

No. 07-2956

Criminal

In the

UNITED STATES COURT OF APPEALS

For the Eighth Circuit

UNITED STATES OF AMERICA,

APPELLEE,

v.

CHRISTOPHER WILLIAM SMITH,

APPELLANT.

Appeal from the United States District Court for the

District of Minnesota

BRIEF OF APPELLEE

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SUMMARY OF THE CASE

After approximately 20 days of trial, including cooperating testimony from the sole physician who issued thousands of prescriptions he admitted were invalid, the jury convicted Defendant Christopher William Smith on all charges stemming from Smith's operation of an illegal online pharmacy. The district court sentenced Smith to 360 months in prison, the bottom of the applicable guidelines range, after applying seven separate enhancements, including an obstruction of justice enhancement based on the defendant's plot to kill a witness.

The defendant seeks reversal of his conviction based on what he claims were alleged errors in the court's instructions of law, inadmissible expert testimony and other evidence, and insufficient evidence to prove the government's case. Smith also contends his sentence was based on procedural errors and was otherwise unreasonable.

The district court made no errors of law, did not abuse its discretion in its evidentiary decisions, and did not err in reaching a reasonable, guidelines sentence. The government presented more than sufficient evidence to prove each of the charges against Smith. The government requests 15 minutes per side for oral argument.

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STATEMENT OF THE ISSUES

I. Did the District Court Correctly Instruct the Jury as to What Constitutes a Prescription Issued Outside the "Usual Course of Professional Practice"?

United States v. Moore, 423 U.S. 122 (1975)

United States v. Hurwitz, 459 F.3d 463 (4th Cir. 2006)

United States v. Vamos, 797 F.2d 1146 (2d Cir. 1986)

II. Did the District Court Correctly Interpret Section 1306.04 Without the Need to Invoke the Rule of Lenity?

United States v. Birbragher, 2008 WL 4183503
(N.D. Ia. July 22, 2008)

United States v. Hernandez, 2007 WL 2915854
(S.D. Fla. Oct. 4, 2007)

III. Did the District Court Correctly Instruct the Jury that a "Prescription" Pursuant to the Food, Drug and Cosmetic Act Means a Valid Prescription?

Brown v. United States, 250 F.2d 745 (5th Cir. 1958)

United States v. Nazir, 211 F. Supp. 2d 1372 (S.D. Fla. 2002)

IV. Did the District Court Act Within Its Discretion When It Permitted a Pharmacist and the Head of the National Association of the Boards of Pharmacy to Provide Expert Testimony About the Standards of Care for Dispensing a Prescription?

United States v. Bek, 493 F.3d 790 (7th Cir. 2007)

United States v. Katz, 445 F.3d 1023 (8th Cir. 2006)

United States v. Mahar, 801 F.2d 1477 (6th Cir. 1986)

V. Did the Government Present Sufficient Evidence to Prove the Prescriptions Were Invalid?

United States v. Moore, 423 U.S. 122 (1975)

United States v. Hayes, 595 F.2d 258 (5th Cir. 1979)

- VI. **Did the District Court Act Within Its Discretion When It Admitted Limited Evidence of the Defendant's Plans to Secure Prostitutes, After a Co-Defendant Opened the Door to this Evidence?**

United States v. Shields, 497 F.3d 789 (8th Cir. 2007)

United States v. Beason, 220 F.3d 964 (8th Cir. 2000)

- VII. **Did the District Court, Which Ultimately Excluded Evidence of a Wrongful Death Lawsuit, Cure Any Alleged Prejudice When It Gave a Curative Instruction?**

United States v. Nelson, 984 F.2d 894 (8th Cir. 1993)

United States v. Blanton, 730 F.2d 1425 (11th Cir. 1984)

- VIII. **Did the District Court Sentence Defendant Without Significant Procedural Error When It Recognized It Could Vary but Nonetheless Imposed a Guidelines Sentence?**

Gall v. United States, 128 S. Ct. 586 (2007)

United States v. Bain, 537 F.3d 876 (8th Cir. 2008)

United States v. Burnette, 519 F.3d 942 (8th Cir. 2008)

- IX. **Did the District Court Impose a Procedurally Sound, Reasonable Sentence of 360 Months, the Bottom of the Guidelines Range, After Properly Weighing All of the Section 3553(a) Factors?**

Rita v. United States, 127 S. Ct. 2456 (2007)

United States v. Fields, 512 F.3d 1009 (8th Cir. 2008)

United States v. Miles, 499 F.3d 906 (8th Cir. 2007)

STATEMENT OF THE CASE

On September 19, 2006, a federal grand jury returned a Third Superseding Indictment charging Smith and co-defendants with various offenses arising out of Smith's online pharmacy. Dkt. 309.¹ Smith was charged with conspiracy to distribute and dispense controlled substances, in violation of 21 U.S.C. §§ 846, 841(a)(1), and 841(b)(1)(D), and 21 C.F.R. § 1306.04 (Count 1); unlawful distribution and dispensing of controlled substances, in violation of 21 U.S.C. §§ 841(a)(1) and 841(b)(1)(D), 18 U.S.C. § 2, and 21 C.F.R. § 1306.04 (Counts 2-4); introduction of misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 353(b)(1), and 18 U.S.C. § 2 (Counts 5-7); conspiracy to commit money laundering, in violation of 18 U.S.C. § 1956(h) (Count 8); and continuing criminal enterprise ("CCE," or the drug kingpin statute), in violation of 21 U.S.C. § 848(a) and (c)(Count 9). Id.

Four days earlier, on September 15, 2006, one of Smith's co-conspirators in his online pharmacy, Philip Mach, M.D., pled guilty to drug conspiracy and drug distribution charges. Dkt. 303-04.

On October 10, 2006, trial commenced before a jury and the Honorable Michael J. Davis. Dkt. 315. On November 22, 2006,

¹Documents filed with the district court are referred to by docket number and are designated herein as "Dkt."

following approximately 20 trial days, the jury convicted Smith on all nine counts of the Third Superseding Indictment.² Dkt. 354.

For two days, on July 31 and August 1, 2007, the court held sentencing proceedings. Dkt. 391, 393. Judge Davis sentenced Smith at the bottom of the guidelines range to 360 months imprisonment, to be followed by 5 years supervised release. Transcript of August 1, 2007, Sentencing ("Sent. Tr.") at 86.³

The defendant now appeals his conviction and his sentence.

²During trial in this matter, co-defendant Darrell Griep (pharmacy recruiter) pled guilty to conspiracy to distribute controlled substances. Co-defendants Bruce Lieberman (accountant) and Daniel Adkins (lawyer) were acquitted by the jury. Prior to trial, in addition to Philip Mach, three other co-conspirators pled guilty: Bernardette Hollis (computer programmer), Alton Scott Poe (business consultant), and Ronald Miller (head of security/bodyguard).

³Because conviction on both the drug conspiracy and CCE counts implicated double jeopardy, the government secured dismissal of the drug conspiracy count at sentencing. Sent. Tr. 89; see United States v. Jones, 101 F.3d 1263, 1268 (8th Cir. 1996).

STATEMENT OF THE FACTS

I. TRIAL FACTS

A. Smith Originally Employed No Doctor

Starting in early 2004, Christopher Smith began selling prescription drugs through Internet web sites and spam emails. Trial Transcript (hereinafter, "Tr."), Vol. VI at 992-93. Smith imported the drugs, including hydrocodone, a Schedule III controlled substance, from India, Canada and Australia. Id. at 993, 997. Smith's web sites falsely claimed the online pharmacy was backed by an entire network of physicians and that customers who placed drug orders would receive a prescription following an online doctor consultation. Id. at 1000. In fact, Smith originally employed no doctors at all, and there were no prescriptions whatsoever. Id. at 1003.

B. Smith Joked About His Addict Customers

From the very beginning, Smith recognized his customers were addicts. Id. at 1005-07. In an April 2004 Internet instant message between Smith and his computer programmer, Bernardette ("Berni") Hollis, Smith chatted about the "f-ing addicts" and joked about how these addicts would be willing to pay even higher prices to get their fix.⁴ Id. at 1005-1007; Government Ex. 95. As it was,

⁴The witness did not read the profanity at trial, but it is contained in Smith's original message. See Dkt 384 (Govt. sentencing memorandum) at 36.

Smith charged almost \$600 for 160 hydrocodone tablets. Id. at 1007.⁵

C. Smith Developed an Online Questionnaire for Customer Drug Orders

After Smith's overseas-based operation experienced shipping problems, Smith shifted the online pharmacy to the United States. Tr. Vol. VI at 1008. Smith developed a brief online questionnaire for customers to complete when placing drug orders. Id. at 1009. The customer entered his or her name, address, date of birth, and phone, and they selected the kind of medication they wanted and in what quantity. Id. at 1011; Tr. Vol. XII 1803-04. They could also list a purported medical condition. Tr. Vol. III at 433.

D. Smith Hired One Doctor, Dr. Mach, to Issue Prescriptions for Thousands of Customers With Whom He Never Consulted

Besides the questionnaire, Smith initiated other steps to make his online pharmacy appear "legitimate" to customers and regulators. Tr. Vol. VI at 1008. Most importantly, in the July 2004 time frame, Smith enlisted a single physician, co-defendant Dr. Philip Mach, to issue prescriptions after customers placed their orders online. Id. at 1020, 1026; Tr. Vol. XII at 1797. Although Mach issued prescriptions for customers throughout the United States, he was only licensed to practice medicine in New Jersey. Tr. Vol. XII at 1784-85.

⁵Because Smith's wholesale cost was 3 cents a tablet, and because he overcharged customers for shipping, Smith's gross profit margin was over 100%. Tr. Vol. XV at 2520-22.

Several times a day Mach logged onto a computer interface set up by Smith for approving prescription drug orders. Id. at 1805. Smith's system defaulted all orders to "approved" status. Id. at 1803; Tr. Vol. VI at 1010. Any order Mach tried to deny was later changed by the system to "approved." Tr. Vol. XII at 1808.

Mach never had a face-to-face examination with any online pharmacy customer, never reviewed any medical records, and had no idea if the customer's information was made up or even if a real person was ordering the drugs. Id. at 1806-07. Where customers gave no condition or reason for requesting medication, Mach still approved the orders. Id. at 1806. Mach also approved orders when the prescribed drug was not suitable for the condition listed. Tr. Vol. XIX at 3137.

Mach acknowledged that the prescriptions were shams. Specifically, he admitted he issued them not for a legitimate medical purpose and outside the usual course of his medical practice. Tr. Vol. XII at 1810. His Internet prescribing was in stark contrast to how he conducted his medical practice. Id. at 1786-87. For example, at his New Jersey practice, before Mach issued prescriptions, he met with patients, took a history, conducted a physical exam, and if applicable, spoke to the primary care physician and reviewed lab results. Id.

Indeed, an FDA agent, acting undercover, purchased large quantities of addictive drugs from Smith's online pharmacy, after providing false information. Tr. Vol. III at 456-503. The male

agent even pretended to be a woman on some orders. Id. at 489. Mach had no communication with the agent, despite the fact the orders each indicated they were approved after a "doctor consultation." Id. at 487. In each case, Mach approved the undercover orders, without any effort to verify the agent's false information. Id. at 459, 474.

Smith was well aware of the sham nature of Mach's approval process because he set up the system. See Tr. Vol. VI at 1025-26. Smith even took hundreds of backlog orders, placed at the time when Smith had no doctor, added false questionnaire information and sent the orders to Mach for approval. Id. Smith also used his Internet pharmacy system to obtain prescription drugs for himself and family members. Id. at 1149; Tr. Vol. XII at 1816-17. Smith was unmoved when he learned Mach approved an order placed in the name of an obscene word. Tr. Vol. VI at 1037-38. Smith knew customers ordered large quantities of drugs, all to be shipped to the same address. Id. at 1057.

Mach approved up to a thousand prescriptions a day. Tr. Vol. XII at 1807-08; Vol. VI at 1045-46. During Smith's total operation from 2004 through mid-2005, Mach approved a total of over 72,000 drug orders. Tr. Vol. VI at 1046. Out of that total, Mach originally denied only about a thousand orders, but at Smith's direction, every one of those orders was put back into the queue and was later approved by Mach. Id. at 1046.

Smith only paid Mach if the orders were approved. Id. at 1042. For every prescription issued, Smith paid Mach \$3.50 and paid another \$3.50 to a middle man from New Jersey, John Guerriero, who had connected Mach with Smith. Tr. Vol. XII at 1800. Smith claimed Guerriero controlled Mach, including with violence, and that Smith had to "kick up" to Guerriero in order to do business with Mach. Tr. Vol. XV at 2534.

Throughout the entire duration of Smith's online pharmacy, Mach was the only physician willing to work for Smith. Tr. Vol. VI at 1015; Vol. XV at 2518.

E. Smith's Top Seller Was the Addictive Pain Killer Hydrocodone

The vast majority of Smith's Internet drug sales were for the highly addictive pain killer, hydrocodone, sold under brand names such as Vicodin and Norco. Tr. Vol. VII at 1170; Vol VI at 1058. Over time, Smith sold over 4 million units (i.e., tablets) of hydrocodone. Tr. Vol. VII at 1170.

F. Smith's Total Sales Were Over \$24 Million

From early 2004 until Smith's online pharmacy was shut down in May 2005, Smith's total drug sales exceeded \$24 million. Id. at 1170; Vol. XVII at 2887.

