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Fear of Prescribing: How the DEA Is Infringing on Patients' Right to Palliative Care

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Fear of Prescribing: How the DEA Is Infringing on Patients' Right to Palliative Care

ASHLEY BRUCE TREHAN*

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INTRODUCTION

[The patient was] confused, could not move his legs, had difficulty breathing, and was in excruciating pain – screaming whenever he moved and grimacing with each breath. He was near death. . . . He was given a subcutaneous infusion of opioids . . . 30 percent higher than his usual dose, and the nurses were instructed to give him another dose, equal to 10 percent of the total daily dose, “as needed” every half hour if he appeared to be in pain (the proper approach, according to standard guidelines).¹

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1. Timothy E. Quill & Diane E. Meier, *The Big Chill: Inserting the DEA into End-of-Life Care*, 354 NEW ENG. J. MED. 1, 2 (2006).

This patient was in an advanced stage of lung cancer.² Because the attending physicians and nurses feared hastening the patient's death – a crime in many states if done knowingly³ – the nurses did not give him the “as needed” dose of opioids.⁴ Only after consulting ethicists and palliative care experts did the staff administer opioids to relieve the patient's agonizing pain, and even after the consultation, some of the nurses doubted that they had done the right thing.⁵

Fear of hastening death is one of several contributing factors leading physicians to administer inadequate pain relief. Abuse of painkillers such as OxyContin has led the Drug Enforcement Administration (“DEA”) to heavily scrutinize physicians who prescribe the drugs to patients.⁶ Stricter enforcement of these physicians is a result of addicts posing as seriously ill patients who need the drug.⁷ Dr. Timothy Quill⁸ protests the DEA's actions, claiming that they will deter otherwise competent, ethical physicians from prescribing such medication.⁹ Quill argues that physicians' fear of stringent government regulation hinders effective end-of-life (palliative) care to patients suffering from terminal conditions.¹⁰ Quill says that “[m]ore than 90 percent of the pain associated with severe illness can be relieved if physicians adhere to well-established guidelines and seek help, when necessary, from experts in pain management or palliative care,” and “there is a growing consensus that sedation to the point of comfortable sleep is permissible.”¹¹

Case law and legislation highlight the double-edged sword that physicians face in their treatment of terminally ill patients. On one hand, ethical and legal considerations require that physicians treat patients to the best of their ability or potentially face heavy fines. On the other hand, the DEA's actions instill caution and even fear in physicians who do not want to be investigated for overprescribing medication to terminally ill patients.

This Note proposes that the DEA's stringent crackdown on the pre-

2. *Id.*

3. *See, e.g.*, MD. CODE ANN., CRIM. LAW § 3-103(a) (West 2006) (permitting physicians to “administer[] or prescrib[e] a procedure or . . . medication to relieve pain, even if the medication or procedure may hasten death or increase the risk of death, unless the licensed health care professional” does so knowing the prescription will hasten the patient's death).

4. Quill & Meier, *supra* note 1, at 2.

5. *Id.*

6. Jane Brody, *Let's Get Serious About Relieving Chronic Pain*, N.Y. TIMES, Jan. 10, 2006, at F7.

7. *See id.*

8. Dr. Quill is a professor at the University of Rochester School of Medicine and the director of the Center for Palliative Care and Clinical Ethics. Quill & Meier, *supra* note 1, at 3.

9. *Id.*

10. *Id.*

11. *Id.* at 1.

scription of pain medications adversely affects physicians' treatment of terminally ill patients and violates patients' right to pain relief. Part I provides an overview of palliative care and its role in end-of-life care. Part II argues that patients have a right to pain relief, supported by a survey of state legislation and Supreme Court cases. Part III outlines the regulations governing physicians' prescription practices at the federal and state level. Part IV details some of the consequences arising from such regulation from the perspective of physicians as well as pain patients. Part V highlights the decision rendered in *Gonzales v. Oregon*¹² and discusses the impact, or lack thereof, of this highly anticipated decision on the medical and legal landscape. Finally, Part VI proposes solutions – both tangible and conceptual – to remedy the increasing tension between relieving pain and regulatory oversight.

I. UNDERSTANDING PALLIATIVE CARE

A. *Defining Palliative Care*

"Palliative" is defined as "[r]educing the severity of; denoting the alleviation of symptoms without curing the underlying disease."¹³ The National Cancer Institute ("NCI"), a subset of the Department of Health and Human Services ("DHHS"), defines palliative care as "[c]are given to improve the quality of life of patients who have a serious or life-threatening disease."¹⁴ In its definition, the NCI states that "[t]he goal of palliative care is to prevent or treat as early as possible the symptoms of the disease, side effects caused by treatment of the disease, and psychological, social, and spiritual problems related to the disease or its treatment," and palliative care is sometimes referred to as "comfort care, "supportive care, [or] symptom management."¹⁵ Similar to the NCI's stated goal, New York legislation states that the goal of palliative care is to "achieve[] . . . the best quality of life for patients and families."¹⁶ Also writing about the importance of palliative care, physicians in a 1999 article focused on how to constructively converse with terminally ill patients about the end of their lives.¹⁷ Like the NCI, this article states that the goal of palliative care is to "focus[] on relief of suffering, psychosocial support, and, as much as possible, closure near the end of

12. 126 S. Ct. 904 (2006).

13. STEDMAN'S ONLINE MEDICAL DICTIONARY, <http://www.stedmans.com/> (type "palliative" in search box; then click "GO"; then click "palliative") (last visited Feb. 1, 2007).

14. NATIONAL CANCER INSTITUTE, NCI DICTIONARY OF CANCER TERMS, http://www.cancer.gov/Templates/db_alpha.aspx?print=1&cdrid=269448 (last visited Feb. 1, 2007).

15. *Id.*

16. N.Y. PUBLIC HEALTH LAW § 4012-b(2)(b) (McKinney 2006).

17. Bernard Lo et al., *Discussing Palliative Care with Patients*, 130 ANNALS INTERNAL MED. 744 (1999).

life.”¹⁸ Another author defined palliative care as “the study and management of patients with active, progressive, far advanced disease, for whom the prognosis is limited and the focus of care is the quality of life.”¹⁹ Alaska’s statute defines palliative care as “medical care or treatment rendered to reduce or moderate temporarily the intensity of pain caused by an otherwise stable medical condition, but does not include those medical services rendered to diagnose, heal, or permanently alleviate or eliminate a medical condition.”²⁰

Other state definitions will be discussed below. These definitions highlight the importance of distinguishing palliative care from life support methods (i.e., a feeding tube) in that palliative care does not aim to prolong a patient’s life. Rather, it is a method of alleviating physical pain as well as psychological and spiritual strife. Indeed, such a distinction serves as the backdrop in the “clash of absolutes” between curative care and palliative care.²¹ The problem with emphasizing curative care, according to one author, is that it is “hostile to effective care of chronic pain patients, [and] to patients with terminal illness as well.”²² As for which “side” of the debate is currently winning, research paints a convincing picture that the curative approach to treatment is prevailing.²³

B. *Physical Pain Relief*

“Common misconceptions are that opioids are dangerous, cause addiction, shorten life, or are used only as a last resort. In fact, they are relatively safe, rarely if ever cause addiction or respiratory depression in the terminally ill, and are a mainstay of therapy . . . for pain.”²⁴

OxyContin is an opioid narcotic containing oxycodone, a pain reliever similar to morphine, which is released slowly over time.²⁵ Most states have enacted statutes deeming opioids such as OxyContin to have “legitimate, therapeutic uses for the treatment of chronic pain.”²⁶ The Food and Drug Administration’s (“FDA”) Web site contains this and

18. *Id.*

19. N. MacDonald, *Palliative Care: The Fourth Phase of Cancer Prevention*, 253 *CANCER DETECTION & PREVENTION* 5 (1991).

20. ALASKA STAT. § 23.30.395(28) (2006).

21. Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 *WM. MITCHELL L. REV.* 1, 21 (2000).

22. *Id.* at 23.

23. *Id.* at 22-25.

24. Lo et al., *supra* note 17, at 748.

25. U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *OxyContin: Questions and Answers*, Aug. 2, 2001, <http://www.fda.gov/cder/drug/infopage/oxycontin/oxycontin-qa.htm#whatkind>.

26. Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 *J.L. MED. & ETHICS* 332, 332 (1998).

other factual information about opioids, but the bulk of the information about OxyContin is cautionary.²⁷ The frequency of OxyContin fatalities and reported addictions discourages physicians from prescribing the narcotic, but some argue that this should not prevent use by patients who are suffering a considerable amount of pain.²⁸

C. Social, Psychological, and Spiritual Comfort

The focus of this Note is on physical pain relief and the DEA's interference with such relief; however, palliative care also requires a therapeutic approach to each patient's social, psychological, and spiritual well-being. To administer effective palliative care beyond physical pain relief, a physician must possess the communication skills necessary to discuss end-of-life care and respond to difficult questions from the patient or the patient's family.²⁹ Although essential, communication is sometimes not sufficient in providing the patient with end-of-life comfort, especially if the patient is religious. Effective palliative care thus often involves seeking outside help from a rabbi or priest to address the patient's spiritual concerns.³⁰ Caring for a patient who is close to death requires the physician to be acutely aware of the patients' concerns both physically and emotionally; this extremely personal level of care and communication is what makes palliative care unique from curative treatment.

II. PATIENTS HAVE A RIGHT TO PALLIATIVE CARE

A. Constitutional Right

The Supreme Court's opinions in *Cruzan v. Director, Missouri Department of Health*,³¹ *Washington v. Glucksberg*,³² and *Vacco v. Quill*³³ have come close to recognizing that access to pain relief may be a fundamental right.³⁴ This right to palliative care, however, should follow from the logical relationship between liberty, privacy, and autonomy.³⁵

The *Cruzan* opinion assumes that there is a liberty interest in refus-

27. See, e.g., *id.* at 332, 336.

28. See generally Brody, *supra* note 6; Quill & Meier, *supra* note 1, at 1.

29. See Lo et al., *supra* note 17, at 746.

30. *Id.* at 746-47.

31. 497 U.S. 261 (1990).

32. 521 U.S. 702 (1997).

33. 521 U.S. 793 (1997).

34. See Beth Packman Weinman, *Freedom from Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495, 525 (2003).

35. See *id.* at 524 (citation omitted).

ing medical treatment.³⁶ *Cruzan* is a seminal case in the right to die debate, not only because of its holding, but also for the issues left open after the case. The plaintiffs' daughter, Nancy Cruzan, suffered severe injuries in a 1983 car accident, rendering her incompetent and in a persistent vegetative state, yet not terminally ill.³⁷ Cruzan's parents wished to remove their daughter's life-sustaining feeding tube, and when the hospital refused to do so, the Cruzans received injunctive relief from the trial court to terminate the nutrition.³⁸ On appeal, the Missouri Supreme Court reversed, holding that "clear and convincing, inherently reliable evidence" with respect to Cruzan's wishes was not presented in the case.³⁹ The broad issue for the U.S. Supreme Court was "whether Cruzan ha[d] a right under the United States Constitution which would require the hospital to withdraw life-sustaining treatment from her under these circumstances."⁴⁰ The Court later framed the issue as "whether the United States Constitution grants what is in common parlance referred to as a 'right to die.'"⁴¹

The narrow holding is not what makes *Cruzan* so important in establishing a right to palliative care.⁴² Rather, Chief Justice Rehnquist's opinion relies largely on the preservation of life and the "maintenance of the ethical integrity of the medical profession."⁴³ The opinion asserts that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment" based on prior Supreme Court decisions.⁴⁴ By emphasizing the liberty interest in refusing unwanted treatment, the opinion implicitly acknowledges the necessity of pain relief. It would be inconsistent for the Court to acknowledge a liberty interest in refusing pain relief but deny an interest in providing or accepting pain relief, as long as it is done so in accordance with legal, medical, and ethical principles.

In *Washington v. Glucksberg*, four physicians, three terminally ill patients, and the non-profit organization Compassion in Dying challenged a Washington statute criminalizing physician-assisted suicide.⁴⁵

36. *Cruzan*, 497 U.S. at 278 ("The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.").

37. *Id.* at 266 & n.1.

38. *Id.* at 267-68.

39. *Id.* at 268-69.

40. *Id.* at 269.

41. *Id.* at 277.

42. The Court ultimately held that it was constitutionally permissible for Missouri to adopt a clear and convincing evidence standard with respect to an incompetent's wishes regarding the removal of life-sustaining treatment. *Id.* at 280-81.

43. *Id.* at 271.

44. *Id.* at 278.

45. *Washington v. Glucksberg*, 521 U.S. 702, 707-08 (1997).

The plaintiffs argued that the statute violated a "mentally competent, terminally ill" adult's liberty interest in committing suicide.⁴⁶ Chief Justice Rehnquist, writing for a five-member majority, rejected this argument and "conclude[d] that the asserted 'right' to assistance in committing suicide is not a fundamental liberty interest."⁴⁷ Rehnquist distinguished *Cruzan* by emphasizing the distinction between the right to refuse unwanted medical treatment and the right to commit suicide; the former, but not the latter, has historically enjoyed common law protection.⁴⁸ One commentator views this distinction as an implied grant of a right to palliative care: "By authoritatively pronouncing that terminal sedation intended for symptomatic relief is not assisted suicide, the Court has licensed an aggressive practice of palliative care."⁴⁹ Dr. Quill agrees with the notion that the *Glucksberg* opinion contains implicit approval of aggressive palliative care, writing that "[t]he justices were concerned about the current inadequacies of access to and delivery of palliative care."⁵⁰

As a companion case to *Glucksberg*, *Vacco v. Quill* similarly upheld the constitutionality of a statute criminalizing assisted suicide.⁵¹ Physicians and terminally ill patients challenged New York's criminalization of assisted suicide under the Equal Protection Clause of the Fourteenth Amendment.⁵² The plaintiffs claimed that the prohibition ran counter to New York's legislation and case law permitting a competent person to refuse lifesaving medical treatment.⁵³ At trial, the district court rejected the plaintiffs' arguments, citing the "difference between allowing nature to take its course . . . and intentionally using an artificial death-producing device."⁵⁴ The Second Circuit Court of Appeals reversed the lower court's decision, finding a violation of the Equal Protection Clause based on the fact that New York did not treat equally all "competent persons who are in the final stages of fatal illness and wish to hasten their deaths."⁵⁵ The Supreme Court reversed the Second Circuit's decision.⁵⁶

46. *Id.* at 708 (internal quotations and citation omitted).

47. *Id.* at 728.

48. *Id.* at 725.

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

50. Timothy E. Quill, *Retrospective: Dying and Decision Making: Evolution of End-of-Life Options*, 350 NEW ENG. J. MED. 2029, 2030 (2004).

51. 521 U.S. 793, 800-01 (1997).

52. *Id.* at 797-98.

53. *Id.* at 798.

54. *Quill v. Koppell*, 870 F. Supp. 78, 84 (S.D.N.Y. 1994).

55. *Quill v. Vacco*, 80 F.3d 716, 727 (2d Cir. 1996).

56. *Vacco v. Quill*, 521 U.S. at 809.

In its opinion, the Supreme Court explicitly distinguished palliative care from physician-assisted suicide by saying: "[W]hen a doctor provides aggressive palliative care[,] . . . painkilling drugs may hasten a patient's death, but the physician's purpose and intent is . . . only to ease his patient's pain. A doctor who assists a suicide, however, must, necessarily and indubitably, intend primarily that the patient be made dead."⁵⁷ In a footnote at the end of the case, Chief Justice Rehnquist noted that "a State . . . may permit palliative care related to that refusal [of unwanted medical treatment], which may have the foreseen but unintended 'double effect' of hastening the patient's death."⁵⁸ This assertion is significant because it gives the states permission to grant a right to palliative care, even if such aggressive pain relief will hasten a patient's death. When the two aforementioned statements are read together, there is a strong inference that aggressive palliative care has been approved by the Court. Throughout the opinion, the Court distinguished assisting suicide from administering palliative care and acknowledged the overwhelming trend, even as of 1997 when the opinion was written, "to protect and promote patients' dignity at the end of life."⁵⁹

Although there was no majority on all of the issues in *Glucksberg* and *Quill*, Beth Packman Weinman analyzed the concurring opinions and concluded that at least four Justices of the Rehnquist Court asserted a fundamental right to pain relief.⁶⁰ Similarly, a 1997 editorial focused on these concurrences and concluded that a majority in both opinions "provided an unexpected but strong and very welcome directive requiring states to remove the barriers that their laws and policies impose on the availability of palliative care."⁶¹ The Court did not explicitly assert a fundamental right to palliative care in these seminal opinions, but it also was not presented squarely with the issue.

Justice O'Connor's concurrence highlights the importance of achieving a "balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure."⁶² Justice O'Connor points out the significance of the availability of palliative care to terminally ill patients in Washington and New York at the time the decision was rendered.⁶³ Justice

57. *Id.* at 802 (quotations and citation omitted).

58. *Id.* at 808 n.11 (citation omitted).

59. *Id.* at 804-06 (internal quotations and citation omitted).

60. Weinman, *supra* note 34, at 526-29.

61. Burt, *supra* note 49, at 1237.

62. *Washington v. Glucksberg*, 521 U.S. 702, 737 (O'Connor, J., concurring).

63. *Id.* at 736-37 ("[I]n these States a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians,

Breyer's concurrence in *Glucksberg* and *Quill*⁶⁴ concludes with a forceful implication that the Court may recognize a right to palliative care: "[W]ere state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life[,] then the law's impact upon serious and otherwise unavoidable physical pain (accompanying death) would be more directly at issue."⁶⁵ Although the immediate intent behind this concluding statement was to give an example of a "gap" in the law that might justify assisted suicide after *Quill* and *Glucksberg*, it assumes the need for further exploration by the Supreme Court as to whether patients have a right to receive pain relief. Justice Breyer also notes that the New York and Washington laws at the time of these two cases "[did] not prohibit doctors from providing patients with drugs sufficient to control pain despite the risk that those drugs themselves will kill."⁶⁶ Justice Stevens' concurrence is even more explicit in asserting a patient's need and right to palliative care. He agrees with the states on one level, that "[e]ncouraging the development and ensuring the availability of adequate pain treatment is of utmost importance," although he refuses to conclude that availability of palliative care should render assisted suicide illegal.⁶⁷ However, using the holdings of *Quill* and *Glucksberg* as a premise, along with Justice Stevens' statement, a statewide ban on assisted suicide seems to necessitate a regime of aggressive palliative care. In other words, if a state has a "legitimate interest[] in preventing suicide,"⁶⁸ then it should follow that citizens of that state have a right to receive the best pain management possible if they are in such a condition. Justice Stevens also makes reference to a liberty interest in dying with dignity.⁶⁹

B. Statutory Right

States are increasingly enacting regulations dealing with palliative care, pain management, or pain relief.⁷⁰ There is also a growing trend in

to alleviate that suffering, even to the point of causing unconsciousness and hastening death."); *id.* at 737-38 ("There is no dispute that dying patients in Washington and New York can obtain palliative care, even when doing so would hasten their deaths.").

64. The concurrences of Justices O'Connor, Breyer, Souter, Ginsburg, and Stevens apply to both *Washington v. Glucksberg* and *Vacco v. Quill*.

65. *Glucksberg*, 521 U.S. at 792 (Breyer, J., concurring); *Vacco v. Quill*, 521 U.S. 793, 810 (Breyer, J., concurring).

66. *Glucksberg*, 521 U.S. at 791 (Breyer, J., concurring); *Vacco*, 521 U.S. at 810 (Breyer, J., concurring).

67. See *Glucksberg*, 521 U.S. at 747, 749-50 (Stevens, J., concurring).

68. *Id.* at 747.

69. See, e.g., *id.* at 743 ("This freedom embraces not merely a person's right to refuse a particular kind of unwanted treatment, but also her interest in dignity, and in determining the character of the memories that will survive long after her death.").

70. Timothy McIntire, *Elder Abuse Litigation and the Duty to Provide Palliative Care*,

states establishing a "Patient's Bill of Rights." To discern whether there is an express or implied right to palliative care contained in these regulations, it is important to first understand the context in which each state regulates "palliative care" and the treatment of "intractable pain." This Part contains a survey of state laws and concludes that, based on the widespread recognition of a need for adequate pain treatment, and in some cases an explicit "right" to receive adequate pain treatment, there is a fundamental right to palliative care.

Alaska defines palliative care in its "Labor and Workers' Compensation" statute, but it does not go further into detail about that to which the general public is entitled with respect to such pain management.⁷¹ In California's Health and Safety Code, a hospice, in its role as a "Special Hospital,"⁷² "shall be deemed to provide acute palliative care."⁷³ Most states that incorporate the phrase "palliative care" into their statutory regime use the phrase in a similar manner to California's hospice statutes⁷⁴ or Alaska's workers' compensation regulations.⁷⁵ States with extensive living wills or advance healthcare directive legislation have

PHYSICIAN EXECUTIVE, Nov.-Dec. 2004, at 45 ("For the protection of physicians and clients alike, many states adopted specific palliative care and intractable pain management statutes or regulations. While the need to limit patient narcotic abuse is still present, many states realize this need must be balanced with guidelines for the treatment of the elderly and the terminally ill suffering from intractable pain. As such, many states emphasize concerns involving narcotics in both the addiction aspect and the treatment of pain in the elderly and the terminally ill."); *see also* AMERICAN PAIN SOCIETY, THE USE OF OPIOIDS FOR THE TREATMENT OF CHRONIC PAIN (1996), available at <http://www.ampainsoc.org/advocacy/opioids.htm> ("State law and policy about opioid use are currently undergoing revision. The trend is to adopt laws or guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.").

71. ALASKA STAT. § 23.30.395(28) (2006).

72. CAL. HEALTH & SAFETY CODE § 1339.31(a) (Deering 2006) (using the phrase "palliative care" in its definition of a hospice and providing seven mandatory criteria of what amounts to palliative care); § 1339.31(e) (defining the term "special hospital: hospice").

73. § 1339.32.

74. *See* COLO. REV. STAT. § 25-1.5-103(2)(d) (West 2006); § 400.601(4), FLA. STAT. (2006); GA. CODE ANN. §§ 31-7-171(b), -172(5) (2006); 210 ILL. COMP. STAT. 60/3(d) (West 2005); IND. CODE §§ 12-15-40-5(1), 16-25-1.1-6(1) (West 2006); IOWA CODE § 1351.3(4) (2005); LA. REV. STAT. ANN. § 40:2182(4), (6) (2006); ME. REV. STAT. ANN. tit. 22, § 8621(9) (2006); MICH. COMP. LAWS ANN. § 333.21534 (West 2006); MINN. STAT. ANN. § 144A.753(2)(3) (West 2006); MISS. CODE ANN. § 41-85-3(d) (West 2006); NEB. REV. STAT. § 71-418 (2006); N.H. REV. STAT. ANN. § 151-C:2(XIX-b) (2006); N.Y. PUB. HEALTH LAW § 4012-b(2)(b) (McKinney 2006); N.C. GEN. STAT. § 131E-201(8) (West 2006); N.D. CENT. CODE § 23-17.4-01(8) (2006); OHIO REV. CODE ANN. § 3712.01(E) (West 2006); OKLA. STAT. tit. 63, § 1-860.2(8) (2006); TEX. HEALTH & SAFETY CODE ANN. § 142.001(15) (Vernon 2006); VA. CODE ANN. § 32.1-162.1 (West 2006); WASH. REV. CODE § 70.38.230(2) (West 2006); WIS. STAT. § 50.90(3) (West 2006).

75. *See* § 440.13(n), FLA. STAT. (2006); MONT. CODE ANN. § 39-71-116(22) (2006); N.C. GEN. STAT. § 97.25-4 (West 2006); OR. REV. STAT. ANN. § 656.005(20) (West 2006); R.I. GEN. LAWS § 28-33-10(c) (2006).

incorporated palliative care into such a regime.⁷⁶ A few states have set out a clear legislative intent to provide pediatric patients with better palliative care.⁷⁷ Until July 2006, Florida encouraged physicians to continue their education in palliative care by allowing a physician to do so in lieu of continuing education in HIV.⁷⁸ States like Florida, Virginia, and Maine require the appropriate agency to pay for palliative care under their respective healthcare regulations.⁷⁹ Maryland explicitly provides an exception for "palliative care" and pain relief from its criminalization of assisted suicide, "even if the medication or procedure may hasten death or increase the risk of death," unless the physician does so with the intent to hasten death.⁸⁰ New York's controlled substances provision explicitly highlights that palliative care is a "legitimate use of controlled substances."⁸¹ North Carolina even gives the Secretary of Correction discretion to authorize a prisoner to leave the confines of the institution to receive palliative care if terminally ill or permanently disabled.⁸²

Many states have specific commissions devoted to increasing understanding and awareness of palliative care. Missouri has a State Advisory Council on Pain and Symptom Management and requires the Council to include "[o]ne physician . . . that is certified and accredited in palliative care."⁸³ Similarly, New Hampshire's Department of Health and Human Services Oversight Committee is required to study "[h]ow to increase understanding and access to palliative care services in all areas of the state."⁸⁴ As part of its Health Care Facilities Planning Act, New Jersey requires its Commissioner of Health and Senior Services to consult with, among other groups, the New Jersey Hospice and Palliative Care Organization.⁸⁵ New Jersey also requires its State Commission on Cancer Research to "encourage the development within the State of research projects on . . . pain management and palliative care for persons

76. See §§ 765.102, 110, 1103, FLA. STAT. (2006); MONT. CODE ANN. § 50-9-102 (West 2006); R.I. GEN. LAWS § 23-4.11-2 (West 2006); TENN. CODE ANN. § 32-11-103 (West 2006).

77. See LA. REV. STAT. ANN. § 40:2175.12(B)(3) (2006) (incorporating "palliative care" in the definition of a "children's respite care center"); R.I. GEN. LAWS § 42-12.3-8(b) (2006) ("[T]he department of human services shall also provide pediatric palliative care services to eligible children under the age of nineteen (19) years who have a terminal illness . . .").

78. See § 458.319(4), FLA. STAT. (2006) (repealed 2006).

79. § 409.905(6), FLA. STAT. (2006); ME. REV. STAT. ANN. tit. 22, § 3174-FF(3)(E)(3) (2006) (MaineCare Basic); VA. CODE ANN. § 38.2-3418.11 (2006) (Virginia Coverage for hospice care).

80. MD. CODE ANN., CRIM. LAW § 3-103(a) (West 2006).

81. N.Y. PUB. HEALTH LAW § 3300-a(2) (McKinney 2006).

82. N.C. GEN. STAT. ANN. § 148-4(8) (West 2006).

83. MO. REV. STAT. ANN. § 192.350(6) (West 2006).

84. N.H. REV. STAT. ANN. § 126-A:15(I-a)(b) (West 2006).

85. N.J. STAT. ANN. § 26:2H-5c (West 2006).

diagnosed with cancer.”⁸⁶ New York’s State Board for Professional Medical Conduct requires at least one of its (minimum) eighteen physicians to “have expertise in palliative care.”⁸⁷ Such widespread recognition of the increasing importance of palliative care demonstrates that states intend for their citizens to receive end-of-life pain relief.

With the same general goal of relieving pain, at least twenty-three states have statutes regulating the treatment of chronic, intractable pain.⁸⁸ A common thread in Intractable Pain Treatment Acts (“IPTA”) is the emphasis on accessibility of pain treatment to patients,⁸⁹ as well as the regular incorporation of pain treatment in a physician’s medical practice for patients who suffer chronic intractable pain.⁹⁰ These statutes were created with the aim of “provid[ing] physicians with some measure of regulatory relief by reducing the real and perceived risks of being subjected to regulatory sanctions for treating pain with opioids.”⁹¹

Some might argue that incorporating a phrase or concept into legislation is merely a sign that the state’s legislators acknowledge the existence of palliative care or pain management, not that the legislators are creating some fundamental right. However, some states, like Florida, plainly express that its citizens should have such a right:

The Legislature recognizes the *need* for all health care professionals to rapidly increase their understanding of end-of-life and palliative care. Therefore, the Legislature encourages the professional regulatory boards to adopt appropriate standards and guidelines regarding end-of-life care and pain management and encourages educational institutions established to train health care professionals and allied health professionals to implement curricula to train such professionals to provide end-of-life care, including pain management and palliative care.⁹²

The section explains palliative care in greater detail, enumerating eleven requirements to which a physician must adhere when administering palliative care, the first being a discussion with the patient regarding end-

86. N.J. STAT. ANN. § 52:9U-5(d)(2) (West 2006).

87. N.Y. PUB. HEALTH LAW § 230(1) (McKinney 2006).

88. Sandra H. Johnson, *The Social, Professional, and Legal Framework for the Problem of Pain Management in Emergency Medicine*, 33 J.L. MED. & ETHICS 741, 754 (2005) (“At least 23 state legislatures have enacted ‘intractable pain statutes’ to further affirm the importance of treating pain, and to set out some guidance for appropriate regulatory oversight of prescribing practices.”); see, e.g., Chronic Intractable Pain Treatment Act, ARK. CODE ANN. § 17-95-701 (West 2006); Intractable Pain Treatment Act, CAL. BUS. & PROF. CODE § 2241.5 (West 2007); Pain Patient’s Bill of Rights, CAL. HEALTH & SAFETY CODE pt. 4.5, § 124960 (West 2006).

89. See, e.g., ARK. CODE ANN. § 17-95-702(2) (West 2006); § 124960(h); see also Martino, *supra* note 26, at 332.

90. See § 17-95-702(3).

91. Martino, *supra* note 26, at 332.

92. § 765.102(4), FLA. STAT. (2006) (emphasis supplied).

of-life care, and the other ten being assurances of the level and quality of care the patient will receive.⁹³

Tennessee expresses a similar sentiment in its Living Wills statute, in that its legislative intent was to ensure "that every person has the *fundamental and inherent right* . . . to accept, refuse, withdraw from, or otherwise control decisions relating to the rendering of . . . palliative care."⁹⁴ On its face, a typical Living Wills or Rights for the Terminally Ill statute focuses on advanced directives in case the patient is eventually no longer competent. However, an analysis of the language of such regulations reveals a state interest in assuring that a patient will be treated adequately, unless the patient thinks otherwise. California legislation explicitly allows doctors to administer controlled substances to patients who are in pain.⁹⁵ California also makes clear that a physician who administers such a substance will not be subject to disciplinary action.⁹⁶

Many states have enacted Patient's Bills of Rights, which set out the level of care to which a patient is entitled.⁹⁷ Florida's Patient's Bill of Rights and Responsibilities grants patients the following rights: individual dignity; information; financial information and disclosure; access to healthcare; experimental research; and patient's knowledge of these

93. § 765.102(5)(b)(1)-(11). This section reads in full:

1. An opportunity to discuss and plan for end-of-life care.
2. Assurance that physical and mental suffering will be carefully attended to.
3. Assurance that preferences for withholding and withdrawing life-sustaining interventions will be honored.
4. Assurance that the personal goals of the dying person will be addressed.
5. Assurance that the dignity of the dying person will be a priority.
6. Assurance that health care providers will not abandon the dying person.
7. Assurance that the burden to family and others will be addressed.
8. Assurance that advance directives for care will be respected regardless of the location of care.
9. Assurance that organizational mechanisms are in place to evaluate the availability and quality of end-of-life, palliative, and hospice care services, including the evaluation of administrative and regulatory barriers.
10. Assurance that necessary health care services will be provided and that relevant reimbursement policies are available.
11. Assurance that the goals expressed in subparagraphs 1.-10. will be accomplished in a culturally appropriate manner.

§ 765.102(5)(b)(1)-(11).

94. TENN. CODE ANN. § 32-11-102(a) (2006) (emphasis supplied).

95. CAL. BUS. & PROF. CODE § 2241.5 (West 2007).

96. § 2241.5(b).

97. See, e.g., Pain Patient's Bill of Rights, CAL. HEALTH & SAFETY CODE § 124960 (West 2006); Florida Patient's Bill of Rights and Responsibilities, § 381.026, FLA. STAT. (2006); Pain Patient's Bill of Rights, HAW. REV. STAT. ANN. § 327H-2 (West 2006); Hospital Patient's Bill of Rights, MD. CODE ANN., HEALTH-GEN. § 19-342 (West 2006); Health Care Bill of Rights, MINN. STAT. ANN. § 144.651 (West 2006); Pain Patient's Bill of Rights, TENN. CODE ANN. § 63-6-1104 (2006).

rights and responsibilities.⁹⁸ Significantly, within the patient's right of "access to health care," Florida provides that "[a] patient has the *right to access* any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient."⁹⁹ This right is not conditioned on physician hesitation; it definitively says that a patient deserves treatment that is in his or her "best interests," according to both the patient and the physician. Tennessee's Pain Patient's Bill of Rights gives a patient in "severe chronic intractable pain" the right to "request . . . the use of any or all modalities in order to relieve" such pain.¹⁰⁰ The statute expressly allows physicians to prescribe opiate medication for the relief of chronic, intractable pain.¹⁰¹ While it does allow a physician to refuse to prescribe such medication, it requires that, as an alternative, the physician "shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates."¹⁰² California's Pain Patient's Bill of Rights is almost identical to Tennessee's.¹⁰³ Hawaii's Pain Patient's Bill of Rights is similar in content to Tennessee's and California's, though a bit narrower in its protection of patient rights because it gives a physician discretion to tell the patient that there are other physicians who specialize in treatment of pain through the use of opiates.¹⁰⁴ Nearly every state provides some form of a "right" for a patient to receive palliative care or pain management. However, because these rights are often implicit, Congress should evaluate the status of pain patients and end-of-life treatment in the United States.

C. *Medicine and Ethics: A Duty to Relieve Suffering*

The Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("Model Guidelines") aim to apply uniform standards across the medical boards of each state.¹⁰⁵ In its Preamble, the Model Guidelines "recognize[] that principles of quality medical practice dictate that the people of the State . . . have access to appropriate and effective pain relief."¹⁰⁶ This language is mandatory, assuming that the

98. § 381.026(4).

99. § 381.026(4)(d)(3) (emphasis supplied).

100. § 63-6-1104(b).

101. § 63-6-1104(c).

102. § 63-6-1104(d).

103. See CAL. HEALTH & SAFETY CODE § 124961 (West 2006).

104. See HAW. REV. STAT. ANN. § 327H-2(3) (West 2006).

105. MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (Fed'n of State Med. Bds. of the United States, Inc. 1998), available at <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>.

106. *Id.* § 1.

physicians who abide by these guidelines aim at achieving "quality medical practice." It ensures that the pain patients in that state will be given proper pain relief, thus implying a right to pain relief and palliative care.

Additionally, many sources presume that physicians have a duty to relieve suffering.¹⁰⁷ A common logical correlation is that between duty and right: where there is a right, there is a duty, and vice versa.¹⁰⁸ One author explores the sources of a physician's duty to relieve pain and suffering, ranging from the Hippocratic Oath to philosophical assertions of a patient's "right to freedom from unnecessary pain."¹⁰⁹ Similarly, the American Medical Association Code of Medical Ethics enumerates an "obligation" of the physician to "provid[e] effective palliative treatment."¹¹⁰ One author asserts that "[e]ven when cure is impossible, the physician's duty of care includes palliation."¹¹¹

In sum, the *Vacco* and *Glucksberg* opinions leave open the question of whether there is a constitutional right to palliative care. Because of this "hole" and because the majority of states have a statutory scheme recognizing a patient's right to adequate pain treatment and palliative care, the time is ripe for either the Supreme Court or Congress to expressly deem that all patients, especially those suffering from intractable pain or terminal illness, have the right to palliative care.

III. REGULATING PRESCRIPTIONS

A. State Regulation

Each state has a state bureau of narcotics and medical licensure board¹¹² which, along with the federal DEA, regulates physicians' practice of prescribing controlled substances such as OxyContin and other Schedule II opioids. The importance of state medical boards in the regulation of physicians' conduct is at least equal to that of the DEA. The difficulty in regulating physician distribution of controlled substances is that two distinct, important public interests intersect and conflict: the

107. See, e.g., Johnson, *supra* note 88, at 742 ("The ethical duty to relieve pain is well established. . . . [T]he core ethical obligation to relieve pain is well established in medicine"); Rich, *supra* note 21, at 31.

108. See WESLEY NEWCOMB HOHFELD, *FUNDAMENTAL LEGAL CONCEPTIONS AS APPLIED IN JUDICIAL REASONING AND OTHER LEGAL ESSAYS* 36, 39 (Walter Wheeler Cook ed., 1919).

109. Rich, *supra* note 21, at 32-33 (quoting Rem B. Edwards, *Pain and the Ethics of Pain Management*, 18 SOC. SCIENCE & MED. 515, 517 (1984)). Other authors assume that physicians have an "obligation . . . to relieve human suffering" that "stretches back into antiquity." Eric J. Cassel, *The Nature of Suffering and the Goals of Medicine*, 306 NEW ENG. J. MED. 639, 639 (1982).

110. CODE OF MED. ETHICS 40 (Am. Med. Ass'n 1996).

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

112. See, e.g., N.D. CENT. CODE § 43-17-18 (2006); OKLA. STAT. tit. 63, § 2-101 (2006).

prevention of addiction and abuse and the aggressive treatment of pain, especially for the terminally ill. In a description of this balancing act, one author gives credit to state medical boards' initiatives to regulate drug abuse and overprescription without sacrificing the state's interest in providing effective treatment for pain patients.¹¹³ In 2004, the Federation of State Medical Boards revised their 1998 guidelines and enumerated three clear goals: "fostering effective pain relief"; judging a physician "not . . . by volume or chronicity alone, but rather by outcomes for the patients"; and obliging the physician to "perform and document a physician examination of the patient and a care plan that includes appropriate follow up."¹¹⁴ As mentioned in Part II, most states have enacted "intractable pain statutes," pain relief statutes, or regulations dealing with the proper administration of palliative care to terminally ill patients.¹¹⁵

State acknowledgment of the importance of pain treatment hardly precludes the state from disciplining physicians and deterring them from overprescribing controlled substances. One example of stringent state regulation is Multiple Copy Prescription Programs ("MCP"), which require physicians to "complete multipart government prescription forms and forward copies of the forms to a designated government agency that monitors prescriptions written and filled."¹¹⁶ California is one of few states that require physicians to fill out prescriptions in triplicate.¹¹⁷ States also limit the amount that a physician may prescribe and dispense to the patient, as well as the length of time a patient has before the valid prescription expires.¹¹⁸

B. Federal Regulation

Unlike the progressive actions of state medical boards, the DEA has tipped the "balance" in the opposite direction, increasing its restrictions and efforts to curb the prescription of controlled substances.¹¹⁹ Regulation of prescription drugs at the federal level is overseen by the DEA and the Controlled Substances Act ("CSA").¹²⁰ On October 30, 2003, the DEA issued a news release that sought to dispel the growing sentiment that the agency's regulation of physicians' prescribing prac-

113. Johnson, *supra* note 88, at 754.

114. *Id.*

115. *See supra* Part II.

116. Weinman, *supra* note 34, at 511 n.94.

117. *See id.* at 532 & n.225.

118. *Id.* at 536-37.

119. *See Johnson, supra* note 88, at 754.

120. 21 U.S.C.A. §§ 801-904 (West 2006).

tices had a "chilling effect."¹²¹ The news release stated that during the 2003 fiscal year, the DEA sanctioned less than one tenth of one percent (<0.1%) of registered physicians.¹²² However, this news release was issued against the backdrop of several documents that painted the DEA as an agency seeking to strike a balance between pain relief and drug abuse. The first statement, issued by the DEA along with twenty-one health organizations in 2001, explicitly approved "aggressive[]" pain management into end-of-life medical care as well as the use of opioids to effectively treat pain.¹²³ Two years after the release of this statement, a Principal Working Group consisting of a group of experts responsible for issuing the first statement produced a list of Frequently Asked Questions ("FAQ").¹²⁴ The FAQ was compiled by medical experts and was supported by the DEA, among other organizations.¹²⁵ The FAQ was deemed to "represent[] a consensus, supported by the available literature and by the laws and regulations that govern the use of controlled prescription drugs."¹²⁶

The DEA's apparent eagerness to work with the medical community to strike a balance between administering aggressive pain management and curtailing drug abuse and addiction came to a halt in 2004. The DEA issued an Interim Policy Statement, which explicitly revoked the FAQ they had supported just a few months earlier, claiming erroneous data and information.¹²⁷ The Interim Policy Statement conceded that the subject of prescribing pain medication is "extremely important to the public health and welfare" and that "the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain."¹²⁸ Regardless of these concessions, the document focused more on regulation than on education, clarification, or awareness. The Interim Policy Statement listed

121. Press Release, Drug Enforcement Admin., The Myth of the "Chilling Effect": Doctors Operating Within Bounds of Accepted Medical Practice Have Nothing to Fear from DEA (Oct. 30, 2003), <http://www.usdoj.gov/dea/pubs/pressrel/pr103003.html>.

122. *Id.*

123. Press Release, A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act (Oct. 2001), <http://www.unr.edu/ncehp/downloads/Consensus.pdf> (advocating a balanced regulation policy).

124. PATRICIA M. GOOD ET AL., PRESCRIPTION PAIN MEDICATIONS: FREQUENTLY ASKED QUESTIONS AND ANSWERS FOR HEALTH CARE PROFESSIONALS, