CJ concurring). The Chief Justice argued that this understanding did not comport with the rule that a defendant “needs to know more than the identity of the substance; he needs to know that the substance is *controlled*.” Id. (emphasis original).

The Chief Justice went on:

In cases involving well-known drugs such as heroin, a defendant’s knowledge of the identity of the substance can be compelling evidence that he knows the substance is controlled. But that is not necessarily true for lesser known drugs. ...

The Court says that knowledge of the substance’s identity suffices because “ignorance of the law is typically no defense to criminal prosecution.” I agree that is “typically” true. But when there is a legal element in the definition of the offense, a person’s lack of knowledge regarding that legal element can be a defense. And here, there is arguably a legal element in Section 841(a)(1)—that the substance be “controlled.”

The analogy the Court drew in Liparota was to a charge of receipt of stolen property: It is no defense that the defendant did not know such receipt was illegal, but it is a defense that he did not know the property was stolen. Here, the argument goes, it is no defense that a defendant did not know it was illegal to possess a controlled substance, but it is a defense that he did not know the substance was controlled.

Id. at 2307–08 (citations and some quotations omitted). Ultimately, the Chief Justice noted that “the Court’s statements on this issue are not necessary to its conclusion” that the district court’s jury instructions on the mens rea requirement were inadequate, and

thus he counseled that “[t]hose statements should therefore not be regarded as controlling if the issue arises in a future case.” Id. at 2308.

Since McFadden, the Eighth Circuit continues to require that the government must prove that a defendant knew “the substance possessed was a controlled substance of some kind.” United States v. Qattoum, 826 F.3d 1062, 1065 (8th Cir. 2016) (quoting United States v. Ramos, 814 F.3d 910, 915 (8th Cir. 2016)). The Government does not provide—nor can the Court find—a single case post-McFadden that holds that all the Government must prove is that Defendants knew the identity of the substance they were dispensing (i.e., that the substance was Fioricet). This is not surprising since the Government reads too much into McFadden and generally mistakes its applicability here.

Fioricet is a prescription drug, one of its component parts (butalbital) is a Schedule III controlled substance, and thus Fioricet is also a controlled substance. See Oz, 2016 WL 1183041 at *2–5. However, the fact that Fioricet is a controlled substance does not conclusively establish that Defendants *knew* its status as such. Fioricet is not a “notorious” controlled substance—like heroin or cocaine—such that any reasonable individual would understand it to be controlled merely by knowing the identity of the drug. Thus, to the extent McFadden held that a defendant’s knowledge that he possessed a specific substance like heroin or cocaine satisfies the CSA’s mens rea requirement,² that reasoning is inapplicable here.

² The Court doubts that McFadden intended its ruling to reach so broadly. As Chief Justice Roberts pointed out, “a defendant’s knowledge of the identity of the substance [like heroin] can be compelling evidence that he knows the substance is controlled[,]” but the fact that such evidence is compelling does not mean it “automatically” satisfies the

Nor does McFadden reduce the Government's burden to proving only that Defendants knew the identity of the substance they were dispensing (i.e., that it was Fioricet). Fioricet is not an analogue drug, but rather a "normal" prescription drug. To the extent McFadden held that the government need only prove that a defendant knew the identity (e.g., name or composition) of an analogue drug,³ that reasoning is inapplicable here.

Defendants are free to argue and present evidence that they did not know Fioricet was a controlled substance. The Government may argue and present evidence that they did know Fioricet was a controlled substance, that Fioricet contained butalbital and that butalbital was a controlled substance, or that they were willfully blind to these facts. The jury will decide what evidence it believes.

An important caveat applies to the Defendants' arguments related to their knowledge—or lack thereof—about Fioricet. The subject of whether Fioricet is exempted as a controlled substance generally—or from criminal enforcement under the CSA—by 21 C.F.R. § 1308.32 (hereinafter, the "Exempting Regulation") has been the subject of extensive motion practice in this case. (See Doc. Nos. 512, 785.) As discussed thoroughly in its previous orders, the Court has held that the Exempting Regulation does

mens rea element. See McFadden, 135 S. Ct. at 2307. A defendant might still argue that despite knowing the substance he possessed was heroin, he did not know that heroin was a controlled substance. A jury would decide what evidence it believed.

³ Again, the Court doubts that McFadden creates this standard. As the Supreme Court clearly stated, a defendant must know not just the identity or composition of an analogue drug, but also its "features"—namely, the similarities between the physiological effects it produces and those of substances that are in fact on the schedules of controlled substances. McFadden, 135 S. Ct. at 2305.

not exempt Fioricet from classification as a controlled substance, or from criminal enforcement actions based on the requirements of the CSA. (See id.) Thus, Defendants may *not* argue that they did not know or believe Fioricet was a controlled substance because of the Exempting Regulation. This would be tantamount to arguing that they lacked the required mens rea because of their mistaken belief about the law, but such mistaken beliefs are not a defense to criminal prosecution. See Cheek, 498 U.S. at 199. Moreover, evidence regarding the Exempting Regulation would likely confuse the jury about Fioricet's status as a controlled substance, substantially outweighing whatever probative value it might have to the Defendants' irrelevant beliefs about the effect of the Exempting Regulation. See Fed. R. Evid. 403. Other courts have excluded argument and evidence under similar circumstances. See Ansaldi, 372 F.3d at 128 (upholding the district court's exclusion of argument and evidence related to the defendants' incorrect understanding that the substance they distributed was "not illegal" by virtue of a regulation and concluding that what the defendants were "attempting to argue as a 'defense' is that their mistake of law negates the intent element of the crimes of conviction. Ignorance or mistake of law is not a defense to all criminal charges."); Carozza, 608 F. App'x at 534 (upholding the district court's exclusion of evidence related to the defendants' subjective beliefs that their conduct complied with the CSA because "the precise issue for the jury's consideration was not Defendants' belief about the *law*, but rather Defendants' good faith belief that a physician was issuing prescriptions in the usual course of professional practice and for a legitimate medical purpose." (emphasis original)).

III. ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED THAT:**

1. The Government's Motion in Limine to Exclude Evidence of Defendants' Mistaken Belief that Their Conduct was Lawful [Doc. No. 699] is **GRANTED IN PART AND DENIED IN PART** as follows:
 - a. To convict Defendants on the charges related to the Controlled Substances Act, Food, Drug, and Cosmetics Act, and mail and wire fraud statutes, the Government need not prove that Defendants knew of or intended to violate these laws;
 - b. To convict Defendants on the charges related to the Controlled Substances Act, the Government must prove that Defendants knew Fioricet was a controlled substance, or were willfully blind to that fact, as described in this Order;
 - c. Defendants are prohibited from arguing or presenting evidence related to their subjective beliefs about their compliance with or knowledge of the Controlled Substances Act or the Food, Drug, and Cosmetics Act. Specifically, any evidence regarding 21 C.F.R. § 1308.32 and the Defendants' beliefs about the effects of this regulation on Fioricet's status as a controlled substance is excluded as irrelevant and likely to cause juror confusion.

Dated: January 30, 2017

s/ Susan Richard Nelson
SUSAN RICHARD NELSON
United States District Judge