UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA, Petitioner,	: :	CIVIL ACTION NO. 3:14-CV-1558 (JCH)
v.	:	
AJAY S. AHUJA, M.D., Defendant.	: :	JULY 21, 2016

RULING RE: MOTION FOR PARTIAL SUMMARY JUDGMENT (DOC. NO. 74)

I. INTRODUCTION

Plaintiff, the United States ("the Government"), brings this action against defendant, Dr. Ajay S. Ahuja, M.D. ("Dr. Ahuja"), pursuant to the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et. seq. The action includes twenty-three counts of alleged violations of the CSA and its related regulations.

Dr. Ahuja filed a Motion for Partial Summary Judgment ("Mot. for Summ. J.") (Doc. No. 74), as to four of the counts, numbered XIX through XXII. Each of these four counts alleges that Dr. Ahuja prescribed or otherwise dispensed controlled substances outside the usual course of his professional practice, thus violating the CSA and sections 1306.21(b) and 1306.04(a) of title 21 of the Code of Federal Regulations. Complaint ("Compl.") (Doc. No. 2) at 6–7. Each of these four counts alleges that Dr. Ahuja dispensed said substances to individuals ("the Recipients") for whom Dr. Ahuja had told investigators he did not maintain a patient chart. Compl. at 6–7.

Dr. Ahuja argues that the Government lacks power to bring an action against a physician for acting outside the usual course of professional practice by failing to maintain a patient chart. Mot. for Summ. J. at 3. Dr. Ahuja bases his argument on the

Supreme Court decision Gonzales v. Oregon, 546 U.S. 243 (2006). See Mot. for Summ. J. at 3–4. For the reasons set forth below, Dr. Ahuja's Motion for Summary Judgment is **DENIED**.

II. FACTUAL BACKGROUND[1]

The parties agree as to very little. The parties agree Dr. Ahuja is a physician. Form 26(f) Report of Parties' Planning Meeting (Doc. No. 33) at 2. The parties agree Dr. Ahuja is registered as a practitioner with the United States Department of Justice Drug Enforcement Administration ("DEA") and authorized to handle controlled substances. Answer (Doc. No. 36) at 1, ¶¶ 2–3; Compl. at 1, ¶¶ 2–3.

DEA Diversion Investigator Marcie Johnson ("Johnson") has written the following: Dr. Ahuja's dispensing records reveal Dr. Ahuja dispensed controlled substances to two of the Recipients, to whom the parties refer as Jane Doe #1 and John Doe #1.[2] Declaration in Response to Motion for Summary Judgment ("Decl.") (Doc. No. 75-2) ¶¶ 14–15. Investigators uncovered prescriptions Dr. Ahuja wrote for a third Recipient, Dr. Ahuja's son, for thirty 12.5 mg Zolpidem CR tablets on June 28, 2013; five of the same on July 29, 2013; twenty-five of the same on August 5, 2013; thirty of the same on September 30, 2013; and thirty of the same on October 28, 2013.[3] Decl. ¶ 16; Investigation Report ("Investigation Rep.") (Doc. No. 74-1) ¶¶ 23, 133. Investigators

[1] The discussion below includes only factual issues relevant to Counts XIX through XXII.

[2] John Doe #1 may refer to Dr. Ahuja himself. Compare Compl. at 6 (alleging Dr. Ahuja dispensed four ounces of Guaifenesin with Codeine to John Doe #1 on February 6, 2014, and told investigators he lacked a patient chart for John Doe #1) with Investigation Report (Doc. No. 74-1) ¶ 134 ("Ahuja dispensed a bottle of Guaifenesin with Codeine to himself on 02/06/2014 and admitted to Investigators that he does not maintain a patient chart for himself.").

