UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 4:07-CV-1161 (CEJ)
	)	
SETH PASKON,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

This matter is before the Court for decision on plaintiff's motion for partial summary judgment and preliminary injunction. The parties have fully briefed the issues. In addition, the Court received testimony and documentary evidence at hearings on April 1, and April 2, 2008.

Defendant Seth Paskon, M.D., practices medicine in Potosi, Missouri. The United States alleges that he issued medically unnecessary prescriptions for narcotic medications and caused improper claims for those prescriptions to be presented to the Medicaid program for payment. On June 21, 2007, plaintiff filed this civil action pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq*., and the Controlled Substances Act (CSA), 21 U.S.C. §§ 801 *et seq*., seeking restitution to the Medicaid program, civil monetary penalties, and an injunction against future violations of the CSA. The case is set for trial on July 21, 2008. On February 20, 2008, plaintiff filed the instant motion for partial summary judgment and preliminary injunction; plaintiff asks the Court to impose monetary penalties and to order defendant to surrender his CSA registration until resolution of plaintiff's claims at trial.

I. Legal Standards

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be entered "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In ruling on a motion for summary judgment the court is required to view the facts in the light most favorable to the non-moving party and must give that party the benefit of all reasonable inferences to be drawn from the underlying facts. AgriStor Leasing v. Farrow, 826 F.2d 732, 734 (8th Cir. 1987). The moving party bears the burden of showing both the absence of a genuine issue of material fact and its entitlement to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986); Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986); Rule 56(c). Once the moving party has met its burden, the non-moving party may not rest on the allegations of his pleadings but must set forth specific facts, by affidavit or other evidence, showing that a genuine issue of material fact exists. Rule 56(e). Rule 56(c) "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corporation v. Catrett, 477 U.S. 317, 322 (1986).

"[W]hether a preliminary injunction should issue involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." Dataphase Sys., Inc. v. C L Systems, Inc., 640 F.2d 109, 114 (8th Cir. 1981). No single factor is dispositive, as the district court must balance all factors to determine whether the injunction should issue. Baker Elec. Co-op., Inc. v. Chaske, 28 F.3d 1466, 1472 (8th Cir. 1994). A preliminary injunction is not appropriate where there is an adequate remedy at law. Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003)

The party seeking injunctive relief ordinarily bears the burden of proving all of the Dataphase factors. Lankford v. Sherman, 451 F.3d 496, 503 (8th Cir. 2006). In this instance, however, an injunction is sought pursuant to a federal statute. 21 U.S.C. § 843(f) (authorizing injunctive relief "tailored to restrain violations" of the Controlled Substances Act). A court considering whether to issue an injunction to enforce Congressional policy performs a different function than when weighing the claims of two private litigants. United States v. Diapulse Corp. of America, 457 F.2d 25, 27 (9th Cir. 1972) (affirming issuance of preliminary injunction to bar shipment of misbranded medical device). The fact that a federal statute is being enforced by the agency charged with that duty may alter the burden of proof of a particular element necessary to obtain injunctive relief. United States v. Odessa Union Warehouse Co-op, 833 F.2d 172, 175 (9th Cir.

1987). Specifically, where the government establishes that a violation of a statute has occurred, irreparable injury is assumed. Id.; Diapulse, 457 F.2d at 28 ("The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained."). However, if the government makes only a colorable evidentiary showing of a violation, the court must consider irreparable injury. United States v. Nutri-cology, Inc., 982 F.2d 394, 398 (9th Cir. 1992) (affirming district court's denial of preliminary injunction for violation of Food, Drug, and Cosmetic Act). Furthermore, the violation of a federal statute does not automatically require a district court to issue an injunction. Tennessee Valley Authority v. Hill, 437 U.S. 153, 193 (1978).

II. Background

In its complaint, plaintiff alleges that defendant issued illegal and medically unnecessary prescriptions to nine patients, in violation of 21 U.S.C. 842(a)(1).[1] The instant motion for partial summary judgment and preliminary injunction is based upon plaintiff's allegations regarding prescriptions issued to two of the nine patients, C.P. and M.S., as discussed below.

