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Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies

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**TREATING PAIN V. REDUCING DRUG DIVERSION AND ABUSE:
RECALIBRATING THE BALANCE IN OUR DRUG CONTROL LAWS
AND POLICIES**

DIANE E. HOFFMANN*

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“The sanctity of the doctor-patient relationship is being destroyed by federal bureaucrats, who have turned the drug war into a war on pain relief. Americans suffering from chronic pain and their doctors are the real victims of this unprincipled and medically unsound federal campaign.”

Rep. Ron Paul, M.D.¹

“[P]hysicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate. . . . [A] physician’s practice is particularly dependent upon the physician’s maintaining a reputation of unimpeachable integrity. A physician’s career can be effectively destroyed merely by the fact that a governmental body has investigated his or her practice.”

Judge Alex Kozinski²

“[T]hese aggressive and ill-informed prosecutions convey a message of intimidation to doctors and of indifference to the plight of patients in pain . . . not even the most honest and competent doctors can practice pain medicine with any assurance of safety for themselves or continuity of care for their patients.”

Dr. William Hurwitz³

1. *The Federal War on Pain Relief*, RON PAUL’S TEXAS STRAIGHT TALK: A WEEKLY COLUMN (Ron Paul, Wash., D.C.), Apr. 19, 2004, at www.house.gov/paul/tst/tst2004/tst041904.htm (last visited July 23, 2008).

2. *Conant v. Walters*, 309 F.3d 629, 640 n.2 (9th Cir. 2002) (Kozinski, J., concurring) (quoting expert witness Alice Pasetta Mead’s report) (alterations in original).

3. Letter from Dr. William Hurwitz to Patients and Colleagues (Aug. 31, 2002) (on file with author) (describing his reasons for closing his pain practice since his arrest and prosecution for the prescription of opioids allegedly resulting in two patient deaths).

I. INTRODUCTION

In the course of the last decade, federal and state prosecutors have arrested and charged several hundred physicians with criminal violations related to their prescribing of opioid analgesics.⁴ In many cases, the physicians pled guilty or were appropriately convicted. In a number of troubling cases, however, the physicians arguably were wrongly charged.⁵ While some of these providers ultimately were exonerated through acquittal or appeal, their careers, and in many cases their personal lives, were destroyed.⁶ Moreover, a number of physicians have been convicted and are serving time (or served time) in prison, but the question of their “wrongdoing” continues to be debated.⁷

4. See *infra* text accompanying notes 20-32.

5. In some of these cases, the original charges were subsequently dropped. See, e.g., *Doctor Ordered to Forfeit Funds*, FORT WAYNE NEWS SENTINEL, June 1, 2005, at L10 (noting that murder charges were dropped in the prosecution of Dr. Jong Bek of Gary, Indiana, “when a toxicologist determined he could not link the deaths to medications Bek prescribed”); Jim Schultz, *Testimony Starts in Fraud Case: Charges Reduced Against Doctor Accused of Trying to Bilk Medi-Cal*, REDDING REC. SEARCHLIGHT, May 13, 2004, at B1 (describing the case of Dr. Frank Fisher of Redding, California, who was prosecuted for eight misdemeanor counts rather than the original suspicion of murder). In some situations, the physicians were tried and acquitted. See, e.g., Rex Bowman, *No Convictions Against Physician; the Jury Acquits on Some Charges, Can’t Reach Verdict on Others*, RICHMOND TIMES-DISPATCH, Nov. 1, 2003, at B4 (describing the case of Dr. Cecil Knox, Roanoke, Virginia); Lisa Thompson, *Troubles Linger for Acquitted Doctor*, ERIE TIMES-NEWS, May 30, 2006, at 1 (describing the case of Dr. Paul Heberle, an Erie, Pennsylvania, physician who struggled with debt and cocaine addiction despite his acquittal). In other instances, the provider was found guilty at the trial court level, but the verdict was later overturned on appeal. See, e.g., Angie Welling, *Psychiatrist Files Lawsuit: Weitzel Sues All Involved in His Murder Trials*, DESERET MORNING NEWS (Salt Lake City), Aug. 18, 2004, at B4 (Dr. Robert Weitzel of Layton, Utah, was convicted in 2000 of “two counts of second-degree felony manslaughter and three counts of misdemeanor negligent homicide. The verdicts were later overturned when a judge ruled prosecutors withheld critical evidence.”).

6. See, e.g., Marc Kaufman, *Worried Pain Doctors Decry Prosecutions*, WASH. POST, Dec. 29, 2003, at A1 (“In recent years, . . . charges of illegally prescribing prescription narcotics, criminal conspiracy, racketeering and even murder have been brought in dozens of states against scores of doctors who treat chronic pain with prescription narcotics. At least two have been imprisoned, one committed suicide, several are awaiting sentencing, many are preparing for trial, and more have lost their licenses to practice medicine and accumulated huge legal bills.”); Sam Stanton, *Murder Case Dissolved, but So Did Doctor’s Life*, SACRAMENTO BEE, May 23, 2004, at A1 (describing Dr. Frank Fisher’s case); Thompson, *supra* note 5 (describing the case of Dr. Paul Heberle).

7. See, e.g., Wayne J. Guglielmo, *Why Is This Indiana Doctor Sitting in Jail?*, MED. ECON., July 21, 2006, at 17 (describing the cases of brothers and co-defendants Drs. David and Charles Chube); Tad Lonergan, *A Personal Experience in the Criminal Justice System*, 3 MED. SENTINEL 139, 140 (1998) (discussing the Court of Appeals for the Ninth Circuit decision against the prosecutor of Dr. Tad Lonergan who was accused of lying and dishonesty in the

The motivation for this increased attention to physician prescribing and legal action by prosecutors appears to have roots in the war on drugs and the recent spate of deaths related to the abuse of OxyContin, a time released opioid analgesic approved by the Food and Drug Administration (FDA) in 1995.⁸ Around the same time that these drug-related deaths were occurring, the Drug Enforcement Administration (DEA) came under criticism for its failure to develop measurable performance targets for its drug control efforts and was looking for a “new front” for its battle against illegal drugs.⁹ As a result, in 2001, the DEA began a new anti-drug campaign targeting the prescribing and use of OxyContin.¹⁰ The campaign raised the level of scrutiny DEA applied to opioid analgesic use to the level applied to non-prescription street drugs such as cocaine, heroin, and marijuana.¹¹ While employing this intense scrutiny was a response to a relatively new drug, prosecuting physicians for prescribing narcotics has a long history in this country and drug regulators have long attempted to balance negative effects (toxicity, addiction, and diversion) with positive effects (therapeutic benefit and pain relief).¹²

In this Article, I argue that these recent prosecutions are a result of a significant imbalance in our drug control laws and policies. In particular, I

prosecution of the case); Frank Bass, *Use of Painkillers Skyrockets*, GRAND RAPIDS PRESS, Sept. 2, 2007, at G1 (discussing threats received by Dr. Deborah Bordeaux of “100-year sentence if she did not help the prosecution.”); John Tierney, Editorial, *Sex, Lies, and OxyContin: A Pittsburgh Case Shows What’s Wrong with the DEA’s War Against Doctors*, PITTSBURGH POST-GAZETTE, Jan. 25, 2006, at B7 (stating that the testimony of one of the key witnesses in the trial of Dr. Bernard Rottschaefer may have been perjured); see also, e.g., *infra* Section II (discussing the cases of Dr. William Hurwitz and Dr. Ronald McIver); Drew Douglas, *Physician Receives Nearly 63-Year Prison Sentence for OxyContin Deaths*, 11 Health L. Rep. (BNA) 461, 470 (Mar. 28, 2002) (discussing the trial of Dr. James Graves and stating that “[a]t trial, the defense argued that many of the patients who came lied about their symptoms, usually chronic lower back pain, in order to receive prescriptions”); Barry Meier, *OxyContin Prescribers Face Charges in Fatal Overdoses*, N.Y. TIMES, Jan. 19, 2002, at A14 (describing the indictment of Florida physician Denis Deonarine for felony murder in the overdose death of a patient).

8. U.S. GEN. ACCT. OFFICE, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION EFFORTS TO ADDRESS THE PROBLEM 8 (2003), available at www.fda.gov/cder/drug/infopage/oxycontin/oxycontinGAOreport.pdf (last visited July 23, 2008).

9. Ronald T. Libby, *Treating Doctors as Drug Dealers: The DEA’s War on Prescription Painkillers*, POL’Y ANALYSIS (CATO Inst., Wash., D.C.), June 16, 2005, at 1, 4, available at www.cato.org/pubs/pas/pa545.pdf (last visited July 23, 2008).

10. OFFICE OF DIVERSION CONTROL, U.S. DEP’T OF JUSTICE, DRUGS AND CHEMICALS OF CONCERN: ACTION PLAN TO PREVENT THE DIVERSION AND ABUSE OF OXYCONTIN, at www.deadiversion.usdoj.gov/drugs_concern/oxycontin/abuse_oxy.htm (last visited Aug. 9, 2008); U.S. GEN. ACCT. OFFICE, *supra* note 8.

11. Libby, *supra* note 9, at 5.

12. Joseph Spillane & William B. McAllister, *Keeping the Lid On: A Century of Drug Regulation and Control*, 70 DRUG & ALCOHOL DEPENDENCE S5, S5 (2003).

assert that this imbalance stems from the standard in the federal Controlled Substances Act, its state counterparts, and implementing regulations used by prosecutors to arrest and prosecute physicians for “inappropriate” prescribing. Under the standard, a physician is guilty of criminal conduct if he or she prescribes without a “legitimate medical purpose” and outside “the usual course of his professional practice.”¹³ Applying this standard in these cases harms not only the physicians who are arguably wrongly accused but also the patients of these physicians and other individuals who suffer from chronic pain. Because many physicians fear criminal sanctions for prescribing opioids, pain sufferers may not be able to receive adequate pain care. The law enforcement climate surrounding prescribing opioid analgesics appears to be causing some physicians to stop prescribing opioids or stop treating chronic pain patients, reducing an already very small number of physicians willing to treat these needy patients.¹⁴ As a result, the physicians who continue to see patients with chronic pain also make themselves an easy target for law enforcement officials.

13. 21 C.F.R. § 1306.04(a) (2007).

14. See Ronald T. Libby, *The DEA’s “One-tenth of One Percent” Myth of Doctors Who Are Sanctioned*, Address at the CATO Institute Conference: Drug Cops and Doctors—Is the DEA Hampering the Treatment of Chronic Pain?, at 2 (Sept. 9, 2005), available at www.doctordeluca.com/Library/WOD/CopsDocsCato-Libby05.pdf (last visited July 23, 2008) (estimating that the number of physicians who specialize in the treatment of chronic pain is between 4,278 and 5,869); see also Marc Kaufman, *Specialists Decry DEA Reversal on Pain Drugs: New Rules Called a ‘Step Backward,’* WASH. POST, Dec. 21, 2004, at A8 (acknowledging the strong concern among pain physicians that the DEA’s recent pronouncements will have a chilling effect on physician prescribing, making it more difficult for pain patients to receive adequate treatment); Tina Rosenberg, Editorial, *Weighing the Difference Between Treating Pain and Dealing Drugs*, N.Y. TIMES, Mar. 26, 2005, at A12 (expressing concern that the recent conviction of a physician treating chronic pain will lead to fewer doctors who are willing to prescribe strong painkillers for their patients who suffer from pain); Sally Satel, *Doctors Behind Bars: Treating Pain Is Now Risky Business*, N.Y. TIMES, Oct. 19, 2004, at F6 (examining the law enforcement climate surrounding the prescription of pain medications); Doug Smith, *Lawmen vs. the Drug Warriors: Attorneys General Seek Change in DEA Policy*, ARK. TIMES, Dec. 15, 2005, at 13 (quoting an advertisement by Common Sense for Drug Policy—a “‘drug reform’ organization”—that quotes a CATO Institute study, *supra* note 9, stating the DEA’s “‘renewed war on pain doctors has frightened many physicians out of pain management altogether, exacerbating an already serious health crisis’”); Jane Spencer, *Crackdown on Drugs Hits Chronic-Pain Patients: Amid Tighter Regulation of Painkillers, Physicians Pull Back on Prescriptions*, WALL ST. J., Mar. 16, 2004, at D1 (describing the federal government’s increasing efforts to end prescription drug abuse and its impact on legitimate physicians and their patients who suffer from chronic pain); Letter from Thirty State Attorneys General to Karen Tandy, Adm’r, U.S. Drug Enforcement Admin. 2 (Jan. 19, 2005), available at www.csdp.org/naagletter.pdf (last visited July 23, 2008) (asserting that a DEA “Interim Policy Statement ‘Dispensing of Controlled Substances for the Treatment of Pain’ . . . seems likely to have a chilling effect on physicians engaged in the legitimate practice of medicine”).

In Part II of this Article I describe the available data on, and selected cases of, recent arrests and prosecutions of physicians for inappropriate prescribing of pain medication. In Parts III and IV, I discuss the “culture clash” and historical tension between physicians and drug enforcement personnel, and in Part V, I describe the evolution of opioid use for chronic pain treatment. In Parts VI and VII, I summarize the legal basis for the arrest and prosecution of physicians in this context along with law enforcement efforts. Finally, in parts VIII and IX, I make a series of arguments based on legal, ethical, and policy grounds as to why the current criminal standard is inappropriate and suggest an alternative standard that arguably more accurately calibrates the balance between the dual goals of pain treatment and reduction of drug diversion and abuse.

II. ARRESTS AND PROSECUTIONS OF PHYSICIANS FOR OPIOID PRESCRIBING

The exact number of physicians who have been investigated, arrested, and/or prosecuted over the last decade for inappropriately prescribing opioids is difficult to determine. Investigations, arrests, and charges are not compiled in a central, publicly available database. Therefore, estimates must be pieced together from reports, news articles, DEA statements, and Web sites that track some of these cases. In 2001, DEA statistics indicate that there were 3,097 diversion investigations, 861 of which were investigations of doctors.¹⁵ In 2003, there were 736 DEA investigations and 51 arrests of physicians for diversion of controlled substances.¹⁶ Focusing only on OxyContin, between October 1999 and March 2002, DEA reported investigating 247 OxyContin diversion cases, which led to 328 arrests.¹⁷ And, between May 2001 and January 2004, DEA agents arrested approximately 600 people for violation of laws related to distribution, dispensing, or possession of OxyContin.¹⁸ Of those arrested, 60% were professionals such as doctors and pharmacists.¹⁹ DEA also has its own Web site that lists “investigations of physician registrants in which DEA was

15. Libby, *supra* note 9, at 15 (citing DEA UPDATE, NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCE AUTHORITIES, Myrtle Beach, South Carolina 17-18 (Oct. 2002)).

16. *The Infinite Mind: The Double Life of OxyContin* (Lichtenstein Creative Media broadcast Mar. 10, 2004), summary at www.lcmedia.com/mind313.htm (last visited July 23, 2008).

17. Controlled Substances Registration and Reregistration Application Fees, 68 Fed. Reg. 7728, 7730 (Feb. 18, 2003) (codified at 21 C.F.R. pt. 1301).

18. *To Do No Harm: Strategies for Preventing Prescription Drug Abuse: Hearing Before the Subcomm. on Criminal Justice, Drug Policy and Human Resources of the H. Comm. on Gov't Reform*, 108th Cong. 40-41 (2004), available at www.access.gpo.gov/congress/house/pdf/108hrg/95555.pdf (last visited July 23, 2008) (statement of Thomas W. Raffanella, Special Agent in Charge, Miami Division, U.S. Drug Enforcement Administration).

19. *Id.*

involved that resulted in the arrest and prosecution of the registrant.”²⁰ The list, covering arrests from January 2003 through February 2008, includes 117 physicians, at least 47 of whom were arrested for prescribing pain medication outside the scope of professional practice or without a legitimate medical purpose.²¹ This figure is based solely on selected federal arrests announced by the DEA. Therefore, it underestimates the total of such law enforcement actions, which also include arrests by state law enforcement personnel.

An effort to compile a list of arrests and prosecutions of physicians for illegal distribution of opioids from newspaper accounts and Web sites between 1998 and 2005 yielded 205 cases.²² Charges in the cases ranged from rape²³ to murder,²⁴ felony murder,²⁵ manslaughter,²⁶ drug trafficking,²⁷

20. Office of Diversion Control, U.S. Drug Enforcement Admin., *Cases Against Doctors: Criminal Cases*, at www.deadiversion.usdoj.gov/crim_admin_actions/crim_actions.htm (last visited Aug. 9, 2008).

21. *Id.* Of the 47 physicians, 32 pled guilty, 13 were convicted by a jury, 2 are awaiting trial, and one has a pending adjudication. *Id.*

22. See David Brushwood, *Criminal Prosecutions of Physicians for Offenses Related to the Prescribing of Scheduled Opioid Analgesics 1998-2003* (on file with the author) (listing criminal prosecutions of sixty-eight physicians in Arizona, California, Florida, Georgia, Indiana, Kentucky, New Mexico, South Carolina, Texas, and Virginia). Other similar lists are available. See, e.g., Ass’n of Am. Physicians & Surgeons, Inc., *Pain Management - Physician Prosecutions and Board Actions*, at www.aapsonline.org/painman/pm-ppba.htm (last visited Aug. 9, 2008) (lists physicians arrested for illegal prescribing of opioids); *Our Chronic Pain Mission, Pain Politics*, at www.cpmmission.com/politics/ (last visited Aug. 9, 2008) (listing physicians prosecuted by the DEA); *Pain Relief Network, Information and Research: Clinical Litigation*, at www.painreliefnetwork.org/clinical-litigation/ (last visited Aug. 9, 2008) (listing information about the cases of eight physicians).

23. See, e.g., Duane Bourne, *Charges Against Doctor Dismissed*, ST. PETERSBURG TIMES, May 31, 2003, at 1 (stating that prosecutors dropped charges against Dr. A. Hussam Armashi, a Florida doctor accused of raping a patient to whom he had prescribed high-dose pain medications).

24. See, e.g., Todd Dvorak, *Court Upholds Ex-Doctor’s Homicide Conviction*, SOUTH BEND TRIB., July 27, 2000, at D1 (discussing South Bend, Indiana, doctor Ernest Stiller’s conviction for killing a woman who died from the combined effects of three drugs, two of which were prescribed and one of which was “a painkiller”); Becky Purser, *Perry Doctor Turns Self In*, MACON TELEGRAPH, July 27, 2004, at A1 (describing Dr. Spurgeon Green, Perry, Georgia, indicted for the murder of six patients due to overdose from prescribed drugs); Scott Sandlin, *Prescribing Doctor Gets Probation*, ALBUQUERQUE J., Nov. 23, 2004, at A1 (discussing the probation order of Dr. Jesse Benjamin Henry, Jr., Albuquerque, New Mexico, who was accused, along with his wife of murdering seven patients for whom methadone and other opioid analgesics were prescribed); Ralph Vartabedian, *Jury Finds Doctor Not Guilty: The Operator of a Shasta County Clinic Was Accused of Improperly Prescribing Painkillers and of Medi-Cal Fraud in a Long-Running Case*, L.A. TIMES, May 20, 2004, at B6 (discussing the not guilty verdict of Dr. Frank Fisher, Redding, California, accused of prescribing high doses of opioids to patients who died).

illegal drug distribution,²⁸ illegal delivery of a controlled substance,²⁹ and unlawful prescribing.³⁰ In February 2002, Dr. James Graves became the first physician to be criminally convicted of OxyContin related deaths.³¹ He was sentenced to 62.9 years in prison.³²

While many of these arrests and prosecutions were appropriate, a number were not. The following represent some of the most troubling

25. See, e.g., Meier, *supra* note 7 (describing the indictment of Florida physician Denis Deonarine, for felony murder in the overdose death of a patient); Sharlonda L. Waterhouse, *Gary Doctor Held on Murder, Charges of Dealing Drugs*, CHI. SUN-TIMES, July 24, 2002, at 16 (describing the case of Dr. Jong H. Bek, who was charged with felony murder based on prescriptions he gave to "two men [who] were killed by a cocktail of legal and illegal drugs, some of which were obtained through Bek").

26. See, e.g., Meier, *supra* note 7 (describing the case of Dr. James Graves, of Pace, Florida, who was accused of causing the overdose deaths of four patients for whom he had prescribed OxyContin and other drugs); John Pacenti & Antigone Barton, *Psychiatrist Gets Year for Patient's Pill Death*, PALM BEACH POST, Feb. 1, 2003, at 1C (describing the case of Dr. George Kubski, a West Palm Beach, Florida physician who prescribed 20,000 pills in the three months prior to a patient's death and was sentenced to jail for "manslaughter by culpable negligence"); Sarah Prohaska, *Doctor Convicted of 1 Death, Trafficking: Acquitted in Gardens Man's Death*, PALM BEACH POST, Mar. 7, 2006, at 1A (describing the case of Dr. Asuncion Luyao, a Port St. Lucie, Florida physician, who had six patients die from alleged OxyContin overdoses).

27. See, e.g., Alex Kuczynski, *Is It Botox, or Is It Bogus?*, N.Y. TIMES, Dec. 5, 2004, § 9, at 1 (describing the case of Dr. Bach McComb, of Sarasota, Florida, who was accused of trafficking addictive pain medications such as oxycodone); Sandlin, *supra* note 24 (describing the case of Dr. Jesse Benjamin Henry, Jr.); Jay Ditzer, *Drug-Abusing Doctors*, WHAS11 NEWS (Louisville, Ky.), Nov. 23, 2004, at www.whas11.com/topstories/stories/WHAS11_TOP_DrugDoctors.81a2e2a0.html (last visited July 23, 2008) (stating that Dr. Brent Ryabik, a psychiatrist from Kentucky, was "accused of trafficking prescription drugs").

28. See, e.g., Anne T. Denogean, *Doctor Faces 108 Charges: Jeri B. Hassman Allegedly Overprescribed Pain Medication and Is Accused of Health-Care Fraud*, TUCSON CITIZEN, Apr. 1, 2003, at 1D (describing charges against a Tucson, Arizona physician, including over 100 counts of prescribing morphine, methadone, Vicodin, and OxyContin "without a legitimate medical reason"); see also News Release, U.S. Attorney's Office, W. Dist. of Va., July 26, 2001, at www.oig.dol.gov/public/media/vmody.html (last visited Aug. 9, 2008) (announcing a 140-count indictment against Oakwood, Virginia doctor Kailas Modi and her husband Dr. Vinod Modi, including "63 counts of unlawfully dispensing prescription drugs").

29. See, e.g., Kelly Wolfe, *Patients Stand by Their Beset Physician*, PALM BEACH POST, Nov. 10, 2003, at 1A (discussing the arrest of Dr. Darshan Shah, a Vero Beach, Florida doctor who allegedly pre-signed blank prescriptions for a nurse practitioner who was doing the actual prescribing of "powerful painkillers").

30. See, e.g., Korie Wilkins, *Two Doctors Accused of Issuing Fake Prescriptions*, DAILY OAKLAND PRESS, Apr. 19, 2005, at A1 (explaining the case of Dr. Subadra Deandra and Dr. Dewundara Dayananda, of Waterford Township, Michigan, who allegedly sold prescriptions for painkillers for \$100).

31. Douglas, *supra* note 7, at 469.

32. *Id.*

arrests and prosecutions of physicians related to their prescribing of opioids and demonstrate the difficulty of applying the prevailing criminal law standard set forth in the Controlled Substances Act (CSA) to these kinds of cases. While they are only a fraction of the cases brought against physicians, they illustrate several themes of the larger body of arrests and prosecutions. For example, in many of the cases, (1) the physicians treated a large number of chronic pain patients and prescribed large volumes of opioids; (2) there was no evidence that the physicians benefited financially from their prescribing (other than for the office visit); (3) experts disputed the “reasonableness” of the physician’s prescribing practices; and (4) the physician’s patients often included drug addicts who lied to the physician to obtain their drugs.

A. *Dr. Frank Fisher*

Dr. Frank Fisher operated a clinic near Redding, California, from 1995 until February 1999, when he was arrested for prescribing large dosages of opioids that allegedly were related to several deaths.³³ At the time of his arrest, his practice consisted of about 3,000 patients.³⁴ Fisher graduated from Harvard Medical School and practiced general medicine for over twenty years, primarily in underserved communities, including healthcare facilities on Native American reservations.³⁵ He opened the clinic near Redding “to serve the general practice and urgent care needs of the MediCal population of Shasta County[,]” California.³⁶ Approximately 5%–10% of his patients suffered from severe, chronic intractable pain and he prescribed opioids for many of them.³⁷

On February 18, 1999, over twenty armed law enforcement agents stormed into Fisher’s clinic and arrested him.³⁸ The California Attorney General charged Dr. Fisher with prescribing excessive amounts of controlled substances and three counts of first degree murder stemming from those prescriptions.³⁹ Later, two additional murder charges were added.⁴⁰

33. Stanton, *supra* note 6; Pain Doctor and Pharmacist Arrested for Mass Murder, at What Was Dr. Fisher’s Clinic Doing? (undated, un-paginated pamphlet from Dr. Fisher’s clinic, on file with author) [hereinafter Fisher Fact Sheet].

34. Stanton, *supra* note 6.

35. Fisher Fact Sheet, *supra* note 33, at Who is Dr. Fisher?.

36. *Id.* at What Was Dr. Fisher’s Clinic Doing?.

37. Stanton, *supra* note 6.

38. David B. Brushwood, Commentary, *Professional Casualties in America’s War on Drugs*, 60 AM. J. HEALTH-SYS. PHARMACY 2004, 2004 (2003); Fisher Fact Sheet, *supra* note 33, at What Was the Arrest Like?.

39. Lynda Gledhill & Suzanne Espinosa Solis, *Doctor, 2 Pharmacists Held in Shasta Drug Sting: Investigators Link Ring to 3 Fatal Overdoses*, S.F. CHRON., Feb. 19, 1999, at A1 (noting

Because Fisher could not make his \$15 million bail, he spent five months in jail during his preliminary hearing.⁴¹ At the close of the hearing, in July 1999, the judge dismissed two of the murder charges and reduced the three remaining murder charges to involuntary manslaughter.⁴² Apparently, the evidence showing the deaths with which Fisher was charged resulted from his patients taking the medications that he prescribed was inadequate.⁴³ For example, one of the patients for whom he prescribed opioids died as a passenger in an automobile accident.⁴⁴ Another death occurred when a non-patient stole and overdosed on medications that Fisher had prescribed to a patient.⁴⁵ While Dr. Fisher was in jail, a patient, with a documented history of pain and need for opioids, became despondent because she was unable to obtain her pain medications and died.⁴⁶ Fisher was “released on [his] own recognizance, subject to the condition that [he] not practice medicine . . . until the matter was resolved.”⁴⁷

The prosecution’s case against Fisher was largely based on the volume of opioids he prescribed—Fisher was the largest prescriber of OxyContin in the state.⁴⁸ Yet, an expert witness for the prosecution testified that the opioid dosages that Dr. Fisher prescribed were not unreasonable and that he, the expert, frequently prescribed higher dosages for his patients.⁴⁹ In his defense, Fisher asserted that he adhered to accepted standards of care and practices for treatment of pain patients including:

- [r]igorous pre-treatment screening to exclude potential abusers of pain medications. . . . ;

the twenty-seven count indictment against Fisher on murder and fraud charges); see also Brushwood, *supra* note 38 (discussing the charges in the Fisher case).

40. Brushwood, *supra* note 38; Carl T. Hall, *Jury Acquits Doctor in Pain-Control Test Case*, S.F. CHRON., May 20, 2004, at A1.

41. Brushwood, *supra* note 38, at 2004-05; Fisher Fact Sheet, *supra* note 33, at What Was the Arrest Like?.

42. Gary Delsohn, *Doctor’s Murder Charges Dropped: Shasta Judge Substitutes Involuntary Manslaughter Counts*, SACRAMENTO BEE, July 16, 1999, at A1. (“The involuntary manslaughter charges were allowed to stand . . . because Fisher . . . should have understood the risk involved in prescribing . . . high amounts of addictive painkillers.”).

43. See *id.*

44. Fisher Fact Sheet, *supra* note 33, at Were Murder Charges Appropriate?.

45. *Id.*

46. *Id.*

47. Brushwood, *supra* note 38, at 2005.

48. See Stanton, *supra* note 6 (“The huge amount of painkilling medicine Fisher was prescribing is what led to the case in the first place. Medi-Cal officials noted there had been an enormous jump in such prescriptions in 1998, with Fisher dispensing more of the medicine than any of the other 50,000 OxyContin prescribers in the state.”).

49. Brushwood, *supra* note 38, at 2005.

- [m]andatory mental health evaluations of all [c]hronic [p]ain patients by a licensed professional;
- [e]jection of patients caught lying, diverting medications or ingesting non-therapeutic doses. . . . ;
- [r]egular and frequent blood and urine testing for medication serum levels, as well as for illegal substances;
- [m]andatory signature of a Controlled Substances Agreement by each [c]hronic [p]ain patient containing: 1) an informed consent, 2) an agreement not to divert medications, and 3) an agreement to report any misuse or diversion of medications.⁵⁰

Following these practices, Fisher terminated more than 400 patients from his clinic.⁵¹

Three years after his arrest, the manslaughter and drug diversion charges against Fisher were dropped, and, approximately one and a half years later, Fisher was acquitted of further charges of defrauding the Medical system.⁵² Fisher claims the alleged fraud amounted to approximately \$150 in overbilling.⁵³ Although Fisher was exonerated of all criminal charges, he faced potential disciplinary action by the state medical board and civil suits brought by the relatives of patients of his who died allegedly as a result of his negligent prescribing of opioids.⁵⁴ In February 2005, the last of four wrongful death suits against him was dismissed.⁵⁵ The court ordered two of the four plaintiffs to pay Fisher damages.⁵⁶

Although the judge presiding over the criminal case had forbidden Fisher to practice medicine while he was out on bail, the state never suspended his license.⁵⁷ However, on August 10, 2005, the Board

50. Fisher Fact Sheet, *supra* note 33, at Did Dr. Fisher Practice Good Medicine?.

51. Radley Balko, *Another Victim of the Drug War*, FREEMAN, Apr. 2005, at 12, 13, available at www.fee.org/publications/the-freeman/issue.asp?fid=276 (last visited July 23, 2008); see also Stanton, *supra* note 6 ("Fisher estimate[d] that state undercover agents visited him at least seven times trying to obtain prescriptions using bogus ailments, and that he refused to provide them with medicine.").

52. Maline Hazle, *Fisher's Ordeal Finally Is Over: Last of Four Death Suits Dismissed*, REDDING REC. SEARCHLIGHT, Feb. 2, 2005, at A1; *Not With a Bang but a Whimper: California Pain Doctor Frank Fisher Exonerated in Last Criminal Case*, DRUG WAR CHRON. (Drug Reform Coordination Network, Wash., D.C.), May 21, 2004, at <http://stopthedrugwar.org/chronicle-old/338/frank.shtml> (last visited Aug. 9, 2008) [hereinafter DRUG WAR CHRON.].

53. Hall, *supra* note 40.

54. *Id.*; see also DRUG WAR CHRON., *supra* note 52 ("[T]he attorney general is now going to prosecute me yet again on the same charges, this time before the state medical board. They will try to go after my license in an administrative venue" (quoting Dr. Fisher)).

55. See Hazle, *supra* note 52.

56. See *id.*

57. See *id.*

sentenced him to three years of probation under the condition that he would take a refresher course in general medicine, keep a list of any controlled substances that he prescribes, and have his cases monitored.⁵⁸

B. *Dr. Cecil Knox*

In 1992, after serving as medical director of the rehabilitation unit at Lewis Gale Hospital in Roanoke, Virginia, Dr. Cecil Knox opened his own outpatient clinic, Southwest Physical Medicine and Rehabilitation.⁵⁹ His practice focused on pain management and physical rehabilitation.⁶⁰

On February 1, 2002, more than a dozen federal agents burst into Knox's office with guns drawn while he was seeing patients and arrested him.⁶¹ He was taken away in handcuffs and leg irons and was indicted on numerous charges that he allegedly prescribed narcotics outside the scope of legitimate medical practice, which led to several overdose deaths.⁶² His office manager was indicted on the same charges.⁶³ In October 2002, a federal grand jury indicted Knox on fifty drug-related charges and nineteen fraud, racketeering, and conspiracy charges related to his billing practices.⁶⁴ According to news accounts of the trial, prosecutors alleged that Knox ran a "pill mill" from his office where he handed out "prescriptions for powerful drugs like OxyContin and methadone to known addicts and others who came to see him with stories of severe pain."⁶⁵ They alleged that his "eagerness to prescribe potent drugs contributed to the deaths of seven patients"⁶⁶ and that he was the nineteenth leading prescriber of OxyContin

58. *In re Fisher*, No. 02-1999-95522, at 3-8 (Div. of Med. Quality, Med. Board of Ca. July 11, 2005) (Stipulated Settlement and Disciplinary Order), available at <http://publicdocs.medbd.ca.gov/pdl/mbc.aspx> (enter Frank Fisher's name in search boxes); see also Hazle, *supra* note 52.

59. Jen McCaffery, *Knox Takes Stand and Testifies in His Own Defense: Oxycontin 'Was a Real Godsend for Chronic Pain Management,' Doctor Says*, ROANOKE TIMES, Oct. 16, 2003, at A1 [hereinafter McCaffery, *Knox Takes Stand and Testifies in His Own Defense*].

60. *Id.*

61. Maia Szalavitz, *Dr. Feelscared: Drug Warriors Put the Fear of Prosecution in Physicians Who Dare to Treat Pain*, REASON, Aug. 2004, at 32.

62. *Id.*

63. Jen McCaffery, *Drug Users' Injuries Could Lengthen Sentences: 2 Heroin Conspiracy Cases Involve 2 Deaths and 6 Other Overdoses, Prosecutor Says*, ROANOKE TIMES, July 28, 2002, at B1 [hereinafter McCaffery, *Drug Users' Injuries Could Lengthen Sentences*]. Two of Knox's employees were charged initially, but only his office manager was indicted. *Id.*

64. Bowman, *supra* note 5.

65. *Id.*

66. *Id.* Other news accounts report as many as ten deaths. See, e.g., McCaffery, *Drug Users' Injuries Could Lengthen Sentences*, *supra* note 63 (describing charges that Knox "overprescribed drugs that either killed or seriously injured 10 of his patients. Federal prosecutors will not confirm how many deaths versus serious injuries, they argue, have

in the country.⁶⁷ They also brought forth witnesses who illustrated the risks of treating patients with chronic pain. Several former patients testified that they lied to Dr. Knox about their pain in order to obtain a prescription for a narcotic.⁶⁸ One patient told Knox “he was in pain and always seemed to run out of his OxyContin weeks early.”⁶⁹ Another patient “injected OxyContin in the sole of his foot so no track marks would be visible in a typical medical exam.”⁷⁰

Knox argued that several of the overdose deaths occurred over a year and a half after he had stopped prescribing medications for these patients.⁷¹ To the extent he prescribed for individuals with a drug addiction, he said that he did so to treat their pain.⁷² For example, Knox treated Edgar O’Brien, a recovering heroin addict, for knee and back pain.⁷³ O’Brien, like many others whom Knox treated, “presented him with difficult choices.”⁷⁴ During Knox’s testimony, he stated that “he regularly had to make decisions about the consequences of treating people [with histories of psychiatric problems or substance abuse] instead of turning them away.”⁷⁵ He was concerned that if he did not treat O’Brien, he would obtain his drugs illegally on the street.⁷⁶ However, after Knox discovered that O’Brien was abusing the painkillers he had prescribed, he stopped prescribing medication for O’Brien and never saw him again.⁷⁷ O’Brien died from an

resulted”); Jen McCaffery, *Knox Defends Care of Patients: Cross-Examination Expected Today*, ROANOKE TIMES, Oct. 17, 2003, at B1 (describing Knox’s testimony defending himself and listing “eight patients who fatally overdosed”) [hereinafter *McCaffery, Knox Defends Care of Patients*].

67. Bowman, *supra* note 5 (stating that “in one year alone, Knox wrote prescriptions for \$1.6 million worth of OxyContin”); see also McCaffery, *Knox Takes Stand and Testifies in His Own Defense*, *supra* note 59 (describing how prosecutors made unrelated allegations to paint an unflattering picture of Knox, including witness testimony that Knox smoked marijuana with patients and an employee on more than one occasion).

68. See, e.g., Jen McCaffery, *Ex-Patients of Dr. Knox Testify They Lied to Him: All 3 Have Been Convicted of Crimes that Stem from Abuse of Prescription Drugs*, ROANOKE TIMES, Sept. 25, 2003, at B1 (describing several of Dr. Knox’s patients who did not become patients through traditional referrals and lied about their backgrounds in order “to get in good with him”).

69. *Id.*

70. *Id.*

71. See Jen McCaffery, *Woman in Knox Trial Cleared of All Charges: Judge Clears Kathleen O’Gee*, ROANOKE TIMES, Oct. 9, 2003, at A1.

72. See McCaffery, *Knox Defends Care of Patients*, *supra* note 66.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. McCaffery, *Knox Defends Care of Patients*, *supra* note 66.

overdose approximately nineteen months after Knox last prescribed any medication for him.⁷⁸

After eight weeks of testimony, one of the longest trials in recent history in western Virginia,⁷⁹ a U.S. District Court jury found Knox not guilty of thirty of the sixty-nine charges against him.⁸⁰ The jurors were unable to reach a verdict on the remaining counts and the presiding judge declared a mistrial.⁸¹ One juror commented that the decision not to convict was based on the prosecution's failure to show that Knox had the knowledge or intent to commit the crimes of which he was accused.⁸² According to the juror, the evidence indicated that Knox had made some mistakes and may have been careless but was not sufficient to show that Knox's prescribing constituted criminal behavior.⁸³

Despite the jury's decision, federal prosecutors continued to pursue Knox aggressively and three months after his first trial ended, Knox was indicted again, facing ninety-five charges, "including racketeering, conspiracy to commit racketeering, criminal conspiracy, mail fraud and perjury."⁸⁴ These new allegations included fourteen charges that Knox's opioid prescriptions were outside the scope of legitimate medical practice and led to death or serious bodily injury.⁸⁵ Shortly before the second trial, Knox entered into a plea bargain with federal prosecutors.⁸⁶ According to an op-ed piece written by his wife, he agreed to the plea bargain for a number of reasons.⁸⁷ In addition to having borrowed over \$1 million and needing another half-million to continue defending himself, Knox was diagnosed with non-

78. *Id.*

79. Jen McCaffery, *Jury Finds Pain Specialist Not Guilty on Many Charges*, ROANOKE TIMES, Nov. 1, 2003, at A1 [hereinafter McCaffery, *Jury Finds Pain Specialist Not Guilty on Many Charges*].

80. Bowman, *supra* note 5; see also McCaffery, *Jury Finds Pain Specialist Not Guilty on Many Charges*, *supra* note 79 (listing the Knox verdicts).

81. Bowman, *supra* note 5.

82. McCaffery, *Jury Finds Pain Specialist Not Guilty on Many Charges*, *supra* note 79.

83. *Id.*

84. Lindsey Nair, *Dr. Knox Pleads Guilty, Surrenders License*, ROANOKE TIMES, Sept. 3, 2005, at A1 ("The racketeering charge relate[d] to two incidents . . . when Knox distributed the controlled substance Fastin [a diet pill] to a patient with the understanding that she would share the drug with him. Those acts constitute racketeering because they represent a pattern of illegal activity committed within the operation of an enterprise, the medical practice.") [hereinafter Nair, *Dr. Knox Pleads Guilty, Surrenders License*].

85. Jen McCaffery, *Grand Jury Hands Down Charges Against Dr. Knox*, ROANOKE TIMES, June 18, 2004, at B8.

86. Donna Knox, Editorial, *Self-Absorbed Prosecutor Goes Too Far*, ROANOKE TIMES, Jan. 26, 2006, at B9.

87. *Id.* Donna Knox is a former journalist, an advocate for missing American servicemen, and a family law practitioner in Roanoke, Virginia. See *id.*

Hodgkin's lymphoma during the criminal proceedings.⁸⁸ Although his cancer was in remission, Knox was concerned that the stress of another trial might provoke a relapse.⁸⁹ Finally, he wanted the ordeal to end for his office manager, whom the federal prosecutor "had tormented for refusing to capitulate."⁹⁰

Knox reluctantly entered into a plea agreement but admitted to only minor misconduct unrelated to treating pain patients.⁹¹ He was sentenced to five years of probation and voluntarily surrendered his state medical license and his DEA registration number.⁹² After the plea bargain, Knox worked as a cobbler in a shoe store in Roanoke, Virginia.⁹³

C. *Dr. William Hurwitz*

In September 2003, Dr. William Hurwitz was arrested on a forty-nine count federal indictment charging him with "drug trafficking resulting in death and serious injury, engaging in a criminal enterprise, conspiracy and health care fraud."⁹⁴ He was visiting his children on the eve of Rosh Hashanah when federal agents took him away in handcuffs.⁹⁵ The indictment was a result of a "wide-ranging federal investigation into doctors, pharmacists and patients suspected of selling potent and addictive painkillers on a lucrative black market."⁹⁶ More than forty people were convicted in the comprehensive probe.⁹⁷ According to a news account of the arrest, "[t]he indictment signal[ed] an aggressive push by federal prosecutors to hold doctors accountable for what happens to the drugs they prescribe" and "highlight[ed] the complexities of proving criminal culpability in cases of licensed and reputable physicians prescribing a legal painkiller."⁹⁸ Hurwitz, like Knox, was one of the first physicians to be charged with conspiracy related to his prescribing of opioids.⁹⁹ According to the grand jury, "Hurwitz prescribed 'countless prescriptions for excessive doses' of controlled drugs with the goal of hooking his patients, getting

88. *Id.*; Nair, *Dr. Knox Pleads Guilty, Surrenders License*, *supra* note 84.

89. Knox, *supra* note 86.

90. *Id.*

91. *Id.*

92. Lindsey Nair, *Pain Doctor Loses License, but Gets No Jail Time*, ROANOKE TIMES, Jan. 21, 2006, at A1.

93. *Id.*

94. Josh White, *N.Va. Doctor Indicted in OxyContin Scheme*, WASH. POST, Sept. 26, 2003, at B6.

95. Szalavitz, *supra* note 61.

96. White, *supra* note 94.

97. *Id.*

98. *Id.*

99. *Id.*

them to pay him a monthly fee and encouraging illegal sales.”¹⁰⁰ Of the forty-nine charges, the most serious were that in two cases the conspiracy caused fatal overdoses.¹⁰¹ Furthermore, “[t]he indictment allege[d] that Hurwitz prescribed medications in as many as [thirty-nine] states, issuing the prescriptions with little or no physical examination and sometimes over the phone, fax, or the Internet.”¹⁰²

Hurwitz received his medical degree from Stanford University in 1971 and law degree from George Mason University School of Law in 1996.¹⁰³ Prior to his criminal arrest, Hurwitz was prosecuted by the Virginia Board of Medicine and, in August 1996, had his license to practice in Virginia revoked based on excessive prescribing and inadequate supervision of his patients.¹⁰⁴ The Board initiated its action after two of his patients died in January 1996.¹⁰⁵ Hurwitz argued that one of the patients committed suicide by taking multiple times the recommended dose of a drug that he prescribed and that the other died as a result of gastric bleeding, not an overdose.¹⁰⁶ The Board took action despite the fact that “expert testimony had essentially disproven the state’s allegation that Hurwitz was at fault.”¹⁰⁷ Based on the evidence, the Board dropped its initial allegations against Hurwitz, recognizing that individuals with chronic pain often require high dosages of narcotics, but pursued action against him based on “prescribing without adequate medical records.”¹⁰⁸ The Board argued that Hurwitz prescribed hundreds and thousands of doses to patients without appropriately monitoring their progress or status.¹⁰⁹ Hurwitz stated that “most of his pain patients came to him with well-established problems” and that his main purpose in doing a physical exam was to ensure that the patient’s complaint

100. *Id.*

101. White, *supra* note 94.

102. *Id.*

103. Common Sense for Drug Policy/Partnership for Responsible Drug Information, CSDP/PRDI Experts Directory: William E. Hurwitz, at www.csdp.org/csdpcgi/experts.pl?i=84 (last visited Aug. 9, 2008).

104. Jacob Sullum, *No Relief in Sight*, REASON, Jan. 1997, at 22, 23, 27 (“[T]he Virginia Board of Medicine had suspended Hurwitz’s license, charging him with excessive prescribing and inadequate supervision of his patients.”).

105. *Id.* at 27.

106. *Id.* at 28.

107. *War on Pain Control: State and DEA Tell Pain Patients to “Drop Dead,”* ACTIVIST GUIDE (Drug Reform Coordination Network, Wash., D.C.), Oct. 20, 1996, at www.drcnet.org/guide10-96/pain.html (last visited July 23, 2008) [hereinafter Drug Reform Coordination Network].

108. Wayne J. Guglielmo, *Treating Pain: Can Doctors Put Their Fears to Rest?*, MED. ECON., Feb. 21, 2000, at 46, 54.

109. See Sullum, *supra* note 104, at 28.

was well founded.¹¹⁰ He saw patients who lived in the area once a month but saw those who lived out of state only once or twice a year.¹¹¹ He supplemented out-of-state patients' visits with "a monthly written report and telephone calls."¹¹²

Hurwitz's license was suspended for three months and then restored on a probationary basis.¹¹³ He also lost his DEA privileges to prescribe narcotics for a year.¹¹⁴ Dr. Hurwitz appealed the Virginia Board's decision, arguing, in part, that the safe harbor provisions of the state's Intractable Pain Act limit the Board's authority to take action against a medical doctor based on the dosages of pain medicine prescribed.¹¹⁵ The Virginia Circuit Court, however, affirmed the Board's decision, finding that it acted in accordance with the law, did not make a procedural error resulting in harm, and had sufficient evidentiary support for its findings of facts.¹¹⁶

During the disciplinary proceedings, a number of pain experts supported Hurwitz's practices. Dr. James Campbell, professor of neurosurgery and director of the Blaustein Pain Treatment Center at Johns Hopkins University in Baltimore, stated that at Hopkins, they have a national practice:

We have great difficulty finding physicians . . . that will take over medications that work in these patients and take over their programs.

I think (Dr. Hurwitz) is doing heroic things for his patients. I think what he is doing involves an enormous sacrifice. There are a lot of bad doctors but he is not one of them.

If we suspend the license of all doctors . . . because one patient committed suicide, the pain field would be out of business.¹¹⁷

110. *Id.*

111. *Id.*

112. *Id.*

113. Arthur Allen, *First Do No Harm*, WASH. POST, July 27, 1997 (Magazine), at W11, W12.

114. *Id.* Approximately forty-eight of Hurwitz's patients testified at the hearing on revocation of his Virginia license, including some from other parts of the country. Two hundred twenty of his patients filed a class action suit against the Board seeking the return of Hurwitz's privileges, "arguing that his inability to prescribe . . . limited their access to drugs they need to live and violated their rights under the 1990 Americans with Disabilities Act." *Id.* The suit was dismissed in an unpublished decision in 1996. See *Cooper v. Hasty*, No. 97-1002, 1997 WL 472160, at *1 (4th Cir. Aug. 20, 1997).

115. See *Hurwitz v. Bd. of Med.*, 46 Va. Cir. 119 (1998).

116. *Id.* Based on the Virginia proceedings, the District of Columbia medical board subsequently suspended Hurwitz's D.C. license by reciprocal action but later reinstated it. See Allen, *supra* note 113, at W29.

117. Deborah Kelly, *Ethics Questions Surround Doctor's Case: Opinions Clash About Hurwitz's Narcotic Treatments, Role in Deaths*, RICHMOND TIMES-DISPATCH, Aug. 8, 1996, at E1 (alterations in original).

Dr. Mitchell Max, director of the Pain Research Clinic at the National Institutes of Health, also defended Hurwitz, stating:

I see nothing wrong with the doses, the amount, the number of pills, per se. . . . He is just taking regimens that work in cancer patients that everyone agrees on, and using them in people who had life-impairing, or even life-threatening, levels of pain. . . . We routinely give doses up to 10 times that size in patients with cancer.¹¹⁸

In the summer of 1998, after his license was reinstated and before his arrest, Hurwitz was able to prescribe controlled substances and began to treat pain again.¹¹⁹ The Web site describing his practice stated:

The practice concentrates on the evaluation and management of patients with intractable pain who require opioid medications. This treatment remains controversial and is subject to close scrutiny by state and federal regulatory authorities.

. . . .

The practice offers Therapeutic Trials of Opioid Medication and Opioid Maintenance Therapy. Opioid therapy is complicated. These medications are potentially dangerous. They may cause a variety of acute and chronic side effects. Both the administration and the discontinuation of these medications require an informed and responsible patient and careful medical management.¹²⁰

Dr. Hurwitz's criminal trial began in November 2004.¹²¹ During the six-week trial, the prosecution called more than sixty witnesses and played tapes of Hurwitz talking to patients who he did not realize were government informants.¹²² Also during the trial, several past presidents of the American Pain Society sent a letter to Hurwitz's lawyer expressing their dismay at how the case was being handled.¹²³ In particular, they cited "misrepresentations"

118. *Id.* (alterations in original).

119. See Dr. William Hurwitz, at www.drhurwitz.com (last visited Aug. 8, 2000) (former Web site, printout on file with author).

120. *Id.*

121. See Jerry Markon, *Pain Doctor Convicted of Drug Charges; Va. Man Faces Possible Life Term on Trafficking Counts*, WASH. POST, Dec. 16, 2004, at A1.

122. *Id.*

123. See Letter from six past presidents of the American Pain Society to Marvin D. Miller, attorney for Dr. William Hurwitz (Dec. 10, 2004), at www.aapsonline.org/painman/hurwitzletter.htm (last visited July 23, 2008) (The letter was written by six pain treatment experts, including physicians from Johns Hopkins University Medical Center, Albert Einstein College of Medicine, Memorial Sloan-Kettering Cancer Center, and Beth Israel Medical Center, among others.).

by one of the Justice Department's expert witnesses.¹²⁴ A similar letter was subsequently presented to the presiding judge.¹²⁵

On December 15, 2004, a federal jury convicted Hurwitz on fifty counts, including drug trafficking, which led to the death of one patient and seriously injured two other patients.¹²⁶ The jury acquitted him of nine other counts and deadlocked on three counts.¹²⁷ The prosecution sought a life sentence without parole,¹²⁸ but the district court sentenced Hurwitz to twenty-five years in prison.¹²⁹

The outcome sent chills through the pain treatment community and was criticized by a number of prominent journalists.¹³⁰ Hurwitz appealed the convictions on three grounds, one of which was that the court instructed the jury that it could not consider Hurwitz's "good faith" in his prescribing.¹³¹ Hurwitz argued that "his 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."¹³²

124. *Id.*

125. Letter from Jane M. Orient, Executive Dir., Ass'n of Am. Physicians & Surgeons, Inc., to Leonard D. Wexler, Judge, United States Dist. Ct., E. Dist. of Va. (Feb. 5, 2004), at www.aapsonline.org/painman/hurwitzletter2.htm (last visited July 23, 2008). The letter to the judge, sent after conviction and before sentencing, describes the expert medical testimony for the prosecution as "false" and "egregious" and the errors of the government's expert witness as "shocking, highly material, and profoundly unjust." *Id.*

126. Markon, *supra* note 121.

127. *Id.*

128. Rosenberg, *supra* note 14.

129. *United States v. Hurwitz*, 459 F.3d 463, 469 (4th Cir. 2006).

130. See, e.g., Rosenberg, *supra* note 14 (describing Hurwitz as "a prominent doctor committed to aggressive treatment of pain" and arguing that, while "[h]is behavior in some cases was inexcusable" and he should have supervised patients on large dosages of opioids more closely, such malpractice should have been cause for the loss of his medical license rather than criminal charges). To many it appears that he was prosecuted and convicted because he prescribed opioids to patients who were drug addicts or subsequently sold their pills. While Hurwitz did terminate patients whom he believed to be abusing their prescriptions, he slowly reduced the dosage for most of them because he felt that "cutting off patients was tantamount to torture, and he did not do so without strong evidence of bad behavior." *Id.*; see also Jacob Sullum, *The Doctor Is Not a Criminal: A Painful Drug-War Case in Virginia*, NAT'L REV., May 23, 2005, at 1, 28 (stating that the jurors "confused their role . . . in a criminal case with the roles of the state medical board that regulates doctors and the civil courts that hear malpractice lawsuits" and that the conviction "is bound to have a chilling effect on pain treatment, which is already scandalously inadequate because of the fear instilled by the war on drugs").

131. *Hurwitz*, 459 F.3d at 475-76.

132. *Id.* at 476.

The court of appeals “agree[d] with Hurwitz that a doctor’s good faith generally is relevant to a jury’s determination of whether the doctor acted outside the bounds of medical practice or with a legitimate medical purpose when prescribing narcotics.”¹³³ The case was retried at the district court level with the appropriate instruction in April 2007.¹³⁴ After deliberating for seven days, on April 27th, a jury found Hurwitz guilty on 16 counts of drug trafficking, acquitted him on 17 counts, and was unable to reach a verdict on the remaining 12 counts.¹³⁵ On July 13, 2007, the district court judge sentenced Hurwitz to fifty-seven months in prison.¹³⁶ The two and a half years he had already served would count toward this term and he would be given time off for good behavior.¹³⁷ While the judge had some sympathy for Hurwitz, she felt that the sentence was warranted because Hurwitz was “willfully blind” to the actions of his patients who were diverting their drugs.¹³⁸

D. Dr. Jeri Hassman

In March 2003, federal officials marched into Dr. Jeri Hassman’s office while she was treating a patient, “took off her jewelry, put her in handcuffs and led her to jail.”¹³⁹ Hassman was a specialist in rehabilitation medicine and pain management in Tucson, Arizona.¹⁴⁰ Before the arrest, the DEA placed Hassman and some of her patients under surveillance and sent undercover patients to her office to complain about pain.¹⁴¹ She was also

133. *Id.*

134. Jerry Markon, *Va. Pain Doctor’s Prison Term Is Cut to 57 Months: Originally Sentenced to 25 Years, Specialist Did More Good Than Harm, Judge Says*, WASH. POST, July 14, 2007, at B1.

135. *Id.*; Tierney Lab: Putting Ideas in Science to the Test, <http://tierneylab.blogs.nytimes.com/2007/04/27/dr-hurwitz-convicted-of-16-drug-trafficking-charges/> (Apr. 27, 2007, 21:00 EST).

136. Transcript of Sentencing at 44-45, *United States v. William Eliot Hurwitz*, No. 1:03cr467 (E.D. Va. July 13, 2007).

137. *Id.* at 45, 47.

138. *See id.* at 44 (“[T]here does need to be a reasonable message sent to the people in the medical profession that if they practice appropriately and by the right rules . . . they should fear nothing, but if they absolutely blind themselves to what are clearly rational, clear signals of illegal conduct, then those doctors working with these types of potent medications simply have to put the brakes on.”).

139. Kaufman, *supra* note 6.

140. *See id.*

141. *Id.* One informant had been seeking treatment from Dr. Hassman over a four-year period and had only received physical therapy for back pain. A. Bates Butler III, Attorney for Dr. Jeri Hassman, *Pitfalls of Chronic Pain Management*, Presentation to the Arizona Society for Healthcare Risk Management 7 (Sept. 10, 2004) (on file with author). When he complained of increased pain and “told her a friend had given him Oxycodone that had helped alleviate

under investigation by the Arizona Medical Board, and the Board had worked with her by arranging for a mentor, an expert in pain management and addiction, to improve her documentation and increase her use of urine drug screens.¹⁴² This mentoring occurred in September and October 2002, but subsequently, without contacting the Arizona Medical Board, the DEA suspended Dr. Hassman's DEA registration (without which she could not prescribe controlled substances).¹⁴³ According to her attorney, "[t]he suspension occurred before Dr. Hassman's records were reviewed by any physician."¹⁴⁴ Just two weeks before a hearing on the suspension was scheduled, Hassman was indicted¹⁴⁵ and "charged with 362 counts of prescribing controlled drugs outside the normal practice of medicine."¹⁴⁶

Based on a news account of her arrest, "[i]n the federal criminal complaint against her, the sole allegation [was] that she prescribed controlled substances 'not being in the usual course of professional practice and not for any legitimate medical purpose.'"¹⁴⁷ The news account further reported that the action was taken against Hassman after the DEA tape-recorded a conversation between her and the state Board.¹⁴⁸

After her arrest, Hassman issued a press statement in which she admitted that there is a problem of drug abusers illegally distributing prescription drugs but that, at the same time, there are millions of people suffering with severe and chronic pain who need the same prescription drugs to help them live a normal life:

Unfortunately, the DEA and the doctors who treat chronic pain are not working collaboratively to meet these important national healthcare interests. Instead an antagonistic relationship has developed between the DEA and doctors, where the DEA appears to think that doctors are over-prescribing pain medication and doctors are trying in good faith to care for

his pain . . . Hassman made the mistake of believing her longtime patient and prescribed Oxycodone and then OXYCONTIN for him. She was indicted for each such prescription." *Id.*

142. See Butler, *supra* note 141.

143. *Id.*

144. *Id.*

145. *Id.*

146. Kaufman, *supra* note 6.

147. *Id.*

148. *Id.* ("Although the right to practice medicine is regulated by state boards, the right to prescribe controlled narcotics is regulated by the DEA . . . [i]n Hassman's case, that working relationship became controversial . . . [because] [s]he was not told . . . that DEA agents were watching the conversation on closed-circuit television and participating in the interview 'by surreptitious means.'").

their patients under the ever-growing fear of being accused of aiding in unlawful drug diversion.¹⁴⁹

Because of the threat of a jail sentence, on January 29, 2004, Dr. Hassman “entered a guilty plea to four counts of knowingly comforting or assisting four patients who possessed controlled drugs obtained through misrepresentation, deception, or fraud—that is, to being an accessory after the fact to [her] patients’ crimes.”¹⁵⁰ In one of the cases, a pharmacist informed Hassman that one of her patients “had filled a prescription for her mother, also a patient, and then handed it to an unknown man in the parking lot, who drove away.”¹⁵¹ The patient later told Hassman that the man in the parking lot was the patient’s nephew.¹⁵² The other charges were based on a patient who “admitted to possessing some drugs prescribed for his deceased father,” a patient who said during an initial office visit that he once possessed someone else’s prescription, and two patients who “told [Hassman] that a certain patient had stolen part of their prescriptions.”¹⁵³ In these cases, although Dr. Hassman documented these facts in the patient’s medical records, she did not call the police.¹⁵⁴

On August 16, 2004, Dr. Hassman was sentenced in federal court.¹⁵⁵ At sentencing, the judge acknowledged that she “ha[d] been punished enough by loss of professional standing and most of her practice, as well as the destitution resulting from her enormous legal expenses.”¹⁵⁶ Nevertheless, the judge believed “that a lenient sentence might be an inadequate deterrent to the rest of the medical community.”¹⁵⁷ While recognizing that “some patients do need and benefit from the prescription of opioids,” he expressed a greater concern about the “scourge of addiction” that could

149. Press Statement, Jerri Hassman, M.D. (June 26, 2003), at www.aapsonline.org/painman/hasstatement.htm (last visited July 23, 2008).

150. Ass’n of Am. Physicians & Surgeons, *Jeri Hassman, M.D. Pleads Guilty to Not Ratting on Patients*, NEWS OF THE DAY...IN PERSPECTIVE, Jan. 31, 2004, at www.aapsonline.org/nod/newsofday39.htm (last visited July 23, 2008). “Under the terms of the plea agreement, she could [have been] sentenced to up to 6 months in prison or up to 5 years probation. The plea agreement enabled her to avoid decades in jail under the sentencing guidelines had she been convicted on any one of the 300 counts” with which she was initially charged. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

155. Ass’n of Am. Physicians & Surgeons, *Dr. Jeri Hassman Sentenced to Probation*, NEWS OF THE DAY...IN PERSPECTIVE, Aug. 18, 2004, at www.aapsonline.org/nod/newsofday83.htm (last visited July 23, 2008).

156. *Id.*

157. *Id.*

result if physicians did not more stringently control their prescribing practices.¹⁵⁸

The judge ultimately imposed a sentence that included “two years of probation, plus 100 hours of community service, 50 in a substance abuse center and 50 serving nonpaying patients in her office.”¹⁵⁹ Hassman was permitted to “reapply for her DEA certification one year after the date of the plea agreement.”¹⁶⁰ The judge, however, conditioned the sentence on a requirement that she “publish in a medical journal an exemplary letter describing the devastating consequences of her own behavior and the righteous prosecution by government, so that others may be influenced.”¹⁶¹

E. Dr. Ronald McIver

After teaching and traveling for a number of years, Ronald McIver entered Michigan State University to become a doctor of osteopathy (D.O.).¹⁶² He began practicing pain medicine in Florence, South Carolina, in the late 1980s, and after declaring bankruptcy in 2000, moved to Greenwood, South Carolina, where he opened a small storefront clinic called the Pain Therapy Center.¹⁶³ According to a news account of his case, he was an “unusual doctor” in this day and age in that he spent significant amounts of time with his patients—the average visit lasted an hour.¹⁶⁴ While an apparently caring doctor, he neglected the administrative side of his practice.¹⁶⁵

McIver was an aggressive pain doctor, prescribing high dosages of opioids for many of his patients, but he required his “[p]atients taking opioids . . . to sign a pain contract and bring their pills in at each visit to be counted.”¹⁶⁶ McIver had concerns about whether some of his patients were legitimate patients or were diverting their medications.¹⁶⁷ As a result, in February 2002, he wrote a letter to a state Board of Drug Control (BDC) inspector, describing his suspicions.¹⁶⁸ He ended the letter stating “I

158. See *id.*

159. *Id.*

160. Ass’n of Am. Physicians & Surgeons, *supra* note 155.

161. *Id.*

162. Tina Rosenberg, *Doctor or Drug Pusher?*, N.Y. TIMES, June 17, 2007, §6 (Magazine), at 48, 52.

163. *Id.* at 50, 52.

164. See *id.* at 52.

165. See *id.* (“While McIver’s treatment rooms were normal, his and his wife’s offices—off limits to patients—were a mess . . . Used syringes, for example, overflowed their storage box.”).

166. See *id.* at 50, 52.

167. See Rosenberg, *supra* note 162, at 54.

168. *Id.*

certainly don't want to refuse help to someone who needs it. On the other hand, I want even less to be implicated in diversion or other improprieties."¹⁶⁹ While the BDC agent did nothing with the letter, Mclver came into the DEA's crosshairs in July 2002 when a health insurance agent was going through files and found that one of his subscribers, Larry Shealy, was receiving very large doses of opioids from Dr. Mclver.¹⁷⁰ The insurance agent called the DEA.¹⁷¹

Larry Shealy began seeing Mclver in February 2002.¹⁷² Shealy was fifty-six years old and suffered from "intense back and knee pain" and other health problems.¹⁷³ He was taking OxyContin when he first came to see Mclver but complained that his pain was still significant.¹⁷⁴ Mclver increased the dose to a level that allowed Shealy to go back to his job in an auto body shop.¹⁷⁵ Shealy died in his sleep approximately fifteen months after he started seeing Mclver.¹⁷⁶

Mclver was indicted "on fifteen counts related to his treatment of ten patients, nine of whom testified for the government at trial."¹⁷⁷ The tenth patient was Larry Shealy, whose "death formed the basis of two counts of the indictment."¹⁷⁸

Of the patients who testified against Mclver, Leslie Smith, the patient who prompted Mclver to write the letter to the BDC, gave the most damaging testimony.¹⁷⁹ Smith admitted he was a drug addict and sought out Mclver to obtain painkillers after learning from one of his friends that Mclver readily gave him a prescription for pain medications.¹⁸⁰ Smith traveled sixty miles each way to see Mclver¹⁸¹ and "testified that he lied to [Mclver] about pain in his wrist, but that [Mclver] prescribed high doses of OxyContin and Dilaudid, the drugs that Smith requested, without ordering x-rays."¹⁸² The prosecution presented evidence that Mclver must have been aware of Smith's drug use as he discovered a syringe in Smith's possession

169. *Id.* (quoting the February 2002 letter from Mclver to Larry McElrath, a state Bureau of Drug Control inspector).

170. *Id.* at 52, 54.

171. *Id.* at 52.

172. Rosenberg, *supra* note 162, at 55.

173. *Id.*

174. *Id.*

175. See *id.* (stating that Mclver doubled Shealy's dose of OxyContin).

176. *Id.* When he died, Shealy "had OxyContin pills in his stomach" and "the levels of drugs were consistent with the prescriptions Mclver had been writing." *Id.*

177. *United States v. Mclver*, 470 F.3d 550, 553 (4th Cir. 2006).

178. *Id.* at 553.

179. Rosenberg, *supra* note 162, at 52, 54.

180. *Mclver*, 470 F.3d at 554 (citing Joint Appendix at 175-76).

181. *Id.*

182. *Id.* at 554 (citing Joint Appendix at 178, 180-83).

during an office visit.¹⁸³ Despite this fact, after Smith told Mclver that he used the syringe for fishing, Mclver continued to prescribe the drugs for him.¹⁸⁴

The others who testified were also either drug addicts or drug diverters who lied to Mclver about their use of the drugs.¹⁸⁵ Apparently, the jury believed the prosecution's claim that Mclver knew or, at least, should have known that these individuals were abusing or diverting the drugs he prescribed and convicted Mclver of one count of conspiracy to distribute controlled substances unlawfully,¹⁸⁶ six counts of unlawful distribution of a controlled substance,¹⁸⁷ and two counts of unlawful distribution of a controlled substance that led to Larry Shealy's death.¹⁸⁸ He was sentenced to concurrently serve thirty years in prison for Shealy's death and twenty years for the other counts.¹⁸⁹

A *New York Times* article published after the court decision raised questions about whether Shealy's death was related to the drugs Mclver prescribed.¹⁹⁰ Although the prosecutor's toxicologist concluded that the OxyContin and Roxicodone that Mclver prescribed "caused Shealy's death by respiratory depression," there was evidence that Shealy had been taking the same amount of the drugs for at least two months before he died.¹⁹¹ According to pain specialists, death by respiratory suppression is unlikely when the dosage of such drugs is consistent.¹⁹² Moreover, there was also a significant possibility that Shealy's death might have been caused by "advanced congestive heart failure."¹⁹³

Mclver appealed the trial court decision to the Court of Appeals for the Fourth Circuit on several grounds.¹⁹⁴ The crux of Mclver's argument was that the jury was allowed "to convict on a civil, rather than a criminal,

183. *Id.* at 554 (citing Joint Appendix at 185).

184. *Id.* at 554-55 (citing Joint Appendix at 185).

185. See *Mclver*, 470 F.3d at 554-57 (discussing the cases of six patients who received prescriptions from Mclver).

186. *Id.* at 553 (in violation of 21 U.S.C. § 846 (2000)).

187. *Id.* (in violation of 21 U.S.C. § 841(a)(1) (2000)).

188. *Id.* (in violation of 21 U.S.C. § 841(a)(1) & (b)(1)(C) (2000)).

189. *Id.*

190. Rosenberg, *supra* note 162, at 55.

191. *Id.*

192. *Id.*

193. *Id.*

194. The grounds included that the jury instructions "improperly lowered the government's burden of proof," that the prosecution's medical expert's testimony "constituted inadmissible legal opinions," that "the district court erred in excluding evidence from [Mclver's] expert witness," and that "there was insufficient evidence to support each of his convictions." *Mclver*, 470 F.3d at 557.

standard of proof.”¹⁹⁵ Despite acknowledging that there is potential for jury confusion as to the civil standard of care applied in medical malpractice cases and the criminal standard of proof required in these prosecutions, the Fourth Circuit rejected McIver’s arguments and upheld the district court’s decision.¹⁹⁶ Interviews with jurors after the trial, however, indicated some confusion over the standard, with a number indicating that what was most influential to their decision was the amount and dosages of drugs prescribed,¹⁹⁷ rather than knowledge or intent to divert or prescribe to feed an addict’s habit.

III. THE ROOTS OF THE CONFLICT—A CLASH OF CULTURES

The scrutiny and prosecution of these physicians is a useful foundation for an examination of the clash between a medical view regarding appropriate prescribing of opioids for pain treatment and a law enforcement perspective that such drugs are dangerous and have the potential for abuse and diversion. But, these prosecutions also represent a more deep-seated adversariness, akin to animosity, between the two groups. This animosity is evident in the language used by each side when describing the other. War and terrorism are major themes in the rhetoric of both sides. While government prosecutors have long referred to their activities against drug diversion as part of a “war on drugs,” they have also likened doctors who prescribe large doses of opioids to terrorists, stating that they will “root [them] out like the Taliban.”¹⁹⁸ Pain advocates have responded in kind, referring to the government’s efforts as “a war on pain doctors,” “a government jihad,” and “state-sponsored terrorism.”¹⁹⁹ Media reports add fuel to this rhetoric, describing the DEA as using “hardball tactics,” including “storming clinics in SWAT-style gear, ransacking offices, and hauling off doctors in handcuffs.”²⁰⁰

State and federal prosecutors have also used the language of organized crime. They have referred to arrested doctors as “being no different than

195. See *id.*

196. *Id.* at 558.

197. Rosenberg, *supra* note 162, at 55.

198. See Melinda Ammann, *The Agony and the Ecstasy: How the OxyContin Crackdown Hurts Patients in Pain*, REASON, Apr. 2003, at 28, 33 (quoting Gene Rossi, an Alexandria, Virginia, federal prosecutor); see also White, *supra* note 94 (quoting former Attorney General John Ashcroft, who stated that “[t]he indictment and arrests in Virginia demonstrate our commitment to bring to justice all those who traffic in this very dangerous drug We will continue to pursue vigorously physicians, patients and others who are responsible for turning OxyContin from a legitimate painkiller to a vehicle of addiction and death.”).

199. Frank Owen, *The DEA’s War on Pain Doctors*, VILLAGE VOICE, Nov. 5-11, 2003, at 40.

200. *Id.*

drug kingpins or crack dealers” and call their patients drug addicts.²⁰¹ Pain advocates, in contrast, refer to these doctors as pioneers and even heroes,²⁰² and patients as vulnerable and suffering human beings.²⁰³ The two sides also characterize the drugs that are the focus of regulation very differently. OxyContin, for example, is characterized by drug enforcement officials as “a seductive, deadly menace,”²⁰⁴ whereas pain physicians and patients refer to it as “a miracle drug.”²⁰⁵

The language of each side, in and of itself, provides evidence of the rift between the two groups and may also illustrate the historical tension between them and the inherent culture of each profession. Prosecutors appear deeply distrustful of addicts or anyone using large quantities of narcotics. That suspicion carries over to anyone willing to help an addict or trust him. This suspicion likely results from their training and indoctrination. In contrast, physicians talk of the need to trust their patients, to listen to them, to prevent their pain and suffering, and to engender their trust. Without such patient trust, they are trained to believe, they will be unable to establish a therapeutic relationship, i.e., patients will not confide in them or share with them information that is essential for accurate diagnosis and treatment. In addition, physicians are trained to make independent medical judgments and value their autonomy in this regard. Efforts by prosecutors and regulators to determine what is a “legitimate medical purpose” invades physicians’ exclusive turf and seriously threatens their professional integrity. The cavernous schism between the two sides appears to prevent rational exploration of the issue and cooperative means of dealing with the problem.

IV. THE HISTORY OF U.S. DRUG ENFORCEMENT RELATED TO PHYSICIAN PRESCRIBING

The recent altercations between physicians and law enforcement agents over the prescribing of opioids is actually part of an ongoing historical struggle between the two groups as to what counts as the practice of medicine and who has the authority to decide what constitutes the practice of medicine in the context of physicians prescribing controlled substances. The modern drug regulatory scheme has its roots in the late nineteenth

201. See, e.g., Kaufman, *supra* note 6; Markon, *supra* note 134.

202. See, e.g., Ralph Vartabedian, *Painful Rift Unnerves Doctors: The Clash over the Use of Opioids to Treat Patients Intensifies*, L.A. TIMES, Oct. 20, 2003, at A1; Owen, *supra* note 199.

203. See, e.g., Markon, *supra* note 134.

204. Ammann, *supra* note 198, at 30.

205. See Timothy Roche, *The Potent Perils of a Miracle Drug: OxyContin is a Leading Treatment for Chronic Pain, but Officials Fear It May Succeed Crack Cocaine on the Street*, TIME, Jan. 8, 2001, at 47.

century, when policymakers began "to define the boundaries of appropriate sale and use of drug products."²⁰⁶ These standards were created about the time that some medical professionals began defining drug addiction as a disease that needed to be treated by health professionals, with some calling for all narcotics to be banned from sale, except with medical approval.²⁰⁷

It was not until 1914, when Congress passed the Harrison Narcotics Act, that federal law addressed the issue of the non-medical use of narcotics.²⁰⁸ As a result of the then prevailing constitutional view that Congress had limited power to create penal laws (because police powers were reserved to the states), the Harrison Act was drafted simply as a tax law requiring those authorized to manufacture and/or distribute "opium, coca leaves and all their compounds and derivatives to register [with the local internal revenue office], pay a fee, and keep records of all such drugs in their possession."²⁰⁹ A narcotics division was established in the U.S. Treasury Department to enforce the law.²¹⁰

The Harrison Act made possession of narcotics by any unregistered person unlawful unless the drugs were obtained from a physician who was registered under the Act, prescribed "in the course of his professional

206. Spillane & McAllister, *supra* note 12, at S5.

207. *Id.* at S6. In addition to balancing concerns about addiction and therapeutic benefit, early efforts to regulate the sale of these drugs sought to address health professionals' concerns about control of the drug supply. See *id.* The American Medical Association, which had recently been established, was seeking to "control the distribution of medicines under physicians." Duane C. McBride et al., *Alternative Perspectives on the Drug Policy Debate, in THE DRUG LEGALIZATION DEBATE* 9, 11 (James A. Inciardi ed., 2d ed. 1999). Large pharmaceutical companies were being established and driven by profit rather than concerns over the public's health. See Spillane & McAllister, *supra* note 12, at S6. In addition to an increased volume of drugs manufactured by these companies, a large quantity of "patent medicines" was being marketed directly to consumers. See DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 14-15 (3d ed. 1999). Many physicians and pharmacists and their respective emerging trade associations (the American Medical Association and the American Pharmaceutical Association) advocated that dispensing of narcotics be limited to these professionals. *Id.* at 11, 14-15.

208. See Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785 (1914) (repealed 1970). Prior to that time, there was no real distinction between therapeutic and recreational or illicit drugs. See Jeffrey Clayton Foster, *The Rocky Road to a "Drug-Free Tennessee": A History of the Early Regulation of Cocaine and the Opiates, 1897-1913*, 29 J. SOC. HIST. 547, 547 (1996). Narcotics were widely available and could be purchased without a physician's prescription at local drugstores. See *id.* Even substances such as heroin and barbiturates were advertised in the 1904 Sears catalog. See McBride et al., *supra* note 207, at 11.

209. JAMES C. WEISSMAN, *DRUG ABUSE: THE LAW AND TREATMENT ALTERNATIVES* 117 (1978); see also MUSTO, *supra* note 207, at 54-68 (discussing the movement that led to the passage of the Harrison Act).

210. See Harrison Act, § 2(a), 38 Stat. at 786.

practice,” and kept records of the amount dispensed or distributed and the name and address of the patient to whom the drugs were dispensed or distributed.²¹¹ According to one author, “in effect, the Act criminalized non-medically authorized possession, use, and distribution of opiates and cocaine . . . [and] was the first time in the history of the United States that criminal sanctions were being imposed upon what previously had been considered a purely medical matter.”²¹²

The Harrison Act afforded physicians a good deal of discretion in prescribing narcotics for medical purposes, yet, even at that time, drug control enforcers and physicians frequently came into conflict. As historical expert David Musto pointed out, “legal definitions could not easily distinguish between well-meaning overuse, use in error, and indiscriminate dispensing that led to addiction.”²¹³ When doctors were brought into court on charges that they were prescribing narcotics for non-medical purposes, they simply countered that they were practicing legitimate medicine.²¹⁴ While drugs were also still being distributed by non-physicians, physicians were a much easier target for law enforcement agents.²¹⁵

A considerable point of contention after passage of the Act was the treatment of drug addicts. Federal drug agents “opposed any form of narcotics distribution and harassed physicians who dared to pursue narcotic treatment efforts.”²¹⁶ Many physicians, on the other hand, “felt that the agonies of unrelieved addiction were as much encompassed in their Hippocratic Oath as any other human suffering.”²¹⁷ The question of whether the Act allowed the treatment or maintenance of addicts was addressed in a series of Supreme Court opinions, which seemed to vacillate on the issue, arguably as a result of the revenue origin of the Act, but also, perhaps, as a result of changes in the way that society viewed addicts.²¹⁸ Over a six-year period starting in 1916, the Court went from viewing the Act as not preventing physicians from prescribing to addicts, as it was simply a

211. *Id.*

212. WEISSMAN, *supra* note 209, at 117.

213. MUSTO, *supra* note 207, at 92.

214. *Id.* at 93-94.

215. See, e.g., *id.* at 94 (“Professionals could be made to conform to law much more effectively than unlicensed peddlers or pushers.”).

216. WEISSMAN, *supra* note 209, at 118.

217. Rufus G. King, *The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick*, 62 YALE L.J. 736, 739 (1953).

218. See MUSTO, *supra* note 207, at 132-34 (discussing the “change in judicial outlook between 1915 and 1919 with regard to addiction maintenance”).

revenue act,²¹⁹ to saying that prescribing to an addict “for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use” was not in the “course of professional treatment,”²²⁰ to adopting a view that professional practice did not include medication for the purpose of curing an addict.²²¹

These Supreme Court “cases clearly established that registered physicians were permitted to prescribe and dispense narcotic drugs strictly within the bounds of their professional practice”²²² and that maintenance therapy for addicts was not within such bounds. They set the stage for “practitioner investigations and prosecutions for years to come.”²²³

According to Rufus King, an early anti-drug law advocate, starting in the 1920s, “the Narcotics Division launched a reign of terror, threatening

219. See *United States v. Jin Fuey Moy*, 241 U.S. 394 (1916) (affirming the district court’s decision to quash an indictment against Dr. Jin Fuey Moy for prescribing morphine to an addict).

220. *Webb v. United States*, 249 U.S. 96, 99-100 (1919); see also *United States v. Doremus*, 249 U.S. 86, 90 (1919) (upholding the conviction of a doctor whose indictment charged that the defendant physician sold “five hundred one-sixth grain tablets of heroin not in the course of the regular professional practice . . . and not for the treatment of any disease from which [his patient] was suffering but as was well known by [the defendant], [his patient] was addicted to the use of the drug as a habit, being a person popularly known as a ‘dope fiend,’ and that [the defendant sold] . . . the drug, heroin, to [his patient] for the purpose of gratifying his appetite for the drug”).

221. See *United States v. Behrman*, 258 U.S. 280, 286 (1922) (“[D]efendant did not dispense any of the drugs for the purpose of treating any disease or condition *other than* [morphine, heroin, or cocaine] addiction.”(emphasis added)); see also King, *supra* note 217, at 743 (asserting that the Solicitor General issued a trick indictment broadening the case to include “whether the so-called ‘ambulatory treatment’ of drug addicts by a physician is or is not, as a matter of law, prohibited by section 2 of the Harrison Narcotic Act.” (quoting Brief on Behalf of the United States at 7, *Behrman*, 258 U.S. 280, No. 582 (1922))).

222. Stephen E. Stone, *The Investigation and Prosecution of Professional Practice Cases Under the Controlled Substances Act: Introduction to Professional Practice Case Law and Investigations*, 10 DRUG ENFORCEMENT 21, 22 (1983).

223. *Id.* The change in the Supreme Court’s interpretation of the Act is attributed in part to “radical social change.” Aryeh Y. Brown, Comment, *In Memoriam: Ralph Seeley, Obscured by Smoke: Medicinal Marijuana and the Need for Representation Reinforcement Review*, 22 SEATTLE U. L. REV. 175, 210 (1998) (citing MUSTO, *supra* note 207, at 132). Between the initial and second *Jin Fuey Moy* decisions, “[t]he country underwent profound changes World War I had been fought, the Eighteenth Amendment had been adopted in a spirit of moralistic fervor, ‘and the liberalizing movements of La-Follette, Theodore Roosevelt, and Wilson had declined into a fervent and intolerant nationalism.’” *Id.* (quoting MUSTO, *supra* note 207, at 132-33). In addition, there was

an enormous fear of Bolsheviks and anarchists which gave rise to the Red Scare of 1919-20. Narcotics came to be associated with perversion and rebellion, addiction was perceived as a threat to the war effort and to the nation, and maintenance of addicts in clinics or by individual physicians was considered immoral and unpatriotic. *Id.* (footnotes omitted).

doctors who had anything further to do with drug addicts, and sending a goodly number of recalcitrant practitioners off to prison."²²⁴ Yet, these offenders often were respected members of the community and the "ratio between arrests and convictions remained notably low, indicating abusive use of the indictment processes."²²⁵

During the time that these cases were making their way to the U.S. Supreme Court, addicts continued to be treated in "morphine maintenance clinics."²²⁶ However, in the early 1920s, largely in response to a "global moral crusade" the clinics were forced to close, and addicts were left to seek out sympathetic individual physicians or obtain their drugs illegally, on the street through a thriving black market.²²⁷ Then, in 1925, the U.S. Supreme Court ruled in *Linder v. United States*²²⁸ that physicians could prescribe narcotics to assist addicts in withdrawal as long as they did so in conformance with accepted medical practice.²²⁹ In *Linder*, a physician who was registered under the Act gave a patient, who the government argued the physician knew was addicted to narcotics, one tablet of morphine and three tablets of cocaine.²³⁰ At issue was whether the physician was dispensing the drugs within the bounds of his professional practice.²³¹ The physician argued that what is meant by "in the course of . . . professional

224. RUFUS KING, *THE DRUG HANG UP: AMERICA'S FIFTY-YEAR FOLLY* 43 (1974).

225. *Id.* at 44. "[I]n 1920, 3,477 arrests produced 908 convictions; in 1921, 4,014 arrests produced 1,583; at the peak, in 1925, 10,297 federal arrests produced 5,600 convictions." *Id.*

226. See WEISSMAN, *supra* note 209, at 117.

227. *Id.* at 117-18.

228. 268 U.S. 5 (1925).

229. *Id.* at 22. The petitioner alleged that prior to this case, the lower courts had, "without any sufficient reason," "engrafted" onto the exception of the Act (that a physician who dispenses or distributes narcotics in the course of his professional practice need not prescribe on an official form) "the further requirement that the dispensing or distribution must . . . have been . . . in good faith as a medicine, and not to satisfy the cravings of an addict." Brief of Petitioner at 8, *Linder*, 268 U.S. 5, No. 183 (1924).

230. 268 U.S. at 11, 15-16. According to one source,

Dr. Charles O. Linder, completing a lifetime of honorable practice in Spokane, Washington, was induced by one of Treasury's addict stool-pigeons to write a prescription for four tablets of cocaine and morphine. (At the trial the doctor claimed she told him she was in great pain from a stomach ailment, and that her regular physician was unavailable; she swore she had disclosed to him that she was a drug addict.) Several Treasury agents thereupon descended on his office on a Saturday afternoon, stomped through his waiting room crowded with patients, and broke in on him in the midst of a consultation. After a rough-and-tumble search of the premises, they dragged him off to jail.

KING, *supra* note 224, at 44-45.

231. *Linder*, 268 U.S. at 17, 22-23.

practice . . . cannot be answered by the application of any hard and fast rule” and that

[i]t is the business of the physician to alleviate the pain and suffering of patients as well as to effectuate their cure. If we are to believe the literature on the subject, the suffering of an addict caused by deprivation of his customary drug is as intense as any suffering caused by disease. It is perhaps more so in the insistent demand for relief. Why should not the physician in the course of his ordinary practice take cognizance of that fact and administer temporary relief? Why should the law be construed as intended to prohibit such an act of mercy? It is, we submit, a strained construction of the law to hold that the language in question was intended to prohibit such an act²³²

The Court ultimately confirmed its earlier interpretation that the Act must be construed and applied as a revenue act.²³³ In addition, the Court took the opportunity to limit the holding of its prior rulings on this issue, stating that earlier opinions “cannot be accepted as authority for holding that a physician, who acts *bona fide* and according to fair medical standards, may never give an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction.”²³⁴

Despite the ruling in *Linder*, federal narcotics agents “continued to vigorously and indiscriminately investigate all physicians prescribing narcotics to addicts.”²³⁵ Addiction continued to be viewed as a “vice” rather than as a treatable disease and certain drugs were “stripped of their healing properties.”²³⁶ Physicians, even those prescribing within legal bounds, became fearful of narcotics agents. According to Musto, “[t]he social and economic position of the registered physician was so sensitive, trials so time-consuming, and appeals so long and costly, that hostile agents could make cases against physicians with impunity and nearly ruin them whether charges were warranted or not.”²³⁷

In the 1930s, controversy remained over the treatment of addicts from both a medical and legal perspective and the regulation of narcotics

232. Brief of Petitioner, *supra* note 229, at 11.

233. See *Linder*, 268 U.S. at 22-23 (“We find no facts alleged in the indictment sufficient to show that petitioner had done anything falling within definite inhibitions or sufficient materially to imperil orderly collection of revenue from sales. . . . The unfortunate condition of the recipient certainly created no reasonable probability that she would sell or otherwise dispose of the few tablets intrusted to her; and we cannot say that by so dispensing them the doctor necessarily transcended the limits of that professional conduct with which Congress never intended to interfere.”).

234. *Id.* at 22.

235. WEISSMAN, *supra* note 209, at 118.

236. Brown, *supra* note 223, at 212.

237. MUSTO, *supra* note 207, at 185.

expanded.²³⁸ In 1930, the Federal Bureau of Narcotics was established under the Treasury Department's control,²³⁹ and in 1932, the National Conference of Commissioners on Uniform State Laws promulgated the Uniform Narcotic Drug Act, a model for state legislatures that criminalized the possession, use, and distribution of opiates and cocaine.²⁴⁰ The model ultimately was adopted by every state in some form and increased uniformity among state laws.²⁴¹

From 1930 to the late 1960s, federal drug policy was largely a matter for the police and was enforced by the Federal Bureau of Narcotics.²⁴² Then, in 1968 Congress established the Bureau of Narcotics and Dangerous Drugs, replacing the Federal Bureau of Narcotics.²⁴³ It was housed in the Justice Department, rather than the Treasury, and was assigned responsibility for enforcement of the federal drug laws.²⁴⁴ The shift in the department housing the enforcement agency symbolized a shift in policy from a tax- to a regulatory-based perspective.

In 1970, Congress passed the Controlled Substances Act (CSA),²⁴⁵ which is the modern day tool used to regulate narcotics and other controlled substances.²⁴⁶ It was also the beginning of President Nixon's "war on drugs," a war that continues today²⁴⁷ and is the root of current tensions between physicians treating pain and the government. The CSA replaced the Harrison Narcotics Act of 1914 but is broader in scope, regulating both

238. See WEISSMAN, *supra* note 209, at 118.

239. Act of June 14, 1930, Pub. L. No. 71-357, 46 Stat. 585.

240. UNIFORM NARCOTIC DRUG ACT (1932), *reprinted in* WILLIAM BUTLER ELDRIDGE, *NARCOTICS AND THE LAW: A CRITIQUE OF THE AMERICAN EXPERIMENT IN NARCOTIC DRUG CONTROL* app. A, at 161, 163-64 (2d ed. rev. 1967).

241. WEISSMAN, *supra* note 209, at 118-19.

242. DAVID F. MUSTO & PAMELA KORSMEYER, *THE QUEST FOR DRUG CONTROL: POLITICS AND FEDERAL POLICY IN A PERIOD OF INCREASING SUBSTANCE ABUSE, 1963-1981*, at x (2002).

243. See MUSTO, *supra* note 207, at 240. This new agency was a consolidation of the prior Bureau of Narcotics (formerly located in the Treasury Department) and the Bureau of Drug Abuse Control (formerly located in the Department of Health, Education, and Welfare). *Id.*

244. *Id.* at 240-41.

245. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801-971 (2000)).

246. Controlled substances covered by the CSA are drugs that have the potential for abuse and dependence. See 21 U.S.C. § 812 (including the potential for abuse and dependence in the descriptions of each of the five "schedules" of drugs the CSA covers).

247. Robert Pavlan, *The Federal Controlled Substances Act*, PHARMACY L. UPDATE (Ne. Univ. Bouvé Coll. of Health Sci., Sch. of Pharmacy, Continuing Educ., Boston, Ma.), 2002, at 1; see DRUG ENFORCEMENT ADMIN., *DRUG ENFORCEMENT ADMINISTRATION: A TRADITION OF EXCELLENCE, 1973-2003*, at 13-14, available at www.usdoj.gov/dea/pubs/history/history_part1.pdf (last visited Aug. 9, 2008); see also MUSTO, *supra* note 207, at 248-50 (discussing Nixon's war on drugs).

narcotic and non-narcotic substances (e.g., barbiturates, amphetamines, and anabolic steroids).²⁴⁸ The CSA and its attendant regulations provide for intensive record keeping and tracking of all organizations and individuals involved in the distribution of controlled substances.²⁴⁹ The CSA is administered and enforced by the Drug Enforcement Administration (DEA), which was established in 1973 and is a unit of the FBI within the U.S. Department of Justice.²⁵⁰

The CSA classifies controlled substances into one of five schedules based on their potential for abuse, psychological or physiological dependence, and medical uses.²⁵¹ Schedule I drugs are substances which have a high potential for abuse and no current medical use.²⁵² They include substances such as heroin, LSD, marijuana,²⁵³ and methaqualone.²⁵⁴ Schedule II substances, which also have a high potential for abuse, have a currently accepted use in medical treatment but are, in general, accepted for medical use only with severe restrictions.²⁵⁵ This group includes morphine, cocaine, methadone, oxycodone, and injectable forms of methamphetamine.²⁵⁶ Several of these drugs are used to control chronic and/or acute pain.²⁵⁷ Schedules III–V substances have a potential for abuse which is lower than substances in Schedules I and II but also have

248. See MUSTO, *supra* note 207, at 255; WEISSMAN, *supra* note 209, at 124. Also, unlike the Harrison Narcotics Act, which was based on the federal government's taxing power, the CSA is based on the federal government's power to regulate interstate commerce. Early constitutional attacks on the statute were unsuccessful, and the "federal courts have upheld Congress' authority to enact the statute based on its power to regulate interstate commerce." Pavlan, *supra* note 247, at 1.

249. See 21 U.S.C. §§ 821-830 (2000) ("Part C - Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances"); Pavlan, *supra* note 247, at 7-9.

250. Pavlan, *supra* note 247, at 2; see DRUG ENFORCEMENT ADMIN., *supra* note 247, at 7, 9, 13-14.

251. Pavlan, *supra* note 247, at 1-2; see 21 U.S.C. § 812 (defining the five schedules and requiring annual updates to be republished at 21 C.F.R. § 1308).

252. 21 U.S.C. § 812(b)(1); see MUSTO, *supra* note 207, at 255.

253. Although "[t]he use of medical marijuana has been approved by voter referendum in several western states . . . [u]nder federal law, marijuana has never been proven safe and effective for use in the treatment of any medical condition [and] [i]t is still listed as a Schedule I controlled substance." Pavlan, *supra* note 247, at 10.

254. 21 C.F.R. § 1308.11 Schedule I (2008).

255. 21 U.S.C. § 812(b)(2); see also MUSTO, *supra* note 207, at 255 (stating that "Schedule Two contains the most dangerous prescribable drugs").

256. See 21 C.F.R. § 1308.12 Schedule II (2008).

257. See Marcia L. Meldrum, *A Capsule History of Pain Management*, 290 JAMA 2470, 2474 (2003); MUSTO, *supra* note 207, at 255.

acceptable medical uses.²⁵⁸ Drugs in each Schedule are subject to different rules for prescribing and distribution.²⁵⁹

Along with the Schedule structure, the CSA requires practitioners who prescribe a substance contained in the five schedules to register with the Attorney General.²⁶⁰ Only registrants acting in compliance with the law are excepted from the criminal provisions of the Act which make it “unlawful for any person knowingly or intentionally . . . to . . . distribute, or dispense, . . . a controlled substance.”²⁶¹ Because these substances are necessary for treatment of many patients, virtually all practicing physicians register with the DEA.

Physicians prescribing controlled substances must do so in accordance with the regulations governing registrants. These regulations require that prescriptions of controlled substances “must be . . . for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”²⁶² Since the CSA was enacted, courts, in numerous cases, have struggled with applying this language.²⁶³ Early cases continued to deal with the treatment of addicts, particularly the prescribing of methadone, and whether prescribing was being done for purposes of pain relief or “under the guise of a ‘detoxification program.’”²⁶⁴ Whether prescribing for addiction treatment was for a “legitimate medical purpose” was largely dealt with by the Narcotic Addict Treatment Act’s passage in 1974.²⁶⁵ The Act responded to the widespread use, at the time, of methadone to treat heroin addiction and “the unique and unusually great risks of diversion and criminal profiteering associated with maintenance programs.”²⁶⁶ While clear guidelines were developed for the prescribing of

258. 21 U.S.C. § 812(b)(3)-(5); see 21 C.F.R. §§ 1308.13-1308.15 (2008).

259. 21 U.S.C. §§ 821-830 (2000) (“Part C - Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances). For example, prescriptions may not be written for Schedule I substances. Prescribing regulations for the drugs in the other groups specify requirements for refilling prescriptions, oral prescriptions, partial filling of prescriptions, and labeling of substances prescribed. See 21 C.F.R. § 1306.07 (2008).

260. 21 U.S.C. § 823.

261. 21 U.S.C. § 841(a)(1) (2000).

262. 21 C.F.R. § 1306.04(a) (2008).

263. See S. REP. NO. 93-192, at 7-9 (1973) (reporting on the Methadone Diversion Control Act of 1973, S. 1115, 93d Cong. (1973)).

264. *Id.* at 7.

265. See *id.* at 11. Shortly after passing the CSA, Congress passed the Narcotic Addict Treatment Act of 1974 (NATA), which established a mechanism for treating addicts outside the mainstream practice of medicine. Pub. L. No. 93-281, 88 Stat. 124 (1974).

266. S. REP. NO. 93-192, at 12. The Act was a response to a new development in medical treatment, i.e., “the widespread use of the narcotic drug methadone both to detoxify and to maintain heroin addicts.” *Id.* at 11. Under NATA and its implementing regulations, practitioners who wish to administer and dispense methadone “for maintenance and

narcotics to treat addiction, similar guidelines do not exist for prescribing of pain medications to treat chronic pain, creating an environment of uncertainty and legal risk for physicians treating this population.

V. THE EVOLUTION OF THE USE OF OPIOIDS FOR TREATMENT OF CHRONIC PAIN

Opium was regarded as a virtual panacea by the medical profession throughout much of the nineteenth century.²⁶⁷ The drug had many uses,²⁶⁸ but “it was particularly prized for its analgesic properties because of the lack of alternative pain-relieving agents at this time.”²⁶⁹

While opioids were used regularly in hospitals to relieve acute pain due to injury or surgery, they were not used for pain of longer duration until relatively recently.²⁷⁰ The modern use of opioids for pain treatment arising from disease grew out of the hospice movement of the 1960s, when it was established that opioids were highly effective in treating cancer pain.²⁷¹ This movement was largely limited to terminally ill patients, but the use of opioids outside the hospice setting began to permeate more traditional medical practices as evidence began to mount that people in pain who received opioids did not become addicted to them.²⁷² In the late 1980s, opioids had

detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program.” OFFICE OF DIVERSION CONTROL, U.S. DEP’T OF JUSTICE, PRACTITIONER’S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 23 (2006), available at www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited July 23, 2008). More recently, Congress passed the Drug Addiction Treatment Act of 2000, allowing physicians who obtain a waiver and certification in addiction from a designated medical specialty board to treat opioid addiction or dependence by prescribing buprenorphine drug products. See Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, §§ 3501-3502, 114 Stat. 1222, 1222-27 (2000) (amending 21 U.S.C. §§ 823(g), 824 (2000)).

267. See MUSTO, *supra* note 207, at 1.

268. *Id.* Prior to the late 1800s, opioids had been used as a “soothe-all” for all types of medical problems, from spasms, restlessness, and allergies to depression. See *id.* at 75. It was only after newer approaches to medical treatment became available that wide ranging uses of opium became understood as “unscientific, unprofessional, and an indulgence fraught with danger.” *Id.*

269. Foster, *supra* note 208, at 548.

270. See Kaufman, *supra* note 6 (“Until the mid-1980s, the law enforcement concern trumped the therapeutic value, and opioids were not widely used outside hospitals.”).

271. See Meldrum, *supra* note 257, at 2473 (describing the “Formation of the Pain Field”).

272. See Randal D. France et al., *Long-Term Use of Narcotic Analgesics in Chronic Pain*, 19 SOC. SCI. & MED. 1379, 1380-81 (1984); William E. Hurwitz, *Pain Control in the Police State of Medicine (Part II)*, 8 J. AM. PHYS. & SURGEONS 13, 13 (2003) (“Beginning in the mid-1980s, there was a reconsideration of the previous rejection of opioid therapy for non-malignant pain. Encouraging clinical experience with chronic opioid administration to cancer patients and to methadone-maintained addicts dispelled fears of this therapeutic modality Early research indicated that patients without a prior history of addiction ran little risk of

become the standard of care for treatment of moderate to severe cancer pain.²⁷³ It was not until 1990, however, when the World Health Organization published guidelines on cancer pain treatment,²⁷⁴ that the standard was more widely acknowledged. Subsequently, in 1992, the American Pain Society published *Principles on Analgesic Medication for Acute Pain and Cancer Pain*,²⁷⁵ and in 1994, the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality (AHRQ)), established that opioids, in combination with other medications, were the appropriate treatment for chronic malignant pain.²⁷⁶

In 1996, for the first time, professional groups addressed guidelines for the treatment of chronic nonmalignant pain. The American Academy of Pain Medicine and the American Pain Society jointly issued a statement entitled *The Use of Opioids for the Treatment of Chronic Pain* (also referred to as the "Consensus Statement").²⁷⁷ The Consensus Statement "provided guidance for regulatory agencies for determining accepted principles of practice for the use of opioids for chronic pain patients" and "indicated that in initially evaluating a patient a complete history and physical examination should be conducted."²⁷⁸ Moreover, the Consensus Statement recommended that physicians develop an individualized treatment plan including "different types of treatment modalities" and that in certain cases "[c]onsultation with a specialist in pain medicine or with a psychologist may

becoming addicted through pain treatment with opioids."); Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171, 184 (1986) (concluding that "opioid medications can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse. . . . [H]owever, this course must be pursued cautiously."); Jane Porter & Hershel Jick, Letter to the Editor, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980); see also Richard M. Marks & Edward J. Sachar, *Undertreatment of Medical Inpatients with Narcotic Analgesics*, 78 ANNALS OF INTERNAL MED. 173 (1973) (concluding that misconceptions about effective doses of narcotic analgesics and exaggeration of the dangers of addiction lead to undertreatment of and needless suffering in medical inpatients); see generally John P. Morgan, *American Opiophobia: Customary Underutilization of Opioid Analgesics*, 5 ADVANCES ALCOHOL & SUBSTANCE ABUSE 163 (1985).

273. Hurwitz, *supra* note 272, at 13.

274. EXPERT COMM. ON CANCER PAIN RELIEF AND ACTIVE SUPPORTIVE CARE, WORLD HEALTH ORG., WHO TECHNICAL REPORT SERIES 804: CANCER PAIN RELIEF AND PALLIATIVE CARE (1990).

275. See AM. PAIN SOC'Y, PRINCIPLES OF ANALGESIC USE IN THE TREATMENT OF ACUTE PAIN AND CANCER PAIN (3d ed. 1992).

276. See AGENCY FOR HEALTH CARE POLICY & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., CLINICAL PRACTICE GUIDELINE NO. 9: MANAGEMENT OF CANCER PAIN (1994).

277. See AM. ACAD. OF PAIN MED. & AM. PAIN SOC'Y, THE USE OF OPIOIDS FOR THE TREATMENT OF CHRONIC PAIN (1996), available at www.ama-assn.org/ama1/pub/upload/mm/455/opioidschronicpain.pdf (last visited July 23, 2008) [hereinafter CONSENSUS STATEMENT].

278. Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. 25,073, 25,075 (Drug Enforcement Admin. May 10, 1999); see CONSENSUS STATEMENT, *supra* note 277, at 3.

be warranted."²⁷⁹ Of significant note, the Consensus Statement also provided that "[t]he management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids."²⁸⁰

In 1998, the Federation of State Medical Boards (FSMB) issued *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.²⁸¹ These Guidelines give clear direction to physicians and to state medical boards regarding opioid use for chronic pain. Like the Consensus Statement, the Guidelines require a physician evaluating a pain patient to take a complete medical history and conduct a physical examination.²⁸² They also require the physician to set a written treatment plan with objectives, to conduct reasonable follow-ups to continue or modify therapy, to comply with applicable controlled substance laws and regulations, and to document everything accurately and completely.²⁸³ Moreover, "[w]hen a physician determines that a patient is at risk for medication abuse or has a history of substance abuse, the guidelines suggest a written agreement between the physician and patient outlining patient responsibilities."²⁸⁴ After 1998, many state medical boards adopted policies consistent with the FSMB's Model Guidelines.²⁸⁵

While the 1990s became the decade in which the medical profession began to recognize the benefits of opioids for the treatment of chronic pain

279. Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. at 25,075; see CONSENSUS STATEMENT, *supra* note 277, at 3.

280. CONSENSUS STATEMENT, *supra* note 277, at 3.

281. FED'N OF STATE MED. BDS. OF THE U.S., MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN, available at www.nsmadocs.org/pdf/ModelGuidelines.pdf (last visited July 23, 2008).

282. *Id.* at SECTION II(1) EVALUATION OF THE PATIENT.

283. *Id.* at TREATMENT PLAN, PERIODIC REVIEW, MEDICAL RECORDS, COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS.

284. Larry K. Houck, *The Drug Enforcement Administration, Controlled Substances and Pain Management*, 1 DEA-INDUSTRY COMMUNICATOR: SPECIAL OXYCONTIN ISSUE (Drug Enforcement Admin., Wash. D.C.), 2001, at 10, 13.

285. See PAIN & POL'Y STUDIES GROUP, UNIV. OF WIS. PAUL P. CARBONE COMPREHENSIVE CANCER CTR., ACHIEVING BALANCE IN FEDERAL AND STATE PAIN POLICY: A GUIDE TO EVALUATION, at SECTION III: BACKGROUND ABOUT PAIN RELIEF AND PUBLIC POLICY- STATE POLICIES ARE CHANGING, Fig.1 (2007), available at www.painpolicy.wisc.edu/Achieving_Balance/EG2007.pdf (last visited July 23, 2008) (illustrating the increasing number of state pain-specific policies); see also FED'N OF STATE MED. BDS. OF THE U.S., MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN, at INTRODUCTION n.1 (2004), available at www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf (last visited July 23, 2008) ("As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.").

and developed guidelines for their use,²⁸⁶ it was also a decade in which great public attention was brought to bear on the fact that pain, both cancer-related and non-malignant chronic pain, was being woefully undertreated in the United States.²⁸⁷ Between 1999 and 2004, in line with the “sea change” in attitudes toward pain treatment, two state medical boards disciplined physicians for failure to adequately prescribe pain medication for their patients.²⁸⁸ On the heels of the second disciplinary action, in 2004, the FSMB provided physicians with an additional incentive to adequately treat pain by updating its Guidelines and issuing a *Model Policy for the Use of Controlled Substances for the Treatment of Pain*.²⁸⁹ The new policy went “beyond attempting to reassure physicians that they [would] not be sanctioned for prescribing large doses of pain medication if

286. See, e.g., Sheldon L. Burchman & Paul S. Pagel, *Implementation of a Formal Treatment Agreement for Outpatient Management of Chronic Nonmalignant Pain with Opioid Analgesics*, 10 J. PAIN & SYMPTOM MGMT. 556, 557, 561 nn.4-14 (1995) (listing studies from 1982-1992 that recommended various approaches to treating chronic nonmalignant pain with opioids).

287. See, e.g., Charles S. Cleeland, Editorial, *Undertreatment of Cancer Pain in Elderly Patients*, 279 JAMA 1914, 1915 (1998) (“Ample evidence indicates that patients, their families, and the public are becoming less tolerant of poor pain management.”); Sullum, *supra* note 104, at 23.

288. See Sandy Kleffman, *Doctor Disciplined over Pain Treatment*, CONTRA COSTA TIMES, Jan. 17, 2004, at A3 [hereinafter Kleffman, *Doctor Disciplined over Pain Treatment*]. In 1999, the Oregon Board of Medical Examiners disciplined Dr. Paul Bilder for failure to prescribe adequate pain relief medication. Ellen Goodman, Op-Ed., *From Oregon, a Call for Compassionate Care*, BOSTON GLOBE, Sept. 9, 1999, at A19. Bilder was cited for several infractions including prescribing only Tylenol for a terminally ill cancer patient’s pain and prescribing insufficient pain medication for a hospice patient. *Id.* The Board ordered Bilder to complete an educational program on pain treatment and on physician-patient communication and to undergo a mental health examination. S. Van McCrary, *Discipline of Oregon Physician for Undertreating Pain Is an Appropriate Response to a Serious Problem*, HEALTH L. PERSP., Sept. 21, 1999, at www.law.uh.edu/Healthlaw/perspectives/Bioethics/990921Discipline.html (last visited July 23, 2008). In March 2003, the Medical Board of California filed a complaint against Dr. Eugene Whitney for failure to adequately treat the pain of Lester Tomlinson, a terminally ill lung cancer patient. Sandy Kleffman, *Suit Filed over Pain Treatment of Ill Man*, CONTRA COSTA TIMES, Mar. 28, 2003, at A1. In January 2004, Dr. Whitney accepted a public reprimand from the Medical Board, and he was required to complete a forty-hour pain management course, undergo a physical and mental health assessment and a clinical and communication skills assessment. Kleffman, *Doctor Disciplined over Pain Treatment*, *supra*.

289. FED’N OF STATE MED. BDS. OF THE U.S., *supra* note 285; see also Diane E. Hoffmann, *The Use of Opioid Analgesics: Legal and Regulatory Issues*, in COMPLICATIONS IN REGIONAL ANESTHESIA & PAIN MEDICINE 353, 354 Box 34-1, 355 (Joseph M. Neal & James P. Rathmell eds., 2007) (discussing the key elements of the FSMB 2004 update to the *Model Guidelines*).

appropriate” and sent “a message that undertreatment of pain [could] be considered substandard care.”²⁹⁰

These actions by medical specialty groups and state medical boards came together to encourage physicians to more appropriately and more aggressively treat their patients’ pain. As a result, many physicians began to prescribe opioids in much larger doses than they had in the past.²⁹¹

Many pain experts now assert that there is no upper limit of safety for opioid dosages. They believe that “[a]s long as the dose is [started] low and increased gradually, large doses [may] be taken [and are] limited only by adverse [side] effects.”²⁹² Unlike non-opioid analgesics, opioids do not cause damage to major organs.²⁹³ The correct amount, they argue, is what reduces or eliminates the patient’s pain without unacceptable side effects.²⁹⁴ Side effects can include “sedation, respiratory depression, nausea, vomiting, itching, urinary retention, and constipation.”²⁹⁵ Often patients develop a tolerance relatively quickly to sedation, respiratory depression, nausea, and vomiting so that they do not experience these negative effects.²⁹⁶

Despite this view that many pain treatment experts have regarding the use of opioids for the treatment of pain, others, including many at the DEA, believe that “there is a difference of opinion [in] the medical profession regarding the use of opioids in the management of chronic pain, with two differing approaches classified as the therapeutic school . . . and the dependency school.”²⁹⁷ Those in the therapeutic school believe that “the measure of successful treatment of a chronic pain patient is whether the patient has experienced an increase in his/her level of comfort and function

290. Hoffmann, *supra* note 289, at 355.

291. During the past decade, medical prescribing practices regarding chronic pain diagnoses in this country have undergone dramatic change. More physicians are prescribing Schedule II narcotics to a larger number of patients, and the dosages prescribed to these patients have increased markedly. See, e.g., Joan Arehart-Treichel, *Opioid Prescribing May Be Increasing*, PSYCHIATRIC NEWS, Apr. 20, 2007, at 38; Bridget M. Kuehn, *Opioid Prescriptions Soar: Increase in Legitimate Use as Well as Abuse*, 297 JAMA 249, 251 (2007).

292. Jennifer P. Schneider, *Rational Use of Opioid Analgesics in Chronic Musculoskeletal Pain*, 23 J. MUSCULOSKELETAL MED. 145, 146 (2006); see also CONSENSUS STATEMENT, *supra* note 277, at 2 (stating that “for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought”).

293. See Schneider, *supra* note 292, at 146 (“Unlike acetaminophen, aspirin, and many other drugs, opioid analgesics do not have any specific organ toxicity.”).

294. *Id.* at 146.

295. Hussam Antoin & Ralph D. Beasley, *Opioids for Chronic Noncancer Pain: Tailoring Therapy to Fit the Patient and the Pain*, 116 POSTGRADUATE MED. 37, 38 (2006).

296. See *id.*

297. Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. 25,073, 25,074 (Drug Enforcement Admin. May 10, 1999).

and has an improved quality of life.”²⁹⁸ They assert that the number of pills consumed is not the appropriate measure and that a physician has to trust the patient’s reporting of pain and individualize his or her treatment.²⁹⁹ Those in the dependency school believe that there is a significant risk of drug addiction in the long-term use of high doses of opioids; therefore, it is not appropriate to prescribe in this manner.³⁰⁰

Law enforcement officials appear to believe that patients complaining of pain who need large volumes of medication often are either addicts or diverters and, therefore, prescribing to them is not a legitimate medical purpose.³⁰¹ The definition of “addict” in the Controlled Substances Act includes “any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare.”³⁰² Experts argue that equating chronic pain patients with addicts “ignores the medical fact” that a very small percentage “of chronic pain patients are addicted and represent[] no threat to public safety and morality.”³⁰³ Moreover, this definition ignores the possibility that some addicts are in physical pain (other than that caused by withdrawal) and need medication to treat their pain.

The debate, in large part, appears to turn on the actual risk of opioid addiction. As long as doctors have administered narcotics, they have been worried about their patients becoming addicted to the drugs. Their worries were often due to a misunderstanding of the differences between addiction, tolerance, and dependence.³⁰⁴ Tolerance results when exposure to a drug leads to a reduction in one or more of the drug’s intended effects over time so that an increased dose may be required to maintain the same physiological effects.³⁰⁵ Physical dependence is a condition manifested by withdrawal symptoms when a drug is abruptly terminated or reduced in dose.³⁰⁶ Addiction, in contrast, is a condition resulting in “impaired control

298. *Id.* at 25,074-75.

299. *See id.* at 25,075.

300. *See id.* at 20,074 (stating that physicians “should start with the most benign medications at the least dose and increase the dose or change the medication as needed . . . [because] increasing dosage levels may not be appropriate if the pain is not responding to the opioids”).

301. Ronald T. Libby, *The DEA’s OxyContin Action Plan: An Unproven Drug Epidemic*, PAIN RELIEF NETWORK, Dec. 16, 2003, at www.painreliefnetwork.org/prn/the-deas-oxycontin-action-plan-an-unproven-drug-epidemic.php (last visited July 23, 2008).

302. 21 U.S.C. § 802(1) (2000).

303. Libby, *supra* note 301.

304. AM. ACAD. OF PAIN MED., AM. PAIN SOC’Y & AM. SOC’Y OF ADDICTION MED., DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN 1 (2001), available at www.painmed.org/pdf/definition.pdf (last visited July 23, 2008) [hereinafter DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN].

305. *Id.* at 3.

306. *Id.*

over drug use, compulsive use, continued use despite harm, and craving.”³⁰⁷

While most individuals receiving opioid therapy do develop physical dependence,³⁰⁸ a number of studies have confirmed that

patients treated with narcotics rarely become addicts. In 1980 researchers at Boston University Medical Center reported that they had reviewed the records of 11,882 hospital patients treated with narcotics and found “only four cases of reasonably well documented addiction in patients who had no history of addiction.” A 1982 study of 10,000 burn victims who had received narcotic injections, most of them for weeks or months, found no cases of drug abuse that could be attributed to pain treatment. In a 1986 study of 38 chronic pain patients who were treated with opioids for years, only two became addicted, and both had histories of drug abuse.³⁰⁹

A 1993 article in a newsletter issued by the National Institute on Drug Abuse stated that opioids “are rarely abused when used for medical purposes.”³¹⁰

The 1996 Consensus Statement from the American Academy of Pain Medicine and the American Pain Society asserts that “[m]isunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications” and notes that “[s]tudies indicate that the de novo development of addiction when opioids are used for the relief of pain is low.”³¹¹ Moreover, the two professional societies agree “that known addicts can benefit from the carefully supervised, judicious use of opioids for the treatment of pain due to cancer, surgery, or recurrent painful illnesses such as sickle cell disease.”³¹²

While the large majority of medical experts agree that most pain patients can successfully use narcotics without negative consequences, some acknowledge that a good deal “remains unknown about the number or types of chronic pain sufferers who will become addicted as a result of medical care, or ‘iatrogenically’ addicted.”³¹³ According to one article, “the

307. *Id.*

308. *See id.* at 3.

309. Sullum, *supra* note 104, at 24.

310. *See id.* at 25 (quoting a 1993 newsletter article from the National Institute on Drug Abuse, National Institutes of Health).

311. CONSENSUS STATEMENT, *supra* note 277, at 2.

312. *Id.*

313. Barry Meier, *The Delicate Balance of Pain and Addiction*, N.Y. TIMES, Nov. 25, 2003, at F1; *see also* Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,718 n.20 (Sept. 6, 2006) (“Further controlled trials [should] be conducted on opioid therapy in patients with chronic noncancer pain in an effort to identify best practice with regard to selection of both medication and treatment regimens [to] identify patient characteristics that predict opioid responsiveness [and to] provide support for guidelines on appropriate precautions, contraindications, and the degree of monitoring required in such patients.”) (quoting AM. MED. ASS’N, DIRECTIVES OF THE AMA HOUSE OF DELEGATES: D-120.999

biggest risk appears to be to patients who have abused drugs or to those who have an underlying, undiagnosed vulnerability to abuse substances, a condition that may affect an estimated 3 to 14 percent of the population.³¹⁴ There is also uncertainty about the best way to treat substance abusers who are also afflicted with chronic pain.³¹⁵

In the midst of the debate over the addictive potential of long-term and high doses of opioids, a renewed concern about drug diversion, in light of the availability and abuse associated with OxyContin, appeared in the late 90s and has continued through the present.³¹⁶ OxyContin “is a 12-hour, timed-release form of oxycodone, a synthetic opioid that has long been available in products such as Percocet, Percodan, and Tylox.”³¹⁷ By the early 2000s, the drug had become the most prescribed Schedule II narcotic in the country.³¹⁸ As the DEA and state drug enforcement officials found evidence of diversion of the drug from legitimate users to addicts, they began to scrutinize physicians and pharmacists who prescribed and dispensed large doses of the drug.³¹⁹ They were able to link OxyContin to a number of overdose deaths, pharmacy robberies, and other criminal activities.³²⁰

USE OF OPIOIDS IN CHRONIC NONCANCER PAIN) (alterations in original); Jane C. Ballantyne & Jianren Mao, *Opioid Therapy for Chronic Pain*, 349 NEW ENG. J. MED. 1943, 1948 fig.2, 1951 (2003) (stating that “it is widely acknowledged that there is a link between previous drug or alcohol abuse and addiction to opioids prescribed for pain”).

314. Meier, *supra* note 313; see also Antoin & Beasley, *supra* note 295, at 39 (citing Savage who used “population studies to estimate the risk of addiction at 3% to 16% in the general population” and suggesting that currently a “10% incidence of addiction is probably the best estimate to discuss with patients when initiating opioid treatment”).

315. See Meier, *supra* note 313.

316. Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21, 21 (2003).

317. Ammann, *supra* note 198, at 30.

318. *Id.*; U.S. DRUG ENFORCEMENT ADMIN., PUB’N NO. DEA-02017, DRUG INTELLIGENCE BRIEF, OXYCONTIN: PHARMACEUTICAL DIVERSION, at BACKGROUND (2002), available at www.avitarinc.com/pdf/Drug-Intelligence-Brief-Oxycotone-Facts.pdf (last visited July 23, 2008).

319. See U.S. DRUG ENFORCEMENT ADMIN., *supra* note 318, at DIVERSION AND DISTRIBUTION.

320. See *id.* “From 1996 to 1999, the number of drug abuse deaths reported to [the Drug Abuse Warning Network] that involved oxycodone more than quadrupled, with 268 deaths in 1999 compared to 51 in 1996.” *Id.* at BACKGROUND.

VI. THE LEGAL BASIS FOR ARREST AND PROSECUTION OF PHYSICIANS FOR OPIOID PRESCRIBING

In the large majority of cases involving physicians who are arrested for violation of the controlled substance laws but who are arguably treating pain patients, the charges are based on distributing or dispensing controlled substances (generally opioids) in violation of section 841(a) of the CSA³²¹ or similar state law provisions.³²² These charges require that the government “prove: (1) ‘that the [physician] distributed . . . a controlled substance’; (2) that the [physician] ‘acted knowingly and intentionally’; and (3) ‘that the [physician’s] actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice.’”³²³

It is the last element that has proved most difficult and problematic for the courts, which have struggled with the concept.³²⁴ Neither the CSA nor its implementing regulations define “legitimate medical purpose”; nor do they set standards as to what constitutes “the usual course of professional practice.”³²⁵ The two phrases were discussed at some length in *United States v. Moore*,³²⁶ one of the first cases involving interpretation of the CSA

321. 21 U.S.C. § 841(a) (2000).

322. The state laws are typically based on the Uniform Controlled Substances Act drafted by the National Conference of Commissioners on Uniform State Laws. UNIFORM CONTROLLED SUBSTANCES ACT (1994), available at www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ucsa94.pdf (last visited July 23, 2008). The Uniform Act has been adopted by every state but New Hampshire and Vermont. See Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,717 n.12 (Sept. 6, 2006).

323. *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (quoting *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995)); see *United States v. Alerre*, 430 F.3d 681, 689-90 (4th Cir. 2005); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994); *United States v. Daniel*, 3 F.3d 775, 778 (4th Cir. 1993); see also 21 C.F.R. § 1306.04 (2007) (describing the purpose of issuing prescriptions); Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. at 52,717 (describing state law requirements).

324. See, e.g., *United States v. Moore*, 423 U.S. 122, 124 (1975); *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir. 1975) (Ely, J. dissenting) (“[I]t is difficult to see how the language can be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress intended to make illegal and subject to sanctions.”); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (“[w]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.”) (quoting *Linder v. United States*, 268 U.S. 5, 18 (1925) (alteration in original)). For a discussion of this struggle, see *infra* notes 426-435 and accompanying text.

325. See 21 U.S.C. § 801(1) (2000) (outlining congressional findings, which include that many controlled substances have a legitimate medical purpose); see also Houck, *supra* note 284, at 11 (“The usual course of professional practice arguably involves such factors as the practitioner’s medical specialty, his or her professional training and applicable practice guidelines.”).

326. 423 U.S. 122.

by the U.S. Supreme Court. At issue in the case was, first, whether registrants under the CSA were exempt from prosecution under section 841(a)(1) and could only be prosecuted under sections 842 and 843, which imposed significantly less harsh penalties;³²⁷ and, second, if physicians could be prosecuted under Sec. 841, whether Moore's conduct was authorized by the Act.³²⁸ Moore, a physician, was convicted of "knowing and unlawful distribution and dispensation of methadone . . . in violation of 21 U.S.C. § 841 (a)(1)."³²⁹ Evidence presented at trial indicated that Moore had "prescribed large quantities of methadone" for patients with "only the most perfunctory [physical] examination" and minimal instructions.³³⁰ He charged fees based on "the quantity [of methadone] prescribed, rather than [on] the medical services performed."³³¹ Moore argued that he was using an innovative protocol in an attempt to treat narcotic addiction³³² and that, by and large, his patients came off heroin as a result of his "treatment."³³³ The Court was required to ascertain whether his acts constituted behavior "outside the usual course of professional practice."³³⁴ In making that determination, the Court referred to Congress' passage of the Narcotic Addict Treatment Act of 1974 (NATA).³³⁵ The Court noted that when Congress passed NATA, "it sought to 'cure'" the difficulty in prosecuting physicians under the CSA "because of the intricate and nearly impossible burden of establishing what is beyond "the course of professional practice" for criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian in nature."³³⁶ NATA

327. Early cases interpreting the CSA debated whether the severe criminal sanctions of section 841 applied to physician registrants or whether Congress intended that registrant violations be dealt with through professional or administrative action and subject to "less-severe criminal and civil sanctions provided in sections 842 and 843" of the Act. *Rosenberg*, 515 F.2d at 203. The issue was resolved in *Moore*, 423 U.S. at 124, which held "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice."

328. *Moore*, 423 U.S. at 124, 131.

329. *Id.* at 124.

330. *Id.* at 126-27.

331. *Id.* at 126.

332. Sentencing Transcript at 129, *United States v. Moore*, Crim. No. 1350-72 (1975) (stating that the protocol "involved a saturation to a point of blockade, in which the euphoria formerly obtained was no longer obtained from heroin and an incentive to become completely drug-free"); see also *Moore*, 423 U.S. at 126 (stating that Moore's "defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner").

333. Sentencing Transcript at 130, *Moore*, Crim. No. 1350-72.

334. *Moore*, 423 U.S. at 124, 139.

335. *Id.* at 139 n.16; Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124.

336. *Moore*, 423 U.S. at 139 n.16 (quoting S. REP. NO. 93-192, at 14 (1973)).

apparently did this by setting up a separate set of explicit requirements that a practitioner must meet in order to dispense narcotic drugs for maintenance or detoxification treatment for addicts.³³⁷ While the new law helped clarify what constituted “legitimate medical practice” when treating addicts, the phrase remains undefined outside of that context.

Another contentious issue in prosecuting these cases arises in establishing the mens rea necessary to convict under section 841. Courts have apparently agreed that the knowledge requirement applies to the third element of the crime, i.e., that the prosecution must prove that the physician knowingly or intentionally prescribed outside the usual course of professional practice or not for a legitimate medical purpose.³³⁸ Because determining what the physician actually knew or intended is difficult, “courts have held that a deliberate course of conduct whereby the defendant avoids the requisite guilty knowledge may be held tantamount to guilty knowledge per se.”³³⁹ In these cases, the trial court may issue to the jury a “conscious avoidance” charge, also known as a “willful blindness” instruction.³⁴⁰ In the context of illegal drug distribution, the instructions have been used primarily for cases where the defendant is accused of transporting drugs and claims not to have been aware that he was carrying the drugs, e.g., did not know the contents of the suitcase he was asked to carry.³⁴¹ But, the instructions have also been used in cases against physicians prescribing drugs to patients who subsequently diverted them with the prosecution arguing that

337. See OFFICE OF DIVERSION CONTROL, *supra* note 266, at 23; see also *supra* note 266 and accompanying text.

338. See, e.g., *United States v. Feingold*, 454 F.3d 1001, 1007-08 (9th Cir. 2006) (“We agree with Dr. Feingold’s contention that a practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) only if he does so intentionally. . . . Simply put, to convict a practitioner under § 841(a), the government must prove . . . that the practitioner acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor’s intent to act as a pusher rather than a medical professional.”).

339. Deborah Sprenger, Annotation, *Propriety of Instruction of Jury on “Conscious Avoidance” of Knowledge of Nature of Substance or Transaction in Prosecution for Possession or Distribution of Drugs*, 109 A.L.R. FED. 710, 713, § 2[a] (1992).

340. See *id.* The charge has also been referred to as “an ostrich instruction, because the defendant is considered by the court to have, figuratively, stuck his head in the sand to avoid learning truths that would otherwise have been patently obvious to the average reasonable person.” *Id.* See also JULIE R. O’SULLIVAN, *FEDERAL WHITE COLLAR CRIME: CASES AND MATERIALS* 100-01 (1st ed. 2001) (discussing the willful blindness jury instruction).

341. See Sprenger, *supra* note 339, at 714, § 2.

the physician deliberately ignored facts that would have led one to believe the patient was diverting the drugs.³⁴²

Defendants have been assisted, to some extent, by the fact that virtually all courts hearing these cases have accepted a good faith defense to the charges.³⁴³ Thus, physicians have been able to argue that they prescribed in good faith, i.e., with the honest belief that they were doing so to treat a patient's pain.³⁴⁴ While the good faith defense may appear helpful to

342. See, e.g., *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006) (“A willful blindness instruction is appropriate when the defendant asserts a lack of guilty knowledge, but the evidence supports an inference of deliberate ignorance. Ignorance is deliberate if the defendant was presented with facts that put her on notice that criminal activity was particularly likely and yet she intentionally failed to investigate those facts.”) (quoting *United States v. Florez*, 368 F.3d 1042, 1044 (8th Cir. 2004)); Transcript of Record at 1221, *United States v. McIver*, 470 F.3d 550 (4th Cir. 2006) (No. 05-4884) (jury instructions stating, “[t]he government may prove the defendant acted knowingly by proving beyond a reasonable doubt that this defendant deliberately closed his eyes to what would otherwise have been obvious to him. No one can avoid responsibility for a crime by deliberately ignoring what is obvious”).

343. See, e.g., *United States v. Moore*, 423 U.S. 122 (1975); *McIver*, 470 F.3d 550; *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006); *Feingold*, 454 F.3d 1001; *United States v. Williams*, 445 F.3d 1302 (11th Cir. 2006), *abrogated on other grounds by United States v. Lewis*, 492 F.3d 1219 (11th Cir. 2007); *United States v. Alerre*, 430 F.3d 681, 689-90 (4th Cir. 2005); *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994); *United States v. Hughes*, 895 F.2d 1135 (6th Cir. 1990); *United States v. Vamos*, 797 F.2d 1146 (2d Cir. 1986); *United States v. Hayes*, 794 F.2d 1348 (9th Cir. 1986); *United States v. Carroll*, 518 F.2d 187 (6th Cir. 1975).

344. For example, the federal pattern jury instruction for the good faith defense states:
 In order to sustain its burden of proof . . . the government must prove beyond a reasonable doubt that the defendant knowingly and deliberately [*distributed*] [*dispensed*] . . . a controlled substance and did so other than in good faith in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States. The defendant may not be convicted if [*he*] [*she*] merely made an honest effort to treat [*his*] [*her*] patients in compliance with an accepted standard of medical practice.
 A controlled substance is [*distributed*] [*dispensed*] . . . by a [*physician*] [*pharmacist*] in the usual course of [*his*] [*her*] professional practice and, therefore, lawfully, if the substance is [*distributed*] [*dispensed*] . . . by [*him*] [*her*] in good faith in medically treating a patient. Good faith in this context means good intentions and the honest exercise of good professional judgment as to a patient's medical needs. Good faith connotes an observance of conduct in accordance with what the [*physician*] [*pharmacist*] should reasonably believe to be proper medical practice.
 In determining whether or not Defendant _____ acted in good faith in the course of a medical practice, you may consider all of the evidence in the case which relates to that conduct.
 Unless you find beyond a reasonable doubt that the conduct charged in Count _____ of the indictment was not done in good faith in the course of a medical practice you must acquit Defendant _____ of that charge.

physicians, the courts have, to some extent, undercut its effectiveness by concluding that the good faith test must be an objective, not a subjective test.³⁴⁵ Such an objective test has allowed prosecutors to bring in evidence of “red flags,” i.e., indications that a reasonable physician would have known that his prescribing was not for a legitimate medical purpose.³⁴⁶

Physicians who are targeted by the DEA and their state-enforcement counterparts find it very difficult to defend against the alleged charges. In these cases, the physicians are often charged with hundreds of counts of criminal wrongdoing.³⁴⁷ The large numbers are somewhat misleading in that “ordinary events in a doctor’s office become criminal when the doctor steps outside the bounds of legitimate medicine.”³⁴⁸ As a result, each time a physician writes a new prescription for a controlled substance it can be a separate crime.³⁴⁹ The same act can be considered healthcare fraud if the prescribing is not medically necessary and a third party payer is billed for the drugs.³⁵⁰ Moreover, if the prescription is sent through the mail, the physician can be guilty of mail fraud.³⁵¹ In addition,

[s]eeing a patient who turns out to be a drug dealer or addict can lead to a conspiracy count, as can working with one’s colleagues. . . . [Moreover], any death that can in any way be connected to use of the doctor’s prescriptions becomes a charge of drug dispensing resulting in death or serious injury—even if the person who died stole the drug from a legitimate patient, lied to get the drug, used it with other drugs or alcohol, or expired while suffering from a potentially fatal illness.³⁵²

In many of these cases, prosecutors use conspiracy and racketeering charges to expand the reach of the underlying charges and bring more evidence into the case.³⁵³ Practically, conspiracy charges allow the

KEVIN F. O’MALLEY ET AL., *FEDERAL JURY PRACTICE & INSTRUCTIONS* § 64.16 at 428-29 (5th ed. 2000) (alterations in original).

345. See *Hurwitz*, 459 F.3d at 480 (“Every court to examine the issue has held that the objective standard that the doctor acted in accordance with what he *reasonably* believed to be proper medical practice should apply.”) (quoting 3 LEONARD B. SAND ET AL., *MODERN FEDERAL JURY INSTRUCTIONS*, Instruction 56-19, cmt. (2003)).

346. See John Tierney, *Trafficker or Healer? And Who’s the Victim?*, N.Y. TIMES, Mar. 27, 2007, at F1 (discussing the use of “red flags” in the prosecution of Dr. William Hurwitz).

347. See, e.g., Kaufman, *supra* note 6 (stating that Dr. Jeri Hassman was “charged with 362 counts of prescribing controlled drugs outside the normal practice of medicine”).

348. Szalavitz, *supra* note 61, at 35.

349. *Id.*

350. *Id.*

351. *Id.*

352. *Id.*

353. In general, conspiracy statutes, because of their broad reach, have been described “as the ‘darling of the modern prosecutor’s nursery.’” O’SULLIVAN, *supra* note 340, at 564 (quoting *Harrison v. United States*, 7 F.2d 259, 263 (2d Cir. 1925) (Learned Hand, J.)).

prosecution to admit statements by co-conspirators into evidence that would otherwise be considered hearsay.³⁵⁴ In these cases, patient informants are the co-conspirators. Their "statements, if believed, can be very damaging to the defense because they often constitute the only direct evidence regarding such central issues as the defendant's knowledge or intent."³⁵⁵ Under the CSA, there is a specific provision outlawing attempt or conspiracy to commit another offense in the Act.³⁵⁶ While most federal conspiracy statutes require "(1) the existence of an agreement to achieve an unlawful objective; (2) the defendant's knowing and voluntary participation in the conspiracy; and (3) the commission of an overt act in furtherance of the conspiracy,"³⁵⁷ the CSA does not require proof of an overt act for conviction.³⁵⁸ Thus, proving the elements of conspiracy under the CSA is significantly easier than under most other federal statutes. In addition, the "knowledge requirement" can be satisfied "by showing either that [the defendant] actually knew of the conspiracy . . . or that he was willfully blind to it by 'purposely clos[ing] his eyes to avoid knowing what was taking place around him.'"³⁵⁹

Federal prosecutors also routinely bring racketeering charges in these cases under the Racketeer Influenced and Corrupt Organizations (RICO) statute.³⁶⁰ Using the RICO statute often is controversial, as it is regularly applied to conduct that is far outside the original purpose of the Act, i.e., to eradicate organized crime.³⁶¹ Prosecutors frequently attempt to invoke RICO outside the organized crime context because of the increased

354. *Id.* (discussing FED. R. EVID. 801(d)(2)(E)).

355. *Id.*

356. See 21 U.S.C. § 846 (2000).

357. *United States v. Cure*, 804 F.2d 625, 628 (11th Cir. 1986).

358. See 21 U.S.C. § 846.

359. *United States v. Mclver*, 470 F.3d 550, 563 (4th Cir. 2006) (quoting *United States v. Ruhe*, 191 F.3d 376, 384 (4th Cir. 1999)).

360. See, e.g., *Nair, Dr. Knox Pleads Guilty, Surrenders License*, *supra* note 84 (describing case against Dr. Cecil Knox, who faced ninety-five charges, among them racketeering and conspiracy to commit racketeering); see also News Release, U.S. Attorney's Office, W. Dist. of Va., *Dr. Cecil Knox Surrenders Medical License and DEA Registration Number; Sentenced to Five Years Probation* (Jan. 20, 2006), at www.usdoj.gov/usao/vaw/press_releases/knox_20jan2006.html (last visited July 23, 2008) ("Knox . . . admitted to owning and operating a criminal enterprise in Roanoke called Southwest Virginia Physical Medicine and Rehabilitation, PC. The criminal enterprise and Dr. Knox made money by billing Medicare, Medicaid, and insurance companies for medical services purportedly performed by Dr. Knox. Beginning in 1997 and continuing through 2002, Dr. Knox unlawfully participated in the conduct of the affairs of that criminal enterprise and conducted a pattern of racketeering activities in an effort to gain monetary profit.").

361. See Gerard E. Lynch, *RICO: The Crime of Being a Criminal, Parts I & II*, 87 COLUM. L. REV. 661, 750 (1987) ("[B]y far the greater number of RICO indictments in the white collar area have no connection whatever to organized crime.").

sanctions and remedies it allows.³⁶² For example, it provides not only traditional criminal penalties, but also criminal forfeiture, i.e., forfeiture of all assets acquired in connection with the criminal enterprise.³⁶³

In addition to conspiracy and racketeering charges and charges based on violation of the CSA or its state counterparts, physicians prescribing opioids are often charged with healthcare fraud. These charges are typically based on allegations that the drugs prescribed by the physician were not “medically necessary” and, thus, were prescribed in violation of federal Medicare and federal/state Medicaid laws.³⁶⁴ The government may also bring a number of federal and state false claims actions.³⁶⁵ Although prosecutions based on alleged false claims in this area have rarely been successful, the charges are often brought forward in the initial stages of prosecution in an effort to force settlement or bolster the government’s claims of unlawful prescribing.³⁶⁶

VII. DEA ENFORCEMENT EFFORTS

The recent arrests and prosecutions of physicians described in this paper have coincided with a series of “campaigns” initiated by the DEA to pursue physicians prescribing opioids. In 2001, the DEA announced a new anti-drug campaign that it called the OxyContin Action Plan.³⁶⁷ DEA Administrator Asa Hutchinson testified that the initiative was necessary to combat what has been called “a deadly drug epidemic spreading throughout rural America” and that the DEA would reallocate its resources to address this threat.³⁶⁸ The DEA targeted doctors, pharmacists, and dentists in this crackdown on illegal prescription diversion.³⁶⁹

362. See 18 U.S.C. § 1963 (2000) (describing the criminal penalties for violating the statute to include fines, imprisonment, and forfeiture of assets acquired in connection with the criminal enterprise).

363. See *id.*

364. See 42 U.S.C. § 1320c-5(a) (2000).

365. See Hoffmann, *supra* note 289, at 359 (noting that in a number of cases the government has charged physicians with fraud and abuse law violations for allegedly prescribing medications that were not “medically necessary”).

366. See *id.* at 358-59 (“To be successful in a false claims action, the government must prove that the defendant submitted a claim to the government for payment, that the defendant had knowledge that the claim was false or fraudulent, and that the claim was in fact false or fraudulent.”).

367. OFFICE OF DIVERSION CONTROL, *supra* note 10; Libby, *supra* note 301. The initiative was partly in response to a G.A.O. report that was highly critical of the DEA’s failure to combat prescription drug abuse. See *id.* (citing U.S. GEN. ACCT. OFFICE, REP. NO. GAO/GGD-99-108, DRUG CONTROL: DEA’S STRATEGIES AND OPERATIONS IN THE 1990S (1999)).

368. Libby, *supra* note 301. In a news briefing, Libby contended that the DEA referral to an OxyContin “epidemic” is unfounded. He stated that the DEA had based this statement on

In 2003, the DEA requested \$24.6 million and 133 new positions to strengthen and improve its diversion control efforts.³⁷⁰ In addition, the Agency developed a “National Action Plan” that targets “key sources of OxyContin and other opioids, including medical professionals it considers unscrupulous.”³⁷¹ In March 2004, the Bush Administration announced “a coordinated drug strategy to confront the illegal diversion and abuse of prescription drugs.”³⁷²

While the DEA was ramping up its enforcement efforts, it came under intense criticism by physician groups for the chilling effects of its high profile arrests and prosecutions of physicians.³⁷³ As a result, in August 2004 after extensive consultation with the Federation of State Medical Boards and other groups, the DEA published on its Web site a set of guidelines “providing ‘some clarifications about what does or does not constitute questionable [prescribing] activity in the eyes of the DEA.’”³⁷⁴ The guidelines, in the form of “Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel” (FAQs) provided physicians with advice on how to identify a person who is likely to

figures of OxyContin-related deaths, many of which were not caused by OxyContin or OxyContin alone, but by a combination of OxyContin and other drugs. *Id.*; see also *Hearing Before the U.S. Senate Caucus on International Narcotics*, 107th Cong. (2002), available at www.justice.gov/dea/pubs/cngrtest/ct041102p.html (last visited July 23, 2008) (statement of Asa Hutchinson, Adm’r, Drug Enforcement Admin.).

369. See Libby, *supra* note 301.

370. Ammann, *supra* note 198, at 33.

371. *Id.* At about the same time, federal agencies began to investigate Purdue Pharma, the manufacturer of OxyContin. See Barry Meier, *3 Officials Are Sentenced In Case Involving OxyContin*, N.Y. TIMES, July 21, 2007, at C4. The investigation ultimately ended in May 2007 with a plea agreement between Purdue Frederick, a holding company affiliated with Purdue Pharma, and three of Purdue Pharma’s top executives and the U.S. Attorney’s Office. *Id.* The company “pleaded guilty to a felony charge that it had fraudulently claimed to doctors and patients that OxyContin would cause less abuse and addiction than competing short-acting narcotics” and agreed to pay \$600 million in fines. *Id.* The executives “pleaded guilty to misdemeanor charges of misbranding,” paid \$34.5 million in fines, and were later sentenced to “three years of probation and . . . 400 hours of service in a drug abuse or drug treatment program.” *Id.*

372. Press Release, Office of Nat’l Drug Control Pol’y, U.S. Drug Prevention, Treatment, Enforcement Agencies Take on “Doctor Shoppers,” “Pill Mills” (Mar. 1, 2004), at www.whitehousedrugpolicy.gov/news/press04/030104.html (last visited July 23, 2008).

373. See Hoffmann & Tarzian, *supra* note 316, at 22.

374. American Cancer Society, *New Guidance Issued for Opioid Pain Medication*, 54 CA CANCER J. FOR CLINICIANS 288, 288 (2004) (quoting Patricia Good of the DEA’s Office of Diversion Control); see *Dispensing of Controlled Substances for the Treatment of Pain*, 69 Fed. Reg. 67,170, 67,170 (Nov. 16, 2004).

abuse or divert drugs for criminal distribution.³⁷⁵ While pain treatment advocates applauded the DEA for its efforts to clarify the bases for its arrests of physicians for opioid prescribing, in October 2004 the DEA withdrew the FAQs, stating that they included some “misstatements.”³⁷⁶

On November 16, 2004, DEA published an Interim Policy Statement (IPS) which, it said, corrected some of the misstatements of the earlier document.³⁷⁷ The pain treatment community and others reacted to the withdrawal of the FAQs and subsequent IPS with surprise and criticism. In response to the DEA actions, thirty attorneys general wrote a letter to DEA Administrator Karen Tandy arguing that “the agency was not properly balancing the need for stopping drug diversion with the need to treat legitimate pain.”³⁷⁸ And, David Joranson, Director of the Pain & Policy Studies Group at the University of Wisconsin-Madison Medical School, wrote a letter to the Deputy Administrator of the DEA’s Office of Diversion Control, asserting that “the IPS misrepresented the FAQ[s] and made suggestions that are likely to interfere in medical practice and pain management, while contributing little if anything to addressing prescription drug abuse and illegal activities that result in diversion.”³⁷⁹ Furthermore, Joranson stated that in the IPS, “[s]ome interpretations of law governing prescribing and dispensing contradict DEA’s own earlier official statements and have already started to cause confusion and concern among pain practitioners.”³⁸⁰ In particular, Joranson complained that the IPS did not acknowledge “that it is within the scope of federal law to prescribe opioids for the purpose of treating pain in patients with addictive disease or a history of substance abuse” while the FAQ did.³⁸¹

In response to these complaints, on January 18, 2005, the DEA issued a statement in the *Federal Register* that it was soliciting comments from

375. See Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67,170.

376. See *id.* While this reason was the official statement regarding the retraction of the FAQs, there is some evidence that they were withdrawn because the defense in the Hurwitz trial attempted to use them as evidence in his favor. See Rosenberg, *supra* note 162, at 68.

377. Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (Nov. 16, 2004); Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain, 70 Fed. Reg. 2883 (Jan. 18, 2005).

378. Ralph Vartabedian, *At Least 20 Years Await Convicted Doctor*, L.A. TIMES, Apr. 14, 2005, at A14 (citing Letter from Thirty State Attorneys General, *supra* note 14).

379. Letter from David Joranson, Dir., Univ. of Wis. Pain & Policy Studies Group, to Michelle Leonhart, Deputy Adm’r, Office of Diversion Control, Drug Enforcement Admin. (Nov. 24, 2004), available at www.painpolicy.wisc.edu/DEA/IPSresponse.pdf (last visited July 23, 2008).

380. *Id.*

381. *Id.* Joranson made the further point that “[s]ome individuals with addictive disease also have severe pain due to cancer and other diseases.” *Id.*

physicians and other interested persons “as to what areas of the law relating to the dispensing of controlled substances for the treatment of pain they would like DEA to address” in a future Federal Register document.³⁸² Subsequently, in September 2006, DEA issued a comprehensive policy statement, responding to the comments it received and setting out “the pertinent principles” under the law “relating to the dispensing of controlled substances for the treatment of pain.”³⁸³ A significant focus of the statement was the extent to which prescription drugs are being abused in this country.³⁸⁴ The statement cited several recent studies documenting an increase in the abuse of prescription drugs, generally, and opioids for pain treatment, more specifically, over the past decade.³⁸⁵

With this backdrop, the statement went on to describe the basis on which DEA acts to address illegal prescribing of pain medications. The starting point for its discussion was the provision of law stating that any prescription of a controlled substance “must be issued for a legitimate medical purpose by a registered physician acting within the usual course of professional practice.”³⁸⁶ The statement summarizes the history of the standard, going back to its roots in the Harrison Narcotics Act, and asserts that the “requirement has been construed to mean that the prescription must be ‘in accordance with a standard of medical practice generally recognized and accepted in the United States’”³⁸⁷ but that “[f]ederal courts have long recognized that it is not possible to expand on the phrase ‘legitimate medical purpose in the usual course of professional practice,’ in a way that will provide definitive guidelines that address all the varied situations physicians might encounter.”³⁸⁸ The courts, the document states, generally have not had to define the circumstances more clearly because the facts

382. Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain, 70 Fed. Reg. at 2883.

383. Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,716 (Sept. 6, 2006).

384. See *id.*

385. See *id.* at 52,716 nn.1, 3-4 (citing NAT’L INST. ON DRUG ABUSE, NAT’L INSTS. OF HEALTH, RESEARCH REPORT SERIES: PRESCRIPTION DRUGS: ABUSE AND ADDICTION (2005), available at www.drugabuse.gov/PDF/RRPrescription.pdf (last visited July 23, 2008); OFFICE OF NAT’L DRUG CONTROL POLICY, 2006 SYNTHETIC DRUG CONTROL STRATEGY: A FOCUS ON METHAMPHETAMINE AND PRESCRIPTION DRUG ABUSE (2006), available at www.whitehousedrugpolicy.gov/publications/synthetic_drg_control_strat/synth_strat.pdf (last visited July 23, 2008); OFFICE OF APPLIED STUDIES, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., THE NSDUH REPORT: NONMEDICAL USERS OF PAIN RELIEVERS: CHARACTERISTICS OF RECENT INITIATES (2006), available at www.oas.samhsa.gov/2k6/pain/pain.pdf (last visited July 23, 2008)).

386. *Id.* at 52,716.

387. *Id.* at 52,717 (quoting *United States v. Moore*, 423 U.S. 122, 139 (1975)).

388. Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. at 52,717.

were “not merely of questionable legality, but instead . . . a glaring example of illegal activity.”³⁸⁹

In response to commenter requests for DEA to provide guidance to physicians as to practices that could get them into trouble, DEA echoed the sentiments of the courts, stating that “when it comes to prescribing controlled substances for pain” treatment, “one cannot provide an exhaustive and foolproof list of ‘do and don’ts.’”³⁹⁰ The Agency further stated that while it does not have the authority to educate physicians as to how to make “sound medical decisions in treating pain,” it “does have the authority and the 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 within the meaning of the CSA and DEA regulations.”³⁹¹

VIII. ARGUMENTS FOR A CHANGE IN THE LAW AND PROSECUTORIAL PRACTICES

In this section, I first present arguments as to why the current standard under the CSA is untenable and should be changed. Second, I argue that, as a policy matter, DEA’s aggressive efforts to prosecute physicians prescribing opioids for chronic pain patients are doing more harm than good.

A. *An Inappropriate Standard*

In passing the CSA, Congress was seeking to control illegal distribution of controlled substances without interfering with legitimate medical practices.³⁹² Individuals concerned with drug control policy and pain treatment have recognized the importance of these two goals and the need for balance³⁹³ in government policies and law enforcement actions so that efforts to prevent abuse and diversion of controlled substances do “not interfere with their essential uses for the relief of pain.”³⁹⁴

At issue in many of the cases brought against physicians prescribing opioids is what constitutes “legitimate medical practice,” which is not defined in the law or regulations.³⁹⁵ While this definitional issue is often at the heart of the relevant court cases, the more significant question may be

389. *Id.*

390. *Id.* at 52,719.

391. *Id.* at 52,719 n.21.

392. See Diane E. Hoffmann, *Criminalizing the Prescribing of Opioids: Where Should We Draw the Line?*, BIOETHICS F., Apr. 12, 2007, at www.bioethicsforum.org/treating-pain-William-Hurwitz-Controlled-Substances-Act.asp (last visited July 23, 2008).

393. *Id.*

394. *Id.*

395. See *supra* notes 321-337 and accompanying text.

whether the current standard for violation of the law, i.e., failure to prescribe within “the usual course of . . . professional practice” and “for a legitimate medical purpose,” is appropriate.³⁹⁶ Arguably, the standard draws the line too far on the side of prosecutions and does not adequately take into account the range of patients seen by physicians treating pain.

On one end of the spectrum are patients who are truly in pain and may need and use significant volumes of pain medication. They do not abuse or divert their medications. . . . On the other end are drug dealers who don’t even pretend to be patients. They may strike a deal with the doctor—drugs for sex or money. . . . Bu[t], also along the continuum are individuals who come to the physician under false pretenses—individuals who pretend to be in pain but actually have no pain and plan to sell the drugs on the street.³⁹⁷

Some of these patients may be good actors and it may not be possible for the well-meaning doctor to ferret out the good from the bad. At this point in time, “[t]here is no objective test for pain.”³⁹⁸ Neither is there an easy test to determine whether the patient is telling the truth. The determination of whether or not a patient is lying is a judgment call a physician must make by observing the patient’s behavior.³⁹⁹

In response to prosecutor claims that doctors should know when individuals are feigning pain solely to obtain prescriptions for opioids, Drs. Jung and Reidenberg did a study to determine how readily physicians can tell when patients lie.⁴⁰⁰ They found that physicians correctly identified patients who were lying (pretending to be patients when they were not) only 10% of the time.⁴⁰¹ The authors attributed this result to an observation that doctors operate with a “truth bias,” i.e., they “assume that patients come to see them because they have a problem for which they want treatment.”⁴⁰² Given this bias, second guessing a physician’s judgment in these matters, after the fact, seems patently unfair.⁴⁰³

396. See 21 C.F.R. § 1306.04(a) (2007) (stating that an effective 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”).

397. See Hoffmann, *supra* note 392.

398. *Id.*

399. See *id.*

400. Beth Jung & Marcus M. Reidenberg, *Physicians Being Deceived*, 8 PAIN MED. 433 (2007).

401. *Id.*

402. *Id.* at 414. In contrast, the authors point out, that law enforcement personnel start with a different assumption – that people are not being truthful. Despite this, they reported on a study of police, judges, and federal law enforcement agents which found that “only Secret Service agents were better than chance at detecting lying.” *Id.* (citing P. Ekman & M. O’Sullivan, *Who Can Catch a Liar?*, 46 AM. PSYCHOL. 913 (1991)).

403. See Hoffmann, *supra* note 392.

Additionally, physicians may see patients who are diverting or abusing narcotics but who are *also* legitimately in pain. Arguably, prosecuting a physician who prescribes opioids to such patients is unfair if he or she is attempting to relieve the patient's pain, even if the physician knows, based on past behavior, that the patient may abuse or divert the drugs.⁴⁰⁴ Despite the possibility for abuse or diversion, "in the absence of some kickback or tangible benefit . . . , or incontrovertible evidence that the doctor has simply exercised no medical judgment at all, it is difficult to justify criminal prosecution of a doctor for his prescribing or dispensing"⁴⁰⁵ of opioids for patients complaining of chronic pain.

While many pain treatment advocates viewed the Fourth Circuit's decision in the *Hurwitz* case as a victory, because it allowed a jury to consider whether the physician was acting in good faith when he prescribed the drugs at issue, I have argued elsewhere that it is

not at all clear that it has rectified the imbalance of the current law, which seems uncomfortably close to a civil negligence standard. An objective good faith test to determine whether a physician is prescribing within the 'usual course of professional practice' and for a 'legitimate medical purpose' appears virtually identical to [a medical malpractice standard wherein the inquiry is] whether the physician was prescribing consistent with the current standard of care.⁴⁰⁶

Not only are the standards difficult to differentiate, but the evidence necessary to establish violation of each standard is practically the same. In applying the malpractice standard, courts typically consider whether the physician performed a thorough exam, took the patient's medical history, asked about other drug use, and prescribed the appropriate drug or dosage.⁴⁰⁷ In prosecuting physicians under the CSA, law enforcers seem to be focusing on similar standard of care issues, particularly the volume and dosage of narcotics that physicians are prescribing.⁴⁰⁸

404. *Id.*

405. *Id.* Such a benefit might include "cash, sexual favors, [or] continuing to receive payment for maintaining an unnecessary doctor-patient relationship." *Id.*

406. *Id.*

407. *Id.*

408. Stephen E. Stone, former Associate Chief Counsel of DEA, describes some of the elements that make up prescribing in the course of one's "professional practice":

In order for a practitioner to prescribe or dispense in the course of his professional practice, there must exist between the doctor and the "patient" a valid physician-patient relationship. To establish this relationship, the patient must come to the physician seeking treatment for some kind of physical or psychological condition or symptomology. The physician must then obtain from the patient enough of a medical history, either through interview or by written form, to assist him in making a diagnosis of the complaint and the patient's general physical condition. Moreover, the physician

Clearly, focusing on volume and dosage is not an appropriate basis for arrest when expert medical opinion is that no consistent upper limit to prescribing for pain across all patients exists. Rather, it is the quantity of medication that eliminates the patient's pain without serious adverse side effects that is appropriate.⁴⁰⁹ That dosage is unique for each patient. Nevertheless, it appears from both news accounts and DEA literature that many doctors have been investigated because of the large volumes of opioids they prescribe and because they are seeing patients from outside of the state where they practice.⁴¹⁰ In part, these prescribing practices result from non-pain experts referring to these doctors out of fear of regulatory scrutiny.⁴¹¹ Therefore, a small number of doctors are becoming saddled with treating a large number of patients in pain.

Because arguments have been made on appeal in a number of these cases that the jury instructions were inappropriate for failing to sufficiently distinguish between a civil and criminal standard, several appellate courts have addressed the issue.⁴¹² The most recent is the Fourth Circuit in *United States v. McIver*.⁴¹³ McIver "argue[d] that by referring to 'norms of professional practice' in the jury instructions, the district court improperly allowed the jury to convict on a civil, rather than a criminal, standard of proof."⁴¹⁴ The Fourth Circuit admitted that the potential for juries to confuse the civil and criminal standard in these cases "requires courts to exercise care in setting out the governing standard."⁴¹⁵ Despite this admission, the court clung to the notion that courts and jurors can adequately differentiate the two norms of behavior.⁴¹⁶ Yet, in the end, it approved a jury instruction that arguably went beyond what is required by the current statutory standard. In *McIver*, the district judge instructed the jury that the government had to prove that the physician "used 'his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose

must conduct an examination or other medically recognized procedure sufficient to make a diagnosis. Finally, there must be a logical connection, or nexus, between the drug ultimately prescribed and the physical or psychological condition diagnosed.

Stone, *supra* note 222, at 24.

409. See *supra* text accompanying notes 291-94.

410. See *supra* Part II.

411. See *infra* Part VIII.C.

412. See, e.g., *United States v. McIver*, 470 F.3d 550 (4th Cir. 2006); *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006); *United States v. Feingold*, 454 F.3d 1001 (9th Cir. 2006); *United States v. Williams*, 445 F.3d 1302 (11th Cir. 2006); *United States v. Alerre*, 430 F.3d 681 (4th Cir. 2005); *United States v. Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994); *United States v. Hayes*, 794 F.2d 1348 (9th Cir. 1986).

413. 470 F.3d at 557.

414. *Id.*

415. *Id.* at 558.

416. See *id.* at 559.

of assisting another in the maintenance of a drug habit' or some other illegitimate purposes, such as his own 'personal profit.'"⁴¹⁷ The Fourth Circuit concluded that "[t]his instruction set the proper threshold for conviction by placing unlawful conduct beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence."⁴¹⁸

While these instructions do appear to set a higher bar than those required by the prevailing law or those that have been given in other prosecutions of physicians for illegally prescribing controlled substances,⁴¹⁹ they only represent a part of the overall instructions. Jurors were also told that they should "consider the extent to which 'any violation of professional norms . . . committed by the defendant interfered with his treatment of his patients and contributed to an over prescription and/or excessive dispensation of controlled substances.'"⁴²⁰ Although the court subsequently stated "that 'a violation of a professional norm does not in and of itself establish a violation of [a] criminal law,'"⁴²¹ subsequent interviews with jurors in the case indicate that jurors were confused about the relevant standard.⁴²²

Apparently, juries are, in fact, often confused in these cases.⁴²³ Although courts that allow expert testimony to establish the standard of care

417. *Id.* (alteration in original) (quoting Joint Appendix at 1292).

418. *Mclver*, 470 F.3d at 559.

419. The court, in fact, distinguishes the instructions in *Mclver* from those given in two prior cases where the defendant also alleged that the court had applied a civil negligence standard rather than a criminal standard. *Id.* at 558-60. In *United States v. Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994), the Fourth Circuit acknowledged that during the trial, the district court had confused the two standards, but nevertheless determined that the jury instructions were appropriate when the jury was instructed "to consider all of the defendant's actions, and provide[] specific examples of behavior that tended to denote illegitimacy, such as prescribing drugs without performing physical examinations, or asking patients about the amount or type of drugs they want." *Mclver*, 470 F.3d at 558. The *Mclver* court also referred to the jury instructions in *United States v. Alerre* (4th Cir. 2005), 430 F.3d 681. See *Mclver*, 470 F.3d at 558.

420. *Mclver*, 470 F.3d at 559 (quoting jury instructions in Joint Appendix at 1293).

421. See *id.* at 560 (alteration in original) (quoting jury instructions in Joint Appendix at 1293).

422. See Rosenberg, *supra* note 162, at 55.

423. Jurors in the *Hurwitz* case, for example, were influenced by the evidence that Hurwitz did not pick up on certain "red flags" indicating that his patients had used controlled substances for recreational purposes and were likely to do so again (e.g., they had been arrested for drug trafficking, had several positive tests for cocaine, or had called in to his office for early refills of their medication in a short period of time). See Tierney Lab: Putting Ideas in Science to the Test, at <http://tierneylab.blogs.nytimes.com/2007/04/30/hurwitz-jurors-explain-their-verdict/> (Apr. 30, 2007, 5:38 EST); Tierney Lab: Putting Ideas in Science to the Test, at <http://tierneylab.blogs.nytimes.com/2007/05/02/the-hurwitz-jurors-explain-further/> (May 2, 2007, 20:14 EST).

state that “mere” malpractice/civil negligence is not enough for a criminal conviction and instruct that a physician’s failure to meet the relevant standard must be established beyond a reasonable doubt, such instructions are insufficient to cure any confusion of civil and criminal standards on the part of lay juries.

The confusion created by the current standard may also encourage physicians to under treat pain or to stop treating chronic pain patients altogether. Fear of potential criminal liability, however, is only one side of the legal pressures they face. Physicians who undertreat pain or who ignore patient complaints of pain also face potential civil malpractice liability and disciplinary action.⁴²⁴ In addition, if a physician suspects that a patient is abusing or diverting drugs, in order to protect him or herself from criminal liability, the physician may decide to terminate the patient-physician relationship. While physicians may stop prescribing a drug whenever the risks, including potential abuse, outweigh the benefits, they may face a lawsuit or disciplinary action for patient abandonment if they stop treating a patient without adequate notice and an opportunity for the patient to find another healthcare provider.⁴²⁵ Abruptly stopping treatment of a patient on opioids also creates healthcare risks, including painful withdrawal symptoms, unless the patient is gradually weaned off the medication.

In sum, the current legal framework makes physicians risk criminal liability for prescribing opioids when they know or should have known that a patient is abusing or diverting his or her drugs (even if the patients are also in pain) and risk civil liability or professional disciplinary action if they ignore their patient’s requests for pain relief or abandon their patient because they believe the patient has diverted their drugs. Given the difficulty in determining when a patient is abusing or diverting and the simultaneous legal risks for undertreating and abandonment, the current criminal standard is inappropriate and should be changed.

424. See Matthew Yi, *Doctor Found Reckless for Not Relieving Pain: \$1.5 Million Jury Verdict for Family of Cancer Patient Who Went Home to Hayward to Die*, S.F. CHRON., June 14, 2001, at A1 (describing case against Dr. Wing Chin); see also *supra* note 288 and accompanying text.

425. The Vermont Board of Medical Practice, for example, considers abandonment unprofessional conduct and considers the following factors in determining whether termination was appropriate: (1) physician provided timely written notice (at least 30 days, presented to patient in a manner to ensure receipt); (2) physician provided care in transition period (at least 30 days); (3) physician transferred records to new physician. VT. BD. OF MED. PRACTICE, ADVISORY: TERMINATION OF THE PHYSICIAN-PATIENT RELATIONSHIP (1999), available at http://healthvermont.gov/hc/med_board/documents/010699terminationadvisory.pdf (last visited July 23, 2008).

B. Constitutional Violations

At least two constitutional arguments can be made to challenge the arrest and prosecution of physicians treating pain patients. First, the standard that is being applied is unconstitutionally vague. Second, using the standard to confine or take away a physician's ability to practice may substantially interfere with chronic pain patients' constitutional right to pain treatment.

1. Void for Vagueness

Shortly after Congress passed the CSA, two court cases addressed the issue of whether the CSA's provisions making "it illegal for a physician to dispense directly to the ultimate user a schedule II controlled substance other than 'in the course of his professional practice'" was unconstitutionally vague.⁴²⁶ In *United States v. Collier*, Dr. Collier argued that the words "in the course of his professional practice" fail to adequately "warn the physician of what conduct is proscribed, and that the statute is without objective standards and is subject to diverse interpretation."⁴²⁷ The court acknowledged that "[i]n making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options."⁴²⁸ Thus, "[w]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances."⁴²⁹ However, the court concluded that such circumstantial evidence can be sufficiently clear so as not to be unconstitutionally vague and referred to two "recent" decisions of the Supreme Court regarding state statutes that make physician performance of abortion criminal if not "'necessary'" or not "'necessary for the preservation of the mother's life or health."⁴³⁰ According to the *Collier* court, the Supreme Court decided that both statutes were constitutionally valid despite neither defining these terms.⁴³¹

In *United States v. Rosenberg*, the court rejected the defendant physician's contention that the phrase "in the course of professional practice" appearing in 21 U.S.C. § 802(20)⁴³² is so vague that it violates the Due Process Clause of the Fifth Amendment and pointed out that the

426. *United States v. Collier*, 478 F.2d 268, 270-71 (5th Cir. 1973); see *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975).

427. *Collier*, 478 F.2d at 271.

428. *Id.* at 272 (citing *Doe v. Bolton*, 410 U.S. 179 (1973)).

429. *Id.* (quoting *Linder*, 268 U.S. 5, 18 (1925)) (alteration in original).

430. *Id.* at 272 (quoting *Doe*, 410 U.S. at 192; *United States v. Vuitch*, 402 U.S. 62, 71 (1971)).

431. *Id.*

432. Section 802(20) referred to in *Rosenberg* is section 802(21) in the current U.S.C.

language in question “has been in the statute books since 1914 and no one has ever had problems with its interpretation.”⁴³³ The court stated that it was convinced by the ease and consistency with which the language had been interpreted by the courts that it was not vague and that it was “difficult to see how the language [could] be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress [had] intended to make illegal and subject to sanctions.”⁴³⁴ Judge Ely, in his dissenting opinion, however, was strident in his disagreement with the majority, arguing that “Congress has, without doubt, used language that is ‘. . . so vague that men of common intelligence must necessarily guess [as to] its meaning and differ as to its application.’ . . . The Constitution plainly condemns such vagueness, especially in criminal statutes.”⁴³⁵

While the majority’s view might have been true in the context of physicians like Rosenberg, who prescribed controlled substances to individuals who never indicated a need for the medications, it is much more complex when the physician is prescribing to treat pain. Moreover, the standard is arguably vaguer today than it was thirty years ago. Today, while there is increased awareness of the need to treat non-cancer chronic pain, differences of opinion remain in the medical community over whether certain patterns of prescribing for pain treatment are appropriate. The standard of care in the treatment of non-malignant chronic pain patients is an area of medical practice in which the boundaries and contours are in flux and one in which the boundaries may differ significantly from patient to patient. While some patients may not tolerate even small doses due to certain side effects, others are able to tolerate extremely high doses with little or no ill effects. As a result, the statutory language as it applies to physicians treating chronic pain patients is, arguably, unconstitutionally vague and there is a need for an alternative standard that provides physicians with greater clarity.

2. Liberty Interest in Pain Treatment

A second legal argument against the current standard is that its application and enforcement violates patients’ constitutional right to adequate pain treatment. In the aftermath of *Washington v. Glucksberg*⁴³⁶ and *Vacco v. Quill*,⁴³⁷ a constitutional right to adequate pain treatment arguably exists. If so, prosecuting doctors for over-prescribing may put an

433. *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975).

434. *Id.* at 198.

435. *Id.* at 204 (Ely, J., dissenting) (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)) (first and third alterations in original).

436. 521 U.S. 702 (1997).

437. 521 U.S. 793 (1997).

undue burden on the exercise of that constitutional right. In a 1997 *New England Journal of Medicine* article, Professor Robert Burt argued that a majority of the Supreme Court believes “that states must not impose barriers on the availability of palliative care for terminally ill patients.”⁴³⁸ Moreover, he argued that the rulings in *Glucksberg* and *Quill* “would have the same status as the right to an abortion established by *Roe v. Wade*—that is, an individual right that cannot be overridden by state actions prohibiting or ‘unreasonably burdening’ access to a physician’s assistance.”⁴³⁹ Professor Burt asserts that, as a result, current state laws that restrict the availability of opioids for pain management, such as “[r]estrictive prescription laws, the imposition of rigid limitations on dosages, and administrative burdens such as the requirement of triplicate forms,” may be challenged by pain treatment advocates.⁴⁴⁰

Neither the Supreme Court Justices nor Burt discuss the treatment of chronic pain patients. Rather, their remarks are limited to palliative care for the terminally ill. Yet, the right to pain relief for those suffering from severe chronic pain would seem to be implicit in the right to pain relief for dying patients based on the Court’s rationale for the latter. Beth Packman Weinman relies on the concurring opinions of Justices Breyer and Stevens to make this argument.⁴⁴¹ Using Justice Breyer’s remarks about a liberty interest in pain relief as a starting point, Packman asserts that “[i]ust as severe pain at the end of life presents an indignity that violates the protected liberty interest, one can make a strong argument that a life with continuous, chronic severe pain is also a life without dignity, and consequently, without liberty.”⁴⁴² She couples Justice Stevens’s remarks with Breyer’s and states that “[l]ike Justice Breyer, Justice Stevens explicitly argues that accessing treatment to alleviate unwanted pain and suffering at the end of life is at the heart of the liberty interest.”⁴⁴³ Moreover, she states that “[i]t would be hard to imagine that this argument does not include within it a liberty interest in freedom from unwanted pain and suffering for those who are not terminally ill.”⁴⁴⁴

438. Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care*, 337 *NEW ENG. J. MED.* 1234, 1235 (1997).

439. *Id.*

440. *Id.*

441. See Beth Packman Weinman, *Freedom from Pain: Establishing a Constitutional Right to Pain Relief*, 24 *J. LEG. MED.* 495, 527-29 (2003).

442. *Id.* at 528.

443. *Id.* at 529.

444. *Id.*; see also *Palko v. Connecticut*, 302 U.S. 319, 325-26 (1937) (stating that being free to take available medications to alleviate pain is “implicit in the concept of ordered liberty” such “that neither liberty nor justice would exist if they were sacrificed” and “so rooted

While prosecution of doctors under section 841 of the CSA does not directly restrict patient access to controlled substances, such prosecution does burden the exercise of the constitutional right by deterring doctors from prescribing, even when a patient's need is legitimate.⁴⁴⁵ Jurisprudence analyzing the "undue burden" of state abortion laws appears to support a conclusion that laws criminalizing physician prescribing or opioid analgesics place an undue burden on a patient's right to palliative care.⁴⁴⁶ While the "undue burden" on pain patients resulting from the prosecution of physicians is more attenuated than that posed by the obstacles put in the way of abortion seekers by state statutes (i.e., waiting periods, requirements of a second opinion, parental consent), the burden may be more significant in the pain treatment context. Improper prosecutions not only place significant obstacles on prosecuted physician's patients, they also have a "chilling effect" on other physicians treating chronic pain patients, i.e., they subsequently may refuse to treat pain patients.⁴⁴⁷ In some ways, the situation is analogous to the abortion context where fewer and fewer physicians are willing to provide abortions, not because of the threat of criminal prosecution, but because of the increasing legal limits on performing abortions.⁴⁴⁸ In both contexts, patients often have to travel

in the traditions and conscience of our people as to be ranked as fundamental") (internal quotation and citation omitted).

445. Studies have established that there is a "chilling effect" on physician prescribing of opioids resulting from legal sanctions for such prescribing. See Charles Schmidt, *Experts Worry About Chilling Effect of Federal Regulations on Treating Pain*, 97 J. NAT'L CANCER INST. 554 (2005). *Contra* News Release, U.S. Drug Enforcement Admin., *The Myth of the "Chilling Effect"* (Oct. 30, 2003), at www.dea.gov/pubs/pressrel/pr103003p.html (last visited July 23, 2008).

446. Burt suggests that physicians threatened with disciplinary action by state medical boards for prescribing large volumes of pain medications may be able to protect themselves by arguing that their patients have a "constitutional right to adequate palliative care." Burt, *supra* note 438, at 1236.

447. See Schmidt, *supra* note 445. *Contra* News Release, U.S. Drug Enforcement Admin., *supra* note 445; see also note 14, *supra*.

448. See GUTTMACHER INST., *FACTS ON INDUCED ABORTION IN THE UNITED STATES* (2008), at www.guttmacher.org/pubs/fb_induced_abortion.html (last visited July 23, 2008) (citing Rachel K. Jones et al., *Abortion in the United States: Incidence and Access to Services*, 2005, 40 PERSP. ON SEXUAL & REPROD. HEALTH 6, 11 tbl.3 (2008) (noting that the number of U.S. abortion providers declined by 2% between 2000 and 2005 (from 1,819 to 1,787)); see also Lawrence B. Finer & Stanley K. Henshaw, *Abortion Incidence and Services in the United States in 2000*, 35 PERSP. ON SEXUAL & REPROD. HEALTH 6, 10, 13-14 (2003) (documenting the continuing decline in U.S. abortion providers, from a high of 2,908 in 1982, to 1,819 in 2000, and attributing the trend to "increasing legal constraints on the circumstances under which abortions may be performed" and the increased risk of violence from anti-abortionists). See *infra* notes 460-466, 474 and accompanying text for information as to how the arrest and

significant distances to find a physician who will treat them or provide the desired service.

A potential counter argument is that the state or federal government has a legitimate interest in preventing the abuse and diversion of addictive narcotics that trumps the individual's right to adequate pain treatment. Burt considers that states could attempt to defend laws restricting access to pain medications for end of life care as justified in order to prevent abuse and diversion for illegal purposes but argues that such a state interest would only trump an interest in providing adequate pain relief if the courts found it appropriate "to give higher priority to the 'war on drugs' than to providing adequate palliative care for dying patients."⁴⁴⁹ While preventing drug addiction and abuse is a legitimate interest, it should not overcome the individual's right to pain relief in the context of either end of life care or chronic pain treatment.⁴⁵⁰

C. *Current Law and Enforcement Practices: An Egregious Imbalance*

The competing policy goals of eliminating drug diversion and abuse and appropriately treating pain are brought into stark relief by the government's policies and practices regarding drug enforcement. With most regulations, the government may either overreach with its regulatory net, capturing too many innocent individuals (false positives), or underreach, failing to capture guilty individuals (false negatives). Scientists refer to these errors inherent in virtually all regulatory schemes respectively as Type I and Type II errors.⁴⁵¹ The question is whether we should be depriving patients in pain of needed opioids (a result of Type I errors) in order to prevent their use for non-medical purposes (a result of Type II errors). While the DEA has recognized

prosecution of pain physicians has affected the number of physicians willing to treat patients with chronic pain and the impact it has had on pain patients.

449. Burt, *supra* note 438, at 1235-36.

450. See *id.* at 1236 (concluding that "[t]he generalized goal of narcotics control could not . . . take precedence over an individual's constitutional right to adequate palliative care"); see also Ann Alpers & Bernard Lo, *The Supreme Court Addresses Physician-Assisted Suicide: Can Its Rulings Improve Palliative Care?*, 8 ARCHIVES FAM. MED. 200, 201 (1999) (arguing that the majority opinion in both *Glucksburg* and *Quill* "concludes that the double-effect doctrine provides a rational and constitutional basis for states to allow narcotics given in high dosages for pain relief in terminally ill patients, while prohibiting assisted suicide" and that "[t]he concurring justices go further, suggesting that the state is obligated to permit physicians to provide adequate pain relief at the end of life, even if such care leads to unconsciousness or hastens death"). Alpers and Lo further assert that "[t]hese concurring opinions . . . may establish a right to pain relief that is closely allied with other personal rights such as the right to an abortion or the right to refuse medical treatment." *Id.*

451. See American College of Physicians, *Primer on Type I and Type II Errors*, 4 EFFECTIVE CLINICAL PRAC. 284, 284-85 (2001), available at www.acponline.org/clinical_information/journals_publications/ecp/novdec01/primer_errors.pdf (last visited July 23, 2008).

the importance of pain treatment through official statements,⁴⁵² its practices do not give adequate weight to this policy goal.⁴⁵³ Arguably, state and federal drug enforcement agents are grossly overreaching with regard to drug policy enforcement, resulting in too many false positives. If regulators and prosecutors must err in their enforcement and prosecution with respect to this issue, it would be more appropriate as a policy matter to underreach than overreach. Such a result, reducing Type I errors, and concomitantly increasing Type II errors, is defensible on both utilitarian and deontological grounds.

1. Utilitarian Analysis

a. The Costs of Overreaching

A utilitarian analysis of this issue requires an articulation and quantification of the costs and benefits of overreaching as compared to underreaching. In this context, *overreaching* means arresting and prosecuting physicians who are legitimately treating pain patients. The costs of such erroneous actions are sweeping. Not only does the innocent physician bear the costs of the harm, including loss of livelihood that may impact the individual and his/her family or dependents, the humiliation, embarrassment, and physical stress of public arrest and prosecution, and the cost of a legal defense, but others also suffer from the prosecution's ripple effect. This ripple effect includes harms to the physician's current pain patients who may not be able to find another physician who will treat their pain, as well as to other current and future chronic pain patients who may not be able to find a pain treatment practitioner because of the chilling effect such criminal actions have on physicians' general willingness to treat chronic pain. The DEA's view is that these high-profile cases "have been a learning lesson to other physicians"—that other physicians are much more cautious now of how they prescribe narcotics.⁴⁵⁴ Unfortunately, it appears that many are so cautious they will no longer prescribe narcotics as pain treatment or treat pain patients at all. They fear that prescribing "opium-

452. In 1999, drug enforcement officials from the DEA and twenty-one health organizations issued a joint statement to announce that they had begun to work "together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need." A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS & THE DRUG ENFORCEMENT ADMIN., PROMOTING PAIN RELIEF AND PREVENTING ABUSE OF PAIN MEDICATIONS: A CRITICAL BALANCING ACT (2001), available at www.aslme.org/news/press_conference/consensus.pdf (last visited July 23, 2008).

453. See Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006).

454. See Kaufman, *supra* note 6 (quoting statement of Elizabeth Willis, Chief of Drug Operations, Office of Diversion Control, U.S. Drug Enforcement Admin.).

based drugs for pain is becoming criminalized by aggressive drug agents and zealous prosecutors."⁴⁵⁵

A number of pain treatment advocates have decried this chilling effect, arguing that

[o]ne of the saddest and least noticed consequences of the war on drugs is the under-treatment and non-treatment of chronic pain. Literally hundreds of thousands of patients endure needless agony—in some cases turning to suicide for relief because they could not find a doctor willing to prescribe adequate doses of narcotics for them.⁴⁵⁶

At the time of Dr. Hurwitz's medical board hearing, Russell Portenoy, then co-chief of Palliative Care at Memorial Sloan Kettering Cancer Center in New York, stated that "most physicians are reluctant to treat pain with narcotics, fearing they will face criminal or regulatory investigations."⁴⁵⁷ Hurwitz was one of the few physicians at the time who was willing to prescribe large doses of narcotics to non-terminally ill pain patients. Many of his patients "spoke of living in agony before finding pain relief from narcotics."⁴⁵⁸ But the evidence is more than anecdotal. Several studies have confirmed the chilling impact of potential legal sanctions for prescribing of narcotics for pain treatment.⁴⁵⁹

The DEA argues that because the number of DEA registrants has increased each year since 1999, the agency's increased scrutiny of physicians for opioid prescribing has not caused a chilling effect.⁴⁶⁰ However, while many physicians are registered to prescribe scheduled drugs, pain treatment advocates argue that many of them do not prescribe scheduled drugs, or do not prescribe them on a long-term basis, and the burden of prescribing opioids for chronic pain patients falls primarily on approximately 4,000–6,000 physicians who specialize in pain

455. *Id.*

456. Drug Reform Coordination Network, *supra* note 107.

457. Peter Finn, *D.C. Internist's Case Spurs Concerns Over Prescribed Narcotics*, WASH. POST, June 18, 1996, at D3.

458. *Id.*

459. See, e.g., Sandra H. Johnson, *Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act*, 24 J.L. MED. & ETHICS 319, 320 (1996); Sharon M. Weinstein et al., *Physicians' Attitudes Toward Pain and the Use of Opioid Analgesics: Results of a Survey from the Texas Cancer Pain Initiative*, 93 S. MED. J. 479 (2000).

460. See News Release, U.S. Drug Enforcement Admin., *supra* note 445 ("Since FY 1999 the DEA registrant population has continually increased reaching almost 1 million doctors (as of June 30, 2003). During this same time, DEA has pursued sanctions on less than one tenth of one percent of the registered doctors.").

management.⁴⁶¹ Professor Ronald Libby has argued that in many states a very small number of physicians prescribe a large volume of opioids.⁴⁶²

According to some, few enough physicians in the country are willing to prescribe narcotics for chronic pain that patients might travel hundreds of miles to see them.⁴⁶³ One physician used the term “the Painful Underground Railroad” to describe the system now in play for patients with chronic pain to find physicians who will treat them.⁴⁶⁴ Others have labeled doctors’ fear of prescribing medications for their patient’s pain as “opiophobia.”⁴⁶⁵ News stories have reported that some doctors display signs in their offices that say ‘Don’t ask for OxyContin’ or ‘No OxyContin prescribed here’ and that medical schools are advising “students not to choose pain management as a career because the field is too fraught with potential legal dangers.”⁴⁶⁶

To fully understand the costs of overreaching, one must also consider the costs of untreated pain for patients unable to find a physician who will treat their pain. For example, when Dr. Frank Fisher was arrested, many of his patients were unable to find care.⁴⁶⁷ According to one news account, hundreds of his patients “deteriorated unnecessarily, and several . . . died.”⁴⁶⁸ At the time of his arrest, “twenty-five people who had been working, with Dr. Fisher’s help, were forced to apply for full disability.”⁴⁶⁹

The American Academy of Pain Management estimates that “about 50 million Americans live with chronic pain, caused by cancer, other diseases

461. See Otesa Middleton, *FDA Panel: OxyContin’s Approval Shouldn’t Be Limited*, DOW JONES NEWSWIRES, Sept. 9, 2003 (statement of Dr. J. David Haddox, Purdue Pharma); Libby, *supra* note 14, at 2 (estimating the number of physicians who specialize in the treatment of chronic pain as between 4,278 and 5,869).

462. See Libby, *supra* note 301 (“One percent of the physicians in Florida were responsible for prescribing large doses of OxyContin and other narcotics. If Florida is representative of the country, that means that only one percent of the 963,385 physicians are responsible for treating between 30 and 80 million chronic and cancer patients in the country.”); see also Fred Schulte, *Drugging the Poor; Deaths Mount as Doctors, Pharmacists and Patients Abuse the Medicaid System*, SUN-SENTINEL (Ft. Lauderdale, Fla.), Nov. 30, 2003, at 1A (stating that based on the newspaper’s own records review, sixteen doctors in Florida had each ordered more than \$1 million in opiates during the “past three years,” compared to only 574 out of the 56,926 medical professionals in Florida who had ordered more than \$100,000 in pharmacy billings during that same time).

463. Sullum, *supra* note 104, at 23.

464. *Id.* (quoting Dr. Harvey L. Rose, a Carmichael, California, family practitioner who battled state regulators accusing him of excessive prescribing).

465. *Id.*; see also Morgan, *supra* note 272 (discussing physician phobia of prescribing opioids that results from misconceptions about drug use and abuse).

466. Owen, *supra* note 199, at 42.

467. DRUG WAR CHRON., *supra* note 52.

468. *Id.*

469. *Id.*

and disorders, and accidents [and that] [a]nother 25 million live with acute pain caused by surgery or accidents."⁴⁷⁰ Moreover, "[t]he majority of those with the most severe pain do not have it under control and suffer substantially in their enjoyment of life, their social relations, and their economic productivity."⁴⁷¹

Estimates of costs associated with loss of productivity due to pain have been as high as \$100 billion per year. A study published in 2003 on lost work time and costs due to pain conditions concluded that "[p]ain is an inordinately common and disabling condition in the US workforce," costing employers an "estimated \$61.2 billion per year in pain-related lost productive time."⁴⁷² But in addition to work related costs, "pain [also] has a tremendous physiologic, sociologic, psychological and existential impact on the individual and society;" it affects marriages, families, and friendships as well as careers.⁴⁷³

Costs to individuals with untreated pain may defy quantification. Pain patients say "[t]heir pain . . . [is] like being on fire[,] . . . like having an electrode shoot juice up your neck all day[,] . . . like having a car parked on your face. So intense [is] their torment . . . that suicide often seem[s] the better alternative."⁴⁷⁴ In some cases, before they found relief from opioid analgesics these individuals were bedridden for years.⁴⁷⁵ Their problems ranged from "crushed vertebrae and damaged jaws, [to] congenital bowel inflammations and disintegrating hips, [to] terrible burns and monstrous migraines."⁴⁷⁶ Individuals with this type of intense and enduring pain may also suffer depression and/or commit suicide.⁴⁷⁷ One of Dr. Hurwitz's patients, a forty-two-year-old resident from upstate New York, did, in fact,

470. *The Infinite Mind*, *supra* note 16; see also Kuehn, *supra* note 291, at 249 (citing a 2005 telephone survey of a random sample of 1204 adults which found 19% of respondents reported chronic pain and 34% reported recurrent pain).

471. *The Infinite Mind*, *supra* note 16; see also Kuehn, *supra* note 291 (stating that "[s]ome 63% of patients with pain had spoken to their physician about their pain, but only 31% reported complete relief and 21% reported little or no relief").

472. Walter F. Stewart et al., *Lost Productive Time and Cost Due to Common Pain Conditions in the US Workforce*, 290 JAMA 2443, 2443, 2449 (2003).

473. See MICHAEL DREYFUSS, OUR CHRONIC PAIN MISSION, FEDERAL PROSECUTION OF PAIN DOCS IMPEDES PAIN TREATMENT, at www.cpmmission.com/main/painpolitics/impedes.html (last visited Aug. 9, 2008) (quoting John F. Peppin, owner of the Iowa Pain Management Clinic).

474. Allen, *supra* note 113, at 12.

475. See *id.* (referring to one of Dr. Hurwitz's patients who was bedridden for two decades).

476. *Id.* at 15.

477. See *id.* at 12, 15 (describing the experiences of Dr. Hurwitz's patients).

commit suicide when Hurwitz was unable to find another physician who would treat him.⁴⁷⁸

While there are several anecdotal reports of such deaths, no accurate statistics of the number of individuals who take their own lives as a result of untreated pain exist. The Pain Relief Network, however, claims that American citizens “by the thousands are being forced into suicide by untreated pain.”⁴⁷⁹

b. The Benefits of Overreaching

In an evenhanded policy analysis, the benefits of overreaching must also be described. These benefits may include preventing drug addiction and diversion. Harms associated with addiction include decline of the addict’s physical health and productivity, financial and emotional harm to the addict’s family, increased crime when addicts steal or commit prostitution to maintain their habit, and even death due to drug overdose. It is difficult to determine, however, the extent of harm that results when physicians inadvertently prescribe narcotics to an addict or to someone who sells them to an addict. To the extent that the physician is “feeding the addict’s habit,” he may be worsening the addict’s health and allowing him or her to continue living in an unproductive way. This result assumes, however, that the addict would have otherwise sought treatment or that by the physician refusing the addict drugs, he or she would be more likely to seek treatment.

Moreover, it is unclear whether one can attribute an increase in crime to a physician giving an addict a narcotic when it is more likely that the addict would not have to steal or prostitute him or herself to obtain the narcotic he or she seeks. On the other hand, a physician could increase the circulation of narcotics in the “market” by prescribing to a patient who subsequently diverts the drugs, selling them illegally to addicts or other abusers. According to one source, some jurisdictions have reported “as much as a

478. Drug Reform Coordination Network, *supra* note 107 (“[The] patient had been seeing Dr. Hurwitz for three years for back and neck pain due to injuries sustained in an auto accident. His pharmacy refused to fill Dr. Hurwitz’s District of Columbia prescriptions after learning of the Virginia medical board’s disciplinary action against him, despite his having been on a stable regimen for over a year. With the help of a member of the AMA Council on Ethical and Judicial Affairs, Dr. Hurwitz was able to make arrangements for the patient to be treated at a clinic in New Jersey and flown there for free. The patient had run out of his medications, however, and didn’t feel he could make the trip without them. No local clinic was willing to provide him with a short-term prescription. In the meantime, a SWAT team of the local police, having been notified of a possible suicide, surrounded his house. The patient, a former policeman himself, proceeded to take his own life.”).

479. James L. Schaller, *Why Are Kind, Ethical & Caring Physicians Treating Your Pain Being Targeted by Tax-Funded Government?*, at www.personalconsult.com/articles/painreliefnetwork.html (last visited Aug. 9, 2008).

75% increase in property and other crimes that they specifically attribute to the abuse of OxyContin."⁴⁸⁰

Numerous news stories describe cases of pain patients who have become "addicted" to their pain medication; however, it is not clear whether these patients are truly addicted or are, instead, physically dependent. According to pain treatment experts, "patients treated with prolonged opioid therapy usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders. . . . Addiction, unlike tolerance and physical dependence, is not a predictable drug effect, but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals."⁴⁸¹

Overreaching may also save some lives because it may prevent a patient or someone to whom a patient sells or gives a prescription or drug from overdosing. Estimates of the number of overdose deaths due to OxyContin differ. Various sources report between 146 and 500 deaths from OxyContin overdose in 2000 and 2001.⁴⁸² Yet, it is uncertain that OxyContin was the primary cause of death as the subjects often had consumed alcohol or other drugs in addition to oxycodone. An article in the *Journal of Analytical Toxicology* found only twelve cases in one year "in which OxyContin was the sole cause of death; all the others fell victim to poly-drug abuse—mixing OxyContin with cocaine, alcohol, Valium, or various other substances."⁴⁸³ Thus, attributing these deaths to inappropriate physician prescribing would seem unjustified; although, perhaps they would have been prevented (in a lengthy backward looking "but for" causation analysis) if the physician had not prescribed the drug at all.

Others have made the point that even if these deaths could have been prevented, the total deaths attributable "to OxyContin over a period of two years represent just one-third of the deaths linked to acetaminophen in a

480. OFFICE OF DIVERSION CONTROL, *supra* note 10.

481. DEFINITIONS RELATED TO THE USE OF OPIOIDS, *supra* note 304; see also text accompanying notes 304-308.

482. See Ammann, *supra* note 198, at 32 (citing the DEA figure of 146 deaths involving OxyContin over a two-year period); OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMIN., DRUGS AND CHEMICALS OF CONCERN: SUMMARY OF MEDICAL EXAMINER REPORTS ON OXYCODONE-RELATED DEATHS, at www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycotin7.htm (last visited Aug. 9, 2008) (stating that for 2000 and 2001, "146 deaths were categorized as 'OxyContin verified' deaths; 318 deaths were re-categorized as 'OxyContin likely'"); see also Owen, *supra* note 199, at 44 (stating that "[f]ederal officials claim that nearly 500 people died from overdosing on OxyContin in 2002").

483. Owen, *supra* note 199, at 44 (citing Edward J. Cone et al., *Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing Over 1000 Cases*, 27 J. ANALYTICAL TOXICOLOGY 57 (2003)).

single year."⁴⁸⁴ While many more people take acetaminophen than OxyContin, the comparison illustrates that in many other areas we tolerate increased risk and adverse side effects because they are overshadowed by the therapeutic benefit the drug provides and raises questions about why we treat opioids differently. In both cases, the deaths may be intentional or accidental. The difference appears to be the possibility of addiction to the opioids.

In sum, in order to truly understand the costs and benefits of overreaching by prosecutors, we need some idea of (1) the numbers of individuals likely denied pain relief because of the arrest and prosecution of physicians for prescribing opioids related to pain treatment and (2) the number of individuals who become addicted or maintain an addiction because a physician intentionally or unintentionally gives a patient an opioid prescription. Although exact numbers are not currently available, the number of individuals with untreated pain is orders of magnitude greater than those who become addicted to opioids, whether as a result of receiving a legitimate prescription or receiving the drug through illegitimate channels. Weinman cites the difference at "'56 million persons in pain" versus "2.6 million abusers."⁴⁸⁵

Lastly, as a policy matter, we must ask whether the law enforcement strategy of targeting physicians is the most effective means of reducing narcotic abuse and addiction. The government's decision to target physicians in their war on prescription drug abuse seems inherently misguided. The most common means of opioid drug diversion have been described by DEA as "fraudulent prescriptions, doctor shopping, over-prescribing, and pharmacy theft."⁴⁸⁶ Physicians are arguably responsible only for "over-prescribing," and it is debatable how much over-prescribing is actually taking place and whether this is the source of most opiate drug diversion. For example, individuals may obtain some drugs, including opioids, illegally over the Internet.⁴⁸⁷

484. Ammann, *supra* note 198, at 32; see also Weinman, *supra* note 441, at 502 (stating that the Drug Abuse Warning Network (DAWN) ranked oxycodone hydrochloride (the substance in OxyContin) seventeenth in the first half of 2000 "on the list of drugs responsible for drug-related visits to hospital emergency departments"; however, both aspirin (ranked tenth) and ibuprofen (ranked eleventh) "were responsible for more emergency department visits than OxyContin").

485. Weinman, *supra* note 441, at 503 (quoting Debra E. Heidrich, *Controlled-Release Oxycodone Hydrochloride (OxyContin)*, 15 *CLINICAL NURSE SPECIALIST* 207, 208 (2001)).

486. OFFICE OF DIVERSION CONTROL, *supra* note 10.

487. Office of Diversion Control, U.S. Drug Enforcement Admin., Question & Answers: Dispensing and Purchasing Controlled Substances over the Internet, at www.dea/diversion.usdoj.gov/faq/internetpurch.htm (last visited Aug. 9, 2008) ("The DEA recognizes that while some Internet sites facilitate legitimate prescribing and dispensing

2. Deontologic Arguments

A practice which is likely to increase the number of individuals treated for chronic pain, even if it also results in a small increase in the number of individuals who become addicts or continue addictive behaviors (i.e., underreaching), can also be defended on deontological (moral) grounds. While moral arguments have largely been the mainstay of those arguing for stricter drug enforcement practices, those arguments may be trumped by higher moral values. Those who espouse stricter drug enforcement practices (i.e., overreaching) believe that addiction is morally repugnant and leads to immoral behavior, e.g., theft and prostitution, separate and apart from the economic or physical harms associated with these behaviors.⁴⁸⁸ This moral reprehensibility, they would argue, requires that we prevent such behavior at all costs (or without regard to cost). In order to bolster their arguments, those with this view have often exaggerated both the number of addicts in this country and the crimes caused by addicts.⁴⁸⁹ In the context of pain patients, those arguing for stricter enforcement of drug laws believe that pain patients treated with opioids are highly likely to become addicted, which they believe is morally reprehensible. However, it is equally reprehensible to fail to treat a patient's pain.

Arguably, there is a moral imperative to treat pain that rises to the level of a human rights issue. The AMA has pronounced that "[p]hysicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care[, including] providing effective palliative treatment even though it may foreseeably hasten death."⁴⁹⁰ Also, "[i]n 1997, the American Society of Addiction Medicine affirmed that physicians are obligated to relieve pain and suffering in their patients, including those with concurrent addictive disorders."⁴⁹¹ Linda Farber Post and her colleagues wrote of the moral imperative to treat pain, stating that

practices, other sites facilitate the illegal sale of controlled substances. These sites of illicit activity enable some consumers to illegally purchase controlled substances without realizing they are committing a crime.").

488. See MUSTO, *supra* note 207, at 244 (describing the belief of historical proponents of strict narcotics controls that "the need for money to buy drugs or a direct physiological incitement to violence led to crime and immoral behavior").

489. See *id.* at 246 ("Like the speculated percentage of crimes caused by narcotic use and sales, the number of addicts estimated for the nation appears often to have been exaggerated.").

490. AM. MED. ASS'N HOUSE OF DELEGATES, HEALTH AND ETHICS POLICIES, H-140.966: DECISIONS NEAR THE END OF LIFE, at www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-140.966.HTM (last visited Aug. 5, 2008).

491. Hurwitz, *supra* note 272, at 13 (citing Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain (adopted by the Am. Soc'y of Addiction Med. Bd. of Dirs., Apr. 16, 1997)).

the physician's "obligation of beneficence requires physicians to do good and prevent harm" and that the list of goods typically includes "prolongation of life, restoration of function, and relief of pain and suffering."⁴⁹² The authors refer to the physician's obligation to treat pain as "what moral philosophers call a *prima facie* or conditional obligation, something physicians ought to do unless some other duty or moral consideration takes precedence."⁴⁹³ Some other duty might take precedence, for example, when a patient refuses pain medication out of concern that it may affect his or her intellectual awareness.⁴⁹⁴ In order to respect the patient's autonomy, a physician, under these circumstances, could ethically decline to treat a patient's pain. However, when a patient requests pain relief both ethical principles of autonomy and beneficence merge to support an ethical obligation to treat the patient's pain.

An additional ethical argument against overreaching is the impact that it has on the doctor-patient relationship. Doctors, as an initial matter, must develop a trusting relationship with their patients, which requires them to listen to their patients and believe their accounts of their symptoms. As stated above, this is especially true in the field of pain management where there is no objective test for pain. Neither is there a wholly accurate test to determine whether the patient is telling the truth or fabricating his symptoms.⁴⁹⁵ Physicians who ignore their patient's pain accounts would be arguably negligent.⁴⁹⁶ Prosecutors and the DEA argue that "doctors violate the law when they prescribe pain pills to patients who they know—or reasonably should know—are selling or abusing the drugs."⁴⁹⁷ But, this puts physicians in the position of being watch dogs for law enforcement or, at least, suspicious of their patients' claims of pain. It compromises the doctor-patient relationship. Moreover, it seems wholly inappropriate as a test for criminal liability when the doctor faces legal risk for undertreating as well as overtreating pain. William Hurwitz has argued that holding physicians responsible for their patients' misbehavior puts doctors in a no

492. Linda Farber Post et al., *Pain: Ethics, Culture, and Informed Consent to Relief*, 24 J.L. MED. & ETHICS 348, 349 (1996).

493. *Id.*

494. *Id.*

495. See Hurwitz, *supra* note 272, at 14 ("Physicians usually can screen out the wholly fraudulent patient without a pain syndrome at all, but current medical technology includes neither a pain 'meter' nor other objective test to ensure against other forms of deception or medication misuse by patients.").

496. See Ben A. Rich, Op-Ed, *Physicians' Legal Duty to Relieve Suffering*, 175 W.J. MED. 151, 152 (2001) (discussing the jury verdict against a doctor for undertreating his elderly patient's pain, in *Bergman v. Wing Chin, MD & Eden Med. Ctr.*, No. H205732-1 (Cal. App. Dep't Super. Ct. 1999)).

497. Vartabedian, *supra* note 202.

win situation: "It forces doctors who try to treat pain to act like police, reinforcing a perverse medical paternalism that subverts the ethical imperatives designed to protect patient autonomy and dignity. This distortion of the patient-physician relationship stigmatizes patients and erodes their trust."⁴⁹⁸

Many physicians who work in pain clinics or who treat chronic pain patients already engage in highly intrusive behaviors in an effort to ensure that their patients are not drug addicts or diverters. In fact, "[p]ain specialists—usually psychiatrists, anesthesiologists or neurosurgeons—often operate within the structure of large clinics that run patients through a gantlet [sic] of rehabilitation techniques, starting with the removal of all medications."⁴⁹⁹ Then, "[o]nce patients do get narcotics, they must follow stringent rules to prevent abuse or diversion of the drugs."⁵⁰⁰ As an example, the Community Health Projects Medical Group in California, which provides opioid therapy at thirty-five clinics, requires each patient to sign a thirty-six-page consent form.⁵⁰¹ "[T]he form warns patients that in exchange for a maximum of 32 pills a day, they must follow scores of rules for behavior inside and outside the clinic, and can be dropped instantly and without recourse."⁵⁰² Pain clinics routinely ration pills, test urine "each visit to make sure the patient is using the medication, not selling it," and require that patients "visit once or twice a month."⁵⁰³

498. Hurwitz, *supra* note 272, at 14.

499. Allen, *supra* note 113, at 15.

500. *Id.*

501. *Id.*

502. *Id.*

503. *Id.* Individual pain treatment practitioners may impose additional requirements. See Walter A. Brown, *Finessing the Fine Line Between Pain Management and Opioid Addiction*, 3 APPLIED NEUROLOGY 39, 40 (2007), available at <http://appneurology.com/showArticle.jhtml?articleId=197003317> (last visited Aug. 9, 2008) (describing a neurologist with a practice focused primarily on pain management who "carries out unannounced pill counts and urine screens in all his patients who have NCP [nonmalignant chronic pain]. For the pill counts, he periodically calls each patient and tells them to get to a pharmacy within 2 hours and bring all their pills for the pharmacist to count. He also periodically calls each patient and tells them to go to a nearby hospital or laboratory within 2 hours for a urine screen. He doesn't do these counts or urine screens during office visits because that is when patients expect them.").

IX. AN ALTERNATIVE STANDARD

A. *Moving away from a Criminal Approach*

The substantial overlap between the current criminal standard set forth in the CSA and its implementing regulations and the civil malpractice standard calls for an alternative criminal basis for prosecution. The current standard appears to require a knowing violation, i.e., knowledge by the physician that he is prescribing outside the bounds of professional practice and not for a "legitimate medical purpose."⁵⁰⁴ Yet, actual knowledge is not required in practice; rather, courts permit a willful blindness standard that, in effect, allows a "jury to convict based on an *ex post facto* 'he should have been more careful' theory or to convict on mere negligence ('the defendant should have known his conduct was illegal')."⁵⁰⁵ Whether the willful blindness instruction is based on a subjective or objective test can also skew the results, with an objective test pushing jurors towards a negligence standard.⁵⁰⁶ An objective willful blindness test coupled with an objective good faith defense further narrows the gap between a *mens rea* requirement based on knowledge versus one based on negligence.⁵⁰⁷

When there is no indication of intent to do harm or proof of knowledge of wrongdoing, the criminal justice system also allows for prosecution when one acts "recklessly" or "negligently."⁵⁰⁸ According to the *Model Penal Code*,

[a] person acts recklessly . . . when he consciously disregards a substantial and unjustifiable risk that . . . exists or will result from his conduct. The risk must be of such a nature and degree that, considering the nature and purpose of the actor's conduct and the circumstances known to him, its disregard involves a gross deviation from the standard of conduct that a law-abiding person would observe in the actor's situation.⁵⁰⁹

The definition of criminal negligence is similar. However, rather than "consciously disregard[ing] a substantial and unjustifiable risk," the individual *fails to perceive the risk* when he should have been aware of it.⁵¹⁰ The risk which the actor either consciously disregards or fails to perceive must be both "substantial and unjustifiable."⁵¹¹ Commentary to the Code

504. See 21 C.F.R. § 1306.04(a) (2007).

505. O'SULLIVAN, *supra* note 340, at 101 (quoting *United States v. Mancuso*, 42 F.3d 836 (4th Cir. 1994)).

506. See *id.* at 102.

507. See *id.* at 101-02.

508. See MODEL PENAL CODE § 2.02 (1962).

509. *Id.* § 2.02(2)(c) (emphasis added).

510. *Id.* § 2.02(2)(c-d).

511. *Id.* § 2.02(2)(d) (emphasis added).

states that “[e]ven substantial risks . . . may be created without recklessness when the actor is seeking to serve a proper purpose, as when a surgeon performs an operation that he knows is very likely to be fatal but reasonably thinks to be necessary because the patient has no other, safer chance.”⁵¹²

In cases of opioid prescribing, it would seem that the inquiry regarding recklessness or criminal negligence would focus on the risk of prescribing, including not only potential overdose and addiction, but also diversion. However, with the prescribing of any narcotic, there is a risk that the drug may be abused or diverted. Yet, the physician must weigh that risk against the real need of the patient for pain relief. Because a physician attempting to treat a patient for pain will virtually always have a justification for such risk, these lower standards are inherently unworkable. As a result, I argue for a higher criminal standard that would help to clearly separate negligent or reckless behavior, which can be more appropriately dealt with in the civil justice system, from criminal behavior. Such a standard would require that the physician had knowingly or intentionally⁵¹³ prescribed a controlled substance for a *non medical purpose or a purpose not authorized by law and that the physician received a tangible benefit (in excess of ordinary fees) for his prescribing.*⁵¹⁴ In order to prevent the knowing standard from crossing into a reckless or negligence test, a willful blindness instruction would not be permitted.

In the cases that have gone to court, prosecutors have generally not provided evidence of financial gain or other benefit on the part of the physician, other than office fees, nor evidence of intent to divert. Frequently, however, evidence is brought forth that “patients” lied to receive their drugs. The proposed higher standard would change the nature of the evidence and expert testimony required for successful prosecution from one where physicians are called upon to testify to the defendant’s lack of conformance with current standards of practice to one where evidence of financial gain or other benefit is put forward to establish intent or knowledge.

This higher standard for criminal prosecution also seems appropriate in this context when considering the goals of the criminal justice system: specific and general deterrence, incapacitation, and retribution.⁵¹⁵ The current standard, i.e., prosecuting pain physicians for prescribing large doses of opioids that seem inconsistent with legitimate medical practice, arguably has had an excessive deterrent effect that greatly reduces the

512. MODEL PENAL CODE & Commentaries § 2.02 cmt. 3 (1985).

513. The *Model Penal Code* defines four kinds of culpability that may serve to establish criminal conduct: purposely, knowingly, recklessly, and negligently. See MODEL PENAL CODE § 2.02(2) (1962).

514. Hoffmann, *supra* note 392.

515. *Id.*

number of physicians willing to treat chronic pain patients.⁵¹⁶ Moreover, incapacitation—through incarceration—is unnecessary to keep suspect physicians from doing harm, as the Attorney General can revoke their DEA registration and the state medical board can revoke or suspend their license to practice.⁵¹⁷

In determining whether to revoke registration from a practitioner, the Attorney General must determine whether such registration is “inconsistent with the public interest.”⁵¹⁸ In determining the public interest, the Attorney General considers, among other factors, whether the applicant has maintained “effective controls against diversion of . . . controlled substances.”⁵¹⁹

Finally, retribution does not seem appropriate when there is some evidence of prescribing for a legally authorized purpose and when there are other means, besides criminal prosecution, to deal with physicians who are dangerous or incompetent in their prescribing.⁵²⁰ Along with registration or licensure revocation, “physicians who prescribe in a manner that is below a professional ‘standard of care,’ and that harms a patient or third party to whom the physician owes a duty, should be liable for civil negligence.”⁵²¹ Such interventions are arguably better suited to prescribing for chronic pain patients, where physicians are required to make “tough judgment calls.”⁵²²

B. A Greater Role for State Medical Boards

While a higher standard for criminal liability will benefit physicians treating chronic pain patients (and their patients), such a higher standard should be accompanied by more aggressive action on the part of state medical boards to weed out physicians who are engaging in prescribing practices that are unsafe, inappropriate, or inconsistent with prevailing standards of care.

State medical boards are certainly better equipped to determine whether the volume and dosages of opioids prescribed for a patient are consistent with acceptable medical practice than are federal and state prosecutors. Moreover, state medical boards have taken action in numerous cases where

516. *Id.*

517. *Id.*; see also Diane E. Hoffmann, *Can State Medical Boards Adequately Respond to Reports that Physicians Are Inappropriately Prescribing Opioids?*, 81 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 799, 800 (2007) (discussing the option of having state medical boards handle these cases instead of prosecutors).

518. 21 U.S.C. § 824(a)(4) (2000).

519. *Id.* § 823(b)(1).

520. Hoffmann, *supra* note 392.

521. *Id.*

522. *Id.*

physicians have improperly prescribed opioids.⁵²³ Although boards were criticized for overaggressive actions against physicians for prescribing opioids in the late 1980s and early 1990s,⁵²⁴ more recent studies indicate that state boards, consistent with guidelines published by the Federation of State Medical Boards,⁵²⁵ have tempered their actions against physicians for prescribing high dosages of opioids and “have made significant progress in adjusting their requirements for disciplinary actions to better reflect emerging standards of care for pain treatment.”⁵²⁶

While state medical boards are more likely to have the institutional competency to assess inappropriate prescribing, they also have shortcomings that may limit their effectiveness as a primary enforcer with regard to disciplinary action or other sanctions against physicians for inappropriate prescribing. As currently constituted, state boards are often underfunded and understaffed and, as a result, not sufficiently aggressive in pursuing physician wrongdoing. Moreover, resource constraints can result in delays in investigation, charging, and license revocation.⁵²⁷ While state medical boards, “with evidence that a physician’s medical practice presents a threat to public health and safety . . . have the ability to issue a summary suspension under which a physician’s license can be suspended immediately, this option is seldom used.”⁵²⁸

If we were to rely on state medical boards to take a more active role in disciplining physicians in light of a higher criminal standard for arrest and prosecution of physicians for opioid prescribing, additional resources would need to be allocated to this function and structural mechanisms put in place to allow boards to “fast track” these cases.⁵²⁹ A separate review committee, including experts in pain management, would help ensure that more accurate decisions are made and that, when appropriate, summary

523. See Hoffmann, *supra* note 517, at 799.

524. See, e.g., *Hoover v. Agency for Health Care Admin.*, 676 So. 2d 1380, 1385 (Fla. Dist. Ct. App. 1996), in which the Florida Court of Appeals referred to the Florida Medical Board’s “policing [of] pain prescription practice[s]” as a “draconian policy.”

525. FED’N OF STATE MED. BDS. OF THE U.S., *supra* note 281; see also Hoffmann, *supra* note 517, at 800 (“These guidelines, adopted by many states, make clear that fostering effective pain relief is a goal of the regulatory process, [and] that physician prescribing will not be judged by volume or duration of prescribing alone but instead by patient outcomes . . .”).

526. Hoffmann, *supra* note 517, at 800; see also *id.* (concluding, based on a 2002 survey of state medical boards, “that boards seem to be moving away from volume or quantity as a primary basis for investigating a physician for overprescribing opioids and are looking more to compliance with established guidelines for appropriate prescribing as the basis for investigation and discipline”).

527. *Id.*

528. *Id.* at 800-01 (footnote omitted).

529. *Id.* at 801.

suspension and disciplinary action would accompany unsafe or incompetent prescribing practices.

X. CONCLUSION

Recent arrests and prosecutions of physicians for prescribing opioids used to treat pain under section 841(a) of the Controlled Substances Act have had a chilling effect on physicians' willingness to treat pain. The fear on the part of physicians is, in large part, based on the uncertainty surrounding the criminal standard and the inability of the DEA and law enforcement agents to clearly articulate practices that are outside the bounds of professional practice. The current standard, i.e., prescribing outside the bounds of professional practice or for other than a legitimate medical purpose, is vague and does not adequately draw the line between what constitutes acceptable and unacceptable conduct. Moreover, the difference between the CSA's criminal standard and a civil malpractice standard is not intuitively obvious and has confused jurors.

The law creates a further barrier to physician willingness to treat chronic pain patients by virtue of the fact that failure to treat and undertreating pain can result in malpractice liability and disciplinary action by state medical boards. These factors collude, resulting in significant undertreatment of patients with chronic pain.

Thus, the current standard inappropriately calibrates the balance between the dual goals of treating pain and reducing drug abuse and diversion and needs to be recalibrated. This recalibration calls for a change in the criminal standard to one that requires a showing of purposeful or knowing action on the part of a physician. While some may argue that this standard tips the scales too far in the other direction, such an overcorrection is arguably warranted. The result may mean that more individuals will be able to obtain opioids for their own use or for sale to others, but it will also mean that more individuals will be rescued from the agony of their untreated pain.

