United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 07-2956

United States of America,	*	
	*	
Plaintiff–Appellee,	*	
	*	Appeal from the United States
v.	*	District Court for the
	*	District of Minnesota.
Christopher William Smith,	*	
also known as Chris Jonson,	*	
also known as Tony Spitalie,	*	
also known as Robert Jonson	*	
also known as Bruce Jonson,	*	
	*	
Defendant–Appellant.	*	

Submitted: February 11, 2009
Filed: July 28, 2009

Before LOKEN, Chief Judge, MELLOY and BENTON, Circuit Judges.

MELLOY, Circuit Judge.

This case involves the prosecution of a businessman who sold millions of dollars of prescription drugs over the Internet without valid prescriptions. A jury convicted Christopher William Smith of conspiracy to distribute and dispense controlled substances without an effective prescription in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(D), and 846; aiding and abetting the unlawful distribution of controlled substances in violation of 21 U.S.C. §§ 841(a)(1) and 841 (b)(1)(D), and

18 U.S.C. § 2; aiding and abetting the introduction of misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 353(b)(1), and 18 U.S.C. § 2; conspiracy to commit money laundering in violation of 18 U.S.C. § 1956(h); and continuing criminal enterprise in violation of 21 U.S.C. § 848(a) and (c). Applying the U.S. Sentencing Guidelines, the Presentence Investigation Report ("PSR") calculated a total offense level of 42, a Category I criminal history, and a resulting advisory imprisonment range of 360 months to life. The district court imposed a sentence of 360 months' imprisonment and five years' supervised release.

Smith appeals, challenging his convictions for the above-described offenses on several grounds. He also contests his sentence, arguing that the district court committed a non-harmless procedural error in violation of Supreme Court's ruling in Gall v. United States, 128 S. Ct. 586 (2007), and that his sentence is substantively unreasonable. We affirm the convictions, vacate the sentence, and remand for resentencing in light of Gall.

I.

Smith first began selling prescription drugs through Internet websites and spam emails in 2004. Smith's business used several different names during its existence, including Xpress Pharmacy Direct ("Xpress") and Online Payment Solutions ("OPS"). After taking an order online, Smith would distribute controlled substances from abroad to numerous customers throughout the United States. He employed no medical doctors and sold drugs without prescriptions. When his business began experiencing shipping problems, however, Smith limited his operations to the United States. Faced with a stricter regulatory regime, Smith developed an online questionnaire that he required his customers to complete prior to obtaining prescription drugs through his sites. The questionnaire required the customer's name, address, date of birth, phone number, height, and weight. It allowed customers to select the type of drug that they wanted to receive and in what quantity. There was also a place on the questionnaire

for the customer to list a purported medical condition and any medical allergies. No additional evidence of a purported ailment was required.

Sometime in July 2004, Smith began employing Philip Mach, M.D., to issue prescriptions to the customers who had filled out the questionnaires posted on Smith's sites. In addition to being involved with other online prescription sites, Dr. Mach ran a traditional medical practice in New Jersey, the only state in which he was licensed to practice medicine. To receive Dr. Mach's "prescriptions," Smith set up a computer system by which Dr. Mach could log on daily and review the orders that customers had placed through Smith's sites. Dr. Mach was therefore never required to examine these customers face-to-face, review their official medical records, or in any way verify the limited information and claims that these customers had submitted on the questionnaires. The system's default was that all orders would be marked "approved," and the evidence at trial established that even in instances where Dr. Mach rejected a claim, Smith resubmitted the request for additional review (at which time it was approved). Despite the customers' lack of interaction with Dr. Mach, each "prescription" he issued stated that it was provided following a "doctor consultation."

In addition to the Internet sites, Smith ran call centers both in the United States and abroad. Customers who wished to place an order for a prescription drug could call a center, and operators would fill out a form similar to the online questionnaire. At Smith's direction, however, the operators employed at the centers also frequently called prior customers to ask whether they wanted drug refills. Because Smith paid the operators a commission, the more drugs the operators sold the more money they made. Testimony established that the entire purpose of the centers was to "sell, sell, sell."

Despite allegedly requiring particular information, many of the questionnaires upon which Dr. Mach issued drugs were lacking in the information necessary for a physician to issue an appropriate prescription. Some customers requested controlled

substances that were in no way related to their claimed ailments, yet Dr. Mach provided "prescriptions" and Smith provided drugs. Some forms lacked basic identifying information. For example, one questionnaire used an obscene word instead of a name. Even in that case, however, Dr. Mach provided the "prescription," and Smith provided the drugs. At one point, during an investigation of Smith's operations, an undercover agent from the Food and Drug Administration ("FDA") made three purchases of controlled substances and three purchases of non-controlled substances through one of Smith's sites with false information about both his identity and medical conditions. At no point did Smith or Dr. Mach contact him to verify any of the information contained on his questionnaires for any of the purchases.

During his work with Smith's online sites and call centers, Dr. Mach approved thousands of "prescriptions" per day and was ultimately responsible for issuing over 72,000 orders for pharmaceuticals from July 2004 until mid-2005. The total drug sales for Smith's operation at the time it was shut down in May 2005 was over $24 million. The high rate of prescription approval and the resulting income was not unanticipated, however, as Smith only compensated Dr. Mach for those orders that Dr. Mach approved. For each "prescription" that Dr. Mach issued, Smith would pay him $3.50. Smith paid another $3.50 to a middle man from New Jersey, John Guerriero, who had connected Dr. Mach with Smith. Despite attempts to recruit additional physicians, Smith was unable to solicit anyone other than Dr. Mach to participate in his business.

Smith's online sites were not licensed to distribute controlled substances directly. As a result, he sought out licensed "brick and mortar" establishments to fill his orders once Dr. Mach issued a "prescription." Smith targeted small, independent pharmacies in numerous states that he believed would become economically dependent on him and refrain from questioning his business model. Smith attempted to assuage any fears that the pharmacies raised by assuring them that he was not dealing in illegitimate Internet prescriptions but that each prescription was a legitimate

prescription backed by numerous physicians. He claimed that in states where a face-to-face meeting was required by law, the prescriptions were issued only after consultation with the customers' primary-care physicians. Additionally, the contracts that Smith entered into with these pharmacies stated that his model was FDA approved and that each "prescription" was issued only after a doctor–patient consultation. When pharmacies questioned the volume of orders for hydrocodone—a powerful painkiller sold under brand names such as Vicodin and Norco—Smith would shift orders to other pharmacies. This shifting occurred several times, as the majority of the "prescriptions" Dr. Mach issued were for hydrocodone. Smith sold over four-million tablets of this drug in addition to a much lesser quantity of non-controlled medication.[1] Smith's business also had a problem with "returned drugs," or those drugs that customers could not receive because they were unable to pay for them cash-on-delivery. Despite the fact that Smith was not authorized to handle controlled substances and despite the fact that the drugs originally came from traditional brick-and-mortar pharmacies, the drugs were returned to one of his offices in violation of federal law.

Around February 2005, the Drug Enforcement Administration ("DEA") issued a nationwide directive to pharmacies warning about the legitimacy of online pharmaceutical operations. The directive explicitly asserted that a questionnaire was an insufficient method to establish a doctor–patient relationship, as required by federal statute and regulations. Many of the pharmacies that Smith used to fill Dr. Mach's "prescriptions" threatened to quit unless Smith provided them with assurances that his business model was in compliance with the DEA directive. In response, Smith arranged to have Dr. Mach and Smith's attorney send a letter to the pharmacies. The letter stated that Smith's business issued valid prescriptions based on legitimate

[1] Testimony established that Smith was aware that many, if not all, of his customers were drug addicts, and he charged high prices for controlled substances with knowledge that addicts would be willing to pay a premium to satisfy their addictions.

doctor–patient relationships. Smith concedes that some of the claims made in the letter were false.

Throughout Xpress and OPS's existence, other organizations and businesses, including boards of pharmacies and the credit-card company, Mastercard, contacted Smith with concerns about the legality of his operation. As it became clear to Smith that he was the target of a criminal investigation, he began moving operations to Canada, along with the laundered proceeds from the drug sales and the personal property he purchased with those proceeds.

In May 2005, the district court entered a preliminary injunction that shut down Smith's online business. The order froze Smith's bank accounts and assets and further enjoined Smith from operating any online pharmacy. In violation of that order, Smith immediately traveled to the Dominican Republic in hopes of setting up another online site there, and he even developed a plan to flee permanently from the United States to avoid trial. When he returned to the United States, he was arrested for contempt and released on bond. Smith was indicted in August 2006 and jailed. Even while in jail, he continually violated the preliminary injunction by attempting to start a new online pharmacy and arranging cash transfers. Smith ultimately was transferred to a maximum-security facility in response to claims that he had threatened to kill a witness. Smith's trial began on October 10, 2006, and on November 22, 2006, a jury found him guilty of the nine counts charged in the Indictment. At various points during the trial and investigation, several of his coconspirators pleaded guilty to conspiracy to distribute controlled substances. These coconspirators included Dr. Mach, a pharmacy recruiter, a business consultant, a computer programmer, and the person who had served as head of security for Smith's business.

Smith challenges his convictions on numerous grounds. First, he alleges that the district court erred in instructing the jury that a prescription's validity under 21 C.F.R. § 1306.04 is determined by generally accepted medical practices rather than the specific, regular practice of the issuing doctor. Smith also claims this instruction

incorporated a civil-liability standard and violated the rule of lenity. Second, Smith argues that the court erred in instructing the jury that a prescription must be valid in order to preclude a charge of misbranding under 21 U.S.C. §§ 331(a), 333(a)(2), and 353(b)(1), and that the court's instruction again violated the rule of lenity. Third, Smith challenges the court's failure to exclude certain expert testimony from a pharmacist, as well as other "prejudicial" testimony. Finally, Smith contends that insufficient evidence supported his conviction under 21 U.S.C. §§ 841(a)(1), 841(b)(1)(D), and 846. We address each of these claims in turn.

II.

"We review challenges to jury instructions for an abuse of discretion" and "will affirm if the entire charge to the jury, when read as a whole, fairly and adequately contains the law applicable to the case." United States v. Webster, 442 F.3d 1065, 1067 (8th Cir. 2006) (internal quotations omitted). Only where the "instructional error was prejudicial to the defendant" will we reverse. Id.

A. Definition of "Prescription" Under 21 C.F.R. § 1306.04

Section 841(a)(1) of the Controlled Substances Act ("CSA") makes it "unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance" unless that person is a registered person acting pursuant to an effective prescription. See 21 U.S.C. §§ 841(a), 822(b); 21 C.F.R. § 1306.04. Title 21 C.F.R. § 1306.04 describes the conditions under which a registered person can distribute a controlled substance and requires that, to be "effective," a prescription must be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of *his professional practice*." 21 C.F.R. § 1306.04 (emphasis added); see 21 U.S.C. § 802(21) (defining "practitioner" as a person who is "licensed, registered, or otherwise permitted . . . to distribute [or] dispense . . . a controlled substance in the course of *professional practice*" (emphasis added)). Lay persons who conspire with or aid and abet a practitioner's unlawful

distribution of drugs can be convicted under the CSA and its regulations. See, e.g., United States v. Hicks, 529 F.2d 841, 844 (5th Cir. 1976) (security guard); United States v. Green, 511 F.2d 1062, 1070–71 (7th Cir. 1975) (pharmacy owner). The CSA also reaches the distribution of controlled substances over the Internet. United States v. Fuchs, 467 F.3d 889, 896 (5th Cir. 2006); United States v. Nelson, 383 F.3d 1227, 1228–29 (10th Cir. 2004).

Smith was convicted of conspiracy to distribute controlled substances and aiding and abetting the distribution of controlled substances without an effective prescription. The instruction the district court provided the jury largely tracked the language of § 1306.04. The instruction provided:

> The [Act] is not violated if a person distributes or dispenses controlled substances pursuant to a lawful prescription issued for a legitimate medical purpose [] by an individual practitioner acting in the usual course of his or her professional practice . . . .

The court further defined "usual course of professional practice" as requiring

> that the practitioner [have] 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.

Smith contends that the instruction was improper because the court's definition of "usual course of professional practice" ignored the subjective element embodied in § 1306.04's use of the term "his," thus contravening the plain language of the regulation. He argues that "his professional practice" is to be judged with reference to the particular practices of the issuing doctor, as opposed to generally accepted medical practices. Because the prescriptions that Dr. Mach issued over the Internet were "the very heart" of Dr. Mach's regular medical practice, Smith argues that Dr. Mach's actions cannot support Smith's conspiracy or aiding-and-abetting convictions.

Smith also argues that to the extent the regulation is ambiguous, the rule of lenity resolves the issue in his favor. We disagree with Smith's creative argument.

While we have never before had occasion to address explicitly whether "his professional practice" under § 1306.04 is to be measured according to a generally accepted standard of treatment or the practice of a particular doctor,[2] the Supreme Court's decision in United States v. Moore, 423 U.S. 122 (1975), and the approaches of our sister circuits are instructive. In Moore, the Supreme Court impliedly approved a jury instruction that allowed a jury to find a doctor guilty of violating § 841(a) if the doctor dispensed methadone "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." Id. at 139. The Court's statements thus counsel against finding that professional practice is to be measured according to the practice of a particular doctor and indicate that the appropriate measure of what constitutes "his professional practice" is an objective one.

[2] We have upheld jury instructions in cases involving convictions under § 841(a) and § 1306.04 where the instruction provided that a prescription must be issued in the "usual course of his professional practice" without any discussion of the potential subjectivity embodied in "his." See United States v. Katz, 445 F.3d 1023 (8th Cir. 2006); United States v. Plesons, 560 F.2d 890, 897 n.6 (8th Cir. 1977) ("If this doctor was . . . acting as a doctor in *the course of his professional practice, then there's no violation*. However, if he was not acting in good faith as a doctor, but simply pushing pills . . . , then he does not come within the exception, and the law is violated." (quotation omitted)); United States v. Kershman, 555 F.2d 198, 201 (8th Cir. 1977) ("[T]he jury was instructed that if the pharmacist believed in good faith that a prescription was issued and prescribed for a legitimate medical purpose by a physician acting in the usual accord of his profession, then the pharmacist is excepted from criminal responsibility.").

Furthermore, the circuit courts to consider a conviction under § 841(a) have applied a general-practice standard when determining whether the practitioner acted in the "usual course of professional practice." See, e.g., United States v. Merrill, 513 F.3d 1293, 1306 (11th Cir. 2008) ("The appropriate focus is not on the subjective intent of the doctor, but rather it rests upon whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." (quotation omitted)); United States v. Feingold, 454 F.3d 1001, 1011 n.3 (9th Cir. 2006) ("The term 'professional practice' implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."); United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986) (relying on Moore, 423 U.S. at 139, in dismissing the defendant's argument that "his" requires that the government prove that the doctor prescribed drugs for a purpose contrary to the doctor's own standards of medical practice because "[o]ne person's treatment methods do not alone constitute a medical practice"); cf. United States v. Hurwitz, 459 F.3d 463, 478, 480 (4th Cir. 2006) ("[A]llowing criminal liability to turn on whether the defendant-doctor complied with his own idiosyncratic view of proper medical practices is inconsistent with the Supreme Court's decision in Moore. . . . Because the instruction proffered by Hurwitz set forth a subjective standard for measuring his good faith, the instruction was not a correct statement of the law."); United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986) ("To 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.").

Smith's argument is further undermined by the regulations use of "professional practice." 8 C.F.R. § 1306.04. Even assuming that "his professional practice" requires us to consider Dr. Mach's individualized practice, that practice must still comport with the tenants of medical professionalism. In line with the Supreme Court's decision in Moore, in United States v. Katz, 445 F.3d 1023 (8th Cir. 2006),

we indicated that prescriptions issued "outside the bounds of professional medical practice" include instances where a doctor issues prescriptions "for the purpose of assisting another in the maintenance of drug habit or . . . for other than a legitimate medical purpose, i.e.[,] the personal profit of the physician." Katz, 445 F.3d 1023, 1028 (8th Cir. 2006) (quotation omitted). We are thus not at liberty to eliminate the requirement that an issuing practitioner's practice be objectively "professional," even assuming that we are required by the regulation to consider "his" particular practice. See generally Moore, 423 U.S. at 140–43; cf. United States v. Boettjer, 569 F.2d 1078, 1081 (9th Cir. 1978) (indicating that Moore "suggests that the 'usual course' standard itself imports considerations of medical legitimacy and accepted medical standards.").

Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the "usual course of professional practice" under § 841(a)(1) and § 1306.04 with reference to generally recognized and accepted medical practices and not a doctor's self-defined particular practice. If Smith's argument that § 1306.04's use of the word "his" establishes a subjective standard were to prevail, it would allow an individual doctor to define the parameters of his or her practice and effectively shield the practitioner from criminal liability despite the fact that the practitioner may be acting as nothing more than a "large-scale 'pusher.'" Moore, 423 U.S. at 143 (finding criminal liability when a practitioner ceases to act as a physician and instead acts as a drug pusher). This cannot be the law.

Smith also argues that the definition of "usual course of professional practice" in Jury Instruction 30 improperly conflated the standard for criminal liability with the standard for medical malpractice and that he was criminally convicted of breaching a civil standard of care. We also find this argument unavailing. While Instruction 30 may have incorporated the standard of care often referenced in medical-malpractice claims, see Boettjer, 569 F.2d at 1081, looking at the jury instructions on the whole,

we do not believe that the district court suggested that a breach of a civil standard alone was sufficient to sustain a criminal conviction. See Kershman, 555 F.2d at 201 ("It is axiomatic that the jury instructions should be construed as a whole."). We are thus confident that Smith's conviction rested on the appropriate criminal standard and not on the lesser, civil one.

It is true that courts have recognized a danger in confusing medical-malpractice and § 841 standards. See United States v. McIver, 470 F.3d 550, 558 (4th Cir. 2006); Feingold, 454 F.3d at 1010. In this case, however, even assuming that the use of the civil standard of care as a definitional tool was improper, the jury instructions on the whole required more than a finding that Dr. Mach did not adhere to generally accepted medical standards. The instructions indicated that the Government bore the burden to prove that Smith distributed or dispensed controlled substances "other than . . . for a legitimate medical purpose and in the usual course of professional practice." Thus, the jury was unable to convict Smith unless it found a failure to adhere to prevailing medical standards *and* a lack of legitimate medical purpose. This dual showing is one that exceeds that required to establish medical malpractice, which focuses largely on the former finding and may or may not include consideration of the latter. Cf. McIver, 470 F.3d at 559.[3]

Additional indicators that the instructions did not conflate civil and criminal standards include the fact that the court explicitly instructed that the standard of proof applicable in this case was "beyond a reasonable doubt." See Katz, 445 F.3d at 1032 (rejecting a claim that the burden of proof was lowered because the court "instructed

[3] We also note that the statute and regulations make distribution unlawful unless there is an "effective prescription." See 21 U.S.C. §§ 841(a), 822(b); 21 C.F.R. § 1306.04. A prescription is only effective if it was both issued in the "usual course of professional practice" and for a "legitimate medical purpose." In other words, under the terms of the statute, the jury is able to convict if either is not met. Arguably, then, the instruction the court provided the jury was more favorable to Smith than that required by law.

the jury that they must find beyond a reasonable doubt that [the doctor] wrote prescriptions outside the scope of medical practice and not for a legitimate medical purpose"); Vamos, 797 F.2d at 1153 ("The suggestion that an objective reasonableness standard exposes a physician to criminal responsibility for nothing more than the equivalent of malpractice ignores the fact that in a criminal prosecution the physician may be found guilty only upon proof beyond a reasonable doubt that he acted outside the scope of medical practice . . . ."). The court also allowed Smith the possibility of a good-faith defense,[4] which is unavailable in malpractice cases. "The inclusion of a good faith instruction is therefore a plainspoken method of explaining to the jury a critical difference between the two standards." McIver, 470 F.3d at 558–60 (indicating courts must "exercise care in setting out the governing standard"

[4] Instruction 64 stated, in part:

> A person who works with or for a pharmacy or a physician may not be convicted when he or she distributes or dispenses controlled substances in good faith for a legitimate medical purpose and in the ususal course of professional practice. . . .
>
> . . . .
>
> A controlled substance is distributed or dispensed by a physician or pharmacist in the usual course of his or her professional practice and, therefore, lawfully, if the substance is distributed or dispensed by him or her in good faith in medically treating a patient.
>
> 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.

in a § 841 prosecution but approving language setting forth the civil standard when the court made clear that the Government had to prove its case "beyond a reasonable doubt," instructed the jury that the "critical issue . . . was not whether the defendants had acted negligently," and included a good-faith instruction (quotation omitted)); Feingold, 454 F.3d at 1011 n.3; United States v. Alerre, 430 F.3d 681, 692 (4th Cir. 2005) ("The trial court was careful to spell out the differences between the criminal standard and the civil standard. Indeed, it . . . emphasized that [the defendants] could not be convicted if they had dispensed the controlled substances at issue 'in good faith.'"). In conclusion, we find that the jury instructions, taken as a whole, precluded a conviction based on the civil standard of liability.

B. "Prescription" Under 21 U.S.C. §§ 331(a), 333(a)(2), 353(b)(1)

Title 21 U.S.C. § 331(a) of the Food, Drug, and Cosmetic Act ("FDCA") prohibits introducing a "misbranded" drug into interstate commerce. A drug is "misbranded" unless dispensed upon a "prescription of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(C). Smith contends that the district court erred when it instructed the jury that Smith must have dispensed the drugs pursuant to a "valid" prescription to avoid conviction under the statute. He contends that the prescription need not be "valid" to avoid a misbranding charge because validity is not required by the plain language of the statute. Smith further argues that even if a valid prescription were required, the district court provided an incorrect definition of what constitutes "valid." The challenged jury instruction stated:

> A "prescription" [under the 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.

Despite the fact that § 353(b) does not explicitly state that a prescription must be valid, we find unpersuasive Smith's argument that any order for a controlled substance issued by someone authorized to issue prescriptions will preclude a

misbranding conviction. The text of the statute provides limited clarity as to the parameters of "prescription," as it is not explicitly defined. See United States v. Whiting, 165 F.3d 631, 633 (8th Cir. 1999) ("The starting point . . . is always the language of the statute itself."). And "[a]bsent a specific statutory definition, words used in a statute should be given their common meaning." Levings v. Califano, 604 F.2d 591, 593 (8th Cir. 1979) (citing Banks v. Chi. Grain Trimmers Ass'n, 390 U.S. 459, 465 (1968)).

To determine whether the prescription must be valid to preclude Smith's conviction, we find helpful a case in the U.S. District Court for the Southern District of Florida. See United States v. Nazir, 211 F. Supp. 2d. 1372 (S.D. Fla. 2002). Nazir addressed the meaning of "prescription" under § 353(b) by surveying various sources for the "ordinary meaning and usage" of the word, and the court ultimately determined that the validity of the prescription was of legal import. Id. at 1375. After discussing the definition of "prescription" in three different sources, including a medical textbook published around the time Congress enacted § 353(b), the court concluded that

> the word prescription in § 353(b)(1), 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. In affirming the district court's conclusion, the Eleventh Circuit described § 353(b)(1) as "deeming a prescription drug misbranded if it is dispensed other than pursuant to a *valid* prescription," United States v. Munoz, 430 F.3d 1357, 1366 (11th Cir. 2005) (emphasis added), and we agree.

In addition to the common meaning of the word, interpretive case law is also helpful in defining "prescription" under the statute. Cf. Gellman v. United States,

235 F.2d 87, 93 (8th Cir. 1956) ("Where words are susceptible of several meanings, the court is at liberty to determine from the legislative history and surrounding circumstances the sense in which the words were used in a statute."). While this court has not addressed the meaning of "prescription" under § 353(b) directly, in White v. United States, 399 F.2d 813, 817–18 (8th Cir. 1968), we impliedly approved the Fifth Circuit's conclusion that an invalid prescription is not a prescription within the meaning of § 353(b) at all. See Brown v. United States, 250 F.2d 745 (5th Cir. 1958). In Brown, a physician sold controlled substances to two undercover federal agents without having "given them any prescription, . . . physically examined either of them, . . . questioned them[,] or . . . otherwise attempted to acquaint himself with either the physical condition or needs of either man." Id. at 745. A jury convicted the physician of violating § 353(b)(1). Id. The Fifth Circuit found no error in a jury instruction that indicated that the existence of "a bona fide [doctor–patient] relationship . . . bears on the question whether there had ever been a 'prescription'" under the provision. Id. at 747. The court then affirmed the conviction, upholding the jury's finding that the doctor had "dispensed the tablets without prescription." Id.

In White, while addressing a conviction under a different statutory provision, we discussed favorably the Fifth Circuit's ultimate conclusion in Brown. White, 399 F.2d 817–18. In White, a doctor had frequently provided controlled substances to numerous people, including an undercover agent. Id. at 815–16. This was despite the fact that the doctor had asked "no questions concerning the state of [the recipients'] health." Id. A jury convicted the doctor under then-existing provisions of the FDCA that prohibited "the sale, delivery or other disposition of a drug" except by certain persons "acting in the ordinary and authorized course of his business, profession, occupation, or employment." 21 U.S.C. §§ 331(q)(2), 360a(b) (1968), amended by 21 U.S.C. § 801 (1970). Persons authorized to distribute drugs under the provision included "[p]ractitioners licensed by law to prescribe" such drugs "while acting in the course of their professional practice." Id. § 360a(a)(4) (1965), amended by 21 U.S.C. § 801 (1970). We affirmed the conviction, highlighting and agreeing with various

courts' reasoning under numerous provisions of the FDCA that "as a prerequisite to the issuance of a prescription . . . a bona fide physician–patient relationship must exist." White, 399 F.2d at 816–18; see also Webb v. United States, 249 U.S. 96, 99–100 (1919) (holding under the Harrison Act that when a doctor provided morphine to a habitual user "for the purpose of providing the user[] with morphine sufficient to keep him comfortable by maintaining his customary use" there was not a "physician's prescription," and that "to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject [was] required").

Besides contravening the common meaning of "prescription" and contradicting persuasive authority, not requiring a "valid" prescription would undermine the FDCA's purpose by allowing practitioners to write fraudulent prescriptions (or prescriptions that otherwise contravened the law) and escape criminal liability for such acts. Treating a prescription as a piece of paper divorced from its context—i.e., with no analysis as to whether it is valid—would, in effect, exempt licensed practitioners from prosecution under the misbranding statute all together. See Kordel v. United States, 335 U.S. 345, 349 (1948) ("[T]here is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it."). The purpose of misbranding laws is to protect the public from potentially dangerous drugs. See Brown, 250 F.2d at 747 ("The Supreme Court has on several occasions held that the purpose of the legislation is the protection of the people from dangerous products . . . ." (citing United States v. Dotterweich, 320 U.S. 277 (1943); United States v. Sullivan, 332 U.S. 689 (1948)); see also Nazir, 211 F. Supp. 2d. at 1375–76 (concluding that the statute should not be interpreted to render the expressed need for physician supervision a nullity). And we refuse to construe the statute in a way that would significantly undermine that purpose.

We further conclude that the district court did not err in defining a "valid prescription" as one issued in the "usual course of professional practice and for a

legitimate medical purpose," distinguishing between the two and requiring a finding of both. First, it was proper to require that the prescription be for a "legitimate medical purpose." See Webb, 249 U.S. at 99–100. Second, as established above, a valid prescription requires a bona fide physician–patient relationship. Whether a prescription was issued in the "usual course of professional practice" required that the jury inquire into whether Dr. Mach adhered to prevailing medical standards when issuing his prescriptions. Many of the factors that establish the existence of a physician–patient relationship and thus a valid prescription under the statute—such as whether Dr. Mach considered the actual needs of the patient, the quantity of the drug he prescribed, the type of drugs he prescribed and for what purpose, and the extent to which he supervised the issuance of the drug—are considerations necessarily included in a determination as to whether or not a prescription was issued in accordance with generally accepted practices. See Brown, 250 F.2d at 747 n.2.

C. Rule of Lenity

The rule of lenity fails to save Smith's arguments that the challenged jury instructions were erroneous. The rule requires that "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity." Cleveland v. United States, 531 U.S. 12, 25 (2000) (quotation omitted). The rule, however, should not be invoked if ambiguity can be otherwise resolved. United States v. Kowal, 527 F.3d 741, 747 (8th Cir.), cert. denied, 129 S. Ct. 612 (2008). Given that the CSA's and FDCA's structure and language resolve any ambiguities contained within "his professional practice" or "prescription," as outlined above, "the rule of lenity is not implicated here." Id.

III.

Smith also challenges the district court's failure to exclude certain expert testimony and other allegedly prejudicial evidence. "We review the district court's evidentiary rulings for abuse of discretion." Katz, 445 F.3d at 1031 (quotation omitted). "Even where we find that the district court has abused its discretion with

respect to an evidentiary ruling, we will not reverse the conviction if the error was harmless." United States v. Lupino, 301 F.3d 642, 645 (8th Cir. 2002).

A. Expert Testimony

The Government offered expert testimony from Dr. Carmen Catizone, a pharmacist. Smith argues that Catizone's testimony exceeded the scope of his expertise when he testified about the standard of care to which a doctor must adhere in order to prescribe properly a controlled substance. More specifically, Smith challenges the admissibility of Catizone's testimony regarding the type of medical practice that satisfies 21 C.F.R. § 1306.04 and Catizone's conclusion that there was insufficient information about Dr. Mach's alleged patients for a physician to have issued valid prescriptions. Smith additionally objects to Catizone's testimony as to the meaning of the text of § 1306.04. Upon review of the trial transcript, we reject Smith's argument.

"Federal Rule of Evidence 702 permits a district court to allow the testimony of a witness whose knowledge, skill, training, experience, or education will assist a trier of fact in understanding the evidence or to determine a fact in issue." United States v. Kirkie, 261 F.3d 761, 765 (8th Cir. 2001) (citing Fed. R. Evid. 702). We have previously admitted "testimony tying standards of care to the existence of a legitimate medical purpose to write a prescription." Katz, 445 F.3d at 1032.

Despite the fact that Catizone was not a medical doctor, we find that his testimony regarding the type of information a doctor should have to prescribe a particular drug, and whether Dr. Mach met that standard, fell within his expertise. Catizone is a certified pharmacist and has been the executive director of the National Association of Boards of Pharmacy ("NABP") for twenty years. The NABP drafts model laws regulating pharmaceuticals, which necessitates that Catizone be particularly familiar with both the CSA and the FDCA. Furthermore, Caitzone annually gives testimony before Congress, state legislatures, and state committees on

Internet pharmacies and the relevant laws. Through his work with the NABP, Catizone also helped institute a national accreditation program that developed standards of operation for legitimate Internet pharmacies in conjunction with the FDA and the DEA, among other agencies and organizations. Under that program, to maintain certification, pharmacies must comply with both state and federal law, which includes filling only legitimate prescriptions and refusing to fill those that appear suspect. See 21 C.F.R. § 1306.04(a) (providing that pharmacists are required by law to determine whether a prescription has been issued in the usual course of professional practice and for a legitimate medical purpose or be subject to criminal liability).

As a result, Catizone's job requires a working knowledge of what constitutes a valid prescription, and this cannot be divorced from having an awareness as to the quantity and quality of patient information a doctor must have in order to prescribe a particular drug. See United States v. Jones, 570 F.2d 765, 769 (8th Cir. 1978) ("Dr. Burton testified that before prescribing any drug, a physician must take a medical history and make some physical examination. Witness Burton possesses a Ph.D. in pharmacology. Although not an M.D., his twenty years of teaching at the Washington University Medical School qualifies him as an expert entitled to express an opinion as to medical procedures in prescribing drugs . . . ."); see also United States v. Bek, 493 F.3d 790, 797 (7th Cir.), cert. denied, 128 S. Ct. 549 (2007) (noting "expert testimony from a pharmacist who explained that [the doctor's] practices were dangerous and very unusual" and that the doctor "should have conducted several diagnostic tests and reviewed patients' medical histories before prescribing drugs such as Vicodin").

Catizone has also helped the Government identify over 1,500 "rogue pharmacies," or pharmacies that operate in contravention of state and federal law and offer medications to patients or customers without legitimate or valid prescriptions. In fact, Smith concedes that Catizone is an expert in identifying rogue pharmacies. Factors that Catizone uses to make a determination of whether a pharmacy is rogue under the NABP standards include the type of medical information the site requests

and whether it requires face-to-face interaction. In order to properly identify a rogue pharmacy, then, Catizone must pass judgment on the substance of a patient–doctor interaction. Again, to make this determination it is important that Catizone have in-depth knowledge regarding what is needed for a medical doctor to issue a legitimate prescription under prevailing practice, and it is apparent from his testimony that he did.

We do not doubt that there may be instances in which a pharmacist is not qualified to provide expert testimony on the standard of care necessary to prescribe a particular drug. Given Catizone's background and extensive involvement with identifying rogue pharmacies, however, the district court's refusal to exclude this testimony does not constitute an abuse of discretion. Catizone thus properly testified within his expertise as to the type of relationship usually considered necessary for a doctor to issue a valid prescription.

Furthermore, while we find Catizone's testimony about the legal meaning of § 1306.04 troubling, we conclude that it was harmless and does not merit remand. As mentioned, Catizone is required to be familiar with state and federal laws and has frequently testified before Congress and legislatures; however, he is not qualified to interpret the text of the statutes and regulations in open court. Thus, we agree with Smith that, at several points, Catizone exceeded his qualifications as an expert:

> Q. I am showing you a copy of 21 CFR 1306.04. Are you familiar with this law?
>
> A. Yes.
>
> Q. What do the phrases, included in this law, "usual course of professional practice" and "legitimate medical purpose" mean?
>
> . . . .

> [A.] Based upon my knowledge of state laws and also the Controlled Substances Act, this refers to the scope of practice that a physician may engage in and also responsibility for that physician to follow all of the laws and requirements as indicated in federal and state law.
>
> . . . .
> Q. You'll notice that I have circled the word "his" in this particular regulation. Why is that included in 1306.04?
> Well, where it indicates "his professional practice," does that mean we are dealing with a subjective standard of professional practice?
>
> [A.] No. What we're dealing with here is a discretion that's provided to the physician to operate within their practice, but the physician must still follow all of the laws governing that practice.

Moreover, it is "the judge and not a witness" that "is to instruct the fact finder on the applicable principles of law." Hogan v. Am. Tel. & Tel. Co., 812 F.2d 409, 411 (8th Cir. 1987) (per curiam) (citing Marx & Co., Inc. v. Diners' Club Inc., 550 F.2d 505, 509–10 (2d Cir. 1977) ("It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge. . . . The special legal knowledge of the judge makes the witness' testimony superfluous.")).

This error alone does not necessarily warrant reversal. Here, Catizone's testimony, although beyond his expertise, stated the correct formulation of the law. More importantly, the district court ultimately instructed as to the correct legal standard under § 1306.04 at the close of the evidence. Absent harm, the district court's evidentiary ruling provides no grounds for relief with regard to Catizone's expert testimony. See Fed. R. Crim. P. 52(a).

B. Prejudicial Evidence

Smith also argues that the district court erred in failing to exclude various unduly prejudicial and irrelevant statements of a Government cooperating witness. The witness testified that Smith had sent him to Prague to solicit prostitutes on

Smith's behalf and that Smith and the witness intended to become "international pimps." The Government argues that the evidence of solicitation was admissible to head-off a co-defendant's attempt to impeach the Government witness's credibility under Federal Rule of Evidence 608 and also as non-character evidence admissible to show Smith's intent to commit his substantive offenses under Federal Rule of Evidence 404(b). The Government alternatively claims that Smith's co-defendant "opened the door" to the evidence by raising it on cross-examination and that there can be no reversible error. See United States v. Beason, 220 F.3d 964, 968 (8th Cir. 2000) ("It is fundamental that where the defendant 'opened the door' and 'invited error' there can be no reversible error." (quotation omitted)).

Assuming without deciding that the challenged evidence was inadmissible impeachment evidence and inadmissible non-character evidence, and assuming without deciding that a co-defendant's testimony that is prejudicial to another co-defendant does not open the door to the evidence, we find that any such error was harmless beyond a reasonable doubt. See Fed. R. Crim. P. 52(a) (providing that an error in the admission of evidence only provides a basis of relief if the error affected the defendant's "substantial rights").

Although Smith argues that the testimony made Smith "look like a lowlife with a criminal character," which "clearly stuck with the jury" and formed the basis of the conviction, we must view the error in light of the evidentiary record as a whole. This analysis includes "the overall strength of the prosecution's case." United States v. Honken, 541 F.3d 1146, 1160 (8th Cir. 2008) (quotation omitted); United States v. No Neck, 472 F.3d 1048, 1054 (8th Cir. 2007) (indicating that the proper question is whether "the guilty verdict actually rendered in this trial was surely unattributable to the error" (quoting Sullivan v. Louisiana, 508 U.S. 275, 279 (1993) (emphasis omitted))). In view of the extensive testimony and documentary evidence that the Government presented detailing Smith's operation of the rogue pharmacy during more than twenty days of trial, discussed *infra*, the evidence of Smith's guilt is overwhelming. Having carefully reviewed the record, we conclude that any

evidentiary error did not affect Smith's substantial rights and was harmless. See United States v. McCauley, 601 F.2d 336, 339 (8th Cir. 1979) (finding that the admission of a recording that contained "vulgarity, racial slurs, and cavalier statements concerning past [bad acts]. . . . was harmless [error] given the overwhelming evidence of [the defendant's] guilt of the crime charged").

In addition to evidence of Smith's attempted solicitation, Smith also contends that the district court abused its discretion by allowing testimonial evidence concerning a wrongful death suit filed against Smith's business. The suit alleged that a drug addict had ordered drugs from Smith's business and subsequently committed suicide. The witness testified that Smith was unconcerned by the suit and had laughed upon learning of the death. Smith objected to the testimony. After sustaining the objection, the court issued a curative instruction telling the jury to disregard evidence of the death because there was no link between OPS and the suicide. The court also issued a similar instruction prior to submitting the case to the jury for deliberation.

"The admission of allegedly prejudicial testimony is ordinarily cured by an instruction to the jury to disregard the testimony." United States v. Nelson, 984 F.2d 894, 897 (8th Cir. 1993). It is our role, however, to "determine with fair assurance whether, in spite of the instruction, the verdict was substantially swayed by the error." Id. (quotation omitted). When considering the "prejudicial effect of any allegedly improper testimony," we look to "the trial context of the error[] and the prejudice created thereby as juxtaposed against the strength of the evidence of the [defendant's] guilt." Id. "This court will affirm a conviction, despite the introduction of an inadvertent prejudicial comment, where there was 'substantial evidence' of guilt." United States v. Urick, 431 F.3d 300, 304 (8th Cir. 2005). While the testimony here concerning the wrongful-death suit was improper, the court immediately issued a curative instruction to the jury and further informed the jury that it was to disregard the evidence of the suicide at the close of the case, even absent such a request from Smith. See Nelson, 984 F.2d at 897 (noting how "aggressively" the district court

acted to cure the error). Furthermore, as discussed *infra*, the evidence as to Smith's guilt was overwhelming. See id. We thus conclude again that the district court committed no reversible evidentiary error.

IV.

"This court reviews the sufficiency of the evidence de novo, viewing the evidence in the light most favorable to the government, with all reasonable inferences and credibility determinations made in support of the jury's verdict." Katz, 445 F.3d at 1028 (quotation omitted). Smith argues that there was insufficient evidence for a reasonable jury to determine that Dr. Mach issued prescriptions outside of the "usual course of his professional practice" and thus for this court to sustain his conspiracy and aiding and abetting convictions under § 841(a). We disagree.

"A prosecution under § 841 requires proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e. the personal profit of the physician." Id. at 1028 (internal quotation omitted). Sufficient evidence supports the jury's conclusion that Dr. Mach was acting outside the ordinary course of professional practice when he issued the prescriptions upon which Smith's conviction was based.

Perhaps the most probative evidence that Dr. Mach was prescribing drugs to "assist[] another in the maintenance of a drug habit or . . . for other than a legitimate medical purpose," id., is that Dr. Mach himself explicitly so stated. In addition to this admission, Dr. Mach further testified about his traditional medical practice and his prescription policy prior to working with online pharmacies. That policy required face-to-face consultations so that Dr. Mach was able to obtain what he considered the information necessary to prescribe an appropriate drug in an appropriate quantity. Dr.

Mach explained that his work with the online pharmacy differed from his office practice because "[t]here was never an established doctor/patient relationship. There was never a face-to-face examination. There was never a history. There was no physical examination. There was no legitimate prescription written and signed and the prescriptions were not valid." See United States v. Hayes, 595 F.2d 258, 261 (5th Cir. 1979) (upholding conviction of a pharmacist where the doctor testified "that any prescriptions written by [the doctor] were not written in the usual course of medical practice or for legitimate medical purpose"). To the extent the Smith's challenge to the sufficiency of the evidence asks us to review the jury's conclusion that Dr. Mach was credible, we decline. Not only are "[q]uestions involving the credibility of witnesses . . . for the jury to resolve," but Dr. Mach's testimony was corroborated by additional documentary and testimonial evidence. United States v. Lop Bounmy, 403 F.3d 1018, 1021 (8th Cir. 2005) ("[T]he uncorroborated testimony of an accomplice is sufficient to sustain a conviction if it is not otherwise incredible or unsubstantial on its face." (quotation omitted)).

Additional evidence supporting Smith's conviction includes testimony that Dr. Mach never physically examined or even met with those who were the recipients of the controlled substances before writing over 72,000 prescriptions. The evidence further indicates that Dr. Mach approved each order submitted to him, despite the fact that, in at least one instance, the name on the prescription was an obscene word and not a person. Dr. Mach placed no limit on the type of drugs that he would prescribe, allowed customers to choose the type and brand of drug that they desired for their self-stated alleged medical conditions, provided no limitations on the quantity of drugs that customers could obtain at one time or within a particular time period, and did not monitor dosage in any way. See, e.g., Moore, 423 U.S. at 142–43; Katz, 445 F.3d at 1026–28 (affirming a conviction where there was testimony that the doctor received no medical history, rarely performed physical exams, and provided month-long prescriptions every two weeks); see also United States v. Paskon, No. 4:07-CV-1161 (CEJ), 2008 WL 2039233, at *5 (E.D. Mo. May 12, 2008) (collecting cases "regarding the scope of 'professional practice' . . . in the context of criminal prosecutions of

physicians under 21 U.S.C. § 841"). The fact that Dr. Mach was paid per order approved also supports a finding that his prescriptions were for other than a legitimate medical purpose but rather for his "personal profit." Katz, 445 F.3d at 1028.

Catizone's testimony regarding the applicable standard of care further supports Smith's conviction. As discussed above, Catizone testified within his expertise as to whether or not Dr. Mach issued prescriptions in accordance with generally prevailing medical standards. He identified several factors pointing to the conclusion that the online pharmacy through which Dr. Mach issued those prescriptions was not legitimate and that the prescriptions were thus invalid. Such indicators included the fact that the questionnaires often failed to list the customer's ailment, the reason for the prescription, and other relevant information about the patient's medications and/or allergies. Additionally, Catizone testified that the prescriptions that Dr. Mach issued were for excessive quantities of drugs relative to the medical condition the prescription was allegedly treating. Dr. Mach also at times prescribed a drug that was not intended or appropriate to treat the claimed ailment. Catizone further questioned Dr. Mach's ability to approve the 72,000 prescriptions at issue, at times, over 1,000 in a single day, given that the "medical literature has reported that the average time it takes for a physician . . . to conduct a medication or patient profile . . . is . . . between twelve and twenty minutes." He further pointed out the disproportionately high percentage of controlled substances that Dr. Mach prescribed relative to prescriptions for non-controlled substances used to treat illnesses or diseases such as diabetes and high blood pressure.

In conclusion, viewing the evidence in a light most favorable to the Government, we consider it sufficient to support the jury's conclusion that Dr. Mach issued the prescriptions outside the ordinary course of professional practice and without legitimate medical purpose. Smith's conviction must stand.

V.

Finally, Smith argues that the district court committed a procedural sentencing error when it required that Smith show extraordinary circumstances to merit a downward variance. Smith also argues that his sentence of 360 months' imprisonment was substantively unreasonable. Because we find reversible procedural error, we do not address Smith's substantive-reasonableness argument.

A. Standard of Review

Reviewing a sentence, this court must "first ensure that the district court committed no significant 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." Gall v. United States, 128 S. Ct. 586, 597 (2007). "If the decision was procedurally sound, we then review the substantive reasonableness of the sentence under the abuse-of-discretion standard considering the totality of the circumstances." United States v. Alvizo-Trujillo, 521 F.3d 1015, 1017 (8th Cir. 2008).

If the defendant properly preserves a procedural error, our review is for harmless error. United States v. Henson, 550 F.3d 739, 741 (8th Cir. 2008), cert. denied, 129 S. Ct. 2736 (2009). "This circuit requires more than a request for a non-guidelines sentence in order to preserve . . . Gall error; the defendant must object to the district court's erroneous application of the law." United States v. Bain, 537 F.3d 876, 881 (8th Cir. 2008), vacated and remanded on other grounds, 129 S. Ct. 2157 (2009). If a party fails to object in the district court, we review a procedural sentencing error for plain error. See United States v. Burnette, 518 F.3d 942, 946 (8th Cir. 2008).

The Government asserts that Smith failed to preserve his objection to the court's treatment of his request for a downward variance and that our review is one

of plain error. We disagree. While failing to use the word "object," Smith engaged in a lengthy dialogue with the district court about the Eighth Circuit's "draconian" and "unreasonable" precedent in relation to the district court's ability to grant a variance. Smith also discussed the fact that the Supreme Court had granted certiorari in United States v. Gall, 446 F.3d 884 (8th Cir. 2006), rev'd 128 S. Ct. 586 (2007), to address what he characterized as "unreasonable" precedent. Finally, he further emphasized that the Supreme Court's determination that the Guidelines are "truly advisory" must govern.

Contrary to the Government's claim, Smith's statements were beyond a simple request for a non-Guidelines sentence and amount to more than mere commentary about the perceived unfairness of the law. Cf. Bain, 537 F.3d at 881 (applying plain-error review when the defendant "inform[ed] the judge of the course of action he wished the judge to take"—i.e., receive a non-Guidelines sentence—and "stat[ed] the exact sentence sought"); Alvizo-Trujillo, 521 F.3d at 1018 (reviewing for plain error where the statement to be construed as an objection "was merely commentary" about the Guidelines range being "unreasonably high" and "was made before the district court announced the improper presumption and the sentence"); Burnette, 518 F.3d at 946–47 ("After withdrawing his objections to the PSR, [the defendant] made no further objections to his sentence."). Given Smith's statements and their context, we find that he preserved the error for appeal. See United States v. Pirani, 406 F.3d 543, 549 (8th Cir. 2005) (en banc) ("To preserve an error . . . , an objection must be timely and must clearly state the grounds for the objection." (internal quotation and alteration omitted)). We therefore review for harmless error.

B. Procedural Error in Sentencing

The district court sentenced Smith to 360 months' imprisonment in August 2007, four months prior to the Supreme Court's decision in Gall. Before Gall, "[o]ur cases required that the justification for a variance be proportional to the extent of the difference between the advisory range and the sentence imposed." United States v.

Marron-Garcia, 555 F.3d 1040, 1041 (8th Cir. 2009) (quotation omitted). "One formulation [of this proportionality review] asked whether an 'extraordinary variance' was supported by 'comparably extraordinary circumstances.'" Id. (quoting United States v. Claiborne, 439 F.3d 479, 481 (8th Cir. 2006), vacated as moot, 551 U.S. 87 (2007)). In Gall, the Supreme Court "held that an appellate standard requiring 'proportional' justifications for variances from the guideline range was inconsistent" with Supreme Court precedent. United States v. Lee, 553 F.3d 598, 601 (8th Cir. 2009) (quoting Gall, 128 S. Ct. at 594). But the Court also "found it 'uncontroversial that a major departure should be supported by a more significant justification than a minor one.'" Id. at 601–02 (quoting Gall, 128 S. Ct. at 597).

We have several times stated that "[u]nder this court's pre-Gall legal framework, district courts had less discretion to make a major variance than they now enjoy [post-Gall], but [that] they had ample discretion to make a minor variance." Marron-Garcia, 555 F.3d 1040, 1041 (internal citation and quotation omitted); see also Lee, 553 F.3d at 602 ("[T]he pre-Gall legal framework gave district courts less discretion to make a major variance than they now enjoy."). The current state of the law stems from the fact that while Gall made clear that we may no longer require "'extraordinary' circumstances to justify a sentence outside the Guidelines range," this court's rule had not been to "require extraordinary circumstances to justify every non-guideline sentence." Marron-Garcia, 555 F.3d at 1041 (quotation omitted).

Smith claims that given the state of the law at the time of his sentencing, and the lack of clarity concerning the amount of discretion district-court judges possessed to make major variances, the district court did not fully realize the extent of its discretion to impose a below-Guidelines sentence. As a result, Smith claims that the district court should have the opportunity to reconsider the sentence in light of Gall.

During the sentencing phase of his trial, Smith argued for a downward variance from 360 months to life to the statutory minimum of 240 months. His argument was based on numerous grounds, including the potential sentencing disparities with other

online-pharmacy cases. In making his motion, he emphasized that the court was empowered to grant the variance in its discretion. But the court refused, stating:

> [Y]ou know what the circuit does for *every* variance that a judge does for a departure downwards, it essentially reverses. . . . I placed somebody on probation and home detention and they said, No, you can't do that variance . . . . And so . . . 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 (emphasis added).

Addressing the potential-sentencing-disparity argument specifically, the court responded that it had "been reversed a number of times dealing with variances and departures . . . based on the issue of similar[ly situated defendants]." The court further stated that even "if there's a variance that's going to be granted, it can't be to 20 years because from 360 to 240, that's automatic reversal." We agree with Smith that these comments raise questions about whether the district court doubted that, as a practical matter in our circuit pre-Gall, it possessed the discretion to vary significantly to the requested statutory minimum. And, as a result, we find that the district court committed procedural error.

Furthermore, we do not find the error harmless. "The government bears the burden of proving the district court's error was harmless and must show that no grave doubt exists as to whether the error substantially influenced the outcome of the proceedings." United States v. Greene, 513 F.3d 904, 908 (8th Cir. 2008) (quotation omitted). While the court showed disdain for Smith's actions and believed that he was eligible for a lengthy sentence based, in part, on his own aggravating conduct, the record also indicates that the court found "some merit" in "the sentencing position of the defendant" but, out of caution, would not vary due to the belief that pre-Gall it would result in "automatic reversal." Taking the court's comments highlighted above in light of the proportionality-focused circuit law at the time, along with the statement that it would "follow the Eighth Circuit precedent dealing with how to sentence an individual," we are unsure whether the court would have given Smith the same

sentence absent an understanding that it was effectively not permitted to vary to the degree that Smith requested. See United States v. Cullen, 432 F.3d 903, 906 (8th Cir. 2006) ("[W]e cannot say with any confidence that the district court would not have sentenced the defendant to a lesser sentence . . . . Because [the defendant] was sentenced at the bottom of the Guidelines range, we are left with grave doubt as to whether the error was harmless, and we remand for resentencing." (quotations omitted)).

As the dissent aptly states, we recognize that the sentencing judge's Statement of Reasons is a "critical part of the sentencing record," and we acknowledge the comprehensive nature of the district court's statements here. We do not believe, however, that the district court's statements that it had "power to grant a variance from the Guideline range" and that a "sentence within the Guideline range is reasonable" undercuts a finding of procedural error in this case. Nor do we believe that these statements differ from the statements the district court made during sentencing. Both the sentencing transcript and the Statement of Reasons indicate that the district court believed that it could vary. The sentencing transcript also indicates, however, that the district court believed that its power to do so was constrained by then-Eighth Circuit precedent and nothing in the Statement of Reasons contradicts that. Given the court's statements and the context of Smith's sentencing, we are not convinced that the district court's statement that it knew it had the power to vary necessitates a conclusion that the district court was confident in the level of discretion it had to grant a departure of the magnitude that Smith requested upon the justifications that Smith presented.[5]

[5] The dissent cites United States v. Garcia, 236 F. App'x 225, 226 (8th Cir. 2007) (per curiam) (unpublished), as evidence that the district court could not have "mistakenly believed" that it "lacked discretion to vary downward to the statutory minimum." In Garcia, the same sentencing judge granted a twenty-month variance to a below-Guidelines range sentence. Garcia, 236 F. App'x at 226. But, again, a grant of a twenty-month variance does not necessarily require a finding in this case that the court believed it had discretion to grant a major variance to a statutory

Contrary to the dissent's contention, our finding of procedural error is not intended to, in any way, burden the sentencing judge. Given the district court's comments during sentencing, it is clear that the court was frustrated by what it perceived as this court's overly rigorous review of sentencing decisions, as well as his personal experience with sentencing reversals. (The former being a perception confirmed by the Supreme Court in Gall.) While the dissent cites statistics indicating the frequency with which District of Minnesota judges granted downward variances and also highlights cases where we upheld pre-Gall, below-Guidelines downward variances, what matters in determining the mind set within which the district court was operating when it sentenced Smith is not the actuality of whether judges varied generally or whether those cases in which this specific judge varied were reversed on appeal. Rather, what matters is the district court's perception of the Eighth Circuit's response to its actions.

In sum, the district court indicated that Smith's claim for a variance had "some merit,"[6] but it generally seemed to have felt constrained by Eighth Circuit practice.

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minimum without requiring extraordinary circumstances. In fact, in Garcia, the court rejected the defendant's motion for a variance to the statutory minimum, which would have been a sixty-eight month variance. Id. Garcia, then, does not eliminate our concern that while the district court believed that it had discretion to vary, it erroneously (and understandably, given the state of the law) questioned whether the reasons to make such a major variance had to be extraordinary. Additionally, as the dissent indicates, we acknowledge that the district court's comments about "automatic reversal" were made in the context of "cases in which he varied downward from a prison sentence to a non-prison sentence." Again, however, this supports rather than undercuts the argument that the district court may not have believed it possessed the discretion to make a major variance such as the one Smith requested. By referencing such cases, the district court appeared to be analogizing a variance from 360 months to 240 months to a prison to non-prison sentence.

[6] One may argue that the refusal to grant even a small variance makes any discussion of a more substantial variance essentially moot. However, the district

Rather than insulting the judge, then, we believe that remanding the case to allow the district court to re-sentence Smith in the first instance after Gall provides the district court with the due deference it deserves to perform its charge with the guidance of clearer precedent. It may be, in fact, that the district court finds that the sentence it originally imposed upon Smith was appropriate, but we prefer to give the district court the chance to exercise that sentencing discretion now that more clarity exists as to its discretion and the level of scrutiny this court will impose. See United States v. Feemster, No. 06-2059, slip op. at 8–9 (8th Cir. July 13, 2009) (en banc).

Accordingly, we vacate Smith's sentence and remand for resentencing.

VI.

Having considered all of the issues raised by the defendant on appeal, we affirm the judgment of conviction. We vacate the sentence, however, and remand in light of Gall.

LOKEN, Chief Judge, concurring in part and dissenting in part.

I join Parts I-IV of the court's opinion. But I dissent from Part V, which misrepresents the sentencing record and ignores relevant prior decisions in contriving a supposed procedure error that imposes unnecessary burdens on a busy, careful and experienced sentencing judge, Chief Judge Michael J. Davis of the United States District Court for the District of Minnesota.

1. Some ten years ago, at the urging of the Sentencing Commission, the Judicial Conference Criminal Law Committee reminded district judges that the

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court's comment about the motion having "some merit" makes us reluctant to resolve the variance issue on that basis. Moreover, as stated before, we feel the district court is in the best position to determine, in the first instance, what it meant by that comment and what it would have done under the more deferential Gall standard.

Statement of Reasons portion of the judiciary's Judgment in a Criminal Case form should be completed as part of every sentence. Compliance, which had been rather lax, is now nearly universal. The Statement of Reasons is a critical part of the sentencing record. It not only helps the Commission gather accurate sentencing data, it also gives the sentencing judge a chance to reflect on the sentence and to supplement, or even supplant, impromptu comments at the sentencing hearing that may have been incomplete or inaccurate. Here, Chief Judge Davis included a thirty-two-page Statement of Reasons in the Judgment five days after Smith's hearing. Findings relating to ten enhancements took up twenty-two pages. After determining the advisory guidelines range, and reciting the advisory nature of the Guidelines[7] and the sentencing factors in 18 U.S.C. § 3553(a), the Statement of Reasons explained:

> Although the Court acknowledges its power to grant a variance from the Guideline range, the Court concludes that a sentence within the Guideline range is reasonable. Smith was a drug kingpin who received great financial gain from his illegal activities while consciously disregarding the risk of death or serious bodily injury to the addicts, upon whose addictions his profits were based. . . . Smith plotted to kill a Government witness and attempted to continue his fraudulent scheme in three different countries . . . . Smith has demonstrated that he does not obey Court orders and that, in the absence of a serious Guideline sentence, he is likely to reoffend . . . .
>
> Although the Court has concluded that a Guideline sentence is reasonable in this case, a sentence at the low end of the Guideline range is sufficient . . . .

(Emphasis added.) Part V pays lip service to Chief Judge Davis's Statement of Reasons but refuses to believe it.

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[7]The court also described the Guidelines as "advisory" at the sentencing hearing, before stating that it "will not vary."

2. Prior to the sentencing hearing, Smith filed a memorandum urging Chief Judge Davis to grant a variance down to the mandatory minimum sentence of 240 months in prison. As Part V notes, in denying Smith the ten-year downward variance he requested, Chief Judge Davis commented, "if there's a variance that's going to be granted, it can't be to 20 years because . . . from 360 to 240, that's automatic reversal." The comment reflected our pre-Gall cases requiring that an *extraordinary* variance be justified by extraordinary circumstances, a formulation rejected in Gall. 128 S. Ct. at 595. However, as Part V acknowledges, the Supreme Court in Gall reaffirmed the proportionality *principle* when it stated, "We find it uncontroversial that a major departure should be supported by a more significant justification than a minor one," id. at 597. Putting aside the hyperbolic reference to "automatic reversal," and focusing on the Statement of Reasons, there was no procedural error in denying the variance Smith requested because Gall did not change the fact that, as Chief Judge Davis determined, Smith requested a "major departure" but presented no "significant justification."

3. The Sentencing Commission's "Sourcebook of Federal Sentencing Statistics" for the three fiscal years prior to Smith's sentencing reveal that District of Minnesota judges granted downward judicial variances in 22%, 21%, and 15% of their post-Booker cases, ranking seventh, eighth, and fifteenth out of the ninety-four federal district courts in that category. See Table 26 in the 2005, 2006, and 2007 Sourcebooks. Less than two months before Smith's sentencing, and six months before the Supreme Court decided Gall, we affirmed Chief Judge Davis's grant of a variance twenty months below the bottom of the advisory guidelines range, rejecting defendant's argument that Chief Judge Davis mistakenly believed he lacked discretion to vary downward to the statutory minimum. United States v. Garcia, 236 F. App'x 225, 225-26 (8th Cir. 2007) (unpublished). Three months before Garcia, we affirmed another sentence in which Chief Judge Davis varied downward, rejecting the argument that he committed procedural error by treating the Guidelines as mandatory. United States v. Lynch, 477 F.3d 993, 998 (8th Cir. 2007).

Part V emphasizes Chief Judge Davis's comments at sentencing expressing frustration at being reversed "a number of times" for granting downward variances. But Chief Judge Davis expressly stated he was speaking "hypothetically," and the comments referred to cases in which he varied downward from a prison sentence to a non-prison sentence, cases presenting the same type of variance later upheld in Gall. See United States v. Miller, 484 F.3d 964, 965-67 (8th Cir. 2007), vacated and remanded, 128 S. Ct. 871 (2008); United States v. Gayekpar, 211 F. App'x 533, 535-36 (8th Cir. 2007) (unpublished). In December 2006, we affirmed Judge Magnuson's grant of a variance from eighteen months in prison to five years' probation in a high-profile case, which demonstrated to District of Minnesota judges that even downward variances to non-prison sentences were not automatically reversed. United States v. Wadena, 470 F.3d 735, 736-37, 740 (8th Cir. 2006). Particularly in light of the Statement of Reasons, Chief Judge Davis's comments do not suggest a belief that he had no authority to grant a substantial variance to Smith.

The sentencing record in this case is a far cry from the sentencing records in the cases on which Part V relies, such as United States v. Greene, 513 F.3d 904, 907 (8th Cir. 2008). Here, the entire sentencing record, including particularly the elaborate Statement of Reasons, leaves me with complete confidence that Chief Judge Davis would not have granted Smith a downward variance had the sentence been imposed a few months after, instead of a few months before, the Supreme Court's decision in Gall. As the sentence was imposed without procedural error and is reasonable, it should be affirmed. Accordingly, I respectfully dissent from Part V.
