Chapter 10. Practicing Medicine in a Drug Enforcement World

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I. Introduction[1]

Recent concerns about the steep rise in prescription drug abuse have generated intensified enforcement activities by federal and state authorities at all points in the distribution chain of controlled substances—manufacturers, distributors, prescribers, and pharmacies. These enforcement activities pit several competing interests against each other—the twin public interests of reducing drug abuse and diversion while simultaneously ensuring patient access to necessary medications, as well as the institutional interests of the Drug Enforcement Administration (DEA) in maintaining its law enforcement authority over each link in the controlled substances chain and the medical community's grip on standards of professional care, particularly for patients suffering from pain or addiction. The struggle between these competing interests arguably raises new issues about the encroachment of law enforcement into the practice of medicine and pharmacy.

DEA's enforcement activities against physicians have increasingly challenged the legitimacy of medical decision-making in issuing controlled substances prescriptions and have encompassed the pharmacists and pharmacies filling those prescriptions. As described in this chapter, DEA has applied the Controlled Substances Act (CSA) and its accompanying regulations to create an enforcement regime in areas that were routinely left to state and community medical and pharmacy standards. In DEA's efforts to address prescription drug abuse, its enforcement actions are blurring the traditional line separating DEA legal authority under the CSA and the establishment of standards for medical care.

In recent years, as DEA has announced and as has been widely reported, DEA has initiated more aggressive administrative and criminal actions against physicians and pharmacists.[2] As DEA enforcement has grown, physicians are becoming more reluctant to prescribe controlled sub-

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[1]The authors are grateful for the diligent work of associates Andrew J. Hull, Hyman, Phelps & McNamara, P.C., and Yune T. Do, Post & Schell, P.C., in researching and assisting with this chapter.

[2]*See, e.g.*, *Examining the Growing Problems of Prescription Drug and Heroin Abuse: Hearing Before the Subcomm. on Oversight and*

stances—in particular, for pain management—out of fear of agency action,[3] and pharmacists, too, are unsure whether to fill pain medication prescriptions. This article explores the legal and regulatory issues arising from federal and state law enforcement of controlled substances and the adverse effect on the physicians and pharmacists who are at personal and professional risk.

II. Drug Control and the Regulation of the Practice of Medicine

A. Authority of the Drug Enforcement Administration

Created in 1973 by President Richard Nixon,[4] the DEA is tasked with preventing the diversion and abuse of controlled substances and listed chemicals through enforcement of the CSA.[5] To address the abuse and diversion of both legitimate and illegitimate controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substances except in a manner authorized by the CSA."[6] A key component of DEA's responsibilities under the CSA is its antidiversion measures as carried out by its Office of Diversion Control. Through its antidiversion efforts, DEA ensures the maintenance of this closed system by tightly regulating and enforcing the handling of controlled substances.

To protect against unlawful diversion and abuse while

Investigations of the H. Comm. on Energy and Commerce, 113th Cong. (Apr. 29, 2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA).

[3] *See* Scott M. Fishman, *Commentary in Response to Paulozzi* et al.*: Prescription Drug Abuse and Safe Pain Management*, 15 Pharmacoepidemiology & Drug Safety 628, 628 (2006); Maia Szalavitz, *IOM Report: Chronic, Undertreated Pain Affects 116 Million Americans*, TIME MAG. (June 29, 2011), *available at*: http://healthland.time.com/2011/06/29/report-chronic-undertreated-pain-affects-116-million-americans/ (last visited Dec. 1, 2014).

[4] Exec. Order No. 11727, 38 Fed. Reg. 18357 (July 10, 1973).

[5] Pub. L. No. 91-513, 84 Stat. 1236, 1242 to 1284 (codified as amended at 21 U.S.C. §§ 801 to 904 (2012)).

[6] *Gonzales v. Raich*, 545 U.S. 1, 13, 125 S. Ct. 2195, 162 L. Ed. 2d 1 (2005).

ensuring accountability, the CSA and DEA regulations restrict the manufacture, distribution, and, ultimately, dispensing of controlled substances. Fundamentally, DEA controls availability of these substances through quotas, registration, recordkeeping, reporting, and security requirements. Failure to comply with these requirements can result in an administrative action to revoke a health care provider's authority to handle controlled substances, which means the provider, who can be an entity or an individual, could lose its DEA registration, making it impossible to handle controlled substances and likely resulting in significant professional harm.[7] In addition, the agency, in collaboration with the Department of Justice and state attorneys general, can pursue criminal and civil actions for more serious, knowing violations and seek imposition of significant criminal and civil penalties.[8]

B. Legal Precedent for Separation of Authority

It is well-settled that DEA and the CSA do not regulate the practice of medicine. In the 2006 case of *Gonzales v. Oregon*,[9] the Supreme Court, addressing a perceived conflict between the CSA's governance of controlled substances and the Oregon Death With Dignity Act, which permitted medical use of controlled substances to assist patients seeking to end their lives, ruled that the CSA does not bar such use of controlled substances where the state's medical regime permits them.[10] The United States Attorney General in an Interpretative Rule had contended that controlled substances

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[7]21 U.S.C. § 824. Before their registrations are revoked, registrants have a right to an administrative hearing on the merits of revocation. *See* Judge John J. Mulrooney, II & Andrew J. Hull, *Drug Diversion Administrative Revocation and Application Hearings for Medical and Pharmacy Practitioners: A Primer for Navigating Murky, Drug-Infested Waters*, 78 ALB. L. REV. (2015) (providing an overview of DEA administrative hearings); Douglas J. Behr, *Did You Forget to Say You're Sorry? Litigating a Show Cause Hearing for a Physician's DEA Registration*, 9 Quinnipiac Health L.J. 99 (2005).

[8]21 U.S.C. §§ 841 to 847.

[9]*Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006).

[10]*Id.* at 244–245.

prescriptions written to assist suicide violated the CSA's requirement that prescriptions be written for a legitimate medical purpose.[11]

After examination of the CSA and its history, the Supreme Court found "that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally . . . The structure and operation of the CSA presume and rely on a functioning medical profession regulated under the State's police powers."[12] The Supreme Court rejected the Attorney General's assertion that prescriptions written in connection with assisted suicide were unlawful because they were not for a legitimate medical purpose, finding that "[t]he prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses."[13]

The Court firmly stated that the Attorney General's powers under the CSA were not intended to "effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality."[14] Given the clarity of that statement from the Supreme Court, the CSA and DEA regulations should not play a role in the practice of medicine other than in ensuring safeguards and accountability to prevent against diversion and abuse.

A few months after *Gonzales v. Oregon*, in response to physician requests for information about prescribing for pain, DEA published a policy statement making "clear that the longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medi-

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[11] *Id.* at 254.

[12] *Id.* at 269–270.

[13] *Id.* at 274 (2006) (citing *U.S. v. Moore*, 423 U.S. 122, 143, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975)); *accord George C. Aycock, M.D.*, 74 Fed. Reg. 17529, 17541 (Drug Enforcement Admin. Apr. 15, 2009).

[14] *Gonzales*, 546 U.S. at 275.

cal purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment."[15] DEA told physicians that the federal courts have always held that it is impossible to define legitimate medical purpose in a way that can adequately address all the varied situations a physician may encounter.[16] According to DEA, a prescription's legitimacy must be determined on a case-by-case basis "as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances."[17]

In the policy statement, DEA noted that state medical boards had both the authority and expertise to regulate and give advice on the practice of medicine.[18] The policy statement also assured physicians that DEA was not embarking on a campaign to target physicians who prescribe painkillers for the treatment of pain.[19] DEA reiterated, however, that it had "the authority and expertise to investigate and determine whether a prescription for a controlled substance was issued for a legitimate medical purpose in the usual course of professional practice."[20]

DEA recently affirmed its 2006 policy statement in an August 2014 announcement reclassifying hydrocodone combination productions from a Schedule III drug to a Schedule II drug.[21] DEA stated that it "does not regulate the general practice of medicine and the agency lacks the authority to issue guidelines (or make policy statements) that consti-

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[15]*Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52715, 52716 (Sep. 6, 2006).

[16]*Id.* at 52715.

[17]*Id.* at 52719.

[18]*Id.*

[19]*Id.* at 52716.