[3] The Declaration refers to this Recipient as John Doe #2. Decl. ¶ 16. As Dr. Ahuja's Motion for Summary Judgment reveals, John Doe #2 is Dr. Ahuja's son. See Compl. at 6–7 (containing Count XXI which details Dr. Ahuja's five prescriptions to John Doe #2); Mot. for Summ. J. at 8 (directing court to compare Government's description of five prescriptions to Dr. Ahuja's son with Count XXI).

uncovered prescriptions Dr. Ahuja wrote for the final Recipient, Dr. Ahuja's brother, for two-hundred milliliters of Cheratussin AC on June 9, 2012; thirty tablets of Hydrocodone Bitartrate on November 24, 2012; and one-hundred milliliters of Hydrocodone Chlorpheniramine on March 27, 2013.[4] Decl. ¶ 17; Investigation Rep. ¶¶ 23, 133. Dr. Ahuja told Johnson he does not keep patient charts when treating relatives. Decl. ¶ 13. Specifically, Dr. Ahuja told investigators he lacked charts for his son and brother. Investigation Rep. ¶ 21. In fact, while Dr. Ahuja lacked charts for his son and brother and for Jane Doe #1 that corresponded to the relevant time periods, Dr. Ahuja had charts for these three Recipients outside the relevant periods. Decl. ¶¶ 14, 16–17.[5] Dr. Ahuja also had a chart for John Doe #1, but Johnson considered the chart inadequate to demonstrate a medically-valid reason for Dr. Ahuja's dispensations to John Doe #1. Id. ¶ 15. Dr. Ahuja first told investigators he does not dispense medications and then told investigators he does. Investigation Rep. ¶ 25. Dr. Ahuja told investigators he "'mostly'" does not treat family members and denied prescribing to family members. Id. ¶ 21. When asked if he would sign a consent not to treat family members, however, Dr. Ahuja told investigators he wanted to continue treating family members. Id. ¶ 22.

Based on a review of patient records, the Government's proffered medical expert, Dr. Adam E. Perrin, M.D. ("Dr. Perrin") opines that Dr. Ahuja dispensed

[4] The Declaration refers to this Recipient as John Doe #3. Decl. ¶ 17. As Dr. Ahuja's Motion for Summary Judgment reveals, John Doe #3 is Dr. Ahuja's brother. See Compl. at 7 (containing Count XXII which details three of Dr. Ahuja's prescriptions to John Doe #3); Mot. for Summ. J. at 8 (directing court to compare Government's description of prescriptions to Dr. Ahuja's brother with Count XXII). The Investigation Report also lists a fourth prescription to Dr. Ahuja's brother on September 25, 2013, see Investigation Rep. ¶ 23; but the Complaint did not include this fourth prescription in Count XXII, see Compl. at 7, and the Investigation Report does not describe this fourth prescription as a violation, see Investigation Rep. ¶ 133.

[5] The Declaration says "the time period referenced in the complaint." Decl. ¶¶ 14, 16–17. Counts XIX, XXI, and XXII of the Complaint reference dates ranging from early 2012 to late 2013. Compl. at 6–7.

controlled medications outside the normal course of professional practice and without a legitimate medical purpose. Dr. Perrin's Expert Medical Opinion ("Perrin Op.") (Doc. No. 74-2) at 7. Dr. Perrin states that Dr. Ahuja "clearly did not adhere to accepted practice standards as [ ] pertains to the safe and proper distribution of controlled medications." Id. at 9. Dr. Perrin indicates that a physician ought to document a controlled substance prescription in the medical record. Id. at 8. Dr. Perrin states that, when prescribing or otherwise dispensing controlled substances, a physician should keep "[a]ccurate and complete documentation." Id. at 8. According to Dr. Perrin, a physician has a responsibility to record in a chart the reason he prescribes a controlled substance, and the fact that he examined the patient when making the prescription. Dr. Perrin Deposition ("Perrin Dep.") (excerpts in Doc. No. 74-3 and Doc. No. 75-5) at 79. Dr. Perrin describes Dr. Ahuja's patient records as "cursory." Perrin Op. at 7. Dr. Ahuja's proffered medical expert, Dr. Gerald J. Hansen, M.D. ("Dr. Hansen"), states, however, that "[i]t is possible for a physician to provide care to a patient that is within the accepted standards of care, and even excellent care, without full or partial documentation." Dr. Hansen Letter (Doc. No. 75-7).

Based on review of Dr. Ahuja's patient records, Dr. Perrin opines that Dr. Ahuja violated a medical code of ethics by the way Dr. Ahuja prescribed controlled medications to family members. Perrin Op. at 7. Dr. Perrin states that an ethical concern exists when physicians prescribe for family members—especially when physicians prescribe controlled substances. Perrin Dep. at 96. Dr. Perrin reports concern within the medical establishment over the ethics of treating family members generally. Perrin Op. at 8. Dr. Hansen opines, however, that whether it is proper for a

physician to treat a family member depends on the situation. Dr. Hansen Deposition ("Hansen Dep.") (Doc. No. 75-6) at 47. Dr. Hansen says that to treat a family member does not necessarily create a conflict. Id. at 58. Dr. Hansen states that a physician who treats a family member is "supposed to" maintain a patient chart for the family member, and that it would be best to note in such chart any controlled substance prescribed. Id. at 47–48. In practice, however, Dr. Hansen says that physicians do not always keep charts for family members they treat. Id. at 48. Discussing whether Dr. Ahuja should have kept patient charts when caring for family members, Dr. Hansen opines that Dr. Ahuja would have been intimately aware of these family members' medical histories, medications, and allergies; and that he would easily be able to perform a physical examination. Dr. Hansen Letter (Doc. No. 75-7).

III. STANDARD OF REVIEW

On a motion for summary judgment, the burden is on the moving party to establish that there are no genuine issues of material fact in dispute and that he is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986); White v. ABCO Engineering Corp., 221 F.3d 293, 300 (2d Cir. 2000). Once the moving party has met its burden, in order to defeat the motion, the nonmoving party must "set forth specific facts showing that there is a genuine issue for trial," Anderson, 477 U.S. at 255, and present such evidence as would allow a jury to find in its favor, Graham v. Long Island R.R., 230 F.3d 34, 38 (2d Cir. 2000).

In assessing the record to determine whether there are disputed issues of material fact, the trial court must resolve all ambiguities and draw all inferences in favor of the party against whom summary judgment is sought. See Anderson, 477 U.S. at

255; Graham, 230 F.3d at 38. Summary judgment "is properly granted only when no rational finder of fact could find in favor of the non-moving party." Carlton v. Mystic Transp., Inc., 202 F.3d 129, 134 (2d Cir. 2000). "When reasonable persons, applying the proper legal standards, could differ in their responses to the question" raised, on the basis of the evidence presented, the question must be left to the finder of fact. Sologub v. City of New York, 202 F.3d 175, 178 (2d Cir. 2000).

IV. CSA STANDARD

A physician violates the CSA when he dispenses a controlled substance "outside the usual course of professional practice." See United States v. Moore, 423 U.S. 122, 124 (1975). Such a violation arises because the CSA prohibits dispensing a controlled substance without authorization, see 21 U.S.C. § 841(a)(1); or without a valid prescription or medical purpose, see 21 U.S.C. §§ 829(a–c); 842(a)(1).[6] To dispense includes to prescribe or to directly deliver a controlled substance to an ultimate user. 21 U.S.C. § 802(10). A DEA-registered practitioner has authorization to directly dispense a controlled substance only "in the course of his/her professional practice." 21 C.F.R. § 1306.21(b). Similarly, a practitioner has authorization to prescribe controlled substances only "for a legitimate medical purpose" when "acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). "The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice." 21 U.S.C. § 829 (e)(2)(A).

[6] Counts XIX through XXII of the Complaint cite section 841(a)(1). Compl. at 6–7. Counts XIX through XXII of the Trial Memorandum, however, cite sections 829 and 842(a)(1). Trial Memorandum (Doc. No. 73) at 31–33, n.84–87. The Government is ordered to file a notice as to which section(s) it is proceeding under.

The phrase "professional practice" implies normal and proper physician behavior, as determined by generally-accepted standards: for a physician to act "in the course of his professional practice" means to act "strictly within the appropriate bounds of a physician's professional practice." United States v. Behrman, 258 U.S. 280, 288 (1922) (internal quotation marks omitted) (quoting interpretation of an earlier narcotics statute). The Second Circuit has explained:

> The term 'professional practice' refers to generally accepted medical practice; a practitioner is not free deliberately to disregard prevailing standards of treatment. In short, the doctor must act in the good faith belief that his distribution of the controlled substance is for a legitimate medical purpose and in accordance with the usual course of generally accepted medical practice.