G. Smith Employed Telemarketers to Push Drug Sales

In addition to web sites, customers could place orders by phone, through call centers Smith had set up to support his Internet pharmacy. Tr. Vol. VI at 1047. While Smith's primary

call center was in Burnsville, Minnesota, Smith also had call centers operating in the Dominican Republic, Philippines, and Canada. Id. at 1047, 1049.⁶

Smith's Minnesota call center was open virtually around the clock, employing telemarketers and "customer service" representatives. Id. at 1048; Vol. V at 769. At Smith's direction, telemarketers placed frequent calls to customers, asking, "Are you ready for a refill?" Tr. Vol. V at 791; Vol. XVIII at 2969. He pushed telemarketers to "sell, sell, sell, sell, sell" prescription drugs. Tr. Vol. XV at 2452; Vol. V at 771. The telemarketers were paid on commission, so the more drugs they pushed, the more money they made. Tr. Vol. V at 770.

H. Smith Recruited a Few Small Pharmacies By Lying About Operations

Because his online pharmacy was not licensed to distribute controlled substances, Smith needed licensed U.S. pharmacies to fill the prescription drug orders. Tr. Vol. VI at 1017-18. Smith intentionally targeted small, struggling independent pharmacies because he believed they would not ask many questions and would quickly become economically dependent on him. Vol. VI at 1046-47; Vol. XV at 2522, 2524.

⁶A woman by the name of Roanna ("Margaux") Cleofe worked at the Philippines call center. Id. at 1049. The jury did not learn of this, but as discussed below, while Smith was in jail awaiting his trial, he called Cleofe to discuss his plans to kill and threaten Hollis, a government witness.

Even the handful of pharmacies that agreed to work with him, however, asked questions about whether Smith's online pharmacy operation was operating legally. Tr. Vol. VI at 1076, 1080. To allay their concerns, Smith repeatedly lied, or encouraged others to lie, about how his Internet operation worked. Id. at 1080-81. Smith even pushed the lie that his prescriptions were "not Internet prescriptions. They are valid prescriptions." Id. at 1080-81.

In his pharmacy contracts, Smith falsely told pharmacies that he employed numerous physicians, that his online questionnaire was "FDA-approved," and that there were consultations between the prescribing physicians and the customers. Id. at 1019-20.

In order to get around state laws (such as in California) that explicitly required a face-to-face examination for a prescription to be valid, Smith told the pharmacies that his physicians (plural) worked closely with the customers' primary care physicians. Id. at 1093. This was false; Smith himself had rejected any requirement that customers supply primary care physician information. Id. at 1012, 1024.

Despite these lies, most prospective pharmacies and physicians flat out refused to work with Smith, in many cases advising him or his associates that Smith's operation was illegal. Tr. Vol. XIII at 2141-59.

In addition to the lies, when Smith's pharmacies raised concerns about the large volume of hydrocodone orders, he simply shifted orders to other pharmacies. Tr. Vol. VI at 1078-79; 1083.

Smith discussed dropping pharmacies that raised too many questions and that brought increased regulatory scrutiny on him. Id. at 1079-80.

I. Smith Responded to DEA Warning Letter With More Lies

In about February 2005, the DEA issued a directive to pharmacies throughout the United States, warning about online pharmacies and asserting that a doctor-patient relationship could not be established on the basis of an online questionnaire. Tr. Vol. XV at 2535; Vol. XVIII at 3022. In response to that directive, the few pharmacies working for Smith threatened to quit unless he could assure them orders were based on proper prescriptions. Tr. Vol. XV at 2537-40. As a result, Smith privately expressed concerns about going to prison and discussed plans to flee from authorities. Tr. Vol. XVIII at 3019-20.

In response to the DEA letter, Smith ultimately arranged to have a false letter prepared and sent to the pharmacies, under Mach's signature. Tr. Vol. XV at 2540-42. The letter falsely stated that Smith's online pharmacy issued valid prescriptions based on a legitimate doctor-patient relationship formed through a review of medical records and through thorough communications between the patient and doctor. Id. at 2540-42. Smith knew none of this was true, but he hoped it would appease the pharmacies long enough to keep shipping drugs. Id. at 2542.⁷

⁷Smith received additional warnings about the illegal nature of his business from various entities such as boards of pharmacies,

J. Smith Began Moving Operations to Canada

After Smith learned the government was investigating him, he began moving operations to Montreal, Canada. Id. at 2490, 2495, 2543-44. Smith began hiding his personal luxury cars by moving some of them to Canada and moving others to local storage facilities secured in others' names. Tr. Vol. XV at 2490, 2561-63.

In addition, Smith arranged for approximately \$650,000 in drug proceeds to be transported to Montreal, Canada to support his online pharmacy. Id. at 2571. This money was part of millions that Smith had originally laundered through a shell entity and that he had hidden in locations throughout the Twin Cities. Id. at 2488-89, 2666, 2693.⁸

K. Smith Destroyed Returned Drugs

If customers did not accept delivery of drug orders, the drugs were returned to Smith's call center. Id. at 2507, 2512. Smith stockpiled the drugs despite his awareness that only licensed

Tr. Vol. XVIII at 3037, and MasterCard, Tr. Vol. VIII at 1380, and he possessed pleadings and research regarding various other online pharmacy operators who had been charged and convicted of illegal drug distribution and related charges. Tr. Vol. XIII at 2043-46. Rather than cease operations, Smith resorted to additional lies and deception. For example, to dupe Mastercard, Smith created fake web sites that displayed no hydrocodone, Tr. Vol. VII at 1297, and he stopped taking Mastercard sales for a time. Tr. Vol. XV at 2481. When Smith believed his operation was under investigation by regulatory agencies, he switched web sites. Tr. Vol. VI at 1079.

⁸Smith had also laundered drug proceeds through a separate, New York-based shell company, Rxorderfill.com, Inc. Id. at 2476-77. He used these funds to pay Mach and to buy personal luxury vehicles, such as a Ferrari, Mercedes, and others. Id. at 2476-79; Vol. XVIII at 2880-881.

pharmacists could lawfully handle such drugs. Id. After a disgruntled, terminated employee (Smith's sister-in-law) informed the police that Smith was illegally maintaining returned drugs, Smith hastily arranged to remove the drugs from his call center premises. Id. at 2507-09. Ultimately, with knowledge of the government's investigation, Smith arranged to have his lawyer, Adkins, destroy the drugs. Id. at 2514, 2554.

L. Court Shut Down Smith's Online Pharmacy

In May 2005, the district court entered an injunction shutting down Smith's online pharmacy business, freezing the company's bank accounts and assets, and enjoining Smith and others from continuing to operate an online pharmacy in violation of the mail and wire fraud statutes. Tr. Vol. VIII at 1435; see Case No. 05-CV-895 (MJD/FLN), Dkt. 5, 27.

M. Smith Set Up Online Pharmacy in Dominican Republic

Within days of his injunction hearing, Smith traveled to the Dominican Republic to set up another online pharmacy. Tr. Vol. XV at 2568. Smith had no plans to change his operation (which included selling to his existing U.S. customers) because he needed to generate cash for legal fees. Id. at 2569, 2578. In about May 2005, Smith had his wife, his mistress and others travel to the Dominican Republic to bring him thousands of dollars in cash (in proceeds frozen by the court's injunction). Tr. Vol. XVII at 2605. Smith's plan was to set up his business overseas where he believed

the U.S. authorities were without jurisdiction to shut him down.
Id. at 2604.

N. Smith Planned to Flee Authorities

In about June 2005, Smith adopted a plan to flee U.S. authorities by relocating first in Canada, then the Turks and Caicos and then Honduras. Tr. Vol. XV at 2558, 2565-66, Vol. XVII at 2607-08.

II. ADDITIONAL SENTENCING FACTS⁹

A. Smith Admitted Violating Injunction

The government moved to have Smith found in contempt of the preliminary injunction. PSR, ¶ 9; see Dkt. 10, 14 in Case No. 05-MC-41 (MJD). Following a contempt hearing,¹⁰ Smith admitted he violated the injunction during his time in Dominican Republic when he withdrew \$2,000 in frozen drug proceeds from his former company's bank account. PSR, ¶ 9. He denied that his online pharmacy violated the injunction, and the district court took the case under advisement. Id. The court placed conditions on Smith

⁹The following facts were brought out at sentencing but were not presented to the jury. They were set forth in the final Presentence Investigation Report ("PSR") and were adopted by the district court. Statement of Reasons for Imposing Sentence ("Statement of Reasons") at 2.

¹⁰Smith was arrested upon a return trip from the Dominican Republic. Id., Dkt. 11.

which prohibited him from using a computer or developing any new web sites. Id.¹¹

B. Smith Violated the Terms of His Pretrial Release

On September 13, 2005, after the initial indictment in this matter, Smith was released to a halfway house. Id., ¶ 10. Within days, his pretrial release was revoked. Id., ¶ 11. Smith had smuggled a contraband laptop computer and cell phone/PDA into the halfway house. Id. Smith used the items to communicate with his Philippines associate, Cleofe, and to set up a new Internet search engine in violation of court orders. Id., ¶¶ 10-11.

C. Smith Violated the Jail's Phone Procedures

Once in Sherburne County Jail, Smith routinely violated the jail's rules and procedures. Id., ¶ 14. Smith schemed to have the jail enter a phone number into their system of unmonitored and unrecorded attorney numbers despite that the number was not actually his attorney's number. Id. Smith was thus able to place unmonitored calls to that fake attorney number, and he had them forwarded, using Voice Over Internet Protocol, to Cleofe in the Philippines. Id. Eventually, jail officials put a stop to the fake attorney number. Id., ¶ 15.

¹¹On April 27, 2007, the Court found Smith guilty of criminal contempt based on the Dominican Republic cash withdrawals. Id. On August 1, 2007, Smith was sentenced to 6 months imprisonment in Case No. 05-MC-41(MJD) to run concurrent to the instant offenses. Id.

D. Smith Violated Court Orders By Setting Up a New Online Pharmacy in Phillipines

Smith used the unmonitored calls to work with Cleofe to set up another Internet pharmacy, based in the Philippines, www.valuemed.ph, in violation of the court's orders. Id., ¶ 12.¹² The government discovered the site and shut it down. Id.

E. Smith Planned to Threaten and Kill a Witness

In March 2006, Smith was discovered using another fake attorney number to place calls that would not be monitored and recorded. Id., ¶ 17. After jail officials began listening to Smith's calls, they heard a particularly bone-chilling call between Smith and Cleofe. ¶ 18. Smith first discussed sending threatening emails to Hollis, a witness in his upcoming trial. Id. Smith stated:

[W]hen we get a little closer to trial, you know? I think we're gonna have to . . . hire a private detective to get pictures of Berni's kids. And ah . . . we can do a little bit of emailing and electronic influence about a week before trial Just let her know that, you know, if, if she wants to talk on the stand, that's perfectly fine, but we're also going to give her the option of picking which one of her kids she's going to sacrifice for doing so.

Dkt. 384 (Government's Sentencing Memorandum) at 20 (quoting from actual recorded call played at sentencing hearing); see Transcript of July 31, 2007, Evidentiary Hearing at 71.

¹²Smith also used his unmonitored calls to Cleofe to have her place false orders for prescription drugs at local pharmacies (presumably to be picked up by local associates). PSR, ¶ 115.

From the threat talk, Smith quickly moved on to discuss actually arranging to kill Hollis. PSR, ¶ 19. Smith stated, "I mean you know what kind of services I'm looking for, right? I'm looking for like a full service," and "[t]here was a famous comment by Joseph Stalin, the most powerful man of the whole world, you want to know what it was? 'No man, no problem.'" Id. To clarify his intent, he stated, "I'm, I'm really not joking. I got to get out of here That's the only way I can do it." Id. He further clarified, "I'm more looking for the, uh, missing persons kind of thing, not, uh, not, you know what I mean, not, uh, something laying around to be stared at and . . . talked about." Id. Smith discussed other details regarding the type of hitman he desired. Id.

Smith's intent in this call was corroborated by one of his attorneys, who acknowledged Smith discussed having one of the witnesses against him killed. Id., ¶20.¹³

F. Firearms and Tasers

During the drug conspiracy, Smith possessed firearms and other weapons, including two Glocks, a stolen SKS 47, and a taser gun. Smith actually used the taser guns on his employees. PSR, ¶ 50.

¹³On March 21, 2006, a federal grand jury returned a separate indictment against Smith, charging him with conspiracy to tamper with a witness and with endeavoring to obstruct justice. Case No. 06-CR-97 (MJD/JJG), Dkt. 1; PSR, ¶ 69. Also in March, Judge Davis ordered Smith to be housed in round-the-clock segregation at Oak Park Heights, a high security facility. See Dkt. 187. After Smith was sentenced in the instant case, the court dismissed the separate case upon the government's motion. Id., Dkt. 44.

G. Customer Deaths

The deaths of three addicted individuals were caused at least in part by their ability readily to obtain large volumes of addictive drugs from Smith's online pharmacy. Id., ¶ 53-55.

III. TRIAL PROCEEDINGS

A. Expert Testimony from Dr. Carmen Catizone

At trial, the government offered expert testimony from Carmen Catizone, M.S., R.Ph., D.Ph., a pharmacist and the chief executive officer and executive director for the National Association of the Boards of Pharmacy ("NABP"). Tr. Vol. XIX at 3109-10. Dr. Catizone's qualifications included his pharmacy training, his experience with the NABP,¹⁴ his knowledge of state and federal law, medical literature, and directives issued by the DEA, FDA, and organizations such as the Federation of State Medical Boards, all of which address the standards pertaining to the issuance of prescriptions. Id. at 3109-116. He had experience providing testimony before courts, Congress, state legislatures, and numerous media outlets. Id. at 3109-116. As preparation for his testimony, he reviewed Smith's Internet pharmacy web site and other materials associated with Smith's operation. Id. at 3117.