[20]*Id.*

[21]DEA divides controlled substances into five schedules (i.e., Schedules I through V), with each schedule reflecting the included drugs' currently accepted medical use in the United States, relative abuse potential, and likelihood of causing dependence when abused. For example, Schedule I contains largely illegal drugs, such as heroin, LSD, and marijuana, whereas Schedule II contains highly abused drugs, such as oxycodone, methadone, morphine, opium, codeine, and, since August 2014, hydrocodone. See Controlled Substance Schedules, DEA Office of Diver-

tute advice on the general practice of medicine."[22] DEA's policy statements are consistent with how DEA had traditionally interpreted its role under the CSA.

An example of DEA's traditional approach is the early 1990s nationally publicized matter involving actress Elizabeth Taylor and the treating physicians who for years had prescribed her inordinate amounts of controlled substances. Ms. Taylor's three doctors were accused of overprescribing painkillers for the actress and of falsifying her medical records in an effort to protect her privacy from the press.[23] The California Attorney General and the state medical board initiated separate actions,[24] and DEA took action to determine whether these doctors' DEA registrations should be revoked as inconsistent with the public interest.[25] While the state medical board reprimanded the physicians for falsifying Ms. Taylor's medical records to cover up the large amount of painkillers they prescribed,[26] DEA refused to revoke the doctors' registrations upon conclusion of administrative hearings.[27] DEA noted that while it was concerned about the number of painkiller prescriptions written by the doctors,

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sion Control website, *available at*: http://www.deadiversion.usdoj.gov/schedules/#define (last visited Dec. 1, 2014).

[22]*Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II*, 79 Fed. Reg. 49661, 49669 (Aug. 22, 2014) (codified at 21 C.F.R. Part 1308).

[23]John H. Lee & Virginia Ellis, *Taylor Doctors Are Accused of Prescription Violations*, L.A. TIMES (Sept. 8, 1990), *available at*: http://articles.latimes.com/1990-09-08/local/me-466__1__elizabeth-taylor (last visited Dec. 1, 2014); Claire Spiegel & Virginia Ellis, *3 Doctors Cited in Taylor Drug Case*, L.A. Times (Aug. 11, 1994),*available at*: http://articles.latimes.com/1994-08-11/local/me-26031__1__medical-board (last visited Dec. 1, 2014); *Three Doctors Reprimanded for Falsifying Actress' Patient Records*, ASSOCIATED PRESS (Aug. 11, 1994), *available at*: http://www.apnewsarchive.com/1994/Three-Doctors-Reprimanded-for-Falsifying-Actress-Patient-Records/id-2ba2cc562cc3b6a6e71060d4b1f7571b (last visited Dec. 1, 2014).

[24]Spiegel & Ellis, *supra* note 23.

[25]*See William F. Skinner, M.D.*, 60 Fed. Reg. 62887 (Drug Enforcement Admin. Dec. 7, 1995); Michael J. Roth, M.D., 60 Fed. Reg. 62262 (Drug Enforcement Admin. Dec. 5, 1995). Ms. Taylor is identified as "Patient A" in these proceedings in order to protect her privacy.

[26]*Three Doctors Reprimanded for Falsifying Actress' Patient Records, supra* note 23.

[27]*Skinner*, 60 Fed. Reg. at 62891; *Roth*, 60 Fed. Reg. at 62267.

"the conflicting expert opinion evidence presented [at the hearing led] to the conclusion that the medical community [had] not reached a consensus as to the appropriate level of prescribing of controlled substances in the treatment of chronic pain patients."[28] DEA held that "[i]t remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of Federal and State law."[29] Because state medical standards regarding the proper prescribing of controlled substances for chronic pain patients were not established, DEA considered it outside of the scope of its authority under the CSA to make a determination as to whether the doctors' prescribing was within the proper practice of medicine.

DEA's actions in this highly publicized account demonstrated a commitment, not only in theory but also in practice, to the commonly understood legal authority of the states to regulate the practice of medicine. DEA's historical role under the CSA had been to ensure accountability and to protect the public from the dangers of diversion by enforcing safety, valid prescription-writing, dispensing, and recordkeeping rules. The role of the states was to ensure that medical practitioners were properly prescribing controlled substances pursuant to appropriate medical standards.

C. The Federal Requirement for a Legitimate Controlled Substance Prescription

The tension between DEA's increasing investigations of participants in pain and addiction treatment and the view of the medical community that appropriate physician decision-making is guided by professional standards has become most apparent in considering what constitutes a legitimate prescription. The federal requirements for a legitimate medical prescription are among the most fundamental provisions of the CSA, yet they have resulted in substantial litigation before the agency and the federal courts.

Under the CSA, a controlled substance generally may not be dispensed unless it is pursuant to a prescription issued by a practitioner. The CSA defines a "practitioner" as a physician or pharmacist, among others, who distributes,

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[28] *Skinner*, 60 Fed. Reg. at 62267.

[29] *Id.*

dispenses, or administers a controlled substance ***in the course of professional practice***.[30] DEA regulations further define "legitimate prescription:" "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***" (emphasis added).[31]

The prescription requirements that a practitioner must be (1) writing for a legitimate medical purpose and (2) acting in the usual course of that practitioner's professional practice are two separate elements, and both must be present in a legitimate prescription.[32] The difference between the two elements can be described as follows. A physician may prescribe controlled substances to a patient who has a legitimate medical need, but the method of prescribing the controlled substances might not conform to the usual course of professional practice (*e.g.*, the script might not contain all the required information, or the physician might be self-prescribing or prescribing without conducting an appropriate examination of the patient). Or the physician may follow all necessary "practice of medicine" steps for writing a prescription for controlled substances, but there might not be a legitimate medical purpose behind the prescription (*e.g.*, the physician knows that the patient does not need the medicine, or the patient is lying about the level of pain experienced or is not in pain at all).

In various publicly available materials—the 2006 policy statement, a 2006 Practitioner's Manual, and numerous agency final orders and decisions—DEA has identified patterns of conduct that it believes reflect prescriptions issued outside of the scope of a legitimate medical purpose or the

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[30]*See* 21 U.S.C. § 802(21) (practitioner means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis a controlled substance in the course of professional practice or research).

[31]21 C.F.R. § 1306.04(a) (2014).

[32]State laws governing controlled substances often mirror this federal prescription requirement. *See, e.g.*, Cal. Health & Safety Code § 11153(a); Idaho Code Ann. § 54-1733(1); LA. Rev. Stat. Ann. § 40.961(32).

usual course of professional practice.[33] In its 2006 Practitioner's Manual, DEA explained that an "acceptable medical practice" could not be definitively described because physicians must address various situations with patients, and therefore, DEA could only offer practitioners examples of conduct that could be indicative of diversion and abuse.[34] DEA described the following physician behaviors as possible indicators of diversion and abuse:

- An inordinately large quantity of controlled substances prescribed or large numbers of prescriptions issued compared to other physicians in the area;
- No physical examination given;[35]
- Warnings to the patient to fill prescriptions at different drug stores;
- Issuing prescriptions knowing that the patient was delivering the drugs to others;
- Issuing prescriptions in exchange for sexual favors;
- Prescribing of controlled drugs at intervals inconsistent with legitimate medical treatment;
- Using street slang rather than medical terminology for the drugs prescribed; and
- No logical relationship between the drugs prescribed and treatment of the condition allegedly existing.[36]

Also relevant is whether there is a "bona fide doctor-patient relationship" between the prescribing physician and the

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[33]The development of DEA's position has been controversial. In fact, DEA had previously issued guidelines after working with industry stakeholders that were removed from DEA's website. *See* Marc Kaufman, *New DEA Statement Has Pain Doctors More Fearful*, Common Sense for Drug Policy (Nov. 30, 2004), *available at*: http://www.mapinc.org/newscsdp/v04/n1705/a02.html (last visited Dec. 1, 2014).

[34]Drug Enforcement Admin., *Practitioner's Manual*, Appendix B (2006), DEA Office of Diversion Control website, *available at*: http://www.deadiversion.usdoj.gov/pubs/manuals/pract/appendices/app__b.htm (last visited Dec. 1, 2014).

[35]*See also Ralph J. Chambers, M.D.*, 79 Fed. Reg. 4962, 4970 to 4971 (Drug Enforcement Admin. Jan. 30, 2014) (DEA revoked the registration of a physician who failed to comply with Florida law requiring a physician prescribing controlled substances to perform a physical examination of the patient and perform a patient history).

[36]*Practitioner's Manual*, Appendix B, *supra* note 34.

patient receiving the prescription.[37] State law governs whether such a bona fide relationship exists.[38]

Notably, certain of DEA's indicators for diversion and abuse, such as the quantity of controlled substances prescribed or the relationship between the drugs prescribed and the condition being treated, involve medical decision-making and medical standards of care. We explore below federal and state criminal cases, as well as agency administrative orders, in which DEA and physicians have confronted each other on the issue of prescription-writing within the bounds of legitimate medical purpose in the usual course of professional practice.

D. Federal Criminal Cases Involving Legitimate Medical Purpose

The federal courts have addressed the prescription requirement of a legitimate medical purpose in many appellate decisions and trial court motions involving physicians. Typically, both the government and the physician defendant provide expert testimony at trial about the physician's conduct at issue and whether the physician's practices were consistent with the medical community's standards. In some instances, the alleged misconduct is so glaringly inappropriate that no expert testimony is required for a jury to determine whether a legitimate medical purpose was

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[37] *Dewey C. Mackay, M.D.*, 75 Fed. Reg. 49956, 49973 to 49974 (Drug Enforcement Admin. Aug. 16, 2010) (physician failed to issue prescriptions for controlled substances in the usual course of professional practice because he engaged in unprofessional conduct by sexually exploiting patients for whom he was prescribing controlled substances in violation of Utah's professional code for physicians); *accord Laurence T. McKinney*, 73 Fed. Reg. 43260, 43265 n.22 (Drug Enforcement Admin. Jul. 24, 2008).

[38] *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20727, 20731 (Drug Enforcement Admin. May 5, 2009); J*oseph Gaudio, M.D.*, 74 Fed. Reg. 10083, 10090 (Drug Enforcement Admin. Mar. 9, 2009) ("The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bona fide doctor-patient relationship."). "The applicable state medical standards to evaluate issues such as the bona fides of a doctor-patient relationship and other issues attendant on a determination of whether a prescription was issued for a legitimate medical purpose in the course of a professional practice can be discerned from expert testimony, state statutes and regulations, or rulings by state disciplinary authorities." *Mulrooney & Hull, supra* note 7.

possible. In others, however, the conflict between a physician's right to practice medicine and DEA's antidiversion efforts is the case's ultimate legal issue, and expert witness testimony provides the framework for the contest.

1. *United States v. Hurwitz*[39]

In 2004, Dr. William Hurwitz was convicted in federal court in Alexandria, Virginia, of 50 counts of drug trafficking and prescribing controlled narcotics outside the scope of legitimate medical purpose, including one count that led to the death of a patient.[40] Dr. Hurwitz became a prosecution target when some of his patients were arrested for attempting to sell their prescriptions, and they identified Dr. Hurwitz as the source of their controlled substances.[41] Dr. Hurwitz's conviction shocked the pain treatment community where he was regarded as a pioneer in high dosage prescription pain treatment. Some voiced concern that his conviction would have "a chilling effect on pain treatment, which is already scandalously inadequate because of the fear instilled by the war on drugs."[42]

The competing interests between reducing diversion and abuse and providing necessary medicines to patients were on full display during Dr. Hurwitz's trial. The government position was that he "was little more than a common drug dealer who operated out of a medical office rather than on a street corner," and its expert witnesses testified that Dr. Hurwitz's conduct was "outside the bounds of legitimate medical practice" because, consistent with evidence at trial, he prescribed large quantities of opioids to known drug abusers or those engaged in diversion.[43] Dr. Hurwitz, by contrast, presented expert testimony that the high dose protocol he

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[39]*U.S. v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006).

[40]*Id.* at 466 (referencing violations of 21 U.S.C. §§ 841(a)(1) and 846).

[41]*Id.*

[42]Jacob Sullen, *The Doctor Is Not a Criminal: A Painful Drug-War Case in Virginia*, NAT'L REV., May 23, 2005.

[43]*Hurwitz*, 459 F.3d at 467.

used "was a proper medical procedure for treating patients with intractable pain."[44]

> [Dr. Hurwitz and the defense experts] testified that the body quickly develops resistance to the dangerous side effects of opioids (such as respiratory depression), which then permits an escalation of the dosage until pain relief is obtained. One expert testified that once a patient becomes tolerant of the side-effects, there is effectively "no ceiling" on the quantity of opioids that can be prescribed if necessary to control pain. [Citation omitted]. That expert also testified that many patients over time will require an increase in their opioid dosage in order to maintain control of their pain. Hurwitz's experts also testified that there is no medical reason to stop treating a patient for pain simply because that patient may be abusing illicit drugs and that, in some cases, stopping such treatment may even be more problematic.[45]

Dr. Hurwitz appealed his conviction to the United States Court of Appeals for the Fourth Circuit on the grounds that the trial court improperly refused to provide the jury with an instruction regarding a physician's good faith conduct.[46] He argued that a doctor's good faith "in issuing the challenged prescriptions was relevant to his intent when treating his patients and thus relevant to the jury's determination of whether he acted outside the bounds of accepted medical practice or without a legitimate medical purpose."[47]

Relying on the Supreme Court 1975 decision in *United States v. Moore*[48] and a long line of cases following that precedent, the Fourth Circuit agreed with Dr. Hurwitz, finding that the jury should have been provided a good faith instruction.[49] The Supreme Court had specifically held in *Moore* that "the defendant could not be convicted if he merely made 'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice."[50]

The Fourth Circuit's ruling was a mixed result for Dr.

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[44] *Id.* at 468.

[45] *Id.*

[46] *Id.* at 476.

[47] *Id.*

[48] *U.S. v. Moore*, 423 U.S. 122, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975).

[49] *Hurwitz*, 459 F.3d at 476.

[50] *Moore*, 423 U.S. at 143.

Hurwitz though. The court held that an objective standard of good faith should be applied by a jury, not the subjective standard that Dr. Hurwitz had asserted on appeal.[51] The objective standard required the jury to consider the prescriber's compliance with generally accepted medical practices as opposed to a practitioner's personal views regarding acceptable medical practice.[52] On retrial, Dr. Hurwitz was convicted of 16 counts of drug trafficking and sentenced to 57 months in prison.[53]

2. *United States v. Boccone*[54]

The objective good faith standard was applied by the Fourth Circuit in the recent decision of *United States v. Boccone,* in which the court affirmed the conviction of a pain clinic's nurse practitioner for violations of 21 U.S.C. §§ 841(a)(1) (unlawful distribution) and 846 (conspiracy to distribute).[55] The court found that the jury could reasonably rely on the government's expert witness qualified in pain management to establish defendant's lack of good faith compliance with accepted medical standards.[56] After reviewing medical records for the patients at issue in the indictment, the expert testified that there was a "disconnect" between the medical issues presented and the patients' treatment.[57] For instance, she expressed concern about prescribing controlled substances to a patient who had pneumonia, questioned the failure to use NSAIDs or offer physical therapy to another pain patient, and noted that there was no physical exam in a patient's record reflecting his

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[51]*Hurwitz*, 459 F.3d at 479.

[52]*Id.*

[53]See Jerry Markon, *VA Pain Doctor's Prison Term is Cut to 57 Months*, The Washington Post (Jul. 13, 2007), *available at*: http://www.washingtonpost.com/wp-dyn/content/article/2007/07/13/AR2007071301035.html (last visited Dec. 1, 2014).

[54]*U.S. v. Boccone*, 556 Fed. Appx. 215 (4th Cir. 2014), cert. denied, 135 S. Ct. 169, 190 L. Ed. 2d 121 (2014).

[55]*Id.* at 221.

[56]*Id.* at 230–231.

[57]*Id.* at 233.

intractable pain.[58] The expert testified that the nurse practitioner's "entire course of treatment was outside the bounds of the accepted standard of care for pain management practice and for no legitimate medical purpose."[59]

As *Boccone* and the many cases like it demonstrate, expert medical testimony plays a key role in the criminal cases against physicians under the CSA. In the vast majority of reported criminal cases under the CSA, expert testimony adequately demonstrates the defendant physician's departure from the standards of medical care. Expert testimony can also, however, support an acquittal as shown in the two cases discussed below.

3. *United States v. Martinez*[60]

In this 2008 decision, the federal court in the Eastern District of Washington granted a motion for acquittal of a physician charged with unlawful distribution of controlled substances in connection with issuing methadone prescriptions to a patient for pain as opposed to for purposes of drug treatment.[61] The government's medical expert, a pain specialist, testified that while methadone could treat both pain and addiction, he concluded that the defendant had prescribed the medication for addiction, which was outside the bounds of medical practice because the defendant was not working at a regulated methadone clinic.[62] By contrast, the defendant's expert in pain management and addictionology testified that the defendant prescribed methadone for a legitimate medical purpose because there had been "clear medical indications for chronic opioid therapy" and that methadone's use in high doses to treat pain was generally accepted in the medical profession.[63]

In light of the conflicting expert testimony, the court held that no rational jury could find that the physician had "completely betrayed any semblance of legitimate medical

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[58] *Id.*

[59] *Id.*

[60] *U.S. v. Martinez*, 2008 WL 819024 (E.D. Wash. 2008).

[61] *Id.*

[62] *Id.*

[63] *Id.* at *3.

treatment"[64] or that she distributed methadone outside the usual course of professional practice.[65] Interestingly and without any elaboration, the court cited the defendant's expert testimony that there is " 'a lot of controversy about chronic pain therapy' arising out of 'cultural, political, and regulatory concerns.' "[66]

4. *United States v. Binder*[67]

In a 2014 decision from the Eastern District of Michigan, a federal court granted a motion for acquittal of a one-count indictment against a defendant physician for unlawful distribution of controlled substances.[68] At trial, neither side presented a physician expert witness to testify about the bounds of appropriate medical practice, but rather, the government called two local pharmacists to explain the prescriptions at issue, and neither pharmacist was able to testify that the prescriptions reflected no legitimate medical purpose.[69] While well-qualified, the pharmacists "were not trained, licensed, or qualified to diagnose patients or prescribe medications," and therefore, they could not testify as to whether the physician's conduct fell outside legitimate medical purposes or the usual course of professional practice.[70]

The court found the government's evidence at trial inadequate, ruling that "where the government presents only 'pattern' or 'red flag' evidence sifted from a large number of patient files, particularly where no expert determination was made as to the suitability of the treatment in each case, the evidence is insufficient, without more, to demonstrate guilt beyond a reasonable doubt."[71] Among the facts at issue were that many patients filled their prescriptions from the

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[64] *Id.* at *10 (quoting *U.S. v. Feingold*, 454 F.3d 1001, 1012–1013 (9th Cir. 2006)).

[65] *Id.*

[66] *Id.* at *7–8.

[67] *U.S. v. Binder*, 26 F. Supp. 3d 656 (E.D. Mich. 2014).

[68] *Id.* at 665.

[69] *Id.* at 658.

[70] *Id.* at 664.

[71] *Id.* at 663.

defendant physician at the same pharmacy located in the same building, but the court held that using the same pharmacy was not a red flag,[72] particularly when patients testified at trial that they had real pain from their medical conditions and that they paid typical insurance copays or routine office fees.[73]

For physicians, the necessity of going through a full criminal jury trial and, in many cases, an appeal to the court of appeals or the Supreme Court to defend their good faith, medical decisions takes a certain emotional, reputational, and financial toll. In addition to the reported decisions discussed above, physicians have secured jury acquittals in both federal and state criminal trials involving CSA violations and, in some instances, murder charges for their controlled substances prescribing practices.[74] In almost all in-

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[72]*Id.* at 661-663.

[73]*Id.* at 663.

[74]*See, e.g.*, David B. Brushwood, *Professional Casualties in America's War on Drugs*, 60 American Journal of Health-System Pharmacy (2003), *available at*: http://www.medscape.com/viewarticle/462841 (last visited Dec. 1, 2014), and Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 231 Saint Louis University Journal of Health Law and Policy 240 (2008) (California Attorney General indicted Dr. Frank Fisher in 1999 for several counts of murder allegedly resulting from prescriptions of high doses of opioids, but Dr. Fisher was acquitted after evidence at trial showed that the high doses prescribed were not unreasonable and frequently less than what the prosecutor's own expert witness prescribed); Vanessa Blum, *Physician Acquitted of Pain Pill Trafficking*, Sun Sentinel (Mar. 13, 2009), *available at*: http://articles.sun-sentinel.com/2009-03-13/news/0903120522__1__prescription-drug-overdoses-drug-dealer-doctors (last visited Dec. 1, 2014) (Dr. Ali Shaygan was acquitted in 2009 in Miami federal court of 141 counts of distributing controlled substances outside the bounds of a legitimate medical purpose because the evidence showed that the patient had a history of abusing illegal narcotics, and the cause of the overdose could not be determined); Paul Harasim and Mike Blasky, *Doctors Defend Colleague Arrested on Murder Charge*, Las Vegas Review Journal (Apr. 3, 2011), *available at*: http://www.reviewjournal.com/news/government/doctors-defend-colleague-arrested-murder-charge (last visited Dec. 1, 2014), and Francis McCabe, *Case Dismissed Against Doctor Charged in Patient's Death*, Las Vegas Review Journal (Nov. 11, 2011), *available at*: http://www.reviewjournal.com/news/crime-courts/case-dismissed-against-doctor-charged-patients-death (last visited Dec. 1, 2014) (Dr. Richard Teh, a Las Vegas physician, was charged in 2011 with murder by the Clark County District Attorney when one of his patients died

stances, the medical expert testimony to establish the physician's legitimate medical purpose (or, in some cases, the patient's cause of death) was critical to the physicians' defense.

E. DEA Agency Orders and Decisions Affecting Medical Practice

In the vast majority of revocation proceedings that it initiates, DEA revokes the physicians' registrations in matters questioning prescriptions' legitimate medical purpose. Rarely, in these final orders, has the agency found that a physician presented sufficient evidence to rebut the DEA's evidence that it was not in the public interest for the physician to maintain or receive a registration. Because few cases have been decided in a physician's favor, the standards for a physician to show that prescriptions were for a legitimate medical purpose and, thus, succeed in these DEA administrative proceedings are difficult to discern.

The CSA provides that the agency may revoke a DEA registration or deny an application upon a showing that the registration is inconsistent with the public interest.[75] Five factors are reviewed to make a determination: (1) recommendation of an appropriate state licensing board or professional disciplinary authority; (2) past experience in dispensing controlled substances; (3) prior conviction record of applicant under federal or state laws relating to the manufacture, distribution, or dispensing of such substances; (4) compliance with applicable federal, state, and local laws regarding controlled substances; and (5) such other factors that may threaten the public health and safety.[76] Once DEA makes a *prima facie* showing on any one of the factors, the physician must rebut with evidence showing that he or she can be entrusted with a registration.[77] The physician must demonstrate both (1) an acceptance of responsibility and (2)

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from an overdose of controlled substances but acquitted when a second autopsy disclosed that the patient died from a bacterial infection and that her toxicology levels were within normal ranges).

[75]21 U.S.C. § 823(f).

[76]*Id.*

[77]*Samuel S. Jackson*, 72 Fed. Reg. 23848, 23853 (Drug Enforcement Admin. May 1, 2007).

measures undertaken to ensure that diversion and abuse will not happen in the future.[78] In considering the physician's acceptance of responsibility and whether misconduct will recur, the agency has historically looked to factors such as genuine remorse,[79] lapse of time since wrongdoing,[80] candor with the court and DEA investigators,[81] and attempts to minimize misconduct.[82] These factors give the agency wide discretion on whether to deny or revoke a registration and have made it difficult to defend against such actions.[83]

One notable example of a physician succeeding in maintaining a registration after an agency proceeding is the matter of *Jayam Krishna-Iyer, M.D.*, involving a physician whose registration was revoked for prescribing painkillers to three undercover agents.[84] In its administrative process, the agency deemed prescriptions written for the undercover agents to be outside the scope of a legitimate medical purpose because, among other reasons, DEA demonstrated Dr. Krishna-Iyer did not perform a physical exam and falsified documents to show that she did.[85] Despite also finding that Dr. Krishna-Iyer "took substantial measures to reform her practice," her registration was revoked for her failure to make a sufficient showing that she accepted responsibility—she testified that she did not knowingly or intentionally distribute a controlled

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[78] *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8195 (Drug Enforcement Admin. Feb. 23, 2010).

[79] *Lawrence C. Hill, M.D.*, 64 Fed. Reg. 30060, 30062 (Drug Enforcement Admin. Jun. 4, 1999).

[80] *Norman Alpert, M.D.*, 58 Fed. Reg. 67420, 67421 (Drug Enforcement Admin. Dec. 21, 1993).

[81] *Jeri Hassman, M.D.*, 75 Fed. Reg. at 8236.

[82] *Ronald Lynch, M.D.*, 75 Fed. Reg. 78745, 78754 (Drug Enforcement Admin. Dec. 16, 2010).

[83] *See, e.g., Michael A. White, M.D.*, 79 Fed. Reg. 62957, 62967 (Drug Enforcement Admin. Oct. 21, 2014) (agency revoked the respondent's registration because "not once during the hearing did Respondent unequivocally admit fault," making any acceptance of responsibility "tenuous at best.").

[84] *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459 (Drug Enforcement Admin. Jan. 6, 2009).

[85] *Id.*

substance because she did not know that the drugs would be sold on the streets.[86]

Dr. Krishna-Iyer appealed the revocation decision to the United States Court of Appeals for the Eleventh Circuit, arguing that DEA did not consider other favorable evidence, namely the thousands of patient files in which she claimed to have legitimately prescribed controlled substances.[87] In an unpublished decision, the Eleventh Circuit agreed, vacating the agency's final order and remanding the case with instructions to DEA to pay attention to the complete patient records involving controlled substances, not just the few undercover cases.[88]

On remand, the agency granted Dr. Krishna-Iyer a new registration subject to certain restrictions finding that she had sufficiently shown remorse for her actions and taken responsibility for her wrongdoing and was willing to adhere to restrictions and take other actions to prevent further diversion. In its final order on remand and in response to the Eleventh Circuit's admonition that DEA should have reviewed all the patients files, the agency noted that, based on its long precedent, thousands of legitimate prescriptions "do not render her prescribing to the undercover officers any less unlawful"[89] and commented that as few as two illegitimate prescriptions have been deemed sufficient for revoking a registration.[90] Thus, even in the face of the Eleventh Circuit remand, DEA maintains that even one misstep or questionable prescription can be the basis for a DEA revocation action.

F. State Drug Control Measures that Affect the Practice of Medicine

A number of recent state laws, regulations, and initiatives directed at drug control have also had an impact on physician practice of medicine and pain treatment. Most states

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[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *Id.* at 463.

[90] *See Alan H. Olefsky*, 57 Fed. Reg. 928, 929 (Drug Enforcement Admin. Jan 9, 1992).

now have laws mirroring the CSA that restrict the writing of prescriptions for controlled substances unless they are written for a legitimate medical purpose in the usual course of professional practice.[91] Though different states might have slightly varying requirements of what a physician must do to be within the scope of a legitimate medical purpose, the general consensus is that physicians are required to conduct a physical exam, evaluate the patient's medical history, follow up on the efficacy of treatment, and adjust the prescription as needed, and most importantly, physicians must document everything in the patient's file.[92] State medical boards have also issued their own guidelines on prescribing controlled substances and treating pain, with suggested strategies on how to identify abuse and how to taper patients off controlled painkillers.[93]

As the prescription drug abuse epidemic continues to spread, states have attempted to follow DEA's lead in fighting against overprescribing. Like the federal measures, these attempts have had an effect on the practice of medicine.

States implementing prescription monitoring programs (PMPs) have the greatest impact on prescribing and dispensing of controlled substance medications. PMPs use various state measures to trace prescriptions and dispensing per patient to assist in the detection of patients who may be "doctor-shopping" for controlled substances. While the PMPs are state initiatives, Congress passed legislation in 2006 to fund such programs,[94] and DEA has reported that states using PMPs had lower numbers of prescriptions for Oxycontin (a Schedule II controlled substance).[95]

In California during the mid-2000s, the state's PMP

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[91] *See, e.g.*, Cal. Health & Safety Code § 11153(a); Idaho Code Ann. § 54-1733(1); LA. Rev. Stat. Ann. § 40.961(32).

[92] *See, e.g.*, Fla. Stat. § 456.44; Pa. Code § 16.92.

[93] Medical Board of California's Guidelines for Prescribing Controlled Substances for Pain (November 14, 2014), *available at*: http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf (last visited Dec. 1, 2014).

[94] National All Schedules Prescription Electronic Reporting Act, Pub. L. No. 109-60 (2005).

[95] The President's National Drug Control Strategy (Mar. 2004), *available at*: http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_2014.pdf (last visited Dec. 1, 2014).

required serialized triplicate prescriptions for all Schedule II controlled substances.[96] Under such a system, the prescribing physician keeps a copy of the prescription and gives the other two copies to the patient. The patient provides both copies to the dispensing pharmacy, which keeps one for its records and provides the other copy to the state regulatory authority. California believed this practice protected citizens from the dangers of overprescribing by tracking prescriptions written for Schedule II controlled substances.[97] Yet the State also had "a disproportionately high rate of Schedule III opioid prescribing, particularly hydrocodone (Vicodin)."[98] California subsequently removed its triplicate prescription PMP requirements.

In 1989 in New York, the State enforced a PMP that required triplicate prescriptions for benzodiazepines with similar consequences.[99] While the number of prescriptions written for benzodiazepines decreased, there were subsequent increases in other drugs that were less effective, had higher rates of toxicity, and had equal or greater risk of abuse.[100]

This "substitution effect" has trended across states with PMPs. Nevertheless, PMPs continue to be implemented as states all across the country have developed electronic PMP systems.

What can be gleaned from these findings? Doubtlessly, these state programs can be effective in identifying potential doctor-shopping or in looking at patterns of physician prescribing. The data also suggest that state initiatives are effective in lowering the number of prescriptions for certain controlled substances. These numbers, however, are generally accompanied by higher numbers of prescriptions for other types of drugs. There is also a concern that the PMP programs will affect how doctors prescribe controlled substances potentially affecting patient care.

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[96] *Fishman* at 629, *supra* note 3.

[97] *Id.*

[98] *Id.*

[99] *Id.* at 630.

[100] *Id.*

III. Enforcement of the Corresponding Responsibility of Pharmacies and Pharmacists

A. The Corresponding Responsibility Doctrine

Similar to the federal prescription requirement for physicians, discussed in section II.C., the CSA places a "corresponding responsibility" requirement on pharmacists and pharmacies to fill only lawful controlled substances prescriptions.[101] Though the initial responsibility for proper prescribing rests on the prescribing practitioners, the regulations at 21 C.F.R. § 1306.04(a) provide that:

> [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 or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

As with physicians, the CSA statutory and regulatory scheme can subject pharmacists and pharmacies to the risk of criminal sentences, civil penalties, and revocation of DEA registrations.[102]

By placing this burden on pharmacists and pharmacies, DEA regulations require them to share with practitioners the role of ensuring that only lawful prescriptions for controlled substances are provided to patients with legitimate medical needs. Originally aimed at protecting against fraudulent prescriptions,[103] DEA's current reliance on the corresponding responsibility doctrine to confirm the legitimate medical purpose of a prescription places pharmacists and pharmacies squarely in the middle of patients' access to legitimate medications.

The corresponding responsibility doctrine requires the

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[101] *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48887, 48895 (Drug Enforcement Admin. Aug. 9, 2011).

[102] 21 U.S.C. §§ 841 to 847.

[103] *See* Drug Enforcement Admin., Pharmacist's Manual at 66–68 (rev. ed. 2010), DEA Office of Diversion Control website, *available at*: http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html (last visited Dec. 1, 2014).

pharmacist and pharmacy[104] to scrutinize independently whether a prescription presented is legitimate and to ensure ***independent of any practitioner decision-making*** that they dispense only lawful prescriptions for controlled substances.[105] The pharmacy "is unauthorized to dispense a controlled substance if the prescription *either* lacks a legitimate medical purpose *or* is outside the usual course of professional practice."[106]

For a pharmacist, determining whether a prescription was not written by the physician for a legitimate medical purpose or outside the usual course of professional practice can be a difficult exercise. Under the body of administrative case law developed by DEA, a pharmacist must not fill a prescription if the pharmacist " 'knows or has reason to know that [a] prescription was not written for a legitimate medical purpose.' "[107] In enforcing this standard, DEA has held pharmacists and pharmacies to a standard of reasonableness.[108]

The corresponding responsibility on pharmacists and pharmacies demands diligence and a high level of care. A

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[104]DEA interprets the corresponding responsibility provision of 21 C.F.R. § 1306.04(a) to also apply to pharmacies. See Holiday CVS, L.L.C., 77 Fed. Reg. 62316, 62341 (Drug Enforcement Admin. Oct. 12, 2012); *United Prescription Servs., Inc.*, 72 Fed. Reg. 50397, 50408 (Drug Enforcement Admin. Aug. 31, 2007).

[105]*Liddy's Pharmacy*, 76 Fed. Reg. at 48895 ("By filling these prescriptions, Respondent again failed to comply with its 'corresponding responsibility' under Federal law to dispense only lawful prescriptions" (quoting 21 C.F.R. § 1306.04(a))).

[106]*U.S. v. Armstrong*, 550 F.3d 382, 397 (5th Cir. 2008).

[107]*Wheatland Pharmacy*, 78 Fed. Reg. 69441, 69445 (Drug Enforcement Admin. Nov. 19, 2013) (quoting Medicine Shoppe-Jonesborough, 73 Fed. Reg. 364, 381 (Drug Enforcement Admin. Jan. 2, 2008)); accord U.S. v. Henry, 727 F.2d 1373, 1379, 15 Fed. R. Evid. Serv. 293 (5th Cir. 1984), on reh'g, 749 F.2d 203 (5th Cir. 1984) (overruled in part, *U.S. v. Jones*, 839 F.2d 1041 (5th Cir. 1988)) ("[T]he 'corresponding responsibility' is corresponding. The physician's responsibility is not to prescribe improperly while the pharmacist's responsibility is not to dispense a controlled substance for non-medical reasons. The regulation does not place an unduly heavy burden on the pharmacist. Proof is required that the pharmacist had reason to believe that the prescription was not issued in the usual course of professional treatment.").

[108]Mulrooney & Hull, *supra* note 7.

reasonable pharmacist must verify the legitimacy of a controlled substance prescription that raises questions, commonly referred to as "resolving red flags," or refuse to fill the prescription in the face of an unresolved red flag.[109] Though DEA does not require omniscience,[110] a pharmacist "may not intentionally close his eyes and thereby avoid knowledge of the real purpose of the prescription" when the prescription is "clearly not issued for a legitimate medical purpose."[111] The federal courts affirmed this standard in, among other cases, *United States v. Ihenacho*, in which the U.S. Court of Appeals for the First Circuit upheld the conviction of the owners of an internet pharmacy that dispensed controlled substances to individuals who did nothing more than fill out an online questionnaire.[112]

The agency has developed a three-part test for violations of the corresponding responsibility requirement: "(1) the [pharmacy] dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of controlled substances."[113] When confronted with a red flag that the prescription may not be for a legitimate medical purpose, a pharmacist must not fill the prescription until the red flag has been resolved.[114]

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[109]*See generally E. Main St. Pharmacy*, 75 Fed. Reg. 66149 (Drug Enforcement Admin. Oct. 27, 2010).

[110]*Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62341 (Drug Enforcement Admin. Oct. 12, 2012) (*citing Carlos Gonzalez*, 76 Fed. Reg. 63118, 63142 (Drug Enforcement Admin. Oct. 11 2011)).

[111]*Ralph J. Bertolino*, 55 Fed. Reg. 4729, 4730 (Drug Enforcement Admin. Feb. 9, 1990).

[112]*U.S. v. Ihenacho*, 716 F.3d 266, 269 (1st Cir. 2013) ("A pharmacist has a corresponding responsibility for the proper dispensing of controlled substances. Issuing prescriptions based solely on online questionnaires falls outside the usual course of medical practice, making such prescriptions invalid."); *see also* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008) (codified in scattered sections of 21 United States Code).

[113]*Holiday CVS*, 77 Fed. Reg. at 62341.

[114]*E. Main St. Pharmacy*, 75 Fed. Reg. at 66164–65; *Winn's Pharmacy*, 56 Fed. Reg. 52559, 52561 (Drug Enforcement Admin. Oct. 21, 1991); *see* Mulrooney & Hull, *supra* note 7.

B. DEA Reliance on Red Flags

DEA has held that the "steps necessary to resolve [a] red flag will *perforce* be influenced by the nature of the circumstances giving rise to the red flag."[115] Resolving red flags can be a complicated and time-consuming process. Patients may present one or more red flags when presenting a controlled substance prescription to a pharmacy. Additionally, red flags can change over time as individuals engaged in diversion and abuse change their behavior to adjust to pharmacies' efforts to resolve the then-known red flags.

Pharmacists cannot limit their inquiries to reviewing the prescription for the use of a proper form and all necessary prescriber and patient information. Also, they cannot rely on the fact that the prescriber holds a valid DEA registration and state medical license and that the prescriber has verified the legitimacy of the prescription to the pharmacist.[116] Pharmacists dispensing controlled substances, particularly narcotics, must do more although precisely what is unclear.[117] Some of the retail chain pharmacies have developed systems to review both the prescriber's prescription writing habits and the patient's medical and prescription histories in an effort to ferret out problem prescriptions. Indeed, certain red flags are simply unresolvable, regardless of the actions of a reasonable pharmacist, and the prescriptions must be rejected.[118]

In 2010, the DEA published a Pharmacist's Manual that identified common red flags. They included:[119]

- Prescribers who write significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.

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[115] *Holiday CVS*, 77 Fed. Reg. at 62341.

[116] *Id.* at 62342–62343.

[117] *Id.* at 62343 (agency held that beyond verifying the legitimacy of the prescription and contacting the prescriber, "the methods that are available [for pharmacists] are flawed," and some combinations of red flags cannot be resolved).

[118] *Id.* at 62345 ("The red flags that existed were recognized, or should have been, and the convincing expert evidence of record establishes that the red flags were not resolvable by a reasonable and professional pharmacist.").

[119] *Pharmacist's Manual* at 66–67 (rev. ed. 2010), *supra* note 103.

- Patients who appear to be returning too frequently (a prescription that should last for a month in legitimate use is being refilled on a biweekly, weekly, or even a daily basis).
- Prescribers who write prescriptions for antagonistic drugs, such as depressants and stimulants, or only short-acting or long-acting drugs, at the same time (drug abusers often request prescriptions for "uppers and downers" at the same time).
- Patients who present prescriptions written in the names of other people.
- Numbers of people who appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community showing up with prescriptions from the same physician.

These red flags are not exhaustive, and additional red flags have been identified in agency final orders since 2010.

In the 2012 matter of *Wheatland Pharmacy*, DEA denied a pharmacy's new application for a DEA registration because the pharmacist, who had previously surrendered the pharmacy's registration, had dispensed prescriptions for "drug cocktails" to 27 patients for the same combination of drugs (hydrocodone, alprazolam, and promethazine with codeine syrup—referred to on the street as "pancakes and syrup" and known to be commonly abused and/or diverted) to one patient written by a practitioner located approximately 240 miles away from the pharmacy.[120] Because the pharmacist should have known that this combination of prescriptions was not for a legitimate medical purpose and because she did not take steps to resolve the "drug cocktail" red flag, DEA found that she and the pharmacy did not meet their corresponding responsibilities and denied the pharmacy's DEA registration application.[121]

Also in 2012, DEA revoked the registrations of two pharmacies in *Holiday CVS,* finding that the pharmacies had not resolved red flags for diversion identified by the government's expert witness upon review of spreadsheets

[120]*Wheatland Pharmacy*, 78 Fed. Reg. at 69445–69447.

[121]*Id.*

containing prescription information.[122] DEA found that the red flags were consistent with agency and circuit precedent[123] and that a reasonable pharmacist would have concluded that the prescriptions were not written for a legitimate medical purpose and in the usual course of a professional practice.[124] The red flags were:

- "Pattern prescribing," meaning the same drugs and same quantities written by the same physician;
- Prescribing of oxycodone and alprazolam to a patient;
- Prescriptions written by a local prescriber for out-of-state patients or where the pharmacy is not near the patient or prescriber; and
- Shared addresses by customers presenting prescriptions on the same day.[125]

Most interestingly, the government expert also testified that "the prescribing of controlled substances in general was a red flag."[126] In explaining why it agreed with the expert that each controlled substance prescription is a red flag, the agency gave "the simple reason that a red flag's overall resolvability does not render it any less of a red flag."[127]

In contrast to the almost universal use of medical expert testimony in the physician cases questioning prescriptions' legitimate medical purpose, the authors are aware of certain DEA proceedings questioning pharmacists' corresponding responsibility to dispense prescriptions for legitimate medical purposes where DEA, on the basis of relevance, excluded expert medical testimony about proper pain management. The agency took the stance that the pharmacist should have been aware of certain red flags and resolved them regardless of whether expert testimony would have demonstrated that the red flags were not dispositive of an illegitimate prescription.

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[122] *Holiday CVS*, 77 Fed. Reg. at 62344.

[123] *Id.*

[124] *Id.* at 62345.

[125] *Id.* at 62344.

[126] *Id.*

[127] *Id.* at 62344 n.104.

C. Industry Response to DEA Focus on Red Flags

In 2009, DEA formed tactical diversion squads combining federal, state, and local law enforcement and redirected enforcement efforts from physicians and independent pharmacies to target companies higher in the chain of controlled substances delivery, namely distributors and large retail chain pharmacies.[128] In 2011 and 2012, DEA executed warrants on Florida distribution centers operated by Cardinal Health (Cardinal) and Walgreens Co. (Walgreens), which supplied controlled substances to CVS Pharmacy, Inc. (CVS), and Walgreens pharmacies, respectively, as well as on a handful of CVS and Walgreens pharmacies in Florida.[129] DEA focused on these distribution centers and pharmacies because high quantities of oxycodone had been supplied by those distribution centers to pharmacies that had oxycodone dispensing rates significantly higher than other pharmacies in Florida.[130]

The national retail chain pharmacies and distributors responded with a two-pronged approach. They took the legal argument regarding the expansion of DEA's authority to the federal courts, and they engaged in renewed and sweeping efforts to identify and turn away problem prescribers and patients whose controlled substances prescriptions were not for legitimate medical purposes.

1. The Legal Response

Several months after its warrants, DEA issued immediate suspension orders of the Cardinal and Walgreens distribu-

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[128] *Florida Doctors No Longer Among the Top Oxycodone Purchasers in the United States*, DEA website, Miami News Releases (Apr. 5, 2013), *available at*: http://www.dea.gov/divisions/mia/2013/mia040513.shtml (last visited Dec. 1, 2014).

[129] *Id.*; *see also* Donna Leinwand Leger, *DEA Aims Big in Cardinal Health Painkiller Case*, USA Today (Feb. 28, 2012), *available at*: http://usatoday30.usatoday.com/news/nation/story/201202-27/painkiller-abuse-DEA/53275844/1 (last visited Dec. 1, 2014); Devlin Barrett and Timothy W. Martin, *Pharmacies Swept Into Drug Wars*, Wall Street Journal (Feb. 15, 2012), *available at*: http://online.wsj.com/news/articles/SB10001424052970204062704577223573533933402 (last visited Dec. 1, 2014).

[130] *Id.*

tion center registrations on the basis that their alleged failure to operate effective suspicious order monitoring programs in Florida caused an "imminent danger" to public health and safety.[131] Similarly, DEA issued immediate suspension orders against the registrations of two CVS pharmacies and orders to show cause to revoke the registrations of six Walgreens pharmacies in Florida, alleging that their failure to properly exercise their corresponding responsibility also endangered public health and safety.[132]

Cardinal, CVS, and Walgreens each initiated preliminary injunction actions in federal court to enjoin DEA's immediate suspension orders arguing, in part, that DEA had exceeded its authority under the CSA by not properly considering remedial actions taken by each company eliminating any "imminent danger" to the public.[133] The federal district court denied both preliminary injunction motions of Cardinal and CVS, finding that they were unlikely to be successful on the merits of any action they brought against DEA for improperly issuing the immediate suspension orders.[134] Both Cardinal and CVS appealed the lower court decisions to the D.C. Circuit Court of Appeals again contending that DEA exceeded its statutory authority by the immediate suspension of facilities that posed no "imminent

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[131] *Id.*

[132] *Id.*

[133] *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012), *vacated and remanded*, 493 Fed. Appx. 108 (D.C. Cir. 2012); *Walgreens Co. v. Drug Enforcement Administration, et al.*, No. 12–1397 (D.C. Cir., Petition for Review Filed Oct. 10, 2012).

[134] *Holiday CVS*, 839 F. Supp. 2d at 163 (In rejecting the arguments of CVS that it did not pose an "imminent danger" to the public, the district court found DEA had properly considered "(1) the rampant pharmaceutical drug abuse problem in Florida, (2) large and increasing amounts of oxycodone dispensed at the pharmacies [. . .], (3) the DEA's earlier specific guidance to CVS that apparently was not heeded, (4) the evidence of illegitimate prescriptions being dispensed at the CVS pharmacies, and (5) the pharmacists' admitted failure to detect warning signs as recently as October 2011"); *Cardinal Health*, 846 F. Supp. 2d at 225 (In addition to CVS factors, DEA considered Cardinal's history of inadequate antidiversion controls at its Florida distribution center and failure to monitor its chain pharmacy customers).

danger" to the public,[135] but both appeals were mooted as Cardinal settled with DEA, and CVS pursued agency administrative remedies.

Walgreens, on behalf of its distribution center, filed a preliminary injunction action directly with the U.S. Court of Appeals for the D.C. Circuit and argued that:[136]

- DEA regulations did not require distributors to investigate pharmacies with valid DEA registrations or refuse to ship suspicious orders;
- DEA could not enforce antidiversion obligations beyond those contained in the federal regulations; and
- DEA could not amend its regulations through administrative final orders or guidance letters.

Walgreens argued that the CSA and its regulations hold physicians and pharmacists, not distributors, responsible for "proper prescribing and dispensing of prescription drugs."[137] Walgreens objected to DEA's imposition on distributors of the obligation to determine whether prescriptions presented at pharmacies they supplied were issued for legitimate medical purposes:[138]

> Requiring distributors to second-guess prescribing and dispensing decisions—as DEA tries to do here—would upend [the] regulatory scheme. After all, the "legitimacy" of any order of controlled substances turns on whether or not the pharmacy's customers have valid prescriptions to use the drugs for "legitimate medical purposes." [Citation omitted.] But distributors are not trained as physicians or pharmacists, and they have no reasonable way of looking over the shoulder of pharmacists and double-checking the validity of each prescription, as DEA apparently envisions. DEA's approach would impose an impossible obligation on distributors that neither the CSA nor the regulations contemplate.

Walgreens further argued that the history and plain language of the CSA clearly evidenced the legislature's intent

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[135]Brief for Appellant at 28–54, *Cardinal Health, Inc. v. U.S. Department of Justice, et al.*, No. 12–5061 (D.C. Cir. Filed May 2, 2012); Appellant's Brief at 26–52, *Holiday CVS, L.L.C. v. Holder, et al.*, No. 12–5072 (D.C. Cir. Filed May 4, 2012).

[136]Final Brief of Petitioner at 32, *Walgreens Co. v. Drug Enforcement Administration, et al*, No. 12–1397 (D.C. Cir., Filed Dec. 26, 2012).

[137]*Id.* at 34.

[138]*Id.*

to limit DEA's discretion and require only specific duties of distributors.[139] Lastly, Walgreens argued that DEA could not unilaterally amend federal regulations through its own agency final orders and guidance documents and ignore the rulemaking procedures required by the Administrative Procedures Act, 5 U.S.C. § 553.[140]

Before the D.C. Circuit could rule on those challenges to DEA's authority, Walgreens and DEA entered a civil and administrative settlement for $80 million in civil penalties and specific obligations that Walgreens would undertake to assure that it was not distributing or dispensing in violation of the CSA.[141] Nevertheless, as DEA continues to pursue industry for allegedly failing to meet obligations announced in DEA guidance and administrative rulings, the arguments made by Cardinal, CVS, and Walgreens in contesting the extent of DEA's authority under the CSA will continue to be raised in the federal courts.

2. Retail Chain Pharmacies Tighten Systems and Policies

National chain pharmacies CVS and Walgreens responded to the agency enforcement actions in Florida and the mounting pressure for antidiversion strategies by adopting stringent dispensing policies and analyzing prescriber and patient information in making dispensing decisions. As a result of these actions, certain physicians are no longer able to have their prescriptions honored at CVS pharmacies, and patients who present red flags at CVS and Walgreens pharmacies that cannot be resolved under tightened dispensing policies are unable to fill their prescriptions.

In a 2013 article in The New England Journal of Medicine, CVS's Chief Medical Officer acknowledged that because "the DEA has now identified both pharmaceutical distributors and chain pharmacies as part of the [drug abuse] problem," the pharmaceutical industry must "develop new programs to

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[139] *Id.* at 37–46.

[140] *Id.* at 47–50.

[141] June 11, 2013 Settlement and Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration and Walgreens Co., Addendum at 1, *available at*: http://www.dea.gov/divisions/mia/2013/mia061113__attach.pdf (last visited Dec. 1, 2014).

reduce inappropriate use."[142] Noting that chain pharmacies have access to aggregated prescription information, CVS developed a program to identify prescribers who "exhibited extreme patterns of use of 'high-risk drugs' relative to other prescribers."[143] CVS used approximately two years of its own prescription data to benchmark prescribers of common geographic regions and medical specialties against one another on factors such as volume of high risk drugs, proportion of high risk drugs versus all drugs prescribed, patients paying cash for high risk drugs, and patients between 18-35 years old with prescriptions for high risk drugs.[144] In its initial review, CVS identified 42 physicians as suspicious. CVS offered physicians identified through this analytical tool an opportunity to explain the nature of their medical practices and prescribing habits. Ultimately, 36 pharmacists had their prescription privileges suspended at CVS pharmacies; six physicians demonstrated to CVS that their prescribing practices were legitimate.[145] CVS recognized that the program is not a perfect solution and suggested greater transparency in controlled substance prescribing, such as through e-prescribing, a national prescription drug monitoring program or access to aggregated databases.[146]

Like CVS, Walgreens has implemented extensive verification procedures to ensure that its pharmacies are filling prescriptions for legitimate medical purposes. As part of its 2013 settlement with DEA, Walgreens agreed to maintain a Good Faith Dispensing Policy and training for its pharmacies regarding red flags for diversion and to regularly update the red flags to incorporate changing diversion threats.[147] At least one version of a Walgreens' Good Faith Dispensing

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[142]Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances—A Pharmacy View*, The New England Journal of Medicine (Sep. 12, 2013), *available at*: http://www.nejm.org/doi/full/10.1056/NEJMp1308222#t=artic (last visited Dec. 1, 2014).

[143]*Id.*

[144]*Id.*

[145]*Id.*

[146]*Id.*

[147]June 11, 2013, Settlement and Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration and Walgreens Co., *supra* note 141.

Checklist was posted on various internet sites in 2013.[148] The checklist showed that Walgreens required pharmacists to identify and resolve particular red flags for controlled substance prescriptions, including whether (i) the prescription is for the same medication and from the same physician as prior prescriptions, (ii) the customer and prescriber are within close geographical proximity to the pharmacy, (iii) the prescription is filled within time limits, (iv) the patient is using insurance, (v) the quantity prescribed is excessive, and (vi) the patient has been taking the same medication and dosage for a long time.[149] Pharmacists were also instructed to obtain valid government photo identification and to check the customer's prescription drug history in the state's prescription drug monitoring program where available.[150]

The checklist further directed pharmacists to use their professional judgment in obtaining the following additional information directly from prescribing physicians: (1) the prescriber's scope of practice; (2) the diagnosis; (3) the standard of care for the treatment; (4) length of the treatment; (5) the date of the last physical and/or pain assessment; (6) the use of available alternative and/or lower prescription medication for pain control; and (7) information regarding coordination with other physicians involved in the patient's care.[151] If the pharmacist's professional judgment was still that the prescription should not be filed, the decision was to be entered into Walgreens' database,[152] which would then make it more likely that the patient's prescription would not be filled by any Walgreens pharmacy.[153]

3. Physician Response to Pharmacy Actions

The American Medical Association (AMA) reacted to the

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[148]Bob Segall, *Walgreens' "Secret Checklist" Reveals Controversial New Policy on Pain Pills*, WTHR Indiana News (September 12, 2013), *available at*: http://www.wthr.com/story/23469086/2013/09/18/walgreens-secret-checklist-reveals-controversial-new-policy-on-pain-pills (last visited Dec. 1, 2014).

[149]*Id.*

[150]*Id.*

[151]*Id.*

[152]*Id.*

[153]*Id.*

national chains' verification programs by denouncing pharmacists for "invading the patient-physician relationship and/or questioning the judgment and/or rationale of a physician in each and every controlled substance prescription [which] perverts the spirit and intent of the DEA regulations."[154] The AMA stated that the appropriateness of issuing a prescription is "purely medical" and "completely within the purview of the treating physician."[155] The AMA passed a resolution deeming pharmacist verification calls to be an inappropriate and unwarranted interference with the practice of medicine and resolving to advocate for legislation to eliminate such calls if the issue was not addressed by the national chains, DEA, and other federal and state regulators.[156]

Resonating from the AMA resolution is the tension noted earlier in this chapter between DEA enforcement objectives and the traditional standards of medical care established by professional communities. The AMA finds pharmacist calls to resolve red flags an intrusion into the doctor-patient relationship while DEA interprets its regulations to require pharmacists to be the "last line of defense" against the prescription drug epidemic[157] and considers pharmacists as "drug experts" in the healthcare arena responsible for policing physicians.[158] Given the difficulty experienced by, and the risks posed for, the national chain pharmacies and the large distributors in litigating these issues with DEA, the AMA's strongly worded resolution has not gained measurable traction in changing the enforcement landscape.

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[154]Resolution 218, *AMA Response to Drug Store Chain Intrusion in Medical Practice*, American Medical Association House of Delegates (May 7, 2013); see also Alaric Dearment, *AMA Adopts Resolution on Pharmacist Drug Inquiries*, Drug Store News (July 8, 2013), *available at*: http://www.drugstorenews.com/article/ama-adopts-resolution-pharmacist-drug-inquiries (last visited Dec. 1, 2014).

[155]*Id.*

[156]*Id.*

[157]*See E. Main St. Pharmacy*, 75 Fed. Reg. at 66165.

[158]*Responding to the Prescription Drug Abuse Epidemic: Hearing Before the S. Caucus on Int'l Narcotic Control*, 112th Cong. 2 (2012) (Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA).

IV. Conclusion

In the wake of DEA enforcement actions against national pharmacy chains CVS and Walgreens, pharmacists and pharmacies have become reluctant to fill patient prescriptions for certain controlled substances or for certain prescribers.[159] Meanwhile, the physician community continues to debate the proper use of controlled substances for pain treatment and for addiction, and the current medical standards are inconsistent, changing, and embedded in political, cultural, and legal controversy.[160] DEA can be credited with bringing forward the important issue of addressing prescription drug abuse in the United States, but the blunt tools used to achieve its goals can cause great personal and professional harm to legitimate physicians and pharmacists seeking to provide patients with access to needed medications. To bring about real change for the patients that suffer from pain and addition, and the providers who treat them, meaningful leadership from the federal government and cooperation among the medical community, pharmaceutical and pharmacy industry, and DEA is needed. This is particularly important given that most physicians cannot continue to treat patients without a DEA registration. Until such collaboration occurs, DEA's authority under the CSA will continue to be challenged as physicians, pharmacists, and even distributors try, one case at a time, to find

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[159] *See* Amy Pavuk, *Rx for Danger: Pain Patients Decry Oxycodone Shortage, but DEA Says There Isn't One*, ORLANDO SENTINEL (Sept. 29, 2012), *available at*: http://articles.orlandosentinel.com/2012-09-29/news/os-oxycodone-shortage-dea-florida-20120929_1_oxycodone-cvs-prescriptions (last visited Dec. 1, 2014); Pat Anson, *DEA: Doctors and Pharmacies Responsible for Pain Med Denials*, Nat'l Pain Report (Jan. 28, 2014), *available at*: http://americannewsreport.com/nationalpainreport/dea-doctors-pharmacies-responsible-pain-med-denials-8822886.html (last visited Dec. 1, 2014).

[160] *See, e.g.*, U.S. Attorney's Working Group on Drug Overdose and Addiction: Prevention, Intervention, Treatment and Recovery, Final Report and Recommendations, Pittsburgh, Pennsylvania (Sep. 29, 2014), *available at*: http://www.justice.gov/usao/paw/pdf/US%20Attorney's%20Working%20Group%20on%20Addiction%20Final%20Report.pdf (last visited Dec. 1, 2014); Margaret A. Hamburg, M.D., *The Way Forward on Opioid Abuse: A Call to Action for Science-Based*, Comprehensive Strategies, FDA Voice (Apr. 29, 2014), *available at*: http://blogs.fda.gov/fdavoice/index.php/2014/04/the-way-forward-on-opioid-abuse-a-call-to-action-for-science-based-comprehensive-strategies-2/ (last visited Dec. 1, 2014).

the bounds of the legitimate medical purpose of controlled substances prescriptions in the treatment of pain and addiction.