Defendant is a physician with board-certification in pediatrics and internal medicine; he operates the Potosi Medical Clinic in Washington County, Missouri, which defendant describes as

[1]In connection with its claim under the False Claims Act, plaintiff also alleges that defendant caused these improper prescriptions to presented to Medicaid for reimbursement. Plaintiff does not seek relief under the False Claim Act in this motion.

a medically-underserved region. Defendant testified that he presently has about 1,000 patients, 60 to 70 percent of whom are insured through the Missouri Medicaid program. According to defendant, many of his patients are the product of an inadequate educational system, and have multiple complex medical and psychological problems; several patients have been diagnosed with intractable pain syndrome.

Defendant testified that he follows the guidelines of the World Health Organization (WHO) Pain Ladder to manage chronic pain. The Pain Ladder outlines a three-step progressive approach to prescribing analgesics in order to achieve and maintain freedom from pain. In Step 1, non-opioids, such as over-the-counter analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs), are prescribed. If the pain persists, mild opioids, *e.g.*, Darvocet, are introduced at Step 2. If the Step 2 drugs are not sufficient to manage pain, strong opioids such as methadone and oxycodone are introduced at Step 3. Defendant testified that he prescribes thirty days of pain medication at a time; patients may not obtain a refill without another office visit. Defendant contends that his prescribing practices are appropriate and in the usual course of sound medical practice, in accordance with commonly accepted principles of pain management.

Patient C.P.

Plaintiff alleges that defendant inappropriately prescribed the Schedule II[2] drugs Valium (diazepam) and Norco (hydrocodone with acetaminophen) to patient C.P. while she was pregnant. C.P. and her child both tested positive for benzodiazepines immediately after the child's birth.

Defendant does not dispute that he prescribed Valium and Norco for C.P. during her pregnancy, but contends that the prescriptions were medically necessary to manage her chronic pain, high anxiety, and risk for seizures. Defendant testified that at the time C.P. became his patient on March 11, 2003, she was taking Darvocet, a Step-1 drug, to treat chronic pain. C.P. complained that the Darvocet was not effective so defendant prescribed Vicodin, a Step-2 drug that combines hydrocodone and acetaminophen. C.P. obtained relief from Vicodin for approximately two years. Vicodin was followed by another Step-2 drug, Lorcet, which is a higher-dose combination of hydrocodone and acetaminophen. Defendant also prescribed Xanax to treat C.P.'s anxiety.

Plaintiff's motion is based upon three prescriptions defendant gave C.P. between March and June 2005. C.P. appeared for an office visit on March 2, 2005; at that time, defendant gave her prescriptions for 30-day supplies of Xanax and Lorcet. On March 15, 2005, C.P.'s husband called the Potosi Medical Clinic to report that C.P. had just learned that she was pregnant; he asked whether

[2]The CSA divides controlled substances into five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision. 21 U.S.C. § 812; Gonzales v. Oregon, 546 U.S. 243, 250 (2006). Schedule I contains the most severe restrictions on access and Schedule V the least. Id.

she should continue to take the medications as prescribed. A note in the record indicates that C.P. was told to slowly reduce her Xanax and Lorcet over the next two weeks and to eventually refrain from taking the medications altogether. Defendant testified that it was his goal to stop medications before C.P. went into labor in order to prevent her child from experiencing withdrawal upon birth.

C.P. returned to defendant's office for a regularly scheduled appointment on March 30, 2005. She confirmed that she was pregnant and stated that her due date was August 20, 2005, placing her in the second trimester of her pregnancy. She also told defendant that she continued to experience pain and anxiety. Defendant testified that C.P. could not reduce her medication at that time, although he still planned to have her medication-free by one week before delivery. Defendant switched C.P. from Xanax to Valium which he testified might reduce the risk of seizures during delivery. Defendant replaced the Lorcet with Norco, which contains the same amount of hydrocodone but has a lower amount of acetaminophen. The use of Valium and Norco is not contraindicated during the second trimester of pregnancy.

According to defendant's records, during office visits C.P. gave inconsistent information regarding her anticipated delivery date. On March 30, 2005, she stated that she was due on August 20, 2005. On May 2nd, she indicated that she was six months pregnant, which would indicate a delivery date earlier in August. On June 2nd, C.P. reported that her due date was July 20, 2005. At each of these office visits, defendant wrote C.P. prescriptions for 30 days

of Norco and Valium. C.P. delivered a full-term baby on June 23, 2005.

Patient M.S.