¹⁴The NABP provides national licensure examinations for pharmacists, provides model laws to the states, and maintains a disciplinary clearinghouse of actions taken against those involved in the practice of pharmacy. Id. at 3110.

Dr. Catizone testified about rogue Internet pharmacies, those which do not follow state and federal law, as compared to legitimate online pharmacies that do, such as Walgreens.com. Id. at 3115-36. Smith's operation appeared consistent with rogue Internet pharmacies because it sold mostly controlled substances and "lifestyle" drugs, represented that no prior prescription was needed, and used disclaimers that attempted to shift responsibility for complying with the law onto the customer. Id.

Dr. Catizone further testified about the prevailing standards of medical practice. He testified that he had reviewed Government Ex. 169, customer information that Dr. Mach relied upon in issuing prescriptions. Id. at 3137. Based on his experience, expertise, and familiarity with federal and state laws governing issuance of prescriptions, Dr. Catizone concluded that there was not enough information for a physician to determine whether or not a person actually needed the prescription order. Id. As a result, in his opinion, a prescription issued pursuant to this insufficient information did not meet the standards of care. Id. at 3140.

B. Wrongful Death Suit

On January 27, 2005, Hollis sent an email to Smith, attaching a complaint for wrongful death, filed against Fallbrook Pharmacy by the family of an addicted person (William Pitts) in California Superior Court. Government Exhibit 118; see Dkt. 312 (Govt. Trial Brief) at 8; Tr. Vol. I at 16, 18-19. The complaint alleged that

in March 2004, the addicted person suffered a self-inflicted gun shot wound after purchasing prescription drugs from online pharmacies, including Smith's. Dkt. 312.¹⁵ Id.

In its trial brief, the government acknowledged that the individual had died before receiving the actual order from Smith's online pharmacy. Dkt. 312 (Govt. Trial Brief) at 8. Smith and his pharmacy were not responsible for the death, but the evidence nonetheless showed Smith was on notice that his online pharmacy could cause the death of addicted persons. Id. at 8-9. Prior to trial, Smith objected to this evidence, and the court deferred its ruling. Tr. Vol. I at 16, 18-19.

Initially, when the government introduced the wrongful death exhibit, Smith's counsel had no objection, and the exhibit was admitted. Tr. Vol. VI at 1061. Over the course of a few minutes, Hollis testified that Smith had received the wrongful death suit and was aware that the person had shot himself, but Smith was unconcerned because the person had died before any drugs from Smith's Internet pharmacy were shipped to him. Id. at 1064-65. At a sidebar requested by the government for another purpose, Smith's counsel then objected to this evidence. Id. at 1065. The court

¹⁵Smith (at 69-70) incorrectly lumps Government Ex. 116 with Ex. 118 and states Robert Londino was the deceased. Exhibit 116, to which Smith did not object, was not related to Exhibit 118. Exhibit 116 was a *federal* grand jury subpoena for Fallbrook Pharmacy issued out of New York. Tr. Vol. VI at 1061-63. Robert Londino was an undercover FBI agent who had purchased drugs from Smith's online pharmacy. Tr. Vol. XIV at 2239.

sustained the objection, concluding there was no evidence that the individual who died had ordered from Smith's online pharmacy. Id. at 1067. The court then asked counsel how it could rectify the situation, and Smith's counsel suggested the court issue a brief cautionary instruction and state further instructions would be forthcoming. Id. at 1070. The court did so, and the defense prepared a proposed instruction. Id. at 1070-71. The court then instructed the jury,

[W]ith regard to the civil case filed in California, there is no evidence that Xpress Pharmacy, Christopher Smith, or any other defendant had anything to do with the alleged death. Indeed, you are not to speculate about what happened to the deceased, nor why it occurred, and the evidence about the case is stricken and you are to disregard it because, in fact, there is no evidence that plaintiff ordered drugs from Xpress Pharmacy.

Id. at 1074. No objections were raised to this instruction. Id. The court gave a similar instruction at the close of the case, see Dkt. 353 (Jury Instruction No. 18), and no objections were raised then. Tr. Vol. XIX at 3299.

C. Prague Incident

Prior to the testimony of a cooperating government witness, Alton Scott Poe, the government moved to exclude cross examination about a number of topics, including a trip Poe made to Prague at Smith's direction to secure prostitutes for Smith. Tr., Vol. XV at 2432. The court initially granted the motion. Id. at 2437. After Poe's direct examination was underway, however, counsel for co-defendant Adkins asked the court to revisit the issue because Poe

was "coming off as clean as can be." Id. at 2462. The court ruled that Adkins' counsel could inquire about the trip to Prague, apparently to impeach Poe's testimony that suggested he was law abiding. Tr., Vol. XVII at 2590-91. Smith's counsel objected on Rule 403 grounds. Id. at 2590.

Anticipating the cross examination, the government briefly inquired on direct about the Prague trip. Id. at 2598-2600. Poe testified that on March 20, 2005, he went to Prague at Smith's direction for the purpose of bringing back prostitutes for Smith but did not in fact bring any women back. Id. at 2598-99.

Adkins' counsel re-raised the issue briefly on cross examination, eliciting the fact that the trip was paid for by online pharmacy proceeds. Id. at 2688-89, 2693. Smith's counsel also examined Poe briefly about the Prague trip. Id. at 2765-67. On redirect, Poe testified that Adkins, who served as Smith's lawyer, was aware of the Prague trip's purpose and laughed about it. Id. at 2503-04.

D. Key Jury Instructions

The court's closing instructions to the jury included Instruction No. 30 as follows:

The Federal Controlled Substances Act is not violated if a person distributes or dispenses controlled substances pursuant to a lawful prescription issued for a legitimate medical purposes by an individual practitioner acting in the usual course of his or her professional practice. However, an order purporting to be a prescription that is issued without a legitimate medical purpose and issued outside the usual course of professional practice is not

a prescription within the meaning of the Federal Controlled Substances Act. **"Usual course of professional practice" means that the practitioner acted in accordance with a standard of medical practice generally recognized and accepted in the United States. In issuing prescriptions, practitioners are not free to disregard prevailing standards of treatment.**

Dkt. 353 (emphasis added).¹⁶ The district court provided similar language in its good faith instruction, a portion of which stated:

In order to sustain its burden of proof under Counts 2-4, the government must prove beyond a reasonable doubt that the defendant knowingly and deliberately distributed or dispensed controlled substances drugs and did so other than in good faith for a legitimate medical purpose and not in the usual course of professional practice and **in accordance with a standard of medical practice generally recognized and accepted in the United States.**

Id. (Instruction No. 64)(emphasis added). At defense counsel's request, the following language was added to the good faith instruction:

When you consider the good faith defense, it is the defendant's belief that is important. It is the sincerity of his belief that determines if he acted in good faith. If the defendant's belief is unreasonable, you may consider that in determining his sincerity of belief, but an unreasonable belief sincerely held is good faith.

Id.; see Tr. Vol. XXI at 3415-17. The drug distribution counts required the jury to find proof beyond all reasonable doubt that (1) each defendant intentionally distributed a controlled substance, and (2) at the time of the distribution, the defendant knew he was distributing a controlled substance other than for a

¹⁶As discussed below, in Smith's appeal, he challenges only the highlighted portion.

legitimate medical purpose and not in the usual course of professional practice. Dkt. 353 (Instruction No. 41).

The court gave Instruction No. 19 as follows:

The defendant is not on trial for any act or conduct not alleged in the indictment.

You have heard evidence concerning possible violations of state laws, medical regulations, pharmacy regulations and organizational policy violations.

As I have stated before, the defendants are not on trial for any act or any conduct not specifically charged in the indictment. You may not consider any evidence concerning possible violations or rules, boards and policies except in deciding if a defendant committed the crimes charged in the indictment.

Dkt. 353. During trial, the court read a shorter version of this instruction, as proposed and prepared by the defense. See Tr. Vol. IV at 555-64, 572-73. The jury was also instructed that "[t]he defendants are, of course, not on trial for any act or crime not contained in the indictment." Instruction No. 9.

The court's Instruction, No. 43, stated as follows:

A prescription as used in the Food, Drug and Cosmetic Act and in these instructions means only a valid prescription. A valid prescription means one issued in the usual course of professional practice and for a legitimate medical purpose, as explained earlier in the Instructions.

Dkt. 353.

In its jury instructions, the court gave Smith's theory of defense, stating in part that "his intent was to operate within the law, not in violation of it." Dkt. 353 (Instruction No. 65).¹⁷

IV. SENTENCING PROCEEDINGS

Ultimately, Smith's conviction on the three counts of introduction of misbranded drugs drove the guidelines analysis. The applicable guidelines section was Section 2B1.1 (offenses involving fraud or deceit).¹⁸ After starting at a base level of 6, the court applied a 22-level enhancement based on a loss amount of more than \$20 million (§ 2B1.1(b)(1)(L)); a 2-level enhancement for mass marketing (§ 2B1.1(b)(2)(A)(ii)); a 2-level enhancement for violation of prior court orders (§ 2B1.1(b)(8)(C))¹⁹; a 2-level

¹⁷Smith did not testify in his trial, so he was never cross examined as to his alleged beliefs about the law, and his beliefs were never substantiated beyond the arguments of his counsel. The evidence strongly contradicted these alleged beliefs because Smith lied about operations, moved to foreign jurisdictions, violated order after order, obstructed justice in countless ways, and plotted to kill a witness against him, all actions not typical of someone who believed he was acting lawfully.

¹⁸Although Smith contested the fraud guidelines at trial, he does not persist in that objection, except as it pertains to the reasonableness of the sentence. Smith Brief at 86. There is no question the fraud guidelines applied here. See, e.g., United States v. Kimball, 291 F.3d 726, 733 (11th Cir. 2002)(where defendant is convicted of distributing a prescription drug without a valid prescription with the intent to defraud or mislead, an essential element is fraud, including fraud against government agencies, and the proper guidelines section is § 2F1.1 (the predecessor to § 2B1.1)).

¹⁹The court found Smith violated court orders three times: when he intentionally withdrew money at a Dominican Republic bank; when he snuck a computer and cell phone/PDA into the halfway house; and when he established a new online pharmacy in the Phillippines from

enhancement for relocation of a fraudulent scheme to another jurisdiction (§ 2B1.1(b)(9)(A)) or, in the alternative, for committing a substantial part of the scheme from outside the United States (§ 2B1.1(b)(9)(B)), or in the further alternative, for employing sophisticated means (§ 2B1.1(b)(9)(C)); a 2-level enhancement for conscious or reckless risk of death or serious bodily injury (§ 2B1.1(b)(12)(A)), or in the alternative, for possessing a dangerous weapon (firearms and tasers)(§ 2B1.1(b)(12)(B)); a 4-level enhancement for being an organizer or leader of criminal activity involving five or more participants (§ 3B1.1(a)); and a 2-level enhancement for obstruction of justice (§ 3C1.1),²⁰ resulting in a total offense level of 42. With a criminal history category of I,²¹ the resulting guideline range was 360 months to life.

The defendant submitted a 20-page sentencing memorandum seeking a variance down to the statutory minimum sentence of 180

jail. Statement of Reasons at 10-13.

²⁰The court found eight separate bases for the obstruction of justice enhancement: Smith's plot to kill a witness; Smith's use of a fake attorney number; Smith's destruction of returned drugs; Smith's online pharmacy operation in the Dominican Republic; Smith's widespread hiding of millions in cash and luxury vehicles after learning of the government's investigation; and Smith's establishment, from jail, of yet another online pharmacy, to be located in the Phillippines. Statement of Reasons at 22-27.

²¹Although Smith had no criminal history points, he had a long history of unlawful behavior, including other Internet and spamming scams, domestic violence calls, and violations of jail procedures, including smuggling Xanax into the jail. PSR, ¶¶ 14, 28, 29, 114, 121, 129.

months. Dkt. 385. He argued the variance was supported by alleged sentencing disparities, the unreasonableness of applying the fraud guidelines to his conduct, and mitigating evidence about his mental health. See Dkt. 385; Sent. Tr. at 14-21, 25, 29-32; see also Sent. Tr. at 66-68. Following two days of hearings, Smith's defense counsel acknowledged, "[w]e've had as complete a sentencing hearing as we possibly could have." Sent. Tr. at 68.

In response to Smith's arguments in support of a variance, the court stated:

Let me ask you this hypothetically. I know that you submitted to me your grounds for the variance, but you know what the circuit does for every variance that a judge does for a departure downwards, it essentially reverses.

* * * *

They have put out beacons about the sentence because I placed somebody on probation and home detention and they said, No, you can't do that variance, you can't do that departure, you have to send them to prison. And so there's -- it's clear, coming from our circuit, they don't even want to see any type of variance downwards unless it can be so agreed to, almost, by the Government.

Sent. Tr. at 70-71. In other cases in which the district court had varied downward to a probationary sentence, the Eighth Circuit had reversed, indicating prison was required.²²

²²Smith (at 81) cites cases from around the time of his sentence that involved either a reversal of Judge Davis' sentence or a pending appeal of his sentence. Each of those cases, United States v. Miller, 484 F.3d 964 (8th Cir. 2007), vacated by 128 S. Ct. 871 (2008); United States v. Chettiar, 501 F.3d 854 (8th Cir. 2007); and United States v. Courtney, Criminal No. 06-72 (MJD)(D. Minn.), involved downward variances from a guidelines prison sentence to probation or the equivalent.

Smith's counsel commented on the Supreme Court's decision to grant certiorari on the issue of whether courts needed to justify a substantial variance with extraordinary circumstances. Sent. Tr. at 71. He argued that despite the uncertainty about the upcoming Supreme Court decision, the court could take a look at sentencing disparities between Smith and other defendants sentenced around the country for similar conduct. Id. at 73. The court responded:

Well, the problem with that - I'm not trying to argue with you, but I've been reversed a number of times dealing with variances and departures and when I've done it based on the issue of similar [conduct], the Court of Appeals has pointed out specific cases that his individual did something entirely different from another individual that got the departure. So I would have to go down each one of those cases and have the presentence investigation report to satisfy the circuit that this gentleman was getting a raw deal by getting a guideline sentence.

* * *

And we couldn't do it on just the sentence alone. Sent. Tr. at 73-74.²³ Smith's counsel then explained that he believed the Supreme Court was going to reverse Eighth Circuit precedent, and he argued that the district court should do the "moral thing" and grant the variance. Id. at 74-75. The court then commented, "And you understand that if there's a variance

²³The government argued the guidelines themselves served to avoid unwarranted sentencing disparities. Dkt. 389 (Govt. responsive memorandum) at 9-10. Smith's arguments about other cases was not helpful because he knew little about the offense characteristics or other facts supporting the sentences in those cases. Id.

that's going to be granted, it can't be to 20 years because that's -- from 360 to 240, that's automatic reversal." Sent. Tr. at 76.

After the defendant spoke, the court commented that this was the first defendant in all of the judge's years in practice whose conduct forced the judge to send him to segregation for 24 hours a day. Sent. Tr. 76-77. The court also pointed out that it had given the defendant many chances before imposing such sanctions. Id. at 77.

The government argued that if the court were sentencing another defendant convicted of being a drug kingpin, a defendant who had callously pushed \$24 million worth of drugs onto our streets, who obstructed justice multiple times over, who violated court order after court order, who protected his stash with guns and threats and plans to kill a witnesses, the court would have no trouble sentencing the person to 30 years in prison. Id. at 80-81.

Before imposing sentence, the court stated that it had listened carefully and ha[d] read over the documents submitted to the Court regarding the sentencing position of the defendant. The Court finds some merit in what has been said. It has been presented to the Court. However, the Court will not vary on the sentence in this matter. Sent. Tr. at 85. The district court found that Smith was "a drug kingpin and you should be sentenced as one for the operation that you had" Sent. Tr. at 86. The court imposed a guidelines sentence of 360 months imprisonment. Id.

In its written Statement of Reasons (at 31), the court further "acknowledge[d] its power to grant a variance from the Guideline

range," but "conclude[d] that a sentence within the Guideline range is reasonable." It specifically noted that Smith's case was different from the other online pharmacy cases cited by the defendant because Smith had so many additional enhancements, each of which he brought upon himself. Id. A guideline sentence was necessary not only to deter Smith but to deter others who might engage in similar behavior in order to reap the same financial benefits. Id.

SUMMARY OF THE ARGUMENT

Based on nothing more than a cursory online questionnaire, Smith's physician issued thousands of prescriptions to people he had never met, never spoken to, and who had supplied only cursory if not false information. The physician, Dr. Mach, cooperated and admitted at trial he issued the prescriptions outside the usual course of professional practice. The government's expert pharmacist, Dr. Catizone, had ample training in what constitutes a valid prescription and was well qualified to testify that Mach failed to meet the standard of care for issuing valid prescriptions. Smith, who conspired with Mach, was well aware of Mach's sham prescriptions because he set up the very system Mach employed, and he himself placed orders with false information through that system. Smith, who only paid Mach for approvals, even ensured that the few orders Mach rejected were put through again and approved.

The district court's instructions correctly defined "usual course of professional practice" to mean "in accordance with a standard of medical practice generally recognized and accepted in the United States." This language was approved by the Supreme Court in 1975 and in numerous decisions since then. Smith argues that this objective standard should give way to a purely subjective standard, one that considers only whether a practitioner acts in the "usual course" of "his" own practice. Smith's interpretation,

which finds no support in the law, would exempt from prosecution practitioners who (like Mach) were nothing more than drug pushers.

The district court was also correct in instructing that the term prescription, as used in the Food, Drug and Cosmetic Act, means only a valid prescription. The instructions were supported by the misbranding statute at issue as well as case law interpreting that statute. Smith's interpretation, that prescription can include a bogus prescription, finds no support in the law and would exempt from prosecution practitioners who (like Mach) endangered the public by issuing invalid prescriptions without providing medical supervision.

The district court was well within its discretion to allow limited evidence of Smith's plan to secure prostitutes from Prague, especially since it was Smith's co-defendant who raised this issue to impeach a government cooperator. The court also acted within its discretion and cured any alleged prejudice when it excluded evidence of a wrongful death suit and gave a curative instruction.

The district court's guidelines sentence of 360 months was reasonable and without significant procedural error. Although the court engaged in a "hypothetical" discussion with Smith's counsel about the state of the law requiring extraordinary circumstances for Smith's 180-month variance request, the court ultimately recognized it had discretion to vary but nonetheless imposed a guidelines sentence.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY INSTRUCTED THE JURY THAT THE PHRASE "USUAL COURSE OF PROFESSIONAL PRACTICE" MEANS WHETHER THE PRACTITIONER ACTED IN ACCORDANCE WITH A STANDARD OF MEDICAL PRACTICE GENERALLY RECOGNIZED AND ACCEPTED IN THE UNITED STATES

The defendant contends that the court erred in its instructions regarding a valid prescription under the Controlled Substances Act and other related charges. Because a long line of authorities demonstrates the court's instructions were a correct statement of law, this Court should affirm the defendant's conviction.

A. Standard of Review

The district court has "wide discretion" when formulating appropriate jury instructions. United States v. Phelps, 168 F.3d 1048, 1057 (8th Cir. 1999); United States v. Casas, 999 F.2d 1225, 1230 (8th Cir. 1993). This Court will affirm "if the entire charge to the jury, when read as a whole, fairly and adequately contains the law applicable to the case." Casas, 999 F.2d at 1230; United States v. Beckman, 222 F.3d 512, 520 (8th Cir. 2000).

B. The District Court's Definition of "Usual Course of Professional Practice" Was A Correct Statement of the Law

1. Background Regarding Controlled Substances Act and Section 1306.04

Under the Controlled Substances Act (the "CSA"), it is unlawful for "any person" knowingly or intentionally to distribute or dispense a controlled substance. 21 U.S.C. § 841(a). The law

provides a limited exception for prescription drugs dispensed by registered "practitioners," such as physicians and pharmacists. The exception, promulgated by the Attorney General at 21 C.F.R. § 1306.04, provides in pertinent part:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . the Act . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. As the Supreme Court has squarely held, physicians can be liable under Section 1306.04 when they no longer act like physicians and instead act like drug pushers. United States v. Moore, 423 U.S. 122, 124, 142-43 (1975). "[T]he scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" Id. at 140. Whether controlled substances have been distributed other than in the usual course of professional practice is ultimately a jury question. Id. at 142-43.

Moreover, lay persons, such as Smith, can be found liable under Section 1306.04 when they conspire with, or aid and abet, licensed practitioners who distribute controlled substances outside

the usual course of professional practice. See United States v. Johnson, 831 F.2d 124, 128 (6th Cir. 1987); United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986);²⁴ United States v. Hicks, 529 F.2d 841, 844 (5th Cir. 1976); cf. United States v. Fuchs, 467 F.3d 889, 897-99 (5th Cir. 2006)(online pharmacy operator and co-conspirators convicted under Section 1306.04).

2. The Court's Instructions Were Correct

The critical language from the court's instructions, No. 30, stated:

"Usual course of professional practice" means that the practitioner acted in accordance with a standard of medical practice generally recognized and accepted in the United States. In issuing prescriptions, practitioners are not free to disregard prevailing standards of treatment.

Dkt. 353 (emphasis added); see also id. (Instruction No. 64)²⁵ As discussed below, the court's instructions were a correct statement of the law, and the defendant's challenges are without merit.

In Moore, the Supreme Court implicitly affirmed a jury instruction that included language very similar to the district

²⁴Smith suggests (at 30) that Vamos is limited to nurses. The Vamos decision cannot be read so narrowly. It holds that while those who assist practitioners in distributing controlled drugs are not held to the standard of such practitioners, they are also not free to rely unreasonably on the practitioners, and will be held liable under Section 1306.04. 797 F.2d at 1153.

²⁵Smith ignores the court's good faith instruction, Instruction No. 64, which repeated these same phrases but also allowed the defendant to be acquitted if the jury found Smith sincerely and even unreasonably believed Mach's prescriptions were issued in the usual course of professional practice. Id. This standard is arguably well below that applicable to the nurse in Vamos.

court's charge in this case. Moore, 423 U.S. at 139; see also United States v. Feingold, 454 F.3d 1001, 1011 (9th Cir. 2006)(the Supreme Court "implicitly approved an instruction that required the jury to find 'beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.'")(quoting Moore, 423 U.S. at 138-39).

Since Moore, numerous courts have approved instructions that defined the "usual course of professional practice" phrase to mean "in accordance with a standard of medical practice generally recognized and accepted in the United States." See, e.g., United States v. Merrill, 513 F.3d 1293, 1306 (11th Cir. 2008); Feingold, 454 F.3d at 1011; United States v. Leal, 75 F.3d 219, 226 (6th Cir. 1996); United States v. Davis, 564 F.2d 840, 846 (9th Cir. 1977); see also Vamos, 797 F.2d at 1153.

Courts have also approved the related concept that "[i]n issuing prescriptions, practitioners are not free to disregard prevailing standards of treatment." See United States v. Hurwitz, 459 F.3d 463, 479 (4th Cir. 2006); Vamos, 797 F.2d at 1153; United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986); see also United States v. Paskon, 2008 WL 2039233 *5 (E.D. Mo. May 12,

2008); United States v. Valdivieso Rodriguez, 532 F.Supp. 2d 316, 331 (D.P.R. 2007).

Courts uniformly reject Smith's argument that Section 1306.04 should require only a subjective inquiry of what the practitioner considered to be outside the "usual course of professional practice." The courts' rationale is that a purely subjective standard would allow practitioners to avoid liability even where they behave as nothing more than drug pushers. See Hurwitz, 459 F.3d at 478 ("allowing criminal liability to turn on whether the defendant-doctor complied with his own idiosyncratic view of proper medical practices is inconsistent with" Supreme Court precedent; "[w]e believe that the inquiry must be an objective one, a conclusion that has been reached by every court to specifically address the question."); Vamos, 797 F.2d at 1153 (quoting Moore, 423 U.S. at 139)("[t]o permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area. As the Supreme Court noted in Moore, 'Congress intended the CSA to strengthen rather than to weaken the prior drug laws.'"); Merrill, 513 F.3d at 1306 (the appropriate focus is not on the subjective intent of the doctor; rather, the issue is whether the physician prescribes

medicine in accordance with a standard of medical practice generally recognized and accepted in the United States).²⁶

Smith argues that the pronoun "his" in the phrase, "usual course of his professional practice," means there must be only a subjective inquiry about what "his" practice is. This argument borders on the absurd and would mean that the government could never prosecute any practitioner who claims "his" usual practice is to push drugs. As Moore made clear, "outside the usual course of his professional practice" means a physician who no longer acts as a physician because the physician has stopped complying with accepted medical standards. 423 U.S. at 141-42; see also Norris, 780 F.2d at 1209 (rejecting argument that the phrase "usual course of his professional practice" in Section 1306.04 meant whether the defendant acted contrary to his own standards of medical practice, holding that "[o]ne person's treatment methods do not alone constitute a medical practice"); United States v. Birbragher, 2008 WL 4183503 *14 (N.D. Iowa July 22, 2008)(rejecting defendant's argument that government had improperly carved out the word "his" in its indictment and throughout the case because Section 1306.04 sets forth an objective standard).

²⁶The cases in this area from the Eighth Circuit, in which courts assume an objective standard without any challenge to that standard by defense, are in accord. See, e.g., United States v. Katz, 445 F.3d 1023, 1029 (8th Cir. 2006); United States v. Jones, 570 F.2d 765, 769 (8th Cir. 1978).

Smith incorrectly argues that the district court's instructions allowed the jury to convict based merely on a malpractice standard. The government's heavy burden of proof in this criminal case ensured Smith was not convicted on a malpractice standard. For example, in the drug distribution counts, the jury had to find proof beyond all reasonable doubt that the defendant intentionally distributed a controlled substance, and that at the time of the distribution, the defendant knew he was distributing a controlled substance other than for a legitimate medical purpose and not in the usual course of professional practice. Dkt. 353 (Instruction No. 41). A malpractice conviction, by contrast, would have required only preponderance of the evidence that Mach engaged in a single act of negligence.²⁷ For these and other reasons, courts have rejected similar arguments that a conviction under Section 1306.04 amounts to a malpractice conviction. See Vamos, 797 F.2d at 1153; United States v. McIver, 470 F.3d 550, 559 (4th Cir. 2006); United States v. Alere, 430 F.3d 681, 691 (4th Cir.

²⁷The standards of practice were certainly relevant to the jury's determination and thus were properly defined in the court's instructions. See United States v. Wexler, 522 F.3d 194, 204 (2d Cir. 2008)("[W]hile failure to comply with the standard of care applicable to a medical specialty does not alone provide a basis for concluding that a physician's activities fall outside the usual course of professional practice, it surely is relevant to that determination.").

2005); United States v. Tran Trong Cuong, 18 F.3d 1132, 1138-40 (4th Cir. 1994).²⁸

Moreover, there was no risk of a conviction based merely on a malpractice standard because the jury had to find not only that Mach acted outside the course of professional practice, but also that he acted "for other than a legitimate medical purpose," a standard well beyond medical practice. McIver, 470 F.3d at 559.²⁹ Additionally, the defense of good faith, something not applicable in malpractice cases, further ensured that the defendant was not convicted on a mere malpractice standard. Id. at 560 (the good faith instruction was "a plainspoken method of explaining to the jury a critical difference between" the criminal standard and the medical malpractice standard).

Here, the district court gave a limiting instruction, further allaying any concern that Smith was wrongfully convicted on a

²⁸Defendant's cited cases do not advance his cause. In addition to citing McIver, a case addressed above, and a banking case not on point, United States v. Christos, 614 F.2d 486 (5th Cir. 1980), Smith relies primarily on United States v. Boettjer, 569 F.2d 1078, 1081 (9th Cir. 1978). In Boettjer, although the court expressed some concern about the theoretical possibility of a defendant being convicted upon a mere showing of malpractice, the court upheld a conviction where the jury was instructed to find that practitioner had acted "other than in good faith for a legitimate medical purpose and in accordance with the medical standards generally recognized and accepted in the medical profession." 569 F.2d at 1082. The court found this language was neither improper nor prejudicial. Id. at 1081.

²⁹Smith ignores this additional language from Section 1306.04, which provides an additional basis for liability. See United States v. Nelson, 383 F.3d 1227, 1232-33 (10th Cir. 2004).

malpractice standard. In Instruction No. 19, the court expressly told the jury that Smith was not on trial for any conduct not alleged in the indictment and that evidence of violations of state laws, pharmacy regulations, and policies could only be used to evaluate whether Smith was guilty of the charges in the indictment. Dkt. 353.³⁰ Such a limiting instruction prevented the jury from concluding that defendant's violation of civil regulations amounted to criminal liability. See United States v. Parker, 364 F.3d 934, 942-43 (8th Cir. 2004).

Smith is also wrong in arguing the court's instructions changed the law in a manner only permitted by Congress. The court's instructions did not change the law; they were in accord with Moore and its progeny. While it is true that, at the time of Smith's prosecution, legislation was pending before Congress specifically addressing online pharmacies, this is of no relevance.³¹ Smith's case was brought under the CSA and an implementing regulation on the books since the early '70s. In

³⁰During trial, the defense proposed a form of this instruction, the court revised it, and read it to the jury. See Tr. Vol. IV at 555-64, 572-73.

³¹That legislation, known as the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, was just signed into law on October 15, 2008. See PL 110-425 (HR 6353). The law enhances the definition of "valid prescription" to require at least one in-person visit with a doctor in most circumstances. It also increases penalties for Schedule III and IV drugs, requires registration and reporting requirements for those seeking to dispense controlled substances over the Internet, and requires specific information to be placed on web sites.

United States v. Lovin, 2008 WL 4492616, at *5 (S.D. Cal. Sept. 29, 2008), the court rejected an argument similar to Smith's, holding "[t]hat Congress has considered clearer legislation . . . does not mean that existing laws do not apply" Id. (citations omitted). "[S]tatutes are construed by the courts with reference to the circumstances existing at the time of the passage. The interpretation placed upon an existing statute by a subsequent group of Congressmen who are promoting legislation and who are unsuccessful has no persuasive significance here.'" Id. (quoting United States v. Wise, 370 U.S. 405, 411 (1962)); see also Birbragher, 2008 WL 4183503 at *13 (holding "[t]he fact this bill has not passed does not render the CSA unconstitutional as applied to Internet pharmacies.").

There is also no merit to Smith's argument that the court's instructions allowed the Attorney General to create law contrary to Gonzales v. Oregon, 546 U.S. 243 (2006).³² Gonzales has no application here. In Gonzales, the sole issue was the validity of a 2001 rule that attempted to preclude physicians from assisting suicides, effectively invalidating an Oregon law that expressly legalized physician-assisted suicides. Id. at 249. The Court held

³²Smith made a similar argument below, and the court soundly rejected it for reasons similar to those stated here. Dkt. 289 (Memorandum of Law and Order) at 3-7. Other courts have similarly rejected Gonzales-based arguments in this context. See United States v. Quinones, 536 F. Supp. 2d 267, 271-72 (E.D.N.Y. 2008); United States v. Edwin, 2006 WL 763653 at *5 (N.D. Ill. Mar. 22, 2006).

that the rule was invalid because, while the Attorney General has rulemaking power under the CSA, "he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." Id. at 245 (emphasis added). In reaching this narrow holding, the Court expressly stated that it was not deciding anything with respect to "matters closer to [the Attorney General's] role under the CSA, namely preventing doctors from engaging in illicit drug trafficking." Id. at 268. The Gonzales Court observed that "[d]ispensing controlled substances without a valid prescription, furthermore, is a federal crime," thus affirming Moore. Id. at 254 (citing Moore, 423 U.S. at 122).

In sum, the district court's entire charge to the jury, which was consistent with Moore and its progeny, fairly and adequately stated the law applicable to the CSA charges. Smith's convictions should be affirmed.³³

II. BECAUSE SECTION 1306.04 IS NOT AMBIGUOUS, THE RULE OF LENITY DOES NOT SAVE DEFENDANT'S FLAWED INTERPRETATION

Although Smith contends that Section 1306.04 is unambiguous and required no explanation, in the alternative, he also argues that any ambiguity should have been resolved in his favor pursuant

³³The government takes exception to Smith's selected excerpts from news articles. These are not part of the record and should not be considered by the appellate court. See Hicks v. Mickelson, 835 F.2d 721, 724 (8th Cir. 1987).

to the rule of lenity. Section 1306.04, as other courts have held, is not ambiguous and does not implicate the rule of lenity.

A. Standard of Review

The rule of lenity provides that where a criminal statute is ambiguous, the ambiguity "should be resolved in favor of lenity." Cleveland v. United States, 531 U.S. 12, 25 (2000); Moskal v. United States, 498 U.S. 103, 107-08 (1990). The rule of lenity cannot be used to create an ambiguity, "[n]or is it used to narrow a statute that has an unambiguously broad thrust." United States v. Hawley, 855 F.2d 595, 602 (8th Cir. 1988) (citations omitted). Moreover, the rule of lenity cannot be "invoked to engraft an illogical requirement to its text." Salinas v. United States, 522 U.S. 52, 66 (1997). As with other questions of federal law involving statutory interpretation, this Court applies a *de novo* review. United States v. Bach, 400 F.3d 622, 627 (8th Cir. 2005).

B. The Rule of Lenity Does Not Apply Because Section 1306.04 Is Not Ambiguous

Because the meaning of Section 1306.04 is plain, the rule of lenity does not apply. See Birbragher, 2008 WL 4183503 at *13 United States v. Hernandez, 2007 WL 2915854 at *10 (S.D. Fla. Oct. 4, 2007).³⁴ Courts similarly reject the argument that the "usual course of professional practice" phrase from Section 1306.04 is unconstitutionally vague. See, e.g., United States v. Collier, 478

³⁴Smith's rule of lenity cases are all distinguishable because they did not address Section 1306.04.

F.2d 268 (5th Cir. 1973); Tran Trong Cuong, 18 F.3d at 1137; United States v. Prejean, 429 F. Supp. 2d 782, 805 (E.D. La. 2006).

At its core, Smith's argument seeks to interpret the "usual course of his professional practice" as exempting from prosecution any individual's practice, even a practice of pushing drugs. Smith's interpretation, which would "engraft an illogical requirement" onto Section 1306.04, see Salinas, 522 U.S. at 66, does not invoke the rule of lenity. Smith's convictions should be affirmed.³⁵

III. THE DISTRICT COURT PROPERLY INSTRUCTED THE JURY THAT A "PRESCRIPTION" PURSUANT TO THE FOOD, DRUG AND COSMETIC ACT MEANS A VALID PRESCRIPTION

Smith contends that the court also erred when it instructed the jury that the term "prescription," as used in the Food, Drug and Cosmetic Act, means a valid prescription. Because the court's instructions correctly stated the law, this Court should affirm Smith's conviction.

A. Standard of Review

Given the district court's wide discretion when formulating jury instructions, this Court will affirm "if the entire charge to the jury, when read as a whole, fairly and adequately contains the law applicable to the case." Casas, 999 F.2d at 1230.

³⁵Throughout trial, Smith's counsel advanced this same interpretation, despite that it has no support in the law and is contrary to Moore and cases following Moore. Thus, to use Smith's own words, it was Smith who attempted to "radically alter[] the legal landscape," not the district court. See Smith's Brief at 36.

B. The District Court's Definition of "Prescription" Was A Correct Statement of the Law

1. Background Regarding FDCA

In Counts 5-7, the government charged Smith with introduction of misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 353(b)(1) of the Food, Drug and Cosmetic Act ("FDCA"), and the aiding and abetting statute, 18 U.S.C. § 2.

Among other things, the FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a).³⁶ The FDCA defines the term "misbranded" to include prescription drugs that are sold without a prescription. See, e.g., United States v. Arlen, 947 F.2d 139, 141 n.2 (5th Cir. 1991)("[A]ny prescription drug that is dispensed without a prescription is deemed 'misbranded' as a matter of law."). Section 353(b)(1) provides in pertinent part:

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;

* * *

³⁶Misbranding is a felony where, as here, drugs are sold with the intent to defraud regulators and the public. 21 U.S.C. § 333(a)(2); see United States v. Ellis, 326 F.3d 550, 556-57 (4th Cir. 2003).

(i) upon a written prescription of a practitioner licensed by law to administer such drug or

(ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 353(b)(1). Thus, the FDCA provides that any drug dispensed without a prescription is misbranded and therefore unlawful.³⁷

2. The Court's Instructions Were Correct

The critical language from the court's instructions, No. 43, stated as follows:

A prescription as used in the Food, Drug and Cosmetic Act and in these instructions means only a valid prescription. A valid prescription means one issued in the usual course of professional practice and for a legitimate medical purpose, as explained earlier in the Instructions.

Dkt. 353. While the FDCA uses the term "prescription" rather than "valid prescription," it is clear from the statute that

³⁷Smith is flat wrong when he claims (at 48-49) the government "sought to substantially stretch the reach of the [FDCA] statute . . . in contravention of [its] traditional uses . . ." While Smith is correct that misbranding under the FDCA encompasses a variety of things not at issue here, such as selling a drug with a false or misleading label, see 21 U.S.C. § 353(a), misbranding also encompasses prescription drug sales made without a prescription. See 21 U.S.C. § 353(b)(1).

prescription means a valid prescription and not merely a piece of paper purporting to be a prescription. Namely, Section 353(b)(1) requires "the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1). If there is no such supervision, there is no lawful prescription.

The case of Brown v. United States, 250 F.2d 745, 746-47 (5th Cir. 1958), is instructive on the meaning of "prescription" in Section 353(b)(1). Brown involved a physician convicted of violating Section 353(b)(1). Id. at 745-46. Not unlike Mach here, the physician in Brown sold large quantities of prescription drugs to undercover government agents without examining them or otherwise determining if they needed the drugs. Id. On appeal, the defendant challenged the court's instruction that the jury consider whether a proper doctor-patient relationship existed between the defendant and drug purchasers to determine whether the drugs were distributed via a prescription. Id. at 747. The Brown court affirmed the instruction, holding "[t]he inquiry whether there was a bona fide relationship of patient and doctor bears on the question whether there had ever been a 'prescription' for the agents." Id. The court further noted that the well-recognized purpose of the FDCA is to protect people from dangerous drugs, and bogus prescriptions are inconsistent with this purpose. Id. at 747.

The court in United States v. Nazir, 211 F. Supp. 2d 1372 (S.D. Fla. 2002), reached a similar conclusion. In that case, a

physician and his co-conspirators were charged with violating 21 U.S.C. §§ 331(a) and 353(b)(1) (the same statutes at issue here) by dispensing drugs which had not been approved by the FDA without a valid prescription.³⁸ Id. at 1373. Namely, the physician first issued prescriptions in patient names, without their permission, and then arranged to forward the prescription drugs to other individuals whom he had never examined. Id. at 1374. The defendants argued that Section 353(b)(1) only requires a prescription, "and it makes no difference whether the prescription is phony." Id. The court, observing that the statute did not define the word "prescription," looked to that term's ordinary meaning and usage. It concluded that prescription

in common parlance, means only a bona fide order--i.e., directions for the preparation and administration of a medicine, remedy, or drug for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor--and does not include pieces of paper by which physicians are directing the issuance of a medicine, remedy, or drug to patients who do not need it, persons they have never met, or individuals who do not exist.

Id. at 1375; see also DeFreese v. United States, 270 F.2d 730, 733 n. 5 (5th Cir. 1959)(under FDCA, "a prescription is infinitely more

³⁸Smith incorrectly contends (at 47) that Nazir is distinguishable because it involved a classic case of misbranding unapproved drugs. Nazir did involve some charges of unapproved drugs (presumably Counts 1-14), but the sole charges at issue in the appeal (Counts 15-24) concerned the same FDCA misbranding provisions at issue here and similar allegations of "dispensing of prescription drugs without a prescription, and with intent to defraud or mislead." 211 F. Supp. 2d at 1373.

than can be simply defined. It is a summary of the physician's diagnosis, prognosis, and treatment of the patient's illness. It brings to focus on one slip of paper the diagnostic acumen and therapeutic proficiency of the physician").

Moreover, the Nazir court found this definition consistent with the entire context of the FDCA, which provides that certain drugs are not safe for use except under the supervision of a licensed practitioner. 211 F. Supp. 2d at 1375. Congress did not intend for physicians to avoid application of Section 353(b)(1) "by simply writing out a phony order for drugs for a person he never examined or consulted." Id.

The Nazir court relied upon analogous holdings in other contexts. Id. at 1376-77 (citing, *inter alia*, Webb v. United States, 249 U.S. 96 (1919); White v. United States, 399 F.2d 813, 818 (8th Cir. 1968)). Admittedly, Webb and White were not decided under the FDCA provisions at issue here, but as the Nazir court noted, they "nevertheless remain[] a useful guidepost in the common-law method of analyzing precedent in similar issues." Nazir, 211 F. Supp. 2d at 1377; see also Brown, 250 F.2d at 747 (court also relied on Webb for its holding that a prescription requires a bona fide relationship of patient and doctor).

In Webb, the Court held that a defendant who issued orders for morphine to anyone who asked had not issued "prescriptions" within the meaning of the Harrison Act (the predecessor to the CSA).

Webb, 249 U.S. at 99-100. “[T]o call such an order for the use of morphine a physician’s prescription would be so plain a perversion of the meaning [of the term] that no discussion of the subject is required.” Id.

White involved a physician convicted under different, older provisions of the FDCA. 399 F.2d at 814-15. Those provisions exempted from liability a licensed practitioner who distributed depressant or stimulant drugs “while such person [was] acting in the ordinary and authorized course of his [] profession,” language similar to that of current Section 1306.04. Id. at 815. The defendant wrote prescriptions for such drugs to various individuals without establishing any sort of physician-patient relationship with them. Id. at 815-16. He claimed that, as a physician, he was legally authorized to write prescriptions and the FDCA did not specify how he could write prescriptions. Id. at 816. The White court, after discussing analogous cases, including Webb and Brown, rejected defendant’s argument, concluding that there must be a bona fide physician-patient relationship before a practitioner can have the right to issue a prescription. Id. at 818. Citing Webb, the White court observed that

the word “prescription” does not include the doctor issuing an order for morphine for the purpose of providing the user with a sufficient amount to keep him comfortable by maintaining his customary use. Such conduct the Court held was not a prescription and it would be a perversion of the word to consider it as such. A like argument could be made in regard to the alleged “physician-patient” relationship in this case.

Id. (citing Webb, 249 U.S. at 497).

In addition to finding support in these holdings, the district court's instructions are supported by a number of cases in which courts assume without discussion that "prescription" in Section 353(b)(1) means valid prescription. See, e.g., United States v. Munoz, 430 F.3d 1357, 1366 n.7 (11th Cir. 2005)(citing 21 U.S.C. § 353(b)(1) as "deeming a prescription drug misbranded if it is dispensed other than pursuant to a valid prescription"); see also Deyo v. United States, 396 F.2d 595, 596 n.2 (9th Cir. 1968)(describing Sections 331 and 353(b)(1) as regulating the sale of dangerous drugs without a "bona fide prescription"); United States v. Bansal, 2006 WL 2246203 at *6 (E.D. Pa. Aug. 1, 2006)("governmental regulations requir[ed] the issuance of a valid prescription before certain medicines could be dispensed" without being deemed misbranded).³⁹

In sum, the district court correctly defined the term "prescription" as used in Section 353(b)(1) to mean a valid prescription. Moreover, because the determination of whether a prescription is valid turns on "whether there was a bona fide relationship of patient and doctor," Brown, 250 F.2d at 747, the

³⁹The defendant in Nazir, 211 F. Supp. 2d at 1374 also raised a rule of lenity argument under the FDCA. The court rejected that argument because the statute is unambiguous and the defendant's interpretation was based on "an implausible reading of the congressional purpose." Id. at 1377. For these same reasons, Smith's rule of lenity argument should be rejected.

district court properly defined valid prescription to mean one issued in the usual course of professional practice and for a legitimate medical purpose, as those terms were defined earlier in the instructions.⁴⁰ The district court's entire charge to the jury fairly and adequately stated the law, and Smith's misbranding convictions should be affirmed.

IV. THE DISTRICT COURT ACTED WITHIN ITS DISCRETION WHEN IT PERMITTED A PHARMACIST AND HEAD OF THE NATIONAL ASSOCIATION OF THE BOARDS OF PHARMACY TO PROVIDE EXPERT TESTIMONY ABOUT THE STANDARDS OF CARE FOR DISPENSING A PRESCRIPTION

Smith contends (at 52) that Dr. Carmen Catizone, the government's expert, was not qualified to testify regarding the standards of care for a valid prescription because he is not a physician. For the reasons that follow, his arguments are without merit.⁴¹

A. Standard of Review

"Decisions concerning the admissibility of expert testimony lie within the broad discretion of the trial court and will not be reversed on appeal unless there has been an abuse of that discretion." United States v. Anderson, 446 F.3d 870, 874 (8th Cir.

⁴⁰In contrast, Smith cites no cases in support of his argument that prescription in Section 353(b)(1) includes even an admittedly invalid prescription issued by a physician without a legitimate medical purpose and outside the usual course of his professional practice.

⁴¹Smith raised these same arguments in connection with a motion for a new trial, and the district court properly rejected them for reasons similar to those set forth here. See Dkt. 359 (Memorandum and Order).

2006)(citations omitted). Pursuant to Federal Rule of Evidence 702, a district court may admit the testimony of a witness whose knowledge, skill, training, experience, or education will assist a trier of fact in understanding the evidence or determining a fact in issue. See United States v. Kirkie, 261 F.3d 761, 765 (8th Cir. 2001).

B. The District Court Properly Held Government Could Provide Expert Testimony as to Usual Course of Professional Practice

It is well settled that the government may introduce expert testimony regarding the standard of medical practice generally recognized and accepted in the United States in order to prove that controlled substances were distributed outside the usual course of professional practice and not for a legitimate medical purpose. See, e.g., Katz, 445 F.3d at 1032; United States v. McIver, 470 F.3d 550, 562 (4th Cir. 2006).⁴²

Dr. Catizone was well qualified to provide expert testimony regarding the standard of care for issuing a prescription and

⁴²Courts specifically reject the argument, made in passing by Smith (at 52 and 55), that expert testimony should not have been permitted here because it addressed the ultimate issue of fact for the jury. See Fed. R. Evid. 704 (so long as expert witness does not state an opinion whether the defendant had the requisite mental state, opinion testimony may embrace an ultimate issue for the jury); see also Katz, 445 F.3d at 1032 (holding expert testimony that tied standards of care to existence of legitimate medical purpose was admissible despite embracing an ultimate issue to be decided by the jury).

Mach's failure to meet that standard.⁴³ His qualifications included his pharmacy training, his experience with the NABP, as well as his knowledge of state and federal law, medical literature, and directives issued by the DEA, FDA, and organizations such as the Federation of State Medical Boards, all of which address the standards pertaining to the issuance of prescriptions. Tr. Vol. XIX at 3109-116. He had experience providing testimony before courts, Congress, state legislatures, and numerous media outlets. Tr. Vol. XIX at 3109-116. As preparation for his testimony, he reviewed Smith's Internet pharmacy web site and other evidence. Id. at 3117.

Smith is wrong in his argument (at 52) that a pharmacist may not provide expert testimony on the standard of care for a physician.⁴⁴ Both physicians and pharmacists are charged with complying with the law regarding valid prescriptions. See 21 C.F.R. § 1306.04 ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the

⁴³Smith raises no objection to Dr. Catizone's testimony regarding how Smith's Internet pharmacy bore many of the hallmarks of a rogue Internet pharmacy.

⁴⁴The government properly noticed its intent to call Dr. Catizone to "testify that the use of a questionnaire as the sole basis for establishing a patient-prescriber relationship does not meet the standards of medical practice and that a pharmacy, including an Internet pharmacy, that knowingly fills such a purported prescription has not filled that prescription within the usual course of professional practice." Dkt. 312 (Govt. Trial Brief) at 37-38.

pharmacist who fills the prescription."). Therefore, pharmacists can testify from a pharmacist's perspective whether a physician's prescriptions are outside the usual course of professional practice.⁴⁵ See United States v. Bek, 493 F.3d 790, 797-99 (7th Cir. 2007)(affirming physician's conviction for illegal distribution of controlled substances which was based in part on "expert testimony from a pharmacist who explained that [the defendant's] practices were dangerous and very unusual"); United States v. Mahar, 801 F.2d 1477, 1487 (6th Cir. 1986) (expert pharmacist testified that pharmacists are not supposed to fill prescriptions that look illegitimate and are supposed to question whether prescriptions are issued outside the usual course of a physician's professional practice); United States v. Chube II, 538 F.3d 693, 697 (7th Cir. 2008)(district court properly allowed expert testimony from a physician as well as an expert on pharmacology who had a doctorate in clinical pharmacy regarding prescriptions issued "[o]utside the scope of medical practice, not for legitimate purposes.'"). Merrill, 513 F.3d at 1302 (case against physician included expert testimony from physician and pharmacist who testified as to "the

⁴⁵Indeed, courts find even non-physicians and non-pharmacists are qualified to testify about the standard of care for issuing prescriptions. See Jones, 570 F.2d at 769 (in case brought against physician for illegal distribution of controlled substances, court held that a non-physician, a medical school professor with a Ph.D. in pharmacology, could provide qualified expert testimony). Therefore, setting aside Dr. Catizone's pharmacist training, his other extensive training and background from the NABP would also have qualified him to testify about the prescriptions issued by Mach in this case.

relevant norm" for issuing prescriptions). In fact, this case concerned a defendant operating an online pharmacy and thus Dr. Catizone's perspective as a pharmacist was particularly relevant.

Dr. Catizone was more than qualified to testify regarding how Mach's prescriptions failed to meet the standard of medical practice for issuing valid prescriptions. The district court's decision to admit that testimony was well within its discretion.

V. THE GOVERNMENT PRESENTED SUFFICIENT EVIDENCE TO PROVE THE PRESCRIPTIONS WERE INVALID

Smith contends there was insufficient evidence to prove that the prescriptions issued by Mach were outside the usual course of professional practice. Because the government presented more than sufficient evidence, his argument fails.

A. Standard of Review

When considering a sufficiency of the evidence argument, this Court "view[s] the evidence in the light most favorable to the verdict and accept as established all reasonable inferences supporting the verdict." United States v. Lam, 338 F.3d 868, 869 (8th Cir. 2003). In reviewing the evidence for sufficiency, this Court has "very limited latitude" and may not weigh the evidence nor assess credibility of witnesses. United States v. Yockel, 320 F.3d 818, 824 (8th Cir. 2003). This Court can overturn a jury's verdict only where "a reasonable fact finder must have entertained a reasonable doubt about the Government's proof of one of the essential elements of the offense." United States v. Kinshaw, 71

F.3d 268, 271 (8th Cir. 1995). Courts "do not lightly overturn a jury verdict." United States v. Williams, 340 F.3d 563, 570 (8th Cir. 2003).

B. The Government Presented More Than Sufficient Evidence to Prove the Prescriptions Were Invalid

The government's evidence was overwhelming. Unlike the majority of reported decisions addressing the illegal distribution of prescription drugs, in this case, the very physician who issued those prescriptions testified for the government.⁴⁶ He admitted that his prescriptions were issued without a legitimate medical purpose and outside the usual course of his professional practice. Tr. Vol. XII at 1810. See United States v. Hayes, 595 F.2d 258, 261 (5th Cir. 1979)(in case against pharmacist, court rejected sufficiency argument where "[t]he doctor himself testified that during the period in question he had no legitimate patients and that any prescriptions written by him were not written in the usual course of medical practice or for a legitimate medical purpose"). Although Smith (at 61-62) challenges Mach's testimony as he did at trial, the jury was entitled to believe Mach, and this Court may not overturn that credibility determination on appeal. Yockel, 320 F.3d at 824.

⁴⁶Smith suggests (at 59) there was something improper about the government's decision not to call a physician expert. Given testimony from Mach, as well as from Dr. Catizone, there was no need for additional testimony from a physician expert.

Mach's testimony was corroborated by the rest of the evidence, introduced over approximately 20 trial days, that proved the prescriptions were unlawful. The evidence showed Smith set up the Internet pharmacy so a single doctor could issue thousands of prescriptions a day to people he had never met, never spoken to, and who had supplied only cursory and/or false information. Tr. Vol. XII at 1806-07; Vol. XII at 1786-87. Mach even approved an order in the name of an obscene word. Tr. Vol VI at 1038. Mach was not only paid per order approved, but over time he approved all 72,000 orders, including some orders he originally rejected. Tr. Vol. VI at 1042, 1046; Vol XII at 1808. Unlike usual physician-patient relationships in which the physician decides what drug to prescribe, here the customers selected the type and quantity of medication and were readily able to place multiple orders for highly addictive drugs. See Vol. VI at 1057.

The evidence showed Mach acted like a pill pusher and not a legitimate doctor, and Smith, the architect behind the Internet pharmacy model, was well aware of how Mach operated. The jury had more than sufficient evidence to conclude that the prescriptions were issued outside the usual course of professional practice and without a legitimate medical purpose. See Moore, 423 U.S. at 142-43 (jury had sufficient evidence to conclude that the physician acted outside the usual course of professional practice where "he gave inadequate physical examinations or none at all[,] . . . ignored the results of the tests he did make[,] . . . took no

precautions against [the drug's] misuse[,] . . . did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded[,] . . . [and] did not charge for medical services rendered, but graduated his fee according to the number of tablets desired.").

VI. THE DISTRICT COURT ACTED WITHIN ITS DISCRETION WHEN IT ADMITTED LIMITED EVIDENCE OF DEFENDANT'S PLANS TO SECURE PROSTITUTES

Smith claims his rights were substantially affected when the district court admitted evidence that Smith was involved in arranging to bring prostitutes from Prague. In fact, the government only introduced limited evidence about Smith's plan to bring back prostitutes from Prague to take the sting out of Smith's co-counsel's impeachment of a government witness on this topic. The evidence was not unduly prejudicial.

A. Standard of Review

The district court has broad discretion in admitting evidence, and its decisions will be overturned on appeal only for an abuse of discretion. See United States v. Rogers, 939 F.2d 591, 594 (8th Cir. 1991). Pursuant to Fed. R. Evid. 404(b), a district court may admit "[e]vidence of other crimes, wrongs or acts" for the purpose of proving "motive, opportunity, intent, preparation." The discretionary decision to admit Rule 404(b) evidence will be reversed only if it is clear that the evidence had no bearing upon any of the issues involved at trial. United States v. Gustafson,

728 F.2d 1078, 1083 (8th Cir. 1984). Under Rule 403, "great deference" is given to a district court's balancing of the relative value of a piece of evidence and its prejudicial effect. United States v. Lupino, 301 F.3d 642, 646 (8th Cir. 2002).

Where the court abused its discretion in admitting evidence, this Court applies the harmless error standard, "reversing only when an improper evidentiary ruling affected the defendant's substantial rights or had more than a slight influence on the verdict." United States v. Shields, 497 F.3d 789, 792 (8th Cir. 2007).

B. District Court Did Not Abuse Its Discretion in Admitting Evidence of Smith's Efforts to Secure Prostitutes From Prague

The government only introduced evidence about Smith's efforts to secure prostitutes from Prague after the court ruled that Smith's co-counsel could use this evidence to impeach Poe, a government witness. Tr., Vol. XV at 2432, 2437, 2462; Tr., Vol. XVII at 2590-91. The direct testimony was brief. Tr. Vol. XVII at 2598-99. Counsel for Adkins and Smith cross examined Poe about the Prague trip. Id. at 2688-89, 2693, 2765-67.

The district court admitted the evidence for the purpose of impeaching Poe, presumably to contradict the impression that Poe was law abiding. The evidence was also arguably relevant under Rule 404(b) to demonstrate Smith's intent and to negate the good faith defense. Namely, Smith's use of proceeds from his online

pharmacy to fund his co-conspirator's trip to Prague showed that his primary purpose was to make money for his own illicit activities, not to operate a legitimate business.

Moreover, in the context of whole case, the brief inquiry regarding Poe's trip to Prague to acquire prostitutes for Smith was not unduly prejudicial.⁴⁷ The jury was instructed that "[t]he defendants are, of course, not on trial for any act or crime not contained in the indictment." Dkt. 353 (Instruction No. 9). This cautionary instruction served to further eliminate any danger of unfair prejudice from limited discussion (only a few minutes) of the Prague situation.

Furthermore, there was no error for the government to inquire about Smith's role with the Prague prostitution activities, given that it was necessary to provide context for the impeaching evidence of Poe, impeachment that also helped Smith. The Eighth Circuit allows the government to respond with even inadmissible evidence where it is necessary to clarify issues raised by the

⁴⁷The government had a lot of other relevant and arguably prejudicial evidence that was not introduced. For example, no evidence was introduced regarding Smith's plot to threaten and kill a witness. See Tr., Vol XV at 2434-35. Given that the death plot was relevant and could have been admitted, see United States v. Montano, 309 F.3d 501, 505 (8th Cir. 2002) (allowing the admission of a telephone threat to harm the children of the witness); United States v. Madrigal, 152 F.3d 777, 780 (8th Cir. 1998) (admitting evidence of the defendant's threat to have the witness's "whole family taken out"), it is difficult to see how Smith can claim prejudice by the limited evidence that Smith arranged to pay for prostitutes.

defense. United States v. Beason, 220 F.3d 964, 968 (8th Cir. 2000); see also United States v. Finch, 16 F.3d 228, 233 (8th Cir. 1994) (government permitted under "opening the door" theory to introduce evidence to rebut facts elicited on cross-examination); United States v. Womochil, 778 F.2d 1311, 1315 (8th Cir. 1985) (the district court did not abuse its discretion when it allowed government to clarify false impression created on cross-examination).

Finally, if this Court concludes that there was an abuse of discretion with regard to the prostitution evidence, there is still no basis for reversal. Smith cannot show that a few minutes of testimony in the face of over 20 days of overwhelming evidence of his guilt "affected the defendant's substantial rights or had more than a slight influence on the verdict." United States v. Shields, 497 F.3d 789, 792 (8th Cir. 2007).⁴⁸ At most, the decision to admit the prostitution evidence constitutes harmless error.

VII. THE DISTRICT COURT'S DECISION TO EXCLUDE EVIDENCE OF A WRONGFUL DEATH LAWSUIT AND TO GIVE A CURATIVE INSTRUCTION ELIMINATED ANY ALLEGED PREJUDICE

Smith argues the district court abused its discretion when it admitted evidence of a wrongful death lawsuit brought against

⁴⁸Indeed, the government also elicited testimony from Poe that co-defendant Adkins, who served as Smith's lawyer, was aware of the trip to Prague and laughed about it. Vol. XV at 2503-04. Despite this evidence and other arguably prejudicial evidence (such as Adkins' involvement in destroying returned drugs, id. at 2554), the jury acquitted Adkins.

Smith's supplying pharmacy by the family of an addicted individual who committed suicide. In fact, the district court ruled this evidence inadmissible and gave a curative instruction that eliminated any potential prejudice.

A. Standard of Review

Ordinarily the admission of allegedly prejudicial evidence is "cured by an instruction to the jury to disregard" the evidence. United States v. Nelson, 984 F.2d 894, 897 (8th Cir. 1993). The jury is presumed to follow the district court's instructions. See United States v. Maza, 93 F.3d 1390, 1397 (8th Cir. 1996). This Court considers the district court's curative instruction in the context of the entire trial, including the strength of the government's evidence, to evaluate whether the jury was "substantially swayed" by any prejudicial evidence. United States v. Urick, 431 F.3d 300, 304 (8th Cir. 2005).

B. The Court Cured Any Potential Prejudice When It Gave the Curative Instruction Requested by Defense

Although Smith had moved prior to trial to exclude evidence of the wrongful death lawsuit, Smith did not object when it was introduced at trial. Tr. Vol. I at 16, 18-19; Vol. VI at 1061. Over the course of a few minutes, Hollis testified Smith had received the wrongful death suit and was aware that the plaintiff's family member had shot himself, but Smith was unconcerned because the person had died before any drugs from Smith's Internet pharmacy were shipped to him. Vol. VI at 1064-65. Smith's counsel objected

to this evidence, and the court sustained the objection. Id. at 1065-67. At Smith's counsel suggestion, the court gave a curative instruction that the defense crafted. Id. at 1070-71. The court instructed the jury to disregard the wrongful death exhibit and to not speculate why the death occurred because there was no evidence Smith or his online pharmacy had anything to do with the death. Id. at 1074. Without objection, the court gave a similar instruction at the close of the case. See Dkt. 353 (Instruction No. 18); Tr. Vol. XIX at 3299.

There is no prejudice because evidence of the wrongful death suit was relevant to show Smith's notice that indiscriminately selling large quantities of addictive drugs could result in death.⁴⁹ See United States v. Blanton, 730 F.2d 1425, 1432 (11th Cir. 1984)(evidence of deaths "was relevant to the attitude defendant displayed toward the substances he dispensed"); see also United States v. Schuster, 777 F.2d 264, 270 (5th Cir.), vacated, remanded and appeal dismissed on other grounds, 778 F.2d 1132 (5th Cir. 1985)(in case brought against physician for illegal distribution of controlled substances, court found no reversible error from limited evidence of patient deaths; court "observe[d] that in a proper setting, such evidence might be relevant and admissible as

⁴⁹The government had evidence of several other deaths caused by Smith's online pharmacy, but because there was no indication Smith was on notice of them, the government did not introduce this evidence at trial. It was presented at sentencing. Dkt. 384 (Government's Sentencing Memorandum) at 38-40.

indicative of a cavalier attitude toward drugs dispensed and the consequences of their free use").

Even if the evidence were prejudicial, the court's instruction to disregard the evidence, given at the time the evidence was introduced and again in the final instructions, was sufficient to cure any potential prejudice. United States v. Nelson, 984 F.2d 894, 897 (8th Cir. 1993). Finally, given the overwhelming evidence of the defendant's guilt, coupled with the curative instruction, there is no indication the jury was "substantially swayed" by the allegedly prejudicial evidence. Urick, 431 F.3d at 304.

VIII.EVEN ASSUMING THE DISTRICT COURT COMMITTED A PROCEDURAL ERROR CONTRARY TO GALL, THE ERROR WAS NOT SIGNIFICANT AND DID NOT AFFECT SMITH'S SUBSTANTIAL RIGHTS BECAUSE THE COURT CORRECTLY RECOGNIZED IT HAD AUTHORITY TO VARY BUT NONETHELESS IMPOSED A GUIDELINES SENTENCE

Smith challenges his sentence for what he alleges was a "Gall error." Because Smith failed to raise this issue below, even if the court erred, the error was not significant and did not affect his substantial rights.

More specifically, this is not a case where the district court chose to vary but then decided to limit its variance based on circuit precedent that required extraordinary circumstances to justify a significant variance. Instead, here the court clearly recognized it had the authority to vary downward, but it chose not to vary at all. Thus, any erroneous belief about the limitations on the extent of variances did not affect the defendant's sentence.

A. Standard of Review

In reviewing a challenge to a sentence, this Court will first ensure that the district court committed no procedural error, such as failing to calculate (or improperly calculating) the Guidelines range, treating the Guidelines as mandatory, failing to consider the § 3553(a) factors, selecting a sentence based on clearly erroneous facts, or failing to adequately explain the chosen sentence – including an explanation for any deviation from the Guidelines range.

United States v. Shy, 538 F.3d 933, 937 (8th Cir. 2008) (quoting Gall v. United States, 128 S. Ct. 586, 597 (2007)).

If the defendant did not object to the district court's procedural error, this Court may review the error only under a plain error review. United States v. Bain, 537 F.3d 876, 880 (8th Cir. 2008). Plain error review requires that the defendant "show (1) an error, (2) that is plain; and (3) that affects substantial rights." Id. at 882 (citations omitted). "The defendant has the burden of proving plain error." United States v. Pirani, 406 F.3d 543, 550 (8th Cir. 2005).

B. The District Court Did Not Make a Significant Procedural Error

In Gall, the Supreme Court rejected the "appellate rule that requires 'extraordinary' circumstances to justify a sentence outside the Guidelines range." Gall, 128 S.Ct. at 594-95. This Court has since held that it is a significant procedural error under Gall if the district court requires extraordinary circumstances as

justification for a non-guidelines sentence. Bain, 537 F.3d at 880.⁵⁰

The district court did not make a significant procedural error because it recognized it had at least some discretion to vary downwards, and it ultimately decided not to vary at all. The court's hypothetical discussion with defense counsel, a discussion not affecting the sentence, does not amount to a procedural error, much less a significant procedural error. See United States v. Goldsmith, 275 Fed. Appx. 566, 568 (8th Cir. 2008)(there is no significant procedural error where "[t]his court's pre-Gall requirement that an extraordinary variance be justified by extraordinary circumstances was not applied by the district court in sentencing.")

The defendant sought a variance down to the statutory mandatory minimum sentence of 180 months. He argued various grounds, including alleged sentencing disparities with sentences in other online pharmacy cases. See Sent. Tr. at 14-21, 29-32, 66-68. The court responded to his motion by asking to speak about matters

⁵⁰Court recognize other types of Gall errors, such as where courts incorrectly assumed they had to apply a presumption of reasonableness at the district court level. United States v. Henson, 534 F.3d 922, 924 (8th Cir. 2008); see United States v. Pittock, 2008 WL 3876419 (8th Cir. Aug. 22, 2008) (incorrect application of presumption of reasonableness also known as Rita error, in violation of Rita v. United States, 127 S. Ct. 2456 (2007)). Other procedural errors include Booker errors in which courts incorrectly assumed that the guidelines were mandatory, in violation of United States v. Booker, 543 U.S. 220 (2005). See United States v. Perez-Ramirez, 415 F.3d 876, 878 (8th Cir. 2005).

"hypothetically." Sent. Tr. at 70. The court complained that "for every variance that a judge does for a departure downwards, [the Eighth Circuit] essentially reverses." Sent. Tr. at 70. While this language covered all variances, the court explained that it had recently "placed somebody on probation and home detention and they said, No, you can't do that variance, you can't do that departure, you have to send them to prison." Sent. Tr. at 70-71.⁵¹ The entire exchange between the court and defense counsel demonstrates the court was expressing some frustration with recent reversals where it had varied down to non-prison sentences. Following further discussion with defense counsel, who argued a variance was the moral thing to do, the court then further clarified that, "you understand that if there's a variance that's going to be granted, it can't be to 20 years because that's -- from 360 to 240, that's automatic reversal." Sent. Tr. at 76. The court thus recognized it had some discretion to vary downward, but just not to the extent requested by Smith.

Following this self-styled "hypothetical" discussion, the district court reminded itself that Smith was the first person in the judge's many years of practice who had to be locked up for 24 hours a day because of his persistent, dangerous conduct. Sent. Tr.

⁵¹The government agrees with Smith's argument (at 81) that it is important to look at Judge Davis' cases from around the time of his sentence. Each of the cases cited by Smith, Miller, Chettiar, and Courtney, involved downward variances by the judge from a guidelines prison sentence to probation or the equivalent.

at 76-77. The government then asked the court not to treat this defendant any differently from any other drug kingpin who had callously pushed \$24 million worth of drugs onto our streets, obstructed justice multiple times over, violated court order after court order, and protected his stash with guns and threats and plans to kill a witnesses. Sent. Tr. at 80-81.

The court then acknowledged its authority to vary, stating:

The Court has listened carefully and has read over the documents submitted to the Court regarding the sentencing position of the defendant. The Court finds some merit in what has been said. It has been presented to the Court. However, the Court will not vary on the sentence in this matter.

Sent. Tr. at 85. It then imposed a guidelines sentence of 360 months. Id. at 86.

In its written Statement of Reasons (at 31), the court further "acknowledge[d] its power to grant a variance from the Guideline range," but "conclude[d] that a sentence within the Guideline range is reasonable." It specifically noted that Smith's case was different from the other online pharmacy cases cited by the defendant because of the numerous enhancements, each of which Smith brought upon himself. Id. A guideline sentence was necessary not only to deter Smith but to deter others who might engage in similar behavior in order to reap the same financial benefits. Id.

In sum, after fully analyzing the factors under 18 U.S.C. § 3553(a), the court recognized it could vary but it declined to do so and instead issued a guidelines sentence. The court's discussion

of hypotheticals and what-ifs had absolutely no bearing on the ultimate sentence issued by the district court and, therefore, did not affect the otherwise procedurally sound sentence.

C. Because the Defendant Did Not Preserve His Objection, He Must Meet the Plain Error Standard

Even if this court were to find that the court erred when it engaged in its discussion with defense counsel, there is still no basis to reverse Smith's sentence. Applying a plain error standard, Smith's substantial rights were not affected because the court's deliberate decision not to vary shows it would not have lowered its sentence in any event.

Smith claims he preserved his error below, pointing to the lengthy discussion his counsel had with the court regarding his variance motion. Def. Brief at 77 n. 21. But this Court requires more than an extended discussion of what the law might be for a defendant to preserve a procedural sentencing error. "[A]n objection must be timely and must 'clearly state[e] the grounds for the objection.'" Pirani, 406, F.3d at 549 (quoting United States v. Williams, 994 F.2d 1287, 1294 (8th Cir. 1993) and Fed. R. Crim. 51(b)); see United States v. Alvizo-Trujillo, 521 F.3d 1015, 1019 (8th Cir. 2008) (alleged error not preserved because it "was merely commentary and was made before the district court announced the improper presumption and sentence"). It is also not enough to request a non-guidelines sentence. Bain, 537 F.3d at 881. The defendant "must object to the district court's erroneous application

of the law.” Id. In the case of a Gall error of this type, the defendant must “object to the district court’s requirement of extraordinary circumstances to justify the requested sentence.” Bain, 537 F.3d at 881.

Here, the defendant never objected on the record that the court was erring by requiring extraordinary circumstances to warrant a lengthy downward variance. In fact, Smith’s counsel never said the word “object” or “objection” or the equivalent during the “hypothetical” discussion, or, more importantly, after the court denied his variance motion. He merely engaged in commentary prior to the court’s sentencing decision. See Alvizo-Trujillo, 521 F.3d at 1019. Accordingly, the issue can be reviewed only for plain error.

D. Any Error Did Not Affect Smith’s Substantial Rights Because He Cannot Show His Sentence Would Have Been Lower

To demonstrate plain error, the defendant must show that the error affected his substantial rights. Bain, 537 F.3d at 882. A sentencing error affects a substantial right if it is prejudicial, meaning “if there is a reasonable probability the defendant would have received a lighter sentence but for the error.” Id. (citing Pirani, 406 F.3d at 552). Here, even assuming the court committed a Gall error, because there is no likelihood that the defendant

would have received a lighter sentence, Smith cannot meet his burden of demonstrating plain error.⁵²

The decision in Bain, 537 F.3d 876, is directly on point. Prior to the Supreme Court's Gall decision, the district court sentenced the defendant to the bottom of the guidelines range, or 210 months. Id. at 879. In rejecting the defendant's motion for a variance to the statutory minimum of 60 months, the district court stated, "I can't do that" without sufficient grounds. Id. It then requested the defendant's justification for such an extensive variance, in light of Eighth Circuit precedent reversing downward variances of 45 or 50 percent even for cooperators. Id. When the defendant came up with only a minimal justification, the court commented that the defendant knew what he was doing was wrong, that he was going to have to pay dearly despite having been a successful member of the community, and that the sentence was going to be painful and harsh. Id.

⁵²The government agrees that whether this issue is reviewed for plain error or harmless error is significant because it means the difference between the government having the burden of persuasion (harmless error) or the defendant having that burden (plain error). See United States v. Gianakos, 415 F.3d 912, 923 n. 6 (8th Cir. 2005). However, here the government can meet the harmless error standard because the district court made it clear that it had considered defendant's variance arguments, knew it could vary, but nonetheless declined to do so. See Pittock, 2008 WL 3876419 at * 1 (under harmless error review, government had met its "burden of demonstrating beyond a grave doubt that the [Rita] error did not substantially influence the outcome of the sentencing proceedings" where district court did not rely solely on presumption of reasonableness but thoroughly considered § 3553(a) factors and expressed no wish to impose a downward variance).

On appeal, the Eighth Circuit in Bain determined that there was a Gall error because the district court believed extraordinary circumstances were required to justify the defendant's downward variance to the statutory minimum. Id. at 880. The court applied plain error analysis because the defendant had not specifically objected "to the district court's requirement of extraordinary circumstances to justify the requested sentence." Id. at 881. It then held there was no plain error. Id. at 882. More specifically, it held that because the district court's statements were unclear (i.e., did the court believe the sentence was justifiably harsh or too harsh?), the appellate court would have to speculate about the effect of the procedural error. As a result, the defendant had not met his burden to show a reasonable probability he would have received a lower sentence but for the error. Id. at 882-83.

The Eighth Circuit in United States v. Burnette, 518 F.3d 942 (8th Cir. 2008), also found an alleged Gall-error was not plain error. At sentencing, the district court stated the "Court of Appeals is very tough on variances," and that variances "below the guidelines range to amount to anything are not easily accomplished." Id. at 947. The judge commented that in all his years on the bench, he had never "seen a case go downhill in the manner this case has," in that the defendant "never stopped digging" himself into a hole and made his situation worse by threatening a witness. Id. at 948. He saw no reason to sentence the defendant, "one of the big time

drug dealers" on his reservation, to a sentence outside the guidelines range. Id. On appeal, the Eighth Circuit held that, "[g]iven the district court's view of [the defendant's] actions, [the defendant] has not met his burden to prove a reasonable probability that he would have received a lighter sentence." Id.

The facts of this case are very similar to those in Burnette. The judge here also took a dim view of the defendant's actions. Like the defendant in Burnette, Smith made his situation worse by threatening to kill a witness, squandering the many chances given to him by the judge, and was a "drug kingpin" who "should be sentenced as one for the operation that [he] had." Sent. Tr. 86. And, as the court found in Burnette, "[g]iven the district court's view of [the defendant's] actions," Smith cannot show "a reasonable probability that he would have received a lighter sentence." Burnette, 519 F.3d at 948.

Other Gall error cases in this area are distinguishable either because they were decided under a harmless error analysis and/or because they involved clear statements by the district court indicating a desire to have given the defendant a lesser sentence. See, e.g., United States v. Huff, 514 F.3d 818, 820 (8th Cir. 2008) (applying harmless error analysis, Eighth Circuit reversed and remanded where district court said it would have given a lower sentence but for the view that it had no authority to vary from the guidelines); United States v. Greene, 513 F.3d 904, 907-08 (8th Cir.

2008)(applying harmless error analysis, Eighth Circuit reversed where district court said if it could have varied, it would have done so); cf. United States v. Weston, 267 Fed. Appx. 476, 477 (8th Cir. 2008)(applying plain error analysis and finding Gall error where court expressly stated it preferred a lower sentence, but was bound by precedent requiring extraordinary circumstances before varying).⁵³

Smith also relies on Henson, 534 F.3d at 924, a case consistent with the government's position here. Applying harmless error analysis, the Henson court found any error was harmless and affirmed the sentence where the district court assumed pre-Gall it had to apply a presumption of reasonableness. The district court in Henson stated that while it assumed it was required to impose a guidelines sentence, it would have imposed a guidelines sentence even absent this requirement. Similarly, in this case, the district court made it clear that it wished to impose a guidelines sentence even absent circuit precedent requiring extraordinary circumstances to justify a substantial variance.

In sum, the district court declined to vary and gave Smith precisely the sentence it wished to give him. Its view that circuit

⁵³Additionally, Smith's cited cases involving Booker error are distinguishable, not only because they were decided under harmless error analysis, but also because, in those cases, it was impossible to tell whether the district court might have imposed a lower sentence if it realized the guidelines were not mandatory. See, e.g., United States v. Cullen, 432 F.3d 903 (8th Cir. 2006); United States v. Haidley, 400 F. 3d 642 (8th Cir. 2005).

precedent required extraordinary circumstances to justify a substantial variance was completely irrelevant to the sentence. Because Smith cannot show a plain error, his sentence should be affirmed.

IX. THE DISTRICT COURT IMPOSED A REASONABLE SENTENCE OF 360 MONTHS, THE BOTTOM OF THE GUIDELINES RANGE, AFTER PROPERLY WEIGHING ALL OF THE SECTION 3553(A) FACTORS

Smith raises additional procedural errors and claims his sentence was unreasonable. Because the district court properly considered the relevant factors of Section 3553(a) in issuing a guidelines sentence, Smith cannot show any procedural errors or that his sentence was unreasonable.

A. Standard of Review

This Court will "presume that a sentence resulting from a proper application of the advisory guidelines is reasonable." United States v. Clay, 524 F.3d 877, 878 (8th Cir. 2008)(citing Rita, 127 S.Ct. at 2462-63). This Court must further give "due deference to the District Court's reasoned and reasonable decision that the § 3553(a) factors, on the whole, justified the sentence," rather than "decide *de novo* whether the justification for a variance is sufficient or the sentence reasonable." Gall, 128 S. Ct. at 602.

B. Smith's Sentence Was Without Significant Procedural Error

Smith argues that the court committed additional significant procedural errors when it failed to give adequate weight to important mitigating factors. Because Smith did not object to these

alleged errors at the time of sentencing, they are reviewed only for plain error. Bain, 537 F.3d at 881.

Smith's sentence was procedurally sound because the court considered all of Smith's arguments. As Smith acknowledges in his brief (at 86 to 87), he made the court fully aware of all the arguments he raises now. See Sent. Tr. at 14-21 (fraud guideline argument); 25 (Smith's biopolar disorder and erratic behavior); 29-32 (alleged disparities with sentences in other online pharmacy cases). These issues were fully briefed and thoroughly addressed during the 2-day sentencing hearing. As his counsel stated on the second full day of sentencing, "[w]e've had as complete a sentencing hearing as we possibly could have." Sent. Tr. at 68. The court also acknowledged that it had "listened carefully and ha[d] read over the documents submitted to the Court regarding the sentencing position of the defendant." Sent. Tr. at 85.

There can be no error where, as here, the court properly considered the defendant's sentencing arguments and ultimately rejected them. See United States v. Fields, 512 F.3d 1009, 1013 (8th Cir. 2008). "[T]he district court's awareness of defendant's arguments precludes the conclusion that the district court abused its discretion by failing to consider them." United States v. Miles, 499 F.3d 906, 909 (8th Cir. 2007).

C. The Sentence Was Reasonable

Smith's sentence was based on significant, multiple enhancements, including the callous sale of more than \$20 million worth of illegal narcotics, violations time and time again of the court's orders, possession of firearms, awareness of the risk of death by his customers, obstruction of justice in various ways, and, ultimately, a plan to kill a government witness. As the district court found, Smith was a drug kingpin and was properly sentenced as one. Sent. Tr. at 86. Under the unique facts of this case, a 30-year sentence was a reasonable sentence.

CONCLUSION

For all the foregoing reasons, the judgment of the District Court should be affirmed.

CERTIFICATE OF COMPLIANCE

The undersigned attorney for the United States certifies this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32. The brief has 19,394 words of monospaced type. The brief was prepared using WordPerfect X3. The undersigned attorney also certifies that the computer diskette containing the full text of the Brief of Appellee has been scanned for viruses and to the best of our ability and technology, believes it is virus-free.

Dated: November 21, 2008

Respectfully submitted,

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