United States v. Vamos, 797 F.2d 1146, 1151 (2d Cir. 1986) (citations omitted).

Whether a practitioner acted outside the usual course of professional practice is generally a question of fact. See United States v. Riccio, 43 F. Supp. 3d 301, 308 (S.D.N.Y. 2014) ("Whether the prescriptions filled here were issued in the usual course of practice, pursuant to a bona fide physician patient relationship, is a question to be argued before and resolved by the jury."); United States v. ALN Corp., No. CIV.A. 3:92-407 (JAC), 1993 WL 402803, at *2 (D. Conn. Sept. 20, 1993) (stating that whether practitioner acted in accordance with what he reasonably believed proper medical practice was a question of fact).

A practitioner acts outside his professional practice when he behaves more as a "pusher" than as a physician. See Moore, 423 U.S. 142–43 (holding that a jury could find a physician exceeded the bounds of professional practice when he failed to properly examine patients, ignored test results, dispensed controlled substances

outside a clinic environment, failed to take precautions against drug misuse and diversion, let patients decide dosage, and based fee on drug quantity). A physician also acts outside professional practice when he issues a prescription for an individual who is not under his direct care. United States v. Salcedo, No. 02-CV-1095 (FB) (VVP), 2003 WL 21196843, at *2 (E.D.N.Y. Feb. 19, 2003).

V. DISCUSSION

Counts XIX through XXII allege Dr. Ahuja violated the CSA by dispensing controlled substances to Recipients outside the course of professional practice. Compl. at 6–7. Evidence that Dr. Ahuja may have dispensed outside professional practice includes evidence suggesting that: (1) Dr. Ahuja dispensed controlled substances to the Recipients, see Decl. ¶¶ 14–15; Investigation Rep. ¶ 23; (2) Dr. Ahuja gave investigators inaccurate and inconsistent answers regarding his patient treatment, charting, and dispensing practices, see Decl. ¶¶ 13, 16–17; Investigation Rep. ¶¶ 21–22, 25; (3) Dr. Ahuja lacked a patient chart for some of the Recipients for the period when he dispensed said Recipients controlled substances, see Decl. ¶¶ 14, 16–17; (4) Dr. Perrin believes physicians should record in patient charts when dispensing, see Perrin Dep. at 79; (5) two Recipients were Dr. Ahuja's relatives, see Investigation Rep. ¶¶ 21, 23; (6) Dr. Perrin believes dispensing controlled substances to relatives creates an ethical concern, see Perrin Dep. at 96; (7) concern exists within the medical community about the ethics of treating relatives generally, see Perrin Op. at 8; (8) Dr. Hansen believes that physicians should keep a patient chart when treating family members and should ideally note controlled substance prescriptions in said chart, see Hansen Dep. at 48; and (9) Dr. Perrin believes Dr. Ahuja dispensed without a legitimate

medical purpose and outside the usual course of professional practice, see Perrin Op. at 7.

The Motion for Summary Judgment does not explicitly assert that no reasonable jury could find Dr. Ahuja dispensed controlled substances outside professional practice. Rather, Dr. Ahuja argues that the Government lacks authority to sue him for dispensing outside professional practice by failing to keep patient charts. Mot. for Summ. J. at 3. Dr. Ahuja argues that states have authority over physicians' maintenance of patient charts, and that federalism precludes federal involvement in this area. Id. at 3. In this regard, Dr. Ahuja cites only one case to show a limitation on federal power over physicians' dispensing of controlled substances: Gonzales, 546 U.S. 243. See Mot. for Summ. J. at 3–8, 10–1; Reply to Plaintiff's Objection ("Reply") (Doc. No. 77) at 1–7.