Plaintiff alleges that defendant inappropriately wrote prescriptions for Percocet, Valium, and Methadone for patient M.S. In addition, plaintiff asserts that defendant relied on a nonprofessional -- the patient's live-in girlfriend V.M. -- to administer medication to M.S.

Defendant testified that M.S. could not read and that V.M. accompanied him to each office visit. During the initial appointment on June 12, 2006, V.M. read the intake questionnaire to M.S. and recorded his responses. M.S. reported that he suffered from chronic back pain as the result of a fall from a three-story building 18 years earlier. He also complained of pain due to an old fracture of his right wrist and arthritis in several joints. He told defendant that pain prevented him from sleeping more than three or four hours per night. M.S. had other medical conditions, including asthma, peptic ulcer disease, and high cholesterol. In addition, M.S. reported a history of depression and panic attacks. Defendant prescribed Celexa for treatment of depression and anxiety, Ultracet for treatment of pain, and Xanax for anxiety. The Xanax was the only controlled substance prescribed at the initial visit.

On July 13, 2006, M.S. reported that he continued to experience high levels of pain and that he was sleeping poorly. Defendant testified that, in accordance with the WHO Pain Ladder,

he prescribed Vicodin, a Step-2 drug, for the pain and Restoril as a sleep aid. Defendant observed that M.S. was "shaky," so he substituted Valium for the Xanax. On August 10, 2006, M.S. again reported high levels of pain and defendant prescribed the Step-3 drug Percocet.

On September 7, 2006, M.S. reported that his pain had reduced only slightly. Defendant prescribed Methadone to be taken one-half tablet twice a day for two days, to be increased to a full tablet twice a day. Defendant testified that it was important that the Methadone be taken properly, so he instructed V.M. to "administer the Methadone" to M.S. Defendant prescribed Percocet and Valium in addition to the Methadone. M.S. died on September 11, 2006; the pathologist listed the cause of death as "mixed drug intoxication."

III. Discussion

Plaintiff brings this action for civil remedies under the CSA. The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Gonzales v. Raich, 545 U.S. 1, 12 (2005). Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. Id. at 12-13. Thus, the CSA creates a "comprehensive, closed regulatory regime" making it unlawful to manufacture, distribute, dispense, or possess controlled substances except in a manner authorized by the CSA. Gonzales v. Oregon, 546 U.S. 243, 250 (2006). In recognition that physicians and other practitioners have legitimate reasons to handle controlled substances, the CSA contains an elaborate

registration and reporting scheme to protect such individuals from prosecution. United States v. Ekinci, 101 F.3d 838, 840-41 (2nd Cir. 1996).

Plaintiff alleges that defendant violated 21 U.S.C. § 842(a)(1), which provides that it shall be unlawful for any person "to distribute or dispense a controlled substance in violation of section 829 of this title." Section 829 provides that "no controlled substance . . . which is a prescription drug . . . may be dispensed without the written prescription of the practitioner." § 829 (a) & (b). In order to be valid, a prescription for a controlled substance must "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); see also 21 U.S.C. § 802 (21) (defining "practitioner" as a physician who is "licensed, registered, or otherwise permitted . . . by the jurisdiction in which he practices . . . to distribute [or] dispense . . . a controlled substance in the course of professional practice").

Plaintiff contends that the challenged prescriptions were not written for a "legitimate medical purpose" in the "usual course of [defendant's] practice." "The term 'professional practice' refers to generally accepted medical practice; a practitioner is not free deliberately to disregard prevailing standards of treatment." United States v. Vamos, 797 F.2d 1146, 1151 (2nd Cir. 1986). In the context of criminal prosecutions, a physician may avoid conviction if he or she acted in the good faith belief that the distribution of a controlled substance is for a legitimate medical

purpose. Id. See also United States v. Carroll, 518 F.2d 187, 189-90 (6th Cir. 1975) (reversing conviction where court failed to instruct jury that physicians are exempt from § 841 when they "prescribe controlled substances in good faith to patients in the regular course of professional practice"). The appropriate focus is not on the subjective intent of the doctor; rather, the issue is whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States. United States v. Merrill, 513 F.3d 1293, 1306 (11th Cir. 2008).

The case law regarding the scope of "professional practice" has been developed in the context of criminal prosecutions of physicians under 21 U.S.C. § 841.[3] See, e.g., United States v. Moore, 423 U.S. 122, 142 (1975) (evidence that defendant physician gave inadequate physical examinations, ignored test results, distributed methadone away from his office, and prescribed as much and as frequently as patient demanded sufficient to support finding that defendant acted outside the bounds of "professional practice"); see also United States v. Bek, 493 F.3d 790 (7th Cir. 2007) (affirming conviction where patients and undercover agents testified that defendant called multiple patients to exam room at once, demanded cash for prescriptions, gave prescriptions for

[3]Section 841 criminalizes the unauthorized distribution and dispensing of controlled substances. The acts listed in Section 842 are considered "more or less technical violations" of the Controlled Substances Act, and the penalties under these sections are less severe than those under Section 841. United States v. Vamos, 797 F.2d 1146, 1152 n. 1 (2nd Cir. 1986), citing H.R.Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4576.

weight loss and weight gain to same patient, prescribed Viagra to female agent, etc.); United States v. Katz, 445 F.3d 1023 (8th Cir. 2006) (affirming conviction where patients and undercover agents testified that doctor did not ask for medical history, rarely conducted physical examinations, did not refer to specialists, provided 30-day prescriptions every two weeks, and did not accept insurance); United States v. Varma, 691 F.2d 460 (10th Cir. 1982) (affirming conviction where agents testified that defendant prescribed Ritalin after cursory examination with no medical history and where agents told defendant they wanted to stay awake); United States v. Kirk, 584 F.2d 773 (6th Cir. 1978) (affirming conviction where patients testified they went to defendant's office three to four times per week, presented several different IDs, had visible track marks from injecting the prescribed drugs, etc.); United States v. Rosen, 582 F.2d 1032 (5th Cir. 1978) (affirming conviction of obesity doctor where agents testified that they did not require advance appointment, did not provide medical history, patients were seen in groups, fees were paid in cash and not recorded, etc.); United States v. Green, 511 F.2d 1062 (7th Cir. 1975) (affirming convictions where prescriptions were written in names of famous people, agent testified that he received Ritalin after stating he wanted to get high; another agent received prescriptions in two names after stating he was selling the drug, etc.).

The record in this matter does not include evidence from patients or undercover agents. The government has provided the opinion of an expert witness that defendant's prescriptions are

outside the scope of legitimate medical practice. Defendant has testified that he followed accepted guidelines for managing patients with chronic pain. The record thus presents genuine disputes of material fact that must be decided by the factfinder at trial. See United States v. ALN Corp., 1993 WL 402803 (D. Conn. Sept. 20, 1993) (denying government's motion for summary judgment in civil action against pharmacist). Plaintiff's motion for partial summary judgment will be denied.

Title 21, section 843(f) of the United States Code authorizes the government to seek injunctive relief "tailored to restrain violations" of § 842. Plaintiff seeks an order directing defendant to immediately cease prescribing any controlled substances listed in Schedules I through V and to surrender his Drug Enforcement Administration (DEA) registration. Giving due consideration to the Dataphase factors, the Court concludes that plaintiff has not met its burden to show why this injunction should issue before trial. The government has not cited, nor has the Court found, any cases in which a court limited a physician's registration before final disposition of the government's claims. In addition, the CSA provides a comprehensive regime -- complete with standards, burdens, and review procedures -- pursuant to which the DEA may revoke or suspend a physician's registration. See 21 U.S.C. § 824(c); see, e.g., Morall v. Drug Enforcement Admin., 412 F.3d 165 (D.C. Cir. 2005); Humphreys v. Drug Enforcement Admin., 96 F.3d 658 (3rd Cir. 1996); Shatz v. United States Dept. of Justice, 873 F.2d 1089 (8th Cir. 1989). Plaintiff has not explained why it did not rely on this administrative process to obtain the relief it seeks.

Finally, plaintiff's action is based upon allegations regarding nine of defendant's patients. Plaintiff has not addressed the impact of removing defendant's registration upon the remainder of his patients. The Court concludes that, absent a finding that defendant has indeed violated the CSA, plaintiff has not established that its proposed injunction is tailored to restrain violations of § 842.

Accordingly,

IT IS HEREBY ORDERED that plaintiff's motion for preliminary injunction and partial summary judgment [Doc. #31] is **denied**.

CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 12th day of May, 2008.