

In The
UNITED STATES COURT OF APPEALS
For The Eighth Circuit

No. 07-2956

Criminal

UNITED STATES OF AMERICA,

Appellee,

v.

CHRISTOPHER WILLIAM SMITH,

Appellant.

Appeal from the United States District Court for the
District of Minnesota

BRIEF OF APPELLANT

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SUMMARY AND REQUEST FOR ORAL ARGUMENT

Christopher Smith was convicted by a jury of crimes related to the operation of an internet pharmacy, including conspiracy to distribute controlled substances, distribution of controlled substances, dispensing of misbranded drugs, money laundering and continuing criminal enterprise. He was sentenced to 30 years in prison.

Mr. Smith raises eight arguments on appeal, six challenging his convictions and two challenging his sentence. Mr. Smith argues that, in two separate ways, the district court erroneously instructed the jury regarding the elements of the offenses for which he was being tried. Most importantly, the district court employed a flawed definition of what constitutes a valid prescription, permitting Mr. Smith to be convicted on something less than proof beyond a reasonable doubt that he violated the criminal laws. The court's erroneous instructions also violated the rule of lenity and its requirement that, if a lack of clarity exists in a criminal case, it must be resolved in favor of the defendant. Because the erroneous jury instruction infected every single count of the Indictment and because it was not harmless, reversal is required.

The district court also erred in two respects when it admitted irrelevant evidence in two respects, both of which were severe enough to require a new trial. First, the court allowed a pharmacist to testify beyond the bounds of his expertise and to opine about generally accepted medical practice for doctors, an area about which he was unqualified. The weakness of this “expert” testimony also resulted in the government failing to meet its burden of proof on an important issue at trial. Second, the court allowed irrelevant and inflammatory testimony about suicide and prostitution to infect the case against Mr. Smith. These errors were severe enough, particularly in light of the weakness of the government’s case, to require reversal.

The sentencing of Mr. Smith was fraught with error as well. First, the district court committed “Gall error” when it determined that it was not permitted to vary downward from the guidelines due to this Court’s erroneous precedent functionally prohibiting such variances. Second, the district court committed procedural errors when it failed to consider important sentencing facts and mitigation that rendered a sentence less of 30 years far greater than necessary to accomplish the statutory goals of sentencing. Remand for resentencing is required.

Mr. Smith seeks 30 minutes in which to present argument to the Court.

Given the voluminous record, with a thousand exhibits and more than twenty days of testimony, and given the complexity of the issues raised, 30 minutes is appropriate.

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Certificate of Compliance and of Virus Free Disk

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Shannon Prather, “Jury Finds Net Pharmacy Kingpin Guilty”, Nov. 23, 2006,
St. Paul Pioneer Press. 38, 75

PRELIMINARY STATEMENT

The Honorable Michael J. Davis, Chief United States District Judge for the District of Minnesota, presided at Christopher Smith's trial and sentencing. The government invoked the jurisdiction of the district court pursuant to 18 U.S.C. § 3231.

The district court clerk entered judgment on the docket on August 6, 2007. Christopher Smith filed a notice of appeal on August 16, 2007. This notice was timely within the meaning of Federal Rule of Appellate Procedure 4(b). Mr. Smith invokes the jurisdiction of this Court pursuant to 18 U.S.C. §3742 and 28 U.S.C. §1291.

STATEMENT OF ISSUES

I.

The District Court’s Erroneous Instructions to the Jury Regarding the Meaning of “Valid Prescription” Misstated the Law and Deprived Christopher Smith of a Fair Trial.

21 C.F.R. §1306.04

Staples v. United States, 511 U.S. 600 (1994)

United States v. Christo, 614 F.2d 486 (5th Cir. 1980)

II.

The Rule of Lenity Requires Reversal of Christopher Smith’s Convictions Because § 1306.04 Should Have Been Interpreted in Favor of the Defendants At Trial.

United States v. Santos, ___ U.S. ___, 128 S. Ct. 2020 (2008)

III.

The District Court’s Jury Instructions Regarding “Misbranded Drugs” Were Erroneous and Violated the Rule of Lenity.

21 U.S.C. §353(b)

Webb v. United States, 249 U.S. 96 (1919)

IV.

The District Court Erred When It Permitted a Pharmacist to Testify As An Expert Regarding The

**Standard of Care For Doctors In The Practice Of
Medicine.**

Weisgram v. Marley Co., 169 F.3d 514 (8th Cir. 1999)

Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.,
254 F.3d 706 (8th Cir. 2001)

V.

**Insufficient Evidence Was Presented that the
Prescriptions Issued Were Invalid Under Any
Interpretation of § 1306.04.**

United States v. Termini, 922 F.2d 879 (8th Cir. 1993)

VI.

**The District Court Erred When it Admitted
Irrelevant Evidence of Prostitution and Suicide
Which Was So Prejudicial As To Deny Christopher
Smith A Fair Trial.**

Federal Rules of Evidence 403

United States v. Blue Bird, 372 F.3d 989, 995 (8th Cir. 2004)

VII.

**The District Court Erroneously Believed Itself
Unable To Depart From the Advisory Guideline
Range And Imposed a 360 Month Sentence In
Violation of Gall v. United States.**

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

VIII.

**The District Court Erred By Failing To Adequately
Consider Mitigating Facts And Imposed An
Unreasonable Sentence of 360 Months.**

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

STATEMENT OF THE CASE

The prosecution of Christopher Smith and several codefendants for operation of an internet pharmacy began with the execution of more than a dozen federal search warrants in Minnesota and around the country on May 10, 2005. (III, 504-05) Honorable Michael J. Davis, now Chief Judge for the District of Minnesota, issued a preliminary injunction on May 9, 2005, ordering Mr. Smith and his companies to cease operations of the online pharmacy which violated federal fraud statutes. (IV, 579-98)

Christopher Smith relocated to the Dominican Republic following the search warrants and the injunction. (Order in Contempt Case # 05-mc-041 (MJD), April 27, 2007, pp. 7-8) He tried to open a new online business to distribute prescription medication and he withdrew cash from accounts which had been frozen by the prosecution. (Presentence Report, ¶ 9; Sentencing Evidentiary Hearing, herinafter “Ev. H.” p. 149) When Mr. Smith returned to the United States, he was arrested for contempt and released on bond on July 8, 2005. (PSR ¶ 9)

An Indictment filed on August 23, 2005, charged Mr. Smith and others with the online distribution of pharmaceuticals. (Docket # 105) He was placed first at a halfway house and then in a local jail. (PSR ¶¶ 10-11) Both places he

engaged in prohibited conduct to attempt to start a new online pharmacy. (PSR ¶¶ 11-18)

While in county jail, Mr. Smith carefully avoided monitoring of his telephone communications and arranged for transfer of cash in violation of the injunction. (PSR ¶¶ 12-18) He also had conversations with an associate in the Philippines regarding the danger a specific witness posed and how much better it would be if she did not testify: the district court interpreted these comments as attempting to hire the murder of the witness. (PSR ¶¶ 20-21; Statement of Reasons for Imposing Sentence, p. 22) Mr. Smith was transferred to a maximum security facility.¹

On September 19, 2006, a Third Superceding Indictment was filed. Mr. Smith was charged with:

Count 1: Conspiracy to Distribute and Dispense Controlled Substances in violation of 21 U.S.C. § 846, 841(b)(1)(D) and (a)(1), and 21 C.F.R. § 1306.04

¹ Mr. Smith was charged in a separate criminal case, # 06-CR-097 (MJD) with obstruction of justice and witness tampering. That case was later dismissed, although the conduct was used to enhance the sentence in the instant case. Mr. Smith disputed having any genuine intent to harm the witness and dismissed the conversations as isolated flights of fancy. (I, 12-13; Sent. Ev. Hearing, pp. 156-58)

Counts 2-4: Aiding and Abetting Unlawful Distribution and Dispensing of Controlled Substances in violation of the above statutes and 18 U.S.C. § 2

Counts 5-7: Aiding and Abetting 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

Count 8: Conspiracy to Commit Money Laundering in violation of 18 U.S.C. § 1956(h)

Count 9: Continuing Criminal Enterprise in violation of 21 U.S.C. § 848(a) and (c)

Trial began October 10, 2006, and lasted until November 22, 2006. The essence of Mr. Smith's defense was that his business was not prohibited by the patchwork of laws governing internet pharmacies. The jury returned guilty verdicts on all counts as to Mr. Smith and not guilty verdicts as to the other defendants who proceeded to trial. Many legal issues arose during the course of the trial; those relevant to the instant appeal will be discussed in the argument sections below.

On July 31 and August 1, 2007, the district court held proceedings related to the sentencing of Mr. Smith. Predictably, the application of the sentencing guidelines was complex in this case. Ultimately, the district court applied the fraud guidelines to the misbranded drugs counts of conviction, 5-7. These guidelines, found at § 2B1.1, began with base offense level 6 and increased 22

levels for “loss value” pursuant to § 2B1.1(b)(1)(L) because the district court adopted the entire gross receipts of the business as loss, \$24 million. (PSR ¶ 89) Many other enhancements applied, including sophisticated means, obstruction of justice, and violating an injunction. (PSR ¶¶ 91-93, 95-96)

Ironically, the misbranded drugs counts, with their statutory maximum of three years on each count for a total of nine years, resulted in the highest guideline calculation of all the counts of conviction, with a final offense level of 42. [The resulting guideline range was 360-life. The Continuing Criminal Enterprise count carried only a level 40, and a mandatory minimum of 20 years. (PSR ¶ 109) The controlled substances counts and the money laundering convictions faced levels 30 and 32 respectively. (PSR ¶¶ 87 & 103)

Mr. Smith challenged the guidelines calculations and the propriety of a sentence within the range, and fought for a variance to 20 years. Judge Davis, expressing his belief that he was unable to vary, decline to depart and sentenced Mr. Smith to 30 years in prison. This appeal followed.

STATEMENT OF FACTS

Online Payment Solutions: A New Model

In 2004, Christopher Smith and several associates began operating an internet business designed to connect customers from around the country with a doctor who could prescribe needed medications and pharmacies who could fill that prescription by mail. (VI, 1008) ² While in the earliest days of the internet operation, some non-controlled substances were imported from overseas (VI, 993-1002; VII, 1335-336), quickly Mr. Smith and his associates began to use “brick and mortar” pharmacies to fill customer’s prescriptions. (III, 506; IV, 591; VI, 1008) Mr. Smith’s business employed several names during its operation, including Xpress Pharmacy Direct and Online Payment Solutions (OPS).³

OPS customers ordered prescription medication in two ways. First, Mr. Smith operated telemarketing centers, with a primary headquarters in Burnsville, Minnesota and secondary call centers overseas. Operators accepting orders by phone completed forms that included a person’s medical conditions, current

²The trial transcript will be cited by volume and page number as (VI, 1008).

³ For clarity throughout this brief, Mr. Smith will refer to the business as “OPS.”

medications, allergies and other information.⁴ (IV, 629) Customers also ordered prescriptions online, using an internet model designed by Mr. Smith and his computer systems professional, Bernie Hollis. (VI, 1008-10) During the process of ordering on-line, customers submitted substantial information, including the reason they needed medications being sought, the name and contact information for their primary care doctor, whether they had any allergies to medication and their age. (III, 45; XII, 1803; VI, 1013; Appendix at 44a-74a) The website provided substantial information about side-effects and contraindications for various medications, drug interactions and warnings about drugs which can be addictive or habit forming.

Between January 2004 and May 2005, OPS filled 72,000 prescriptions and grossed approximately \$24,000,000. (XVIII, 2901; VI, 1046) The prescriptions filled included controlled substances such as Vicodin and non-controlled medication such as Cialis and Ambien. (III, 413) The company employed dozens of telemarketers as well as security guards, accountants, supervisors and managers.

Dr. Phillip Mach: The Key to OPS

⁴ A sample of these forms was introduced by Mr. Smith at trial. The first 20 of those forms are in the Appendix at 75a.

When Christopher Smith designed his domestic business, he sought a legitimate doctor to issue valid prescriptions so that he could operate legally, avoiding the legal uncertainty that accompanied drug importation. (VI, 1008) To accomplish this, Mr. Smith needed a doctor with experience prescribing medication on line. Through a consultant named John Guerriero, Mr. Smith met Dr. Phillip Mach, a licensed and board certified medical doctor with a practice in New Jersey. (XII, 1784-85) Dr. Mach's practice employed seven people. (XII, 1785) Before Dr. Mach began working for OPS, he had already issued more than 55,000 on-line prescriptions for other internet pharmacies. (XII, 1858, 1792-95, 1850-51) Dr. Mach believed that online issuance of prescriptions was legal when he first began the practice. (XII, 1852-53) He told the government while cooperating in their case against Christopher Smith that "he wasn't aware at the time that it was illegal," and that he had not seen any legislation banning the practice. (XII, 1855-56)

Dr. Mach issued prescriptions after OPS received the online forms completed either by a telemarketer or by the customer himself. Dr. Mach received a description of the patient's condition, age, allergies, body mass index and other information. (XII, 1803) He was specifically advised by Mr. Guerriero that he could refuse to issue requested prescriptions if appropriate, and he either declined

or approved the prescriptions electronically. (XII, 1806-08, 1887) Often the prescription was then printed or faxed with a facsimile of Dr. Mach's signature. (III, 514) Dr. Mach never asked anyone from OPS to redesign the system generally or to get him additional information about a particular prospective patient or about prospective patients generally. (XII, 1826) He never complained that he needed additional procedures or review in order to issue valid prescriptions.

Once Dr. Mach joined OPS, Mr. Smith believed he was receiving \$6 of the \$7 directed through Mr. Guerriero for each prescription issued and each questionnaire reviewed. (IV, 641-42) During the time period that Dr. Mach personally issued 72,000 prescriptions for OPS, he also issued hundreds of prescriptions daily for an unrelated online pharmacy. (XII, 1860) There was no evidence that Mr. Smith knew Dr. Mach reviewed all of the orders himself; indeed the jury learned that Mr. Guerriero may have falsely represented to Mr. Smith that Dr. Mach's staff of seven assisted the process (XII, 1785, 1891, 1900, 1916)

Dr. Mach ultimately pleaded guilty to distribution of controlled substances in Minnesota and to a separate charge in New Jersey, and also admitted to criminal conduct involving an illegal kickback scheme. (XII, 1781) At trial Dr. Mach testified that he pleaded guilty, claiming that he knew all along that what he was

doing was unlawful.⁵ (XII, 1775-78) Although Dr. Mach testified that he also ran a traditional medical practice in New Jersey personally seeing patients, he admitted that he issued at least 125,000 online prescriptions and the record suggests many more over three years. (XII, 1885)

Dr. Mach originally told the government that he spent one to two minutes reviewing each request for medication for OPS. (XII, 1904) However, he later claimed that it was more cursory, because even one minute per prescription would have allowed little time for any other practice of medicine. (XII, 1904) He also claimed on the stand that he knew that what he was doing was illegal because of the lack of review of patient records and the lack of an exam, but he signed a letter to pharmacies stating that his review of the requests for prescriptions was thorough and lawful. (XII, 1819-25) Dr. Mach also signed a written contract indicating that he possessed a valid doctor-patient relationship with those to whom he issued prescriptions. (XII, 1832)

The Role of the Brick and Mortar Pharmacies

⁵ Even a cursory review of the transcript of Dr Mach's testimony during Mr. Smith's trial reveals that he repeatedly was not only a recalcitrant and self-serving witness, but that he testified at trial inconsistently with the statements he had made to law enforcement during proffer sessions.

After Dr. Mach issued a written online prescription for an OPS customer, that prescription was mailed or transmitted electronically to a traditional pharmacy, which would fill the prescription and federal express it to the customer with the customary literature about dosages, side effects and warnings. (III, 477) OPS worked primarily with four pharmacies, Fallbrook Pharmacy in California, Yociss Pharmacy in Illinois, College Discount Pharmacy in North Carolina and Astoria Pharmacy in Oregon. These pharmacies were staffed by licensed pharmacists and technicians. (III, 506) The pharmacies were paid for the medications, plus an additional fee for each prescription filled.

Designing a Lawful “Internet Pharmacy”

No only did Christopher Smith seek partnership with a licensed medical doctor in operating OPS, but he sought help from other professionals as well. Over the course of OPS’s operation, Mr. Smith received advice and analysis from several attorneys regarding the patchwork of laws and regulations affecting “internet pharmacies” and businesses such as OPS. (XVII, 2757-59; V, 860-61) He and other employees of and counsel for OPS also tracked prosecution of other internet pharmacies, which employed clearly illegal models, gathered information about pending state and federal legislation, and reviewed §1306.04, the central

regulation governing valid prescriptions. (XVIII, 2597-98) Mr. Smith consistently maintained that OPS's Internet business was legal. (XVII, 2760).

Congressional Inaction and the DEA's Campaign

From the very first internet pharmacy, the Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA) struggled to prohibit and prevent online distribution of prescription medication. However, Congress was essentially unwilling to change the existing patchwork of laws which govern these operations. (IV, 605) At the time of Mr. Smith's business, no federal laws existed which expressly prohibited internet pharmacies. (V, 862-63) Likewise, there was no federal requirement that a doctor conduct a face-to-face examination of a patient prior to issuing a prescription. (See, e.g., IX 1592; XIV 3171) While some states had regulations in place which governed pharmacies, those were neither criminal laws nor implicated in the federal prosecution of Mr. Smith. (VII, 1199) Although legislation had been introduced in Congress to place legal requirements on internet pharmacies, such efforts were unsuccessful during the years of OPS's operation and the prosecution of Mr. Smith. (IX, 1592-94) Even after the prosecution of Mr. Smith, at least one employee testified that she felt there were not laws in place plainly prohibiting Internet pharmacies. (V, 862)

Despite the void in legislation and the arguable legality of Internet distribution of pharmaceuticals, the DEA sent a fax notice to pharmacies around the country, including the pharmacies which filled prescriptions written by Dr. Mach for OPS. (Appendix at 36a; IV, 601-03) In that notice, the DEA expressed its interpretation that all internet pharmacies which issued prescriptions without a face-to-face doctor's appointment were breaking the law. The Warning cited to § 1306.04 to support its claim about the legal limitations on Internet pharmacies, even though that provision makes no such mandates. (IV, 603)

In response to this, the pharmacies working with OPS became concerned about the legality of the operation. Daniel Adkins, then legal counsel for OPS, and Dr. Mach both prepared letters for the pharmacies claiming full compliance with the law. (XII, 1819-25; Appendix at 42a.) Some of the contents of the letter, including the claim that OPS had doctors in all 50 states, were untrue.

Unorthodox Operations At OPS

OPS admittedly operated in unusual ways. Mr. Smith himself was at times erratic and excitable. He ordered and received substantial proceeds from OPS in cash rather than check and arranged for large weekly deliveries by Brinks truck. (V, 891-92) Mr. Smith also used aliases, in part to distance himself from his online history as a spammer. (V, 900; IX, 1714)

In addition, OPS had a problem with “returned drugs.” When an OPS customer returned a prescription or was unable to pay for a C.O.D. delivery, those pharmaceuticals sometimes ended up at OPS’s Burnsville office. (III, 536-541) The DEA viewed the presence of returned drugs as a violation of the law because no one at OPS was licensed to handle controlled substances. (III, 537) At one point, a family member embroiled in a feud with Mr. Smith alerted the police to the presence of returned drugs onsite and advised that some drugs were hidden in the ceiling of the offices. (V, 843-852) The drugs were removed before the police arrived. (V, 843-852, 931) Eventually, Mr. Smith redesigned the system so that returned prescriptions were sent to the pharmacies rather than OPS. (VII, 1235)

Investigation of OPS

In February 2005, Agent Ken Kulick of the FDA became involved in an investigation of Xpress Pharmacy Direct, which was already being conducted by the IRS. (III, 415) The object of the early investigation was mail and wire fraud, and an examination of whether OPS customer were receiving their orders. (IV, 592) Agent Kulick engaged in several undercover purchases from the website and over the phone, using aliases and ordering different drugs. (III, 451-53; 454-499) He made three separate purchases of controlled substances, and three of non-controlled prescription drugs. All purchases made by Agent Kulick were filled by

pharmacies based on prescriptions issued by Dr. Mach. These purchases formed the basis of counts 2-7 of the Indictment.

By May 10, 2005, the operations of OPS were shut down by the government through the search warrants and preliminary injunction discussed above.

SUMMARY OF ARGUMENT

Christopher Smith was convicted by a jury of crimes related to the operation of an internet pharmacy, including conspiracy to distribute controlled substances, distribution of controlled substances, dispensing of misbranded drugs, money laundering and continuing criminal enterprise. He was ultimately sentenced to 30 years in prison.

Mr. Smith raises eight arguments on appeal, six challenging his convictions and two challenging his sentence. Mr. Smith argues that, in two separate ways, the district court erroneously instructed the jury regarding the elements of the offenses for which he was being tried. Most importantly, the district court employed a flawed definition of what constitutes a valid prescription, permitting Mr. Smith to be convicted on something less than proof beyond a reasonable doubt that he violated the criminal laws. The court's erroneous instructions also violated the rule of lenity and its requirement that, if a lack of clarity exists in a criminal case, it must be resolved in favor of the defendant. Because the erroneous jury instruction infected every single count of the Indictment and because it was not harmless, reversal is required.

The district court also erred when it admitted evidence in two respects, both of which were severe enough to require a new trial. First, the court allowed a

pharmacist to testify far beyond the bounds of his expertise and to opine about generally accepted medical practice for doctors, an area about which he was simply unqualified. The weakness of this “expert” testimony also resulted in the government failing to meet its burden of proof on an important issue at trial. Second, the court allowed irrelevant and inflammatory testimony about suicide and prostitution to infect the case against Mr. Smith. These errors were severe enough, particularly in light of the weakness of the government’s case, to require reversal.

The sentencing of Mr. Smith was fraught with error as well. First, the district court committed “Gall error” when it determined that it was not permitted to vary downward from the guidelines due to this Court’s erroneous precedent functionally prohibiting such variances. Second, the district court committed procedural errors when it failed to consider important sentencing facts and mitigation that rendered a sentence less of 30 years far greater than necessary to accomplish the statutory goals of sentencing. Remand for resentencing is required.

ARGUMENT

I. The District Court's Erroneous Instructions to the Jury Regarding the Meaning of "Valid Prescription" Misstated the Law and Deprived Christopher Smith of a Fair Trial.

Christopher Smith was charged with distributing prescription drugs, many of which were controlled substances, without a valid prescription. The claimed absence of a valid prescription underlay every count of which Mr. Smith was convicted at trial, from conspiracy and distribution of controlled substances and misbranded drugs to money laundering and continuing criminal enterprise.⁶ However, the district court committed clear and reversible error when it instructed the jury regarding what was required for a prescription to be valid.

The district court, in crafting its jury instruction regarding the meaning of a valid prescription, went well beyond the text of the statutes and the regulation which Mr. Smith was accused of violating, 21 C.F.R. § 1306.04.⁷ Not only did the

⁶ Both the money laundering count and the Continuing Criminal Enterprise count required the jury to find that the distribution of controlled substances which generated the money was unlawful. (Jury Instruction 49-51, 54) Likewise the jury was instructed to use the same definition for "valid prescription" in assessing the misbranded drug counts as for the controlled substances counts. (Jury Instruction 43)

⁷ Throughout this brief, Mr. Smith will refer to this provision simply as "§1306.04."

court ignore the plain language of § 1306.04, but it actually embraced a definition which contradicted that plain language. Moreover, the court's instruction erroneously imported the requirements of medical malpractice into a criminal prosecution, exposing Christopher Smith to criminal liability for a mere civil violation. The effect of the court's flawed jury instructions regarding the central issue in the case was to so prejudice Mr. Smith and deny him a fair trial that reversal of all eight convictions is required.

A. Standard of Review

A district court's instructions to the jury are generally reviewed for abuse of discretion. See e.g., United States v. Walker, 428 F.3d 1165, 1171 (8th Cir. 2005). A reviewing court must consider whether the instructions accurately state the law, and should reverse if the error prejudiced one of the parties. Id. (citing United States v. Milk, 281 F.3d 762, 768 (8th Cir. 2002) and United States v. Whitehead, 176 F.3d 1030, 1037 (8th Cir. 1999)).

In the instant case, not only did the district court abuse its discretion, but the error affected the outcome of the trial and prejudiced Mr. Smith.

B. § 1306.04 and the Erroneous Instruction

The government alleged at trial that the prescriptions issued by Dr. Mach for OPS were invalid, rendering resulting the drug distribution unlawful.

The Indictment referred to § 1306.04 to define what constitutes a valid prescription.

Section 1306.04(a), the part of the regulation relevant to Mr. Smith's prosecution, provides

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.

21 C.F.R. § 1306.04(a).

During the jury charge conferences conducted by the district court, the parties and the judge explored many versions of the instruction regarding § 1306.04 and what constitutes a valid prescription. The defense urged the district court to adopt the plain and clear language of § 1306.04 as the core of its instruction:

[I]t is a violation of Title 18 and Title 21 to distribute or dispense prescript drugs unless it is done pursuant to a valid prescription. What is a valid prescription is defined by 21 C.F.R. § 1306.04. If a prescription is distributed or dispensed not in conformance with 21

C.F.R. 1306.04, you may or also may not find the defendants guilty after consideration of a number of other instructions I will give to you. However, if § 1306.04 was not violated, no crime was committed.

(Defendant’s Supplemental Proposed Jury Instructions, No. 20; XIX, 3314-15;

Appendix at 118a.) The government objected to this instruction, endorsing

instead the importation of terms and definitions from civil law to expand upon §

1306.04. Indeed, when urging the court to reach well beyond the plain language,

the prosecution argued that the meaning of “valid prescription” was “more a

concept for the FDA law than for . . . Title 21 and the C.F.R.” (XIX, 3317)

When addressing the dispute, Mr. Smith asserted, “[t]his regulation and this

statute does not need explanation. 1306.04 is written in plain English. The

government can argue what they think it means.” (XIX, 3328) Mr. Smith and

fellow defendants further argued that the government had failed to offer evidence

regarding the standard of care applicable to doctors sufficient to justify the

requested instruction. (XIX, 3321-29)

The district court ultimately gave a jury instruction very similar to that

requested by the government, importing civil concepts of medical malpractice into

the criminal prosecution of Christopher Smith:

As indicated, the Federal Controlled Substances Act, Title 21, United States Code, Section 841(a)(1), combined with its implementing

regulation found in Title 21, Code of Federal Regulations, Sections 1306.04, make it a crime for any “person” to knowingly or intentionally distribute or dispense controlled substances other than for a legitimate medical purpose and in the usual court of professional practice.

* * * *

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 (sic) by an individual practitioner acting in the usual court 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 court 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.

(Final Jury Instruction Number 30, (Appendix at 119a). Mr. Smith and the other defendants consistently objected. (XIX, 3318-19)⁸

The final two sentences of this instruction created an erroneous, over broad and highly prejudicial definition of conduct which violates § 1306.04.⁹ However,

⁸In addition to raising repeated objections, Mr. Smith reviewed his argument that the instruction was flawed in a motion for a new trial. The court’s Order denying that motion and the motion are found in the appendix at 158a and 150a..

⁹ In addition to instruction 30, the flawed interpretation affected other instructions as well, including 38, 42, 43.

the error did not stop there. As explored below, Instruction 30 was reiterated as proper in response to a question from the jury during deliberations, despite explicit objections by the defense. (XXII, 3701-03) The result of these erroneous instructions was, in essence, a directed verdict of guilt for Mr. Smith.

C. Instruction 30 Was A Misstatement of Law.

The instruction given by the district court constituted a misstatement of the law because it ignored the plain language of the statutes which Mr. Smith was accused of violating and because it erroneously imported language from the paradigm of medical malpractice to impose criminal liability improperly. It also used jury instructions to fill a “gap” in the law which Congress declined to fix.

1. The Plain Language Required No Clarification.

A bedrock principle of statutory interpretation is that a court must begin any legal analysis with the plain language of the law. “The first question in interpreting a statute is ‘whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.’” United States v. Kowal, 527 F.3d 741, 746 (8th Cir. 2008)(quoting Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997)). A court should go beyond the statute’s plain text

only if there exists ambiguity as to that statute's meaning. Id.; see also Staples v. United States, 511 U.S. 600, 605 (1994).

In the present case, the plain language of § 1306.04 speaks for itself and requires no explication. “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 meaning of the sentence is clear: a prescription must be part of the usual course of his, meaning the practitioner's, practice. No interpretation is needed. See United States v. Young, 458 F.3d 998, 1005-07 (9th Cir. 2006)(holding that a district court need not define a statutory term for the jury if its meaning is plain). The district court's first error in instructing the jury, therefore, occurred when it reached beyond the plain language to define an unambiguous term which needed no elucidation.

2. The District Court Read “His” Out of the Law.

The court erred even more plainly when it interpreted § 1306.04 for the jury in a way that read the key term “his” completely out of the statute. It is a bedrock principle of statutory interpretation that a court must not read a statute in such a way as to render superfluous or meaningless any term. See e.g., Colautti v. Franklin, 439 U.S. 379, 392 (1979)(declining to embrace interpretation which

renders term in a statute meaningless); United States v. Menasche, 348 U.S. 528, 538-39 (1955).

The district court's instructions to the jury completely deleted the term "his" from § 1306.04, and thereby changed the meaning of the law entirely. Even a cursory examination of Instruction 30 itself reveals this mistake: when it summarizes § 1306.04 in the first paragraph of the statute, the instruction restates the regulatory language incorrectly by eliminating "his" from the term "usual course of his professional practice." The court then repeats that misstatement three separate times during the single jury instruction.

The court's excising of "his" from the law continues when it defines "usual course of professional practice" as requiring that a practitioner act in accordance with a generally accepted standard of medical practice. While "his" professional practice clearly requires a somewhat subjective examination of whether a prescription was issued in the course of the doctor's own practice, the district court's articulation eliminates such analysis and allows a person to be criminally convicted for nothing more than medical malpractice. Such a reading is contrary to the plain language of § 1306.04.

3. The Importation Of Malpractice Standards was Error.

In addition to adopting an erroneous interpretation of § 1306.04 which contravened basic rules of statutory interpretation and the law's plain language, the district court's jury instruction improperly imported concepts from civil law and medical malpractice to permit Mr. Smith to be convicted of a criminal charge on less than proof beyond a reasonable doubt. First, it is undisputed that the language in the contested jury instruction derives from sources outside of the criminal law. (XIX, 3317) By importing such language, the instruction permitted Christopher Smith to be convicted of criminal violations and sent to prison on nothing more than a finding that he violated commonly accepted standards of care in the medical profession.

In United States v. Christo, 614 F.2d 486 (5th Cir. 1980), the court of appeals considered a case where the district court employed a civil statute to define concepts in a criminal statute in its instructions to the jury. In essence, the Christo trial court instructed the jury that the defendant's violation of civil banking laws could constitute criminal misapplication of funds, despite the fact that the criminal statute at issue did not expressly or implicitly incorporate the civil provision at issue. Id. at 489-93. The Fifth Circuit reversed Mr. Christo's conviction, because the faulty jury instruction made it possible he was serving a

prison sentence for merely violating a civil bankruptcy rule. The appeals court described the prosecution and the jury instructions as an “attempt to bootstrap” regulatory missteps into criminal felonies. Id. at 492. “[O]ne questions whether Christo was found guilty of willful misapplication with intent to injure and defraud the bank, or whether he was given eighteen concurrent 5-year sentences and fined \$90,000 for overdrafting his checking account.” Id.

The same error which required reversal in Christo occurred in Mr. Smith’s case. When the district court adopted the government’s proffered jury instruction and defined terms from § 1306.04 by relying on standards of generally accepted medical care, it created the strong possibility that Mr. Smith would be convicted even if the jury found he did nothing more than encourage medical malpractice, conduct which is plainly not covered by the statutes at issue.

The Ninth Circuit, in a case presenting issues similar to those raised by Mr. Smith, explicitly criticized a jury instruction which imported concepts of civil regulation and medical malpractice into interpretation of § 1306.04. See United States v. Boettjer, 569 F.2d 1078, 1080 (9th Cir. 1978). The appellant urged the appeals court to reverse his convictions on the ground that the district court’s instructions to the jury permitted a criminal conviction on a showing of nothing more than the practice of “bad medicine.” Id. at 1080. The specific language

complained of by Mr. Boettjer invited conviction if the defendant's dispensing of controlled substances occurred "other than...in accordance with the medical standards generally recognized and accepted in the medical profession." Id.

The Ninth Circuit expressly agreed that this was a flaw in the district court's jury instructions.

"[Appellant's] interpretation, if arrived at by a sufficient number of jurors, would theoretically permit a conviction where a practitioner had merely fallen below the standards 'generally recognized and accepted in the medical profession,' i.e., merely upon a showing of malpractice. Such a result would clearly be contrary to the letter and spirit of the statute."

Id. At 1082. Although the court found the error harmless in light of other facts of Mr. Boettjer's case, it noted being "unsure how the phrase 'in accordance with medical standards generally recognized and accepted in the medical profession,' which presumably had its genesis in medical malpractice cases, found its way into charges under the Controlled Substance Act." Id. at 1081.

A recent case from the Fourth Circuit implicitly agrees not only with Boettjer and Christo, but with Mr. Smith regarding the error of the instruction given in this case. As the Fourth Circuit recently warned, "[t]he potential for juries to confuse the civil standard of care applied in medical malpractice cases and the criminal standard of proof applied in § 841 (a)(1) prosecutions requires courts to exercise care in setting out the governing standard in the latter

circumstance.” United States v. McIver, 470 F.3d 550, 558 (4th Cir. 2006). Such care was plainly missing in the instant case where the district court instructed the jury to disregard the plain language of the statute.

As it did below, the government will undoubtedly point this Court to three decisions which it claims supported jury instruction 30. United States v. Fuchs, United States v. Nelson, and United States v. Moore. However, upon closer examination, none supports the jury instruction given at Mr. Smith’s trial, and none addresses the argument raised by Mr. Smith below or in the instant appeal.

In United States v. Nelson, 383 F.3d 1227 (10th Cir. 2004), the reviewing court did not consider the argument raised by Mr. Smith, that the plain language of § 1306.04 requires consideration of “**his** professional practice” rather than broad standards of quality control in the medical industry. Instead, the argument raised was whether the jury could convict if it found that the drugs were issued “outside the usual course of medical practice,” **or** “without legitimate medical purpose,” rather than being required to find that both were true. Id. At no point did the Nelson court consider the role the word “his” plays in the plain language of the statute.

Moreover, the defendant in Nelson was himself a medical doctor, and therefore familiar with and indeed responsible for insuring that “his” professional

practice was legitimate when he issued prescriptions. In contrast, while it might be proper to apply the objective standard which went uncontested in Nelson to Dr. Mach, it is improper to adopt a requirement of understanding general standards of medical care to a non-physician who oversees an internet pharmacy. This important point of distinction finds support in United States v. Vamos, a case actually relied upon by the government below. 797 F.2d 1146, 1153-54 (2nd Cir. 1986). In Vamos, the reviewing court considered the conviction of a nurse for joining a conspiracy to distribute controlled substances with her boss, a medical doctor. The Vamos court first explained why it was appropriate to apply an objective standard of “professional practice” to a doctor licensed to issue prescriptions under the Controlled Substances Act.

In view of the special responsibilities assumed by a practitioner registered under the C.S.A. we believe that, although not mandated, an instruction that the jury should use an objective standard of reasonableness in determining whether a practitioner acted in accord with what he believed to be proper medical practice is not improper and does not amount to error. . . . 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, as distinguished from the lesser burden assumed in a civil malpractice suit.

Id. at 1153. The court's discussion made clear that the doctor's professional training, privileges and responsibilities justified the application of an objective standard.

The Vamos court then turned to the appropriate standard to apply to a nurse. The court found that although the standard to which she was held could not be as high as that of a physician, she was a nurse, and had some knowledge and responsibility. Id. at 1153-54. Christopher Smith, in contrast, is neither a doctor nor a nurse, but a layperson in the medical field. He relied on an experienced doctor with a staff of seven to issue valid prescriptions. Any justification offered by the Nelson, Moore, and Vamos courts for applying a standard of objective care rather than the plain language of § 1306.04 is missing in his case.

The Supreme Court's decision from United States v. Moore, 423 U.S. 122, 124 (1975), is similarly unpersuasive in the instant case. In Moore the Court considered a doctor who prescribed methadone in substantial quantities with little limitation. The doctor argued, among other things, that his approach to dispensing methadone was in support of a new theory of treatment of addicts. Id. at 143. In determining that Dr. Moore's conduct exceeded the scope of his professional practice, the Court relied upon a specific statutory provision which sets forth rules for prescriptions for treatment of narcotic addiction. Id. at 144-45.

Although Moore certainly supports a suggestion that some consideration of generally accepted medical practice is proper in considering a medical doctor's refusal to follow a statute of which he was aware, it does not stand for the greater proposition that an objective assessment of the quality of a doctor's medical practice can form the basis of criminal prosecution for a non-doctor.

While United States v. Fuchs, 467 F.3d 889 (5th Cir. 2006), is more factually similar to Mr. Smith's case than either Moore or Nelson, it is nonetheless inapposite to Mr. Smith's argument and does not support rejection of the plain reading of § 1306.04. The primary issue raised in Fuchs, is precisely that raised in Nelson, namely whether the relevant language was disjunctive requiring proof of either a lack of compliance with professional practice OR lack of a legitimate medical purpose. No mention was ever made that the plain language of § 1306.04, with its reference to "his professional practice," was significant. Second, the question in Fuchs was whether the jury instruction which only mentioned that the government had to show that the prescription was not issued in the usual course of professional practice was not "plain error," because it had not been objected to. The Fuchs court stated, "[u]nder current law, a medical professional can be prosecuted under § 841 when [his] activities fall outside the usual course of professional practice." Id. at 901. The court found, not that the

jury instructions were necessarily correct, but that no “clearly established law in the Fifth Circuit” rendered them plainly erroneous.

The government has not cited to a single case exploring the plain language of § 1306.04, and whether it requires the jury instructions urged by the defendants in this case rather than the one adopted by the district court. While Nelson, Fuchs, and Moore each affirmed convictions in cases of varying degrees of similarity to Mr. Smith’s case, none address the argument raised herein, and none plainly support the government’s position.

4. A Jury Instruction Cannot “Fix” Congressional Inaction

The error in the district court’s jury instruction becomes more clear in light of even a cursory examination of the legislative landscape surrounding internet pharmacies at the time of both the operation of OPS and the trial of Mr. Smith.

By seeking a jury instruction which disregarded the plain language of § 1306.04, the government used the district court to accomplish a change in the law that Congress had, consistently declined to do. As the testimony at trial established, the “Online Pharmacy Consumer Protection Act of 2006” was then pending before Congress. (IX, 1592; Appendix at 104a) A copy of the not-yet-passed legislation was introduced into evidence for review by the jury. (IX, 1589) That Act, in addition to defining a bona fide doctor patient relationship, also

sought to amend § 1306.04 to remove “his” from “the usual course of his professional practice.” (IX, 1593-94)

Indeed at trial, Mr. Smith’s counsel elicited testimony from several witnesses regarding the ongoing efforts of the Justice Department to change the existing law and correct its loopholes, and the continuing inaction by Congress. (See, e.g., IX, 1592; S. 980, the “Ryan Haight Online Pharmacy Consumer Protection Act of 2008.) Even the government’s own expert on pharmacy, Mr. Carmen Catizone, testified to the house that a regulatory loophole existed in the laws governing doctor-patient relationships. (XIX, 3171; Appendix at 96a)

The Supreme Court recently warned of the limitation on the power of the Attorney General to functionally create law in this arena. In Gonzales v. Oregon, 546 U.S. 243, 263-65 (2006), the Court considered the Attorney General’s efforts to deem the prescription of life-ending drugs outside the bounds of professional medical practice through the use of an interpretive rule. The Court warned that the Attorney General did not have the power to decide what the law says in the arena of valid prescriptions and § 1306.04. Id. at 261-62. The Court reminded that while the Attorney General can make a determination of compliance with the law in deciding whom to prosecute, it is not up to him to decide what medical practice is consistent with the law.

The Oregon case is plainly instructive in reminding that the Attorney General, which ultimately oversaw the prosecution of Mr. Smith, cannot attempt to criminalize conduct which Congress has not forbidden. It cannot be that the government, in a criminal prosecution, can use jury instructions to fill “gaps” or expand statutory language which Congress has declined to “fix” itself. Yet that is precisely the result which occurred in Mr. Smith’s case.

D. The Erroneous Instruction Caused Severe Prejudice

Admittedly, even though the error in the district court’s jury instructions is undeniable, Mr. Smith must also show prejudice and unfairness in order to secure a reversal of his convictions. The record of prejudice in this case is abundant.

First, Mr. Smith’s entire defense was that his conduct did not violate the plain language of § 1306.04. (See, e.g., IV, 566) The text of § 1306.04 was known to Mr. Smith, and his associates and his counsel during the months of the internet pharmacy’s operations. (XIII, 2044; 2159-65; XX, 3383). Mr. Smith’s theory of defense instruction stated that “he believed that all the drugs dispensed were lawfully dispensed pursuant to valid prescriptions issued within the usual course of Dr. Mach’s practice and therefore Mr. Smith did not have the required intent to commit a crime.” (XXII, 3677)

Mr. Smith elicited testimony from Dr. Mach and others to establish that indeed the internet prescriptions he issued for OPS were precisely within the bounds of his professional practice because Dr. Mach was, more than anything else, an internet doctor. Dr. Mach had already issued more than 50,000 online prescriptions before he ever began to work with Mr. Smith, and continued to issue hundreds or thousands of prescriptions for other companies during the very time he was working with OPS. Although he and the government attempted to characterize this part of his practice as an embarrassing little habit on the edge of a traditional doctor's office, the record belied that claim. The jury should have been required to decide whether the prescriptions issued were done in the course of Dr. Mach's own professional practice, not whether they satisfied unclear standards of generally accepted medical practice.

Furthermore, Mr. Smith's counsel examined witnesses about the language of the regulations. Agent Kulick, for instance, conceded that the "whole theory" of prosecution was based on violation of § 1306.04. (III, 600-01) It was conceded by government witnesses that the Department of Justice tried to get legislation from Congress to correct the perceived "loopholes" in § 1306.04, but that Congress had thus far failed to pass any new laws or alter the existing ones. (IX, 1592) Mr. Smith's opening and closing arguments emphasized the plain and

unambiguous language of § 1306.04, urging the jury to find that his conduct was lawful under that text. For instance, in closing argument counsel for Mr. Smith stated: “What is our position? Simple. The law has not made the conduct criminal.” (XXI, 3565) When the district court, at the end of the trial, radically altered the legal landscape by expanding upon and misreading § 1306.04 in its instructions to the jury, the result was very close to a directed verdict.

This Court does not need to guess at or speculate regarding whether the erroneous jury instruction caused prejudice. The record itself demonstrates the effect of the instruction. After closing arguments and lengthy jury instructions, the jury began its deliberations. Three hours later, the jury sent a question to the Court:

Clarification: In jury ins. 30: starting with my * it seems to expand on 1306.04. Should we use jury ins. 30 to expand on 1306.04 or not? It seems to define “usual course of professional practice.” Can we use this to interpret the law or just use the exact words in 1306.04? ¹⁰

(XXII, 3700-01; Appendix at 124a). The district court sought input from the parties regarding how to answer the question. Counsel for the defendants

¹⁰ The * began at this point of Jury Instruction No. 30: “‘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.” (Jury Question #1, Attachment.)

renewed their objections to the final two sentences of Jury Instruction No. 30, stating that “we believe the law doesn’t need an interpretation. It is what it says it is. . . .” (XXII, 3703.) They asked for the court to simply reiterate the plain language of § 1306.04. The defendants also renewed their earlier request for an instruction on the rule of lenity. (XXII, 3701-02.)

These objections and requests of the defense were denied. The district court responded to the jury’s question as follows:

Members of the Jury, as you know, I have told you many times during the course of the trial and at the end of the trial that the instructions that I give you is the law of this case and Jury Instruction No. 30 defines several terms for your consideration, including the definition of “usual course of professional practice.

(XXII, 3704)

It almost goes without saying that this question evidences the contradiction between the plain language of the regulation at issue and the court’s flawed instruction. Moreover, it demonstrates that the contradiction was of critical importance to the jury: it was confused as to which law to apply and was unable to proceed without clarification. The court’s response, rather than correctly

answering the question, again ordered the jury to substitute the court's analysis, imported from medical malpractice, for an otherwise unambiguous statute.¹¹

In sum, not only was the contested instruction erroneous, but it undermined the government's burden of proof and invited conviction of Chris Smith for facilitating medical malpractice rather than for distributing drugs without a valid prescription. The harm caused by this error is evident throughout the record, as the plain language of the law was central to Mr. Smith's defense. Reversal is required.

II. The Rule of Lenity Requires Reversal of Christopher Smith's Convictions Because § 1306.04 Should Have Been Interpreted in Favor of the Defendants At Trial.

Mr. Smith urges that § 1306.04 has a clear meaning and required no explanation from the district court during jury instructions, certainly not an explanation which contradicted that plain meaning. However, to the extent there was any ambiguity whatsoever regarding the meaning of § 1306.04, it should have been resolved in favor of Mr. Smith. Indeed, at trial, Mr. Smith and counsel for

¹¹ There is further evidence that Jury Instruction No. 30 deeply influenced the jurors' decision from local media report on the verdict. "Jurors said they struggled to reach a verdict. Several said they believed the federal prescription drug law contains a loophole when it comes to Internet pharmacies providing prescriptions without a doctor's visit." Shannon Prather, "Jury Finds Net Pharmacy Kingpin Guilty," St. Paul Pioneer Press, Nov. 23, 2006, at 1.A.

his codefendants urged that the rule of lenity required the court to instruct the jury in the manner Mr. Smith advocated and further sought to have the jury specifically instructed on the concept of the rule of lenity. (XX, 3399; XXII, 3700-03) At every turn, however, the district court rejected both an instruction based upon the plain language of the regulation and any application of the rule of lenity. The court's instructions violated the rule of lenity and reversal is required.

A. Standard of Review

The rule of lenity is one of statutory interpretation and its application presents a legal question. Therefore de novo review by this Court of the lower court's interpretation of the statute is required. See e.g. United States v. Brummels, 15 F.3d 769, 771 (8th Cir. 1994)(applying de novo standard of review of statutory interpretation); see also United States v. Kowal, 527 F.3d 741 (8th Cir. 2008)(implicitly applying de novo review to rule of lenity argument).

B. The Rule Of Lenity: An Important Protection

The rule of lenity is a classic cannon of statutory interpretation in the arena of criminal law. In the Supreme Court's seminal rule-of-lenity decision, United States v. Wiltberger, 5 Wheat. 76, 5 L. Ed. 37 (1820), penned almost two centuries ago, Chief Justice Marhsall "rejected the impulse to speculate regarding a dubious congressional intent," in interpreting a criminal statute. United States v.

Santos, ___ U.S. ___, 128 S. Ct. 2020, 2026 (2008)(discussing Wiltberger).

“[P]robability is not a guide which a court, in construing a penal statute, can safely take.” Justice Holmes reiterated this concept a century later in McBoyle v. United States, when he spoke of the requirement of “fair warning” and said it requires “language that the common world will understand, of what the law intends to do if a certain line is passed. To make the warning fair, so far as possible, the line should be clear.” McBoyle, 283 U.S. 25, 27 (1931). Justice Frankfurter employed the now well-known term of lenity in Bell v. United States, 349 U.S. 81, 83 (1955). “When Congress leaves to the Judiciary the task of imputing to Congress an undeclared will, the ambiguity should be resolved in favor of lenity.”

Far from an archaic cannon which is rarely dusted off, the rule of lenity continues to operate today, not only to interpret statutes but to preserve due process in criminal cases. Just last term, the Court embraced the rule of lenity, as well as other methods of statutory interpretation, to affirm the vacation of criminal convictions for money laundering. See United States v. Santos, ___ U.S. ___, 128 S. Ct. 2020 (2008). The Santos Court, was faced with determining whether the term “proceeds” in the money laundering statute, means “receipts,” a broader term advocated by the government, or “profits,” a narrower term favorable to criminal defendants.

From the face of the statute, there is not more reason to think that “proceeds” means “receipts” than there is to think that “proceeds” means “profits.” Under a long line of our decisions, the tie must go to the defendant. The rule of lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them.

Santos, __ U.S. __, 128 S. Ct. at 2025 (plurality opinion). The Court went on to describe the reasoning behind the rule of lenity: “This venerable rule not only vindicates the fundamental principle that no citizen should be held accountable for a violation of a statute whose commands are uncertain, or subjected to punishment that is not clearly prescribed. It also places the weight of inertia upon the party that can best induce Congress to speak more clearly and keeps courts from making criminal law in Congress’s stead.” Id. The Santos Court then applied the rule and defined “proceeds” as “profits” in favor of defendants.

Even a cursory review of recent case law reveals numerous instances in which sentences or convictions have been reversed or cases dismissed pursuant to the rule of lenity. For instance, in United States v. Godin, 534 F.3d 51 (1st Cir. 2008), the Court of Appeals reversed a conviction because the district court had erroneously instructed the jury regarding the meaning of an ambiguous term. The court found that the statute contained a serious ambiguity which, pursuant to the

rule of lenity, should have been interpreted in favor of the accused. Id.¹² Similarly, in United States v. Ramos, ___ F.3d ___, 2008 WL 2875791 (5th Cir. 2008), the Fifth Circuit determined not only that the term at issue plainly carried the meaning the defendants advocated rather than that proffered by the government, but it further stated that even if the meaning were less clear, it would reach the same result by following the rule of lenity. Expressing that the rule of lenity provided an independent basis upon which to vacate the convictions, the court stated “we resolve ambiguity in criminal statutes by construing such statutes narrowly.” Id. at *20 (citations omitted).

In United States v. Madera, 528 F.3d 852, 859 (11th Cir. 2008), the court considered the retroactive application of SORNA, the Sex Offender Registration and Notification Act. The court found that the rule of lenity required it to settle a question in favor of the defense regarding conduct which occurred in the gap between the law’s initial enactment and the Attorney General’s later decision to apply it retroactively in favor of the defendant. Id. See also United States v.

¹² Mr. Smith acknowledges that this Court has reached a different decision regarding the existence of ambiguity in the statute interpreted by the Godin court. See United States v. Mendoza-Gonzalez, 520 F.3d 912, 915 (8th Cir. 2008). However, the Godin decision is important in the instant case not because of the specific statute being considered, but because the court found that the rule of lenity could require reversal following erroneous jury instructions regarding an ambiguous term in a criminal statute.

Lanier, 520 U.S. 259 (1997)(“[T]he canon of strict construction of criminal statutes, or rule of lenity, ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered.”)

In sum, the rule of lenity is not only a core principle of statutory interpretation, but it is essential to due process and fairness in the criminal arena.

C. Rule of Lenity Requires Reversal In This Case

As explored in argument I, supra, it has been the position of Mr. Smith throughout his prosecution that § 1306.04 has a plain meaning which was ignored in favor of a contradictory and erroneous interpretation derived from civil law. Mr. Smith urges that no explanation of the statutory language was required. However, if there were any ambiguity justifying explanation of terms for the jury, the district court should have embraced a reading which resolved that ambiguity in favor of the defendant rather than the prosecution. In this case, the district court failed to do so and the convictions must be reversed.

Although the disagreements between the parties about the jury instructions regarding what constitutes a “valid prescription” went beyond a single word, at the heart the dispute involved the meaning of “issued in the course of **his** professional practice.” Mr. Smith urged that this language had a plain and obvious meaning which required reference to the actual professional practice of the doctor in

question rather than a general standard of medical professionalism. However, to the extent the district court found there was a question regarding the meaning, it committed clear and reversible error when it allowed the prosecution to borrow from concepts of civil regulation of the practice of medicine to find a definition. Clearly, the interpretation ultimately embraced criminalizes a far wider range of behavior and renders invalid many more prescriptions than the plain language of § 1306.04 and the interpretation offered by the defense. While such judicial expansion of terms might be permitted in a civil regulatory context, it is simply not allowed in a criminal prosecution.

As explored above, the error was not harmless or isolated. Indeed not only did the entire defense put forth by Mr. Smith rely on the plain language of § 1306.04, but the jury itself quickly recognized the plain contradiction of the expansive definition adopted by the court and the more narrow one advocated by the defense and found in the plain language. In this case, if Congress and the FDA permitted uncertainty to remain in the definition of a valid prescription, that lack of clarity must be resolved in favor of Mr. Smith and reversal is required. See Santos, ___ U.S. ___, 128 S. Ct. at 2026 (“... the ambiguity should be resolved in favor of lenity.”)

III. The District Court’s Jury Instructions Regarding “Misbranded Drugs” Were Erroneous and Violated the Rule of Lenity.

The district court instructed the jury that it could find Mr. Smith guilty of counts 5-7, distribution of misbranded drugs in violation of 21 U.S.C. § 331(a) and 353(b) even the drugs were dispensed pursuant to a prescription, if it found that the prescription was not valid. (Jury instructions 42 & 43) The district court then referred the jury to the same flawed definition of what constitutes a valid prescription discussed above. Mr. Smith argues that not only was the definition of valid prescription erroneous, but the court erred when it instructed the jury that a prescription had to be valid to avoid a charge of misbranding. In fact, the plain language of the relevant statutes provides only that a prescription must exist, but contains no requirement of validity. Mr. Smith argues that the instruction was erroneous on its face, and further that the rule of lenity was violated.

A. Relevant Legal Standards and Standards of Review

The relevant standards of review for consideration of flawed jury instructions and for assessment of a claim under the rule of lenity are set forth in sections I and II, supra. This error was objected to by Mr. Smith during the charge conferences at trial, and therefore has been preserved for review. (XIX ,3332-33; XX, 3358-60)

B. Jury Instructions 42 and 43 Were Erroneous

As in any case, an examination of the jury instructions must begin with the plain language of the statute being presented to the jury. In the instant case, several provisions of Title 21 of the United States Code were cited by the government in the Indictment and explored during the charge conference.

Title 21 U.S.C. § 331(a), in relevant part, prohibits the “introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” Section 353(b) provides that a prescription drug:

shall be dispensed only (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.

Nowhere in these or other relevant statutes is there a requirement that the prescription be “valid” or in any specific way comply with a generally accepted standard of medical care.

At trial, the government argued that implicit in the requirement that medications be dispensed pursuant to a prescription is a mandate that the prescription be bona fide, namely that it be issued in compliance with an accepted standard of medical care. (XIX, 3332-33) However, unlike the controlled substances counts which directly refer to § 1306.04, there is no mandate anywhere in the statutes which prohibit misbranding that the prescription be valid. The government instead pointed to caselaw to support its claim that only a valid prescription could preclude a finding of misbranding, citing Webb v. United States, 249 U.S. 96 (1919), United States v. Nazir, 211 F.Supp.2d 1372 (5th Cir. 2002), and White v. United States, 399 F.2d 813 (8th Cir. 1968).

Mr. Smith urges this Court to find that the instruction was flawed for two reasons. First, each case relied upon by the government and the district court to attempt to import a requirement of a bona fide prescription is distinguishable in critical ways from Mr. Smith's case. The Nazir case involved a doctor who issued prescriptions for drugs which had never been approved by the FDA, in the names of patients who had never ordered them, and then repackaged the drugs with different labels and distributed them to others. Nazir, 211 F. Supp. 2d. at 1374. In contrast, Mr. Smith here relied upon a doctor to review records and issue prescriptions for patients, dispensing precisely the drugs they ordered. While

Nazir represents a classic case of misbranding, Mr. Smith's conduct simply does not.

Both Webb and White are distinguishable as well. Both interpret, not 21 U.S.C. § 353(b)'s requirement that a prescription exist, but other statutory provisions. In White the court considered a statute that placed limitations on dispensing of stimulants and depressants, §§ 331 and 360 of title 21. Id. at 815. While those statutes may have been the antecedents of the statutes at issue in Mr. Smith's case, they contained different language and an express requirement that the subscriber be acting in the "ordinary and authorized course of his business. . . ." Id. Likewise, in Webb, which is almost 90 years old, the Court considered a case in which the prescriptions at issue were not for a patient, but were used to stockpile morphine, which was then issued to persons "with no order blank," the early term for prescription. Webb, 249 U.S. at 98. The statute being interpreted bore no similarity, except perhaps of subject matter, to the statutes at issue in the prosecution of Mr. Smith.

The error is made more obvious by realizing that the statutes which Mr. Smith was alleged to have violated indeed had a heartland meaning at issue in the majority of prosecutions, namely the introduction into commerce of adulterated, tampered with or mislabeled drugs. The government sought to substantially

stretch the reach of the statute without mandate from the statute's plain language, and in contravention of the statutes traditional uses, and cited cases that ranged between old and ancient that interpreted other statutes entirely in support of that effort. The district court erred when it accepted the government's invitation and misinstructed the jury.

Second, the rule of lenity is violated by interpreting the cited statutes well beyond their plain language in an effort to criminalize Mr. Smith's conduct. In this case, the testimony establishes that the patients received the very prescription drugs they ordered and that those drugs were dispensed following a prescription issued by Dr. Mach. The statute does not invite consideration of whether Dr. Mach should have issued the prescriptions. Indeed, if Congress intended to include such a consideration into this criminal statute, it could have easily done so. It did not, and therefore the rule of lenity prohibited the district court from doing so through its jury instructions.

As explored above, the error cannot be dismissed as harmless. The evidence showed that a prescription existed for each of the three acts of dispensing misbranded drugs. The government conceded that if no requirement were imposed that the prescriptions be valid, it would lose. (XIX, 3333) The convictions on those counts must be vacated. Moreover, it is noteworthy that the misbranded

drug counts of conviction, under this tortured reading of the statute, actually led to Mr. Smith's placement at offense level 42 of the sentencing guidelines and to his 30 year sentence. The flawed convictions had a substantial impact on his sentence, and must be vacated.

IV. The District Court Erred When It Permitted a Pharmacist to Testify As An Expert Regarding The Standard of Care For Doctors In The Practice Of Medicine.

In advance of Mr. Smith's trial, the government announced its intention to introduce expert testimony through at least one medical doctor regarding the standard of care for doctors to follow in issuing prescriptions. (Government's Trial Brief, Docket No. 312, p. 37) However, at trial it instead examined a pharmacist, Mr. Carmen Catizone, who was neither trained as nor practiced as a medical doctor, regarding the practice of medicine in order to meet its burden of proving that Dr. Mach's practice fell below an objective threshold of quality of care. Mr. Smith objected to any testimony from this person beyond his own area of expertise, pharmacy, but the district court allowed it nonetheless. (XIX, 3138-3140, et. seq.) Mr. Smith urges that this was obvious error and unfairly influenced the outcome of his trial.

A. The Contested Testimony

Mr. Catziona is not a medical doctor, but has a pharmacy degree, a D. Ph. (XIX, 3138, 3163) For more than 20 years prior to his testimony in the Smith trial, Mr. Catizone had served not as a practicing pharmacist but as CEO and executive director of the National Association of Boards of Pharmacy. (XIX, 3110) This organization provides a national licensure examination for pharmacists and maintains a clearinghouse of disciplinary actions taken against pharmacists among other things. Mr. Catizone testified that, as part of his training, he is familiar with laws “pertaining to pharmacies operating on the Internet.” (XIX, 3111) He described himself as an expert in pharmacy laws and practices but not in the medical field; indeed no testimony was offered regarding either qualifications he might have or the basis for any knowledge he might possess regarding standards of care for medical doctors.

At trial, the government called Mr. Catizone for the seeming purpose of testifying about whether the OPS website was legitimate or operated out of the norm of pharmacy. Indeed, many pages of his testimony regarding standard pharmaceutical practices went un-objected to by Mr. Smith and fellow defendants. (XIX, 3100-3138) However, following this, the government elicited testimony from Dr. Catizone regarding his opinions about whether Dr. Mach’s prescriptions were issued in the regular course of medical practice and whether they were the

proper medications for stated medical conditions. (XIX, 3138-3146)¹³ The government next elicited Mr. Catizone’s opinion regarding the law and its meaning, including asking him to interpret § 1306.04 for the jury. (XIX, 3153-3163)

Mr. Smith objected to questioning of Mr. Catizone by the government regarding matters outside of his expertise in pharmacy. Mr. Smith first urged that because he is neither trained as nor an expert in standards of care for medical doctors he should not testify regarding how a medical doctor should issue prescriptions and what prescriptions should issue for various conditions. (XIX, 3138-3139) He then argued that Mr. Catizone should not be invited to testify about the meaning of § 1306.04 and the phrase “his professional practice.” (XIX, 3153-58):

He’s presented pharmaceutical expertise, then he presented medical expertise, and now he’s going to present legal expertise. He’s going to define that which doesn’t need to be defined. There is absolutely no basis for him to tell the jury what in his opinion plain English means. That’s way outside of anybody’s expertise. That is the ultimate jury question and the Government is attempting to take that question away from the jury by the testimony of a person who is not a legal expert, and a legal expert couldn’t do it.

¹³ In the government’s trial brief, Docket No. 312, it only noticed an intention to elicit testimony regarding the practice of pharmacy not medicine. Trial Brief at p. 37.

(XIX, 3153) At every turn, the district court rejected the objections of the defense and admitted the testimony, despite the absence of foundation for Mr. Catizone's expertise.

B. Standard of Review

A district court's decision to admit expert testimony must be reviewed for an abuse of discretion. See e.g., Kumho Tyre Corp. v. Carmichael, 526 U.S. 137, 142 (1999). This Court has reversed district courts for abusing their discretion as gatekeepers by allowing witnesses to testify beyond their expertise. See e.g., Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706 (8th Cir. 2001)(finding district court abused discretion by allowing witness to testify beyond scope of expertise); Weisgram v. Marley Co., 169 F.3d 514, 517-21 (8th Cir. 1999)(finding three instances of abuse of discretion for admission of testimony beyond expertise).

C. The "Expert" Testimony of Dr. Catizone Was Admitted In Error.

The admission of expert testimony is governed, in both criminal and civil cases, by Federal Rule of Evidence 702, which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods,

and (3) the witness has applied the principles and methods reliably to the facts of the case.

FRE 702. A trial judge considering the admissibility of expert testimony has a “gatekeeping responsibility” to “ensur[e] that an expert’s testimony rests on a reliable foundation and is relevant to the task at hand.” Wheeling Pittsburgh Steel Corp. V. Beelman River Terminals, Inc., 254 F.3d 706, 714-15 (8th Cir. 2001)(quoting Kumho Tire Co. Ltd. V. Carmichael, 526 U.S. 137, 141 (1999)).

The trial court’s responsibility is not limited to determining that an expert is qualified; it must also ensure the actual testimony “does not exceed the scope of the expert’s expertise,” which if not done can render expert testimony unreliable under Rule 702, Kumho Tire and related precedents.” Wheeling, 254 F.3d at 715.

Although admissibility of expert testimony rests with the discretion of the trial court, such discretion is not beyond review. In the Wheeling case, this Court reversed and remanded a jury verdict in a civil case in part because the district court erroneously allowed an expert to testify beyond his arena of expertise. Id. The expert in question was a hydrologist specializing in flood risk management and the court expressed ready agreement that he was qualified in that subject. However, the court also found he lacked the education and experience to testify as an expert regarding the related topic of safe warehousing practices for avoiding flood damage. Id. at 715. The Wheeling court found not only that error occurred

but that the error prejudiced Wheeling because the contested testimony regarded “ultimate issues of fact that the jury was required to answer. . . .” Id. at 715. Similarly, in Weisgram v. Marley Co., 169 F.3d 514 (8th Cir. 1999), the court decided the lower court had abused its discretion in allowing three persons to testify beyond the arenas of their expertise. The court found that a fire captain properly testified as an expert in fire investigation, but should not have been permitted to testify beyond his expertise to opine about his own theory for how the fire began. Id. at 519. Likewise, the lower court erred when it allowed a master electrician to testify regarding the cause of the fire in question, and a metallurgist to testify who had not performed experiments to test his theory. Id. The Eighth Circuit described the metallurgist’s opinions as “no more than ‘subjective belief or unsupported speculation.’” Id. at 520 (quoting Daubert v. Merrell Dow Pharm., 509 U.S. 579, 589 (1993)). In the end, the Weisgram court found the testimony of the over-reaching experts had a clear effect on the outcome at the trial and reversed the jury’s verdict. Id. at 522.

In this case, the objected-to testimony of Mr. Catizone was admitted in error and constituted an abuse of discretion. No evidence was offered regarding the

foundation for his opinions about standards of care for medical doctors.¹⁴ Similarly, no evidence was offered of any reviews he had conducted of rules applicable to doctors and their process for issuing prescriptions. There was no discussing of surveys of relevant medical literature, experiments, tests or specialized education. As in Weisgram, the government allowed Mr. Catizone to not only testify far beyond his area of expertise, but also permitted rank speculation based on nothing more than his opinions of what should be considered against the law. Even given proper deference to the district court, Mr. Catizone's testimony should have been limited to his area of professional practice, pharmacy.

D. Substantial Prejudice Occurred

Not only did the district court commit serious error regarding the testimony of Mr. Catizone, but the mistake substantially prejudiced Mr. Smith. First, as explored in sections I and II, supra, the question of the meaning of the plain language of § 1306.04 was not only of enormous importance during Mr. Smith's trial, but was

¹⁴ During the first side bar regarding the scope of Mr. Catizone's testimony, counsel for the government stated "I believe he testified that he's very well versed in regulations, state rules and laws, regulations, federal laws pertaining to standard practice both for pharmacies and for medical practitioners." (XIX, 3138) However, a close review of the transcript of his testimony shows that in fact Mr. Catizone had very specifically explained his experience and expertise as involving pharmacy and pharmacists, and did not discuss medical doctors or any familiarity with laws pertaining to doctors.

arguably the central question for the jury to answer as it determined Mr. Smith's guilt or innocence on every count of the indictment. The government offered no other expert testimony on this issue, relying almost entirely on the unqualified speculation of Mr. Catizone and on the incredible claims of Dr. Mach.

In Weisgram and Wheeling, panels of this Court determined that the erroneous admission of improper expert testimony affected the outcomes of the trials, and reversed both jury verdicts. In Wheeling, the court noted that the expert's improper testimony "went to the primary issue upon which the jury had to make a judgment." Wheeling, 254 F.3d at 715. In Weisgram, the court observed that the erroneous testimony was the only evidence regarding a central issue. Similarly, in this case, Mr. Catizone's testimony exceeded his expertise and addressed the very issues contested by Mr. Smith necessary for conviction: whether an objective standard of care was applicable and whether Mr. Smith's operation met that standard. Reversal is required.

V. Insufficient Evidence Was Presented that the Prescriptions Issued Were Invalid Under Any Interpretation of § 1306.04.

Although Mr. Smith strenuously disputes that the jury should have been instructed to convict him if the prescriptions issued by Dr. Mach violated generally accepted medical practice, he further urges that the government failed to meet its burden of proof even under that erroneous and over-broad definition. At

trial, despite its original intention to do so, the government offered no testimony from any medical doctor or expert on medicine to establish what constituted generally accepted medical practice.¹⁵ Instead, the only evidence offered by the prosecution on this issue, an issue which they were required to prove, was the testimony of the pharmacist Mr. Catizone, described above, and the self-serving testimony of Dr. Mach himself. Mr. Smith urges that this weak evidence failed to meet the government's burden of proof beyond a reasonable doubt, and therefore reversal is required.¹⁶

A. Standard of Review

On an appeal from a jury verdict, the evidence must be viewed in the light most favorable to the government, giving the government the benefit of all reasonable inferences. See United States v. Moe, 536 F.3d 825, 832-33 (8th Cir.

¹⁵ In the government's trial brief it expressed its intention to call a medical doctor.

¹⁶ As with issues I and II, supra, the government's failure to meet its burden of proof regarding generally accepted medical practice is a flaw that infects each and every count of conviction. The controlled substance counts and the misbranding counts both relied upon the same definitions for what constitutes a valid prescription and both imported the concept of generally accepted standard of medical care; the money laundering and continuing criminal enterprise counts all required a finding that the underlying drug distribution was unlawful. Therefore, should the Court agree that the government failed to meet its burden of proof on this issue, every count of conviction must be vacated.

2008); United States v. Termini, 922 F.2d 879, 881 (8th Cir. 1993). A jury verdict will be overturned only if the “evidence is such that a reasonable-minded jury must have entertained a reasonable doubt as to the government’s proof of one of the essential elements of the offense.” Termini, 922 F.2d at 881 (citing United States v. Watson, 952 F.2d 982, 987 (8th Cir. 1991)).

B. A Failure to Prove The Government’s Case

In the instant case, the government called no experts from the medical field to testify regarding the standard of care imposed upon physicians by generally accepted medical practice, and offered no direct proof regarding the burdens placed by the state of Minnesota or almost any other states on physicians prior to issuing prescriptions. Nor did they call a practicing doctor, other than Dr. Mach, to describe what his or her practice looked like with respect to prescriptions. The government simply failed to prove its case.

First, it is noteworthy that Mr. Smith’s case is unique, almost singular, among similar prosecutions in the government’s failure to call a medical doctor to testify about the applicable standard of care. For instance, in United States v. Katz, 445 F.3d 1023,1027, 1031-32 (8th Cir. 2006), the government called as an expert Dr. Paran, a medical doctor who testified regarding “the standard of care to be followed by physicians in treating persons suffering from pain or anxiety.” Dr.

Parran also reviewed the records from the defendant's medical practice, compared them to the standard of care, and opined that the prescriptions in questions were not issued for a legitimate medical purpose. Id. at 1031. Similarly, in United States v. Hurwitz, 459 F.3d 463, 467 (4th Cir. 2006), the government presented multiple expert witnesses regarding whether the defendant's prescription of opioids to addicts was outside the bounds of legitimate medical practice. See also United States v. McIver, 470 F.3d 550 (6th Cir. 2006)(discussing testimony of government's expert.)

In contrast, in the instant case, the government's only evidence regarding the appropriate standard of medical care and whether Mr. Mach's practice met that standard was the unreliable and improper "expert" testimony of "Dr." Catizone, explored above, and the self-serving testimony of Dr. Mach. This testimony is inadequate.

With respect to Mr. Catizone, even if a pharmacist could ever reasonably testify as to the standard of care required of medical doctors, his testimony was inadequate on this point. No foundation was established for his knowledge of the requirements for a medical doctor to issue a valid prescription and no testimony was presented that he had specific knowledge of or experience with the practice of medicine.

The government will likely argue, as it did below, that because § 1306.04 places a corresponding duty on a pharmacist to insure the validity of a prescription prior to its issuance, somehow Mr. Catizone's testimony on this issue gained credibility. However, that argument is unpersuasive. While Mr. Catizone should have been free to testify regarding how a pharmacist can meet his "corresponding duty," it gives him no more expertise or even basic knowledge about how a doctor must perform in meeting her end of the duty. Mere speculation is not enough.

Dr. Mach's testimony is likewise inadequate to meet the government's burden of proof. Admittedly, the testimony of an accomplice can be sufficient to sustain a government's burden of proof in a criminal case if it is "not otherwise incredible or unsubstantial on its face." See United States v. Bounmy, 403 F.3d 1018, 1021 (8th Cir. 2005). Mr. Smith urges that in this case, even that low threshold is not met by the testimony of Dr. Mach regarding generally accepted standards of care.

First, Dr. Mach's testimony was facially incredible because it was apparent that he was repeatedly altering the "truth" to match what he believed the government expected of him. For instance, although Dr. Mach had originally claimed to spend a minute or two with each request for a prescription, he recanted this estimate shortly before trial seemingly because it gave credibility to the

defense that issuing online prescriptions based on cursory review was the very heart and soul of his professional practice.(XII, 1860-62) He fought cross-examination at every turn, refusing to answer a question directly and had to be repeatedly admonished by the court and even threatened with jail in order to cooperate during cross-examination. (XII, 1853, 1863-64, 1904) Even during the course of a single cross-examinations lies were revealed. (XII, 1859) To put it simply, Dr. Mach was too incredible to sustain the government's burden of proof on such a critical issue.

Moreover, Dr. Mach's own professional practice, which he claimed to believe was legal for months or years, was prescribing medications online. (XII, 1903-04) His subsequent claim that it was not consistent with generally accepted medical practice and that he knew all along that it was not was clearly made to maintain his plea agreement and earn acceptance of responsibility. (XII, 1883) With such clear motive to color the truth, the government should not be permitted to rely on his testimony to meet a burden of proof usually satisfied in most cases by expert testimony.

In sum, the government fought hard for an instruction that permitted the jury to convict Mr. Smith if it found that Dr. Mach's practice was negligent, and then it failed to prove that negligence. Reversal is required.

VI. The District Court Erred When it Admitted Irrelevant Evidence of Prostitution and Suicide Which Was So Prejudicial As To Deny Christopher Smith A Fair Trial.

At trial, over the strenuous objections of Christopher Smith, the district court admitted two pieces of evidence which were both utterly irrelevant and highly prejudicial, even inflammatory.¹⁷ First, the district court admitted evidence that Mr. Smith sent a co-conspirator to Prague to investigate, among other things, whether he could bring women to the states to serve as Mr. Smith's "paid girlfriends." Second, the district court admitted evidence that an addict who might have attempted to order drugs from OPS but never received them committed suicide. (VI, 1061-65) Neither incident was probative of any issues before the jury, and both were remarkably prejudicial. Although the district court changed its decision regarding the admissibility of the suicide and ordered the jury to disregard the suicide in reaching its deliberation, that Order was woefully

¹⁷ The two pieces of evidence contested on appeal were by no means the only prejudicial and largely irrelevant evidence introduced at trial. For instance, the government introduced testimony of Mr. Smith's collection of luxury cars, and offered photographs of eight of them. (III, 586; government exhibits 40-47) The jury also heard that Mr. Smith, who was married, flew his girlfriend and her entourage around the country with him. (XV, 2491) Despite the irrelevance of this and other prejudicial evidence which seeped into the trial, Mr. Smith confines his specific challenge to the two most egregious evidentiary flaws.

inadequate to correct to serious unfair prejudice which occurred. No corrective action whatsoever was taken regarding the trip to Prague.

While admittedly evidentiary errors do not often give rise to vacation of convictions on appeal, Mr. Smith urges that the egregious nature of the evidence at issue, combined with the weaknesses in the government's case, require reversal and remand for a new trial.

A. Standard of Review

This Court must review a district court's admission of evidence under an abuse of discretion standard. See e.g., United States v. Johnson, 535 F.3d 892, (8th Cir. 2008); United States v. Abdul-Aziz, 486 F.3d 471, 475 (8th Cir. 2007).

While a trial court is accorded deference in determining the relevancy and admissibility of evidence, United States v. Hollister, 746 F.2d 420, 422 (8th Cir. 1984), its decision must adhere to the limiting provisions under Federal Rules of Evidence §§ 401, 402, and 403. Where the reviewing court finds that "an improper evidentiary ruling affect[ed] the substantial rights of the defendant," it must reverse. United States v. Bamberg, 478 F.3d 934, 938-939 (8th Cir. 2007)(citations omitted).

If the Court finds a trial court abused its discretion in its evidentiary rulings, it must review for harmless error. United States v. Lupino, 301 F.3d 642, 645 (8th

Cir. 2002). If error occurred and cannot be dismissed as harmless, this Court should reverse. United States v. Guerrero-Cortez, 110 F.3d 647, 651 (8th Cir. 1997). “An error is harmless if the reviewing court, after viewing the entire record, determines that no substantial rights of the defendant were affected, and that the error did not influence or had only a very slight influence on the verdict.” United States v. Cortez, 935 F.2d 135, 140 (8th Cir. 1991).

Reversal in this case is appropriate because evidence of the trip to Prague and the suicide were irrelevant and created a serious risk of unfair prejudice against Christopher Smith that substantially outweighed any probative value. The error almost certainly had a large impact on the jury’s verdict and therefore cannot be dismissed as harmless.

B. Relevance and FRE 401

Under the Federal Rules of Evidence, only evidence which is relevant may be admitted at trial. See FRE 402. “Relevant evidence” means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” FRE 401.

To be relevant, proffered evidence must have a “tendency to make the existence of a fact more or less probable than would be the case without the

benefit of the evidence.” See United States v. Hollister, 746 F.2d 420, 422 (8th Cir. 1984)(“Evidence must be probative of a fact of consequence in the matter, and must have a tendency to make the existence of that fact more or less probable than it would have been without the evidence.”) “Relevance is established by any showing, however slight, that makes it more or less likely that the defendant committed the crime in question.” United States v. Casares-Cardenas, 14 F.3d 1283, 1287 (8th Cir. 1994). Admittedly, evidence which is not directly necessary to the government’s proof in a criminal prosecution can be admitted in certain circumstances where it supports less directly the government’s case. See e.g., United States v. Abdul-Aziz, 486 F.3d 471, 475-76 (8th Cir. 2006).

The openness of the relevance standard, however, does not mean that a truly tangential fact offered by the merely curious can be admitted; the scope of relevancy under FRE 401 and 402 admits of several limitations, bounded by the particular offense at issue, by a defense theory, and by the principle of fairness. See United States v. Hollister, 746 F.2d 420, 422 (8th Cir. 1984)(“Although definition of “relevant evidence” given in [§ 401] is broad, it does have limits; evidence must be probative of fact of consequence in matter and must have tendency to make existence of that fact more or less probable than it would have been without evidence.”). These limitations are particularly essential in the arena

of criminal prosecutions, where concerns of due process are at issue. See Williams v. New York, 337 U.S. 241, 247 (1949)(noting that in criminal trials, rules of evidence are fashioned to limit evidence to be “strictly relevant to the particular offense charged.”).

Despite deference afforded a district court in making relevance determinations, this Court has found irrelevant evidence to be erroneously admitted in a number of cases. For example, in United States v. Blue Bird, 372 F.3d 989, 995 (8th Cir. 2004)(overruled on other grounds), a man was prosecuted for statutory rape after having consensual sex with a thirteen year old girl. The reviewing court held that the district court erred when it admitted evidence the girl had been a virgin prior to the encounter, as the government “failed to provide a convincing argument for how any legally relevant inferences could be drawn from her virginity.” Similarly, in United States v. Fleck, 413 F.3d 883, 890 (8th Cir. 2005), the reviewing court found the district court abused its discretion when it allowed testimony regarding Fleck’s involvement in an insurance fraud to enter the prosecution for unlawful possession of a firearm. The court reasoned that because the fraud neither provided context to the offense at issue, nor was it “closely or inextricably intertwined with the charged crime,” it should not have been admitted.

In sum, while a district court enjoys latitude regarding the admissibility of relevant evidence at trial, that latitude is not without limits, particularly in the context of a criminal trial, and evidence which is not relevant should be excluded.

C. The Contested Evidence Was Irrelevant.

In the instant case, the trip to Prague and suicide death of Mr. Londino were flatly irrelevant to the question of whether or not Mr. Smith's Internet pharmacy amounted to a violation of 21 U.S.C. § 841 or to any other charges at issue during trial.

The Trip To Prague

Evidence alleging that Mr. Smith sent his associate, Scott Poe, to Prague to secure paid companionship for Mr. Smith was introduced both by the government and during the cross-examination of Mr. Poe by Earl Gray, counsel for a codefendant. Mr. Gray claimed at side-bar that the evidence was somehow necessary to impeach Mr. Poe, though he did not explain how the evidence was relevant to honesty or veracity in any way. (XV, 2462; XVII, 2591) Over strenuous objection by Mr. Smith, the questions were permitted. (XV, 2432; XVII, 2591) Mr. Poe was permitted to testify that Mr. Smith had hatched the plan for importing women (XVII, 2598) and that he looked for "girls" for Mr. Smith at brothels. (XVII, 2689)

It almost goes without saying that the evidence regarding the trip to Prague was not relevant to establishing the criminal nature of OPS. Indeed, even were it relevant to a contested fact at issue, its introduction should have been analyzed pursuant to Federal Rules of Criminal Procedure § 404(b), which provides for a defendant's "bad acts" to be admissible under certain circumstances; that rule and its careful analysis were neither invoked by any party nor applied by the district court.

It is likewise not proper impeachment evidence by Mr. Adkins against Mr. Poe. Being sent, at the behest of another, to Prague to hire prostitutes does not make Mr. Poe less credible or more likely to lie. In sum, this highly inflammatory evidence was admitted for no reason and proved nothing useful, while making Mr. Smith look simply abhorrent.

The Suicide of Mr. Londino

The second challenged area of evidence, the suicide death of Robert Londino was entered into evidence by the government during direct examination Mr. Smith's computer programmer and through documentary exhibits 116 and 118. (VI, 1061) Exhibit 116 was a subpoena for Fallbrook Pharmacy to appear before a grand jury for the criminal investigation regarding the suicide death of Robert Londino. (VI, 1062-63, 1065) Exhibit 118 was a document naming

Fallbrook Pharmacy and Mr. Smith as parties to the wrongful death suit initiated by the family of Mr. Londino. Mr. Smith objected in advance of trial and again during trial to the admission of this testimony. (I, 13 18 V;VI, 1065)

The government argued that the evidence was relevant because it put Mr. Smith on notice regarding the danger of internet pharmacies. (VI, 1067-69) The district court allowed admission of the suicide death as notice of this dangerousness under the assumption¹⁸ that Mr. Londino himself had ordered drugs from OPS, but such an assumption was quickly revealed to be incorrect or wholly unsubstantiated when it came out that Mr. Londino's wife may have ordered the prescription. (VI, 1066) Without evidence that Mr. Londino had either ordered or taken the OPS prescription, there was no relevance. Moreover, the evidence made plain that the prescription arrived *after* Mr. Londino's suicide. (VI, 1068)

The utter lack of connection between OPS and the death is reflected in the district court's own words during side-bar discussion of the suicide evidence:

¹⁸ That the district court admitted Londino's suicide based primarily on the assumption that Mr. Londino himself made the online order is reflected in the side-bar discussion where the court makes the following remarks: "What is the relevance? This is the first time that I had heard that it was the wife that ordered it. . . . I was assuming that [the government] had it. Now it has come forth that it may not have been the deceased that ordered the drugs." (VI, 1066) "I was – it seemed logical if [the government] was putting this forth, I was allowing you to do that on the basis that you knew that [Mr. Londino] had ordered from this online pharmacy; and you don't even know that." (VI, 1068)

“There’s no connection. There’s no connection. Just because he may have possibly ordered drugs from a pharmacy does not make it one of notice that it is a dangerous situation.” (VI, 1067) The district court eventually changed its earlier ruling and ordered the evidence stricken from the record. (VI, 1070) Expressing concern about how to “get the horse back in the barn,” the court also gave a corrective instruction to attempt to undo the damage.¹⁹

Evidence of Mr. Londino’s death was not probative of any issue at trial. Even had there been a connection between OPS and Mr. Londino’s death, that would have done nothing to prove the illegality (as opposed to the dangerousness) of the online company. With no relevancy, the district court abused its discretion in admitting evidence of Mr. Londino’s suicide death.

D. Rule 403: Substantial Unfair Prejudice

Even if the contested pieces of evidence were somehow relevant to any issues before the jury, their admission created a grave danger of unfair prejudice that substantially outweighed any probative value and led to confusion of the

¹⁹ “You are instructed that with 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 as to 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 the plaintiff ordered drugs from Xpress Pharmacy.” (VI, 1074)

issues. Mr. Smith was not on trial for his wealth, for his adultery, for the suicide death of Mr. Londino, or for anything related to prostitutes from Prague.

Nonetheless, the contested evidence was arguably enough to tip the balance against Christopher Smith.

Evidence should be excluded if its “probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” FRE 403. “The term ‘unfair prejudice,’ as to a criminal defendant, speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged or on an improper basis.” Old Chief v. United States, 519 U.S. 172, 646 (1997). Unfair prejudice does not necessarily refer to the damage that occurs to a defendant's case because of the “legitimate probative force of the evidence; rather it refers to evidence which tends to suggest decision on an improper basis.” United States v. Guerrero-Cortez, 110 F.3d 647, 651 (8th Cir. 1997)(citations omitted); see also Wade v. Haynes, 663 F.2d 778, 783 (8th Cir.1981)(“The rule protects against evidence that is unfairly prejudicial, that is, if it tends to suggest decision on an improper basis.”)(*aff'd sub nom. Smith v. Wade*, 461 U.S. 30 (1983); Carter v. Hewitt, 617 F.2d 961, 972 (3d Cr. 1980)(“It

is unfairly prejudicial if it ‘appeals to the jury’s sympathies, arouses its sense of horror, provokes its instinct to punish, or otherwise may cause a jury to base its decision on something other than the established propositions in the case’.”).

Although admittedly balancing under FRE 403 is the domain of the district court, this Court must closely examine whether that assessment constituted an abuse of discretion. In United States v. Lupino, 301 F.3d 642, 646 (8th Cir. 2002), the district court allowed the police to testify that when he arrested Lupino for the assault at issue in the trial, he offered to sell the undercover drugs. The reviewing court found this testimony was unfairly prejudicial to the defendant because it “created the risk that the jury would assume that Lupino was someone with a propensity for criminal behavior.” Furthermore, the court continued, “[a]t the very least, the testimony created the danger that the jury would draw an unfavorable conclusion about Lupino’s character based solely on his association with drugs.” Id. Likewise, in Old Chief, the Court found that the erroneous admission of and repeated reference to the defendant’s prior conviction had so prejudiced the jury that reversal was required. Old Chief, 519 U.S. 172.

In the instant case, both categories of contested evidence caused unfair substantial prejudice to Mr. Smith. Like the evidence in Lupino held to be damaging, the evidence of the Prague trip to acquire girls created a strong danger

that the jury would condemn Mr. Smith based on soliciting prostitution or at the very least, conclude that Mr. Smith had a criminal propensity. Similarly, admitting the evidence of the suicide was unfairly prejudicial in great excess of any probative value. Mr. Londino's suicide was described in blunt terms right after the government elicited testimony about the refill policies of OPS. (VI, 1064-65) The prejudice was increased by evidence of Mr. Smith's cavalier attitude toward the lawsuit. In essence, admission of the suicide death served as a powerful and inflammatory symbol which distracted the jury from its job of assessing the lawfulness of OPS. The limiting instruction was unable to "get the horse back in the barn."

Both the trip to Prague and the suicide plainly fail Rule 403's balancing test for admissibility. The nonexistent or minimal relevance of each was readily and overwhelmingly outweighed by the prejudice they caused. Both cast Mr. Smith personally and OPS generally as amoral renegades. The jury was, beyond any dispute, invited to punish Mr. Smith for failings not alleged in the Indictment.

E. Rule 52(a): The Admission Was Not Harmless Error

Where this Court finds unfair prejudice, it must also review for the harmlessness of the error under Federal Rules of Evidence § 52(a). FRE 52(a) (2008)(Under Rule 52(a),"[a]ny error, defect, irregularity, or variance that does

not affect substantial rights must be disregarded.”). In the case of evidentiary challenges, “[t]he test for harmless error is whether the erroneous evidentiary ruling “had a ‘substantial influence’ on the jury’s verdict.” United States v. Lupino, 301 F.3d 642, 645 (8th Cir. 2002).

That the jury was overwhelmingly swayed by the contested evidence may be gleaned from the media, when a reporter wrote “Jurors agreed Smith was not very likable - calling him cocky, overconfident, calloused and a 'dirtbag.'" Shannon Prather, *Jury Finds Net Pharmacy Kingpin Guilty*, St. Paul Pioneer Press, Nov. 23, 2006 at 1A. Moreover, the government’s case was far from a “slam dunk.” Indeed the jury fully acquitted defendants against whom no similar character evidence was introduced. In sum, the evidence of Mr. Londino’s suicide and the prostitution of girls from Prague created a real risk that the jury rendered guilty verdicts for Mr Smith based on the emotional responses of anger and horror, rather than solely on admissible, relevant evidence. Reversal is required.

VII. District Court Erroneously Believed Itself Unable To Depart From the Advisory Guideline Range And Imposed a 360 Month Sentence In Violation of Gall v. United States

At sentencing, the district court erroneously applied the sentencing guidelines as mandatory and imposed a sentence at the bottom of those guidelines. The court indicated it believed this Court would reverse him without hesitation for

giving any reduction, particularly the ten year reduction sought by Mr. Smith. Counsel for Mr. Smith urged the district court that it was error to apply the guidelines as mandatory and reject variances, and predicted that in the pending case of Gall, the Supreme Court would reverse this Court's jurisprudence regarding downward variances. However, the district court nonetheless followed this Court's functional rule against variances and did not depart.

Mr. Smith argues that this error constituted a significant procedural error which was not harmless in any way, and remand is required for resentencing.

A. Review of a Sentence in the Wake of Gall

This Court must now review a sentence for "reasonableness" according to the United States Supreme Court. See Gall v. United States, ___ U.S. ___, 128 S.Ct. 586, 594 (2007). At the outset, the Court must determine whether there were any mistakes in the process employed to determine the sentence.

[A reviewing court] must first ensure that the district court committed no significant procedural error, such as failing to calculate (or improperly calculate) the Guidelines range, treating the Guidelines as mandatory, failing to consider the § 3553(a) factors, selecting a sentence based on the clearly erroneous facts, or failing to adequately explain the chosen sentence -- including an explanation for any deviation from the Guidelines range.

Id. at 597; see also United States v. Azure, 536 F. 3d 922, 930 (8th Cir. 2008).

Procedural errors include not only misapplying the guidelines or the statutes, but

improperly weighing the role of the guidelines in the sentencing process. For instance, application of a presumption of reasonableness to the guideline range is a procedural error. See United States v. Greene, 513 F.3d 904, 905-08 (8th Cir. 2008). In addition, it is procedural error in the wake of Gall v. United States, if a district court limited its consideration of a variance because it believed that the Eighth Circuit will reverse such a variance or require a high degree of justification to support such a sentence. See e.g., United States v. Greene, 513 F.3d 904, 905-08 (8th Cir. 2008); United States v. Weston, 267 Fed. Appx. 476, 477 (8th Cir. 2008)(vacating sentence where district court applied presumption of reasonableness and expressed belief it was bound by this circuit’s precedent requiring extraordinary justification to support requested sentence).²⁰

If this Court determines that a procedural error has occurred at sentencing, it must then consider whether that error requires reversal or can be dismissed as harmless.²¹ See United States v. Henson, 534 F.3d 922 2008 WL 2852963 (8th Cir.

²⁰ In Gall, the Supreme Court expressly overruled this Court’s requirement that a variance be strongly justified and its functional de novo review and frequent reversal of below-guidelines sentences.

²¹ In some cases, where a defendant sought a sentence below the guidelines but did not object to the court’s application of erroneous standards, this Court imposes plain error review. See e.g. United States v. Bain, 537 F. 3d 876, 2008 WL 3166244 (8th Cir. 2008). However, in this case, as will be made clear in section B., infra, Mr. Smith strenuously objected to the application of the

2008) (“We see nothing in Gall that . . . makes harmless error analysis inapplicable to procedural sentencing errors). However, the burden rests with the government to establish that any error which occurred was indeed harmless. Id.; see also United States v. Gianakos, 415 F.3d 912, 923 n. 6 (8th Cir. 2005) (noting that the government, not the defendant, bears the burden of establishing harmless error); United States v. Pittock, 2008 WL 3876419, * 1-2 (8th Cir. 2008)(not pub’d in Federal Reporter).

In the sentencing context, an error is deemed harmless only if the government proves that “no ‘grave doubt’ exists as to whether the error substantially influenced the outcome of the proceedings.” United States v. Cullen, 432 F.3d 903, 906 (8th Cir. 2006)(describing harmless error threshold in sentencing)(citations omitted). This Court explained in United States v. Haidley, 400 F. 3d 642, 645 (8th Cir. 2005), that a case requires reversal if it is unclear that the error did not impact the sentence. “On the basis of the record before us, we cannot say with any confidence that the district court would not have sentenced the defendant to a lesser sentence. . . had the district court realized that the federal sentencing guidelines were only advisory.” Haidley, 400 F. 3d at 645; Cullen, 432

erroneous standards. Therefore the issue is preserved for appeal. See United States v. Henson, 534 F.3d 922, 2008 WL 2852963, *2 (8th Cir. 2008).

F. 3d at 906 (reversing case because grave doubt existed about what sentence would have been imposed under non-mandatory guidelines). In sum, if a district court, over the objection of the defendant, applied this Court's overly rigid pre-Gall precedent to decide whether to vary and the sentence was affected by that mistake, reversal is required.

B. Procedural Error Occurred At Mr. Smith's Sentencing.

At Christopher Smith's sentencing, the district court committed obvious procedural error when it declined to vary because it believed this Court would reverse that decision. The district court understood itself unable to vary from the guidelines due to the precedent from this Court which functionally prohibited variance in the majority of cases. See , e.g. United States v. Gall, 446 F. 3d 884 (8th Cir. 2006) (vacated by Supreme Court); United States v. Ture, 450 F. 3d 352 (8th Cir. 2006); United States v. Claiborne, 439 F.3d 479 (8th Cir. 2006); United States v. Dalton, 478 F.3d 879 (8th Cir. 2007). Indeed, this Court had, almost uniformly, reversed downward variances which were challenged on appeal by the government.

At Mr. Smith's sentencing, the district court stated, "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.” (Sentencing at 70) The court’s expression of its belief in its powerlessness went on from there. “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.” (Sentencing, p. 71) Although Mr. Smith urged that the Eighth Circuit precedent was incorrect and argued at length that the Supreme Court was sure to reverse in the much-anticipated Gall decision, the district court reiterated that it felt bound by this Court’s precedent even if it was wrong. (Sentencing pp. 71-74)

Mr. Smith based his motion for a variance, in part, on the enormous disparity which a guideline sentence of 360 months would create between himself and similarly situated defendants around the country.²² Mr. Smith’s sentencing position contained a six page chart detailing sentences imposed on each defendant in virtually every internet pharmacy around the country and established that a 30 year sentence would be radically disproportionate. (Defendant’s Position Regarding Sentencing, pp. 14-19, Appendix at 129a) However, the district court didn’t even explore the details of this substantial showing, expressing its

²² This was by no means the only mitigating factor § 3553(a) factor urged by Mr. Smith in support of a 20 year sentence, but it well exemplifies the degree to which the court felt its hands were tied. Other mitigating facts are explored in section XII, infra.

understanding that this Court’s precedent limited his ability to depart to correct disparity:

“ . . . 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, the Court of Appeals has pointed out specific cases that this individual did something entirely different from another individual that got the departure.”

Sentencing p. 73. The district court then refused to further explore the voluminous evidence that a 30 year sentence was unreasonable and out of step.

Indeed, at the time of Mr. Smith’s sentencing in August, 2007, a downward variance granted by the same district court had just recently been reversed by this Court, see United States v. Todd Miller, 484 F. 3d 964 (8th Cir. May 2, 2007), vacated by Miller v. United States, ___ U.S. ___, 128 S.Ct. 871 (2008),²³ and two more were then-pending on appeal, one of which was predictably reversed the next month. See U.S. v. Chettiar, 501 F. 3d 854 (8th Cir. 2007), and United States v. Yvonne Courtney, App. No. 07-2135 (appeal filed by government May 10, 2007, and later dismissed in the wake of Gall.) The district court, as it sentenced Mr. Smith, had not only read the jurisprudence which reversed downward variances at

²³ The Westlaw version of the Miller opinion erroneously states the name of the district judge as Andrew Bogue, who is not even on the bench in Minnesota, rather than Judge Davis.

every turn, but it had itself been reversed and feared the same result again. It clearly believed itself forbidden to vary.

C. Reversal is Required

The obvious and objected-to error which occurred in this case cannot be dismissed as harmless. The court expressed its now-erroneous belief that its hands were tied to the guidelines four separate times and ultimately stated “[t]he Court will follow the Eighth Circuit precedent dealing with how to sentence an individual . . .” prior to imposing a 30-year sentence on Mr. Smith. (Sentencing p. 85) The court even expressed that it believed the variance argument was compelling but implied its powerlessness to depart. “The Court has listened carefully and has read over the documents submitted to the Court regarding the position of the defendant. The Court finds some merit in what has been said . . . However, the Court will not vary on the sentence in this matter.” (Sentencing p. 86)

Mr. Smith’s case is well-distinct from those in which this Court has dismissed a Gall error as harmless. For instance, in United States v. Bain, 537 F. 3d 876, 2008 WL 3166244 (8th Cir. 2008), a panel of this Court, over a strongly-worded concurrence, applied plain error review to an unpreserved Rita and Gall error. Although plain error review is much less searching and places a burden on

the defense rather than the government, the prejudice prong is instructive even in a harmless error context. The Bain, court found that the district court's vague reference to the severity of the sentence was not adequate to justify reversal. Bain, 537 F. 3d at 876. Similarly, in United States v. Henson, 534 F. 3d 922, 2008 WL 2852963 (8th Cir. 2008), two members of a panel found a Gall/Rita, error to be harmless when the judge more clearly suggested that his sentence would be the same even absent a presumption of reasonableness. Henson, 534 F. 3d at 922.²⁴ In contrast, in the instant case the district court made very clear its belief that the caselaw gave him no choice and declined to even examine the merits of the individual mitigating factors put forth because of the futility of doing so. The record before the Court is far more similar to United States v. Cullen, 432 F. 3d 903, 905 (8th Cir. 2008) (reversing Booker error because government failed to establish harmlessness) and United States v. Weston, 267 Fed. Appx. 476, 2008 WL 564815 (8th Cir. 2008). Reversal is required.

²⁴ It is clear that this Court's approach to harmless error and plain error review of Gall and Rita errors is in flux and contentious. See, e.g., Judge Shepard's dissent in Henson, and Judge Benton's concurrence in Bain. Mr. Smith respectfully disagrees with the current trend that few obvious errors merit resentencing and heartily embraces the dissenting and concurring opinions described above. However, even under the more stringent implications of the majority opinions in those cases, Mr. Smith urges that reversal is plainly required.

VIII. The District Court Erred By Failing To Adequately Consider Mitigating Facts And Imposed An Unreasonable Sentence of 360 Months.

In addition to committing “Gall error,” as explored above, the district court erred when it imposed a sentence of 360 months on Mr. Smith. Not only did the court commit procedural error by failing to give adequate weight to important mitigating factors and sentencing arguments, but the ultimate sentence of 30 years was substantively unreasonable. Remand for resentencing is required.

A. Standard of Review

The standard of review for this challenge to Mr. Smith’s sentence is addressed in section VII, A, supra.

B. Legal Analysis

Even if this Court finds that the district court’s obvious Gall error was somehow harmless, it should nonetheless find that the district court failed to give adequate consideration and weight to sentencing factors and the mitigating evidence regarding Mr. Smith which that made a sentence far below 360 months “sufficient but not greater than necessary,” as required by § 3553(a). This constituted procedural error and rendered the 360 month sentence substantively unreasonable. See, e.g., Gall v. United States, 446 U.S. 884, 128 S.Ct. 586, 597 (2007). In three key respects, Mr. Smith argues that the sentencing court erred.

First, as explored above, the district court declined to even consider whether imposition of a 30 year sentence on Christopher Smith would create an unwarranted disparity with other similarly situated convicted defendants from around the country. Section 3553(a) requires the sentencing court to consider, among other things, “the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct.” Even before Gall reminded courts of their sentencing discretion, this Court emphasized the importance of avoiding unwarranted disparity and thereby promoting respect for the law. See United States v. Lazenby, 439 F.3d 928 (8th Cir. 2006). The district court here committed procedural error when it refused to consider the very strong evidence of unwarranted disparity. Mr. Smith submitted substantial evidence that no other defendant in an internet pharmacy case, no matter his or her role or culpability, had received a 30 year sentence of imprisonment. Indeed, of the cases documented in his sentencing position, only two persons had been sentenced to 20 year terms, fully a third lower than the sentence imposed on Mr. Smith. The district court’s failure to consider the radical disparity was procedural error in its own right.

Second, § 3553(a)(1) requires the court to consider “the nature and circumstances of the offense” in imposing sentence. Mr. Smith urges the district

court committed further procedural error when it applied a 22 level enhancement for loss value under the fraud guidelines found at § 2B1.1 Without assessing whether that gigantic leap in penalty was proper given the details of the offense.

As Mr. Smith highlighted at sentencing, he was in the unique and unfair position of having his sentencing guideline range of 360-life based upon three individual counts of conviction with statutory maximum penalties of a mere 3 years each, for a total penalty of 9 years. Mr. Smith also urged that unfettered application of the fraud guidelines to a pharmaceuticals case for which they were not plainly designed was unreasonable.²⁵ It was unreasonable to apply a 22 level enhancement for “loss value” based on the total gross receipts of OPS, when the vast majority of customers of OPS received precisely the pharmaceutical products they ordered and paid for. Indeed in the recent case of Kimbrough v. United States, ___ U.S. ___, 128 S.Ct. 558 (2007), the Supreme Court reminded that a district court has the responsibility to consider a non-guideline sentence when those guidelines fail to accurately reflect the severity of the offense conduct, fail to be based on empirical data or legitimate policy concerns, or otherwise result in

²⁵ Indeed, the guidelines name §2N2.1 as proper for most FDA offenses and only employ a cross-reference to §2B in cases where fraud is shown. As Mr. Smith argued below, only a tortured interpretation of fraud encompassed the misbranded drug conduct of OPS, because the customer received precisely what he paid for with each of the three orders.

sentences out of step with the many other considerations of § 3553(a). In this case, the fact that the 22 level enhancement radically increased the sentence for a case far outside the heartland covered by the fraud guidelines was very clear at sentencing. The court erred when it failed to examine whether the adjusted offense level of 42 was an accurate reflection of the misbranded drug offenses.

Third, the district court failed to give adequate weight to the other mitigating factors present in Mr. Smith's case that made 30 years far "greater than necessary." These facts included Mr. Smith's mental illness and bipolar disorder (Presentence Report ¶ 134-136), and his lack of meaningful criminal history.²⁶ As the PSR reflected, Mr. Smith was first diagnosed with bipolar and anxiety disorders in 1999, and that diagnosis was confirmed in 2006, while Mr. Smith was in custody. (PSR ¶¶ 134, 136) Indeed much of Mr. Smith's self-destructive behavior during his prosecution case be partially explained by that diagnosis. Mr. Smith attempted suicide while incarcerated in 2006. (PSR ¶ 137) The court scarcely mentioned the important mitigation provided by his illness and his status

²⁶ Mr. Smith was in criminal history category I, and had zero criminal history points. Although he did have prior citations for littering, public nuisance on a road and loud music, none received points under the guidelines and none resulted in even a day in custody.

as a virtual first offender, which combined to support a sentence far less than 30 years.

In addition to the procedural error created by failure to consider these facts, the district court imposed an unreasonable sentence of 30 years on a non-violent unstable young man with no real criminal history. The sentence was unreasonable in part because it was far greater than necessary to accomplish the goals of sentencing, in contravention of the parsimony principle inherent in § 3553(a). In sum, the district court erred in failing to carefully weigh the mitigating facts regarding Mr. Smith and imposing a sentence well less than 30 years. Remand for resentencing is required.

CONCLUSION

For the foregoing reasons, Mr. Smith urges this Court to vacate each and every one of his criminal convictions and remand his case. If the Court disagrees that his convictions are themselves flawed, it should nonetheless vacate and remand for resentencing in light of the Supreme Court's decisions in Gall v. United States and Kimbrough v. United States.

Dated: October 6, 2008

Respectfully submitted,

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In The
UNITED STATES COURT OF APPEALS
For The Eighth Circuit

UNITED STATES OF AMERICA,)	
)	
Appellee,)	APPEAL NO. 07-2956
)	
v.)	CERTIFICATE OF COMPLIANCE
)	AND OF VIRUS FREE DISK
CHRISTOPHER SMITH,)	
)	
Appellant.)	

*I hereby certify that the Brief of Appellant filed in contains 19,976 words, excluding the table of contents, table of citations, statements with respect to oral argument, preliminary statement, statement of issues, addendum and certificates of counsel and service, as counted by the word-processing system (WordPerfect 11) used to generate the brief. The brief otherwise complies with the type-volume limitations set forth in F.R.A.P. 32(a)(7)(B) and (C)(Dec. 1, 1998) and Eighth Circuit Rule 28A(c). ***Pursuant to this Court's order of September 4, 2008, we were granted 20,000 words.**

I also certify that the floppy disks forwarded to the court and opposing counsel have been scanned for viruses and are virus free.

Dated: October 6, 2008

Respectfully submitted,

s/ Katherine Menendez

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ADDENDUM