Dr. Ahuja's argument fails because it misapplies Gonzales. Gonzales held only that the Attorney General lacked power under the CSA to define legitimate medical practices so as to directly oppose state law. See 546 U.S. at 258 ("[H]e is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law."); see also United States v. Feingold, 454 F.3d 1001, 1011 n.2 (9th Cir. 2006) (describing Gonzales as "holding that the Attorney General lacked authority to declare illegitimate a medical standard for care . . . that was specifically authorized under state law"). Specifically, Gonzales concluded that the CSA's prescription requirement did not authorize the Attorney General's interpretive rule, which intentionally countered Oregon's physician-assisted suicide regime by declaring suicide not a legitimate medical purpose. 546 U.S. at 253–54, 274–75. The interpretive rule that Gonzales invalidated had sought to put an

interpretive gloss on section 1306.04 of title 21 of the Code of Federal Regulations. Id. at 254. Gonzales did not invalidate section 1306.04 itself. See, e.g., id. at 250 (quoting the regulation's professional practice requirement without stating or implying invalidity); United States v. Joseph, 709 F.3d 1082, 1088 (11th Cir. 2013) (citing section 1306.04(a) when affirming conviction of physician and others for dispensing outside "the usual course of his professional practice"). The Government thus retains the power to enforce the CSA against physicians who dispense controlled substances outside professional practice. The Second Circuit has made clear that the Government retains such power after Gonzales, holding that, "[a] doctor may be convicted of unlawful . . . dispensation of a controlled substance if his activities fall outside the usual course of professional practice." United States v. Quinones, 635 F.3d 590, 594 (2d Cir. 2011) (internal quotation marks omitted).[7]

Counts XIX through XII here differ from the Gonzales interpretive rule in two important repects: First, the Government here refrains from unilaterally defining proper physician behavior. Rather, the Government merely seeks to prove to the court that Dr. Ahuja deviated from "professional practice." Compl. at 6–7. Such a claim means that the Government asks the court to find that Dr. Ahuja acted inappropriately, see

[7] The Reply also states that Gonzales, "concluded that the CSA does not regulate the practice of medicine outside the criminal context." Reply at 4. The Reply fails to cite to a page in Gonzales for this proposition. Id. at 4. The court cannot find language in Gonzales limiting the CSA's power over medicine to criminal enforcement. To the contrary, Gonzales described the interpretive rule it struck down as one that "declares certain conduct criminal." 546 U.S. at 262. Moreover, Gonzales merely struck down an interpretive rule because it exceeded the CSA, see id. at 274–75; Gonzales did not strike down any part of the CSA, see, e.g., id. at 274–75 (referencing the CSA's prescription requirement without stating or implying invalidity). Thus, the CSA civil penalty provision survives. See 21 U.S.C. § 842 (c). Civil penalties apply to certain medical practice violations, including dispensing without a valid prescription. See, e.g., 21 U.S.C. §§ 829, 842(a)(1),(c). While not common, civil CSA enforcement against physicians does occur. See, e.g., United States v. Butterbaugh, No. C14-515 (TSZ), 2015 WL 4660096, at *1 (W.D. Wash. Aug. 5, 2015); United States v. Paskon, No. 4:07-CV-1161 (CEJ), 2008 WL 2039233, at *1 (E.D. Mo. May 12, 2008); Salcedo, 2003 WL 21196843, at *2.

Behrman, 258 U.S. at 288; and outside generally-accepted physician behavior, see Vamos, 797 F.2d at 1151. Unlike an interpretive rule that purports to make a certain action per se improper, Counts XIX through XII leave Dr. Ahuja free to put on evidence showing that it is in fact proper and generally-accepted to dispense without recording in a patient chart. To illustrate, the Government lists a physician's purported obligation to keep a patient chart when treating family members as a disputed issue of fact, rather than simply declaring that such a per se obligation exists as a matter of law. See Plaintiff's 56(a)(3) Statement ("Pl.'s 56(a)(3)") (Doc. No. 76) ¶ 21. The Eastern District of New York's statement distinguishing Gonzales from a case analogous to the present litigation applies here:

> The government is not trying to establish a per se rule that [a certain method of dispensing is] invalid; rather, it is prosecuting the defendants under the rule established in Moore that prescribing drugs outside the usual scope of professional practice is illegal. The government is making no attempt, as in Gonzales, to unilaterally define which practices fall outside that scope; rather, it intends to leave that question where it has been for over 30 years—with the jury.

United States v. Quinones, 536 F. Supp. 2d 267, 271 (E.D.N.Y. 2008).

Second, unlike in Gonzales, no conflict exists with state law here. Dr. Ahuja bases the Motion for Summary Judgment on the argument that the Government cannot sue him for failing to maintain patient charts. Mot. for Summ. J. at 3. Dr. Ahuja concedes, however, that Connecticut regulations require physicians to keep such charts. See Reply at 6 ("Public Health Codes §§ 19a-14-40 & 19a-14-41 discuss a physician's obligation to maintain a patient chart."). Gonzales does not preclude the Government from arguing that a physician's dispensing of controlled substances without recording in a patient chart falls outside the scope of professional practice, at least for a

physician in a state that requires such charts. To the contrary, a conflict between Dr. Ahuja's dispensing practices and Connecticut's public health codes may be used as evidence that Dr. Ahuja violated the CSA. See United States v. Prejean, 429 F. Supp. 2d 782, 799-800 (E.D. La. 2006) (agreeing with the Government's argument "that Gonzales v. Oregon does not disturb the body of case law that holds that violations of state regulations of medical practice may be evidence supporting a conviction under 21 U.S.C. § 841").

The premise of the Motion for Summary Judgment is false because it mischaracterizes the Government's case. The Motion for Summary Judgment implies that the Government intends to prove Dr. Ahuja violated the CSA solely by failing to maintain patient charts. See, e.g., Mot. for Summ. J. at 8. The Government actually treats charting deficiencies as just one purported fact in support of its allegation that Dr. Ahuja dispensed outside professional practice. See Pl.'s 56(a)(3) ¶ 7. Other purported facts that the Government considers material to proving Dr. Ahuja dispensed outside professional practice include that Dr. Ahuja dispensed to family members, see id. ¶ 3, 10; dispensed to himself, see id. ¶ 3, 28; and responded inconsistently and inaccurately to investigators, see id. ¶ 2, 9. Additionally, even if professional practice does not require charting, a jury could potentially conclude that failure to chart may provide some evidence of acting outside professional practice. Such failure might suggest to a jury that a physician considered his own dispensation improper and thus wanted to avoid creating a paper trail in the chart.

Courts have previously accepted inadequate patient charting as one piece of evidence that a physician may have prescribed outside professional practice. For

instance, in a conviction for prescribing outside professional practice, the Ninth Circuit stated that testimony "overwhelmingly demonstrated" a physician's "disregard for proper prescribing practices" when such testimony included the fact that the physician "never recorded the medical basis for prescribing [ ] controlled substances in his patients' medical charts." See Feingold, 454 F.3d at 1004. Similarly, the Third Circuit affirmed a physician's conviction for prescribing outside professional practice when an expert had testified as to deficiencies including that (1) the physician lacked old patient charts, (2) existing patient charts lacked information regarding work-up or diagnostic evaluations, and (3) existing patient charts had insufficient information on patient histories and physical examinations. See United States v. Maynard, 278 F. App'x 214, 217 n.1 (3d Cir. 2008).

The court finds that nothing in Gonzales or other case law forbids the Government from presenting Dr. Ahuja's allegedly inadequate patient charting practices as evidence of a CSA violation, and the court notes that other courts have properly allowed this type of evidence in the past.

VI. CONCLUSION

The court is concerned regarding the defense counsel's pleadings. For example, the defense counsel writes that the Government "avers that, in failing to maintain an adequate chart, the Defendant has per se acted outside the scope of a 'legitimate medical practice.'" Reply at 1 (citing "Plaintiff's Objection, p.8"). After thoroughly searching page eight of the Plaintiff's Memorandum in Opposition to the Motion for Summary Judgment (Doc. No. 75-3) and reading the rest of said document, the court

finds no such averment. The court expects in the future when the defense counsel files, that he will be aware of his obligations. See Fed. R. Civ. P. 11.

For the reasons set forth above, the court **DENIES** Dr. Ahuja's Motion for Partial Summary Judgment (Doc. No. 74).

SO ORDERED.

Dated this 21st day of July, 2016, at New Haven, Connecticut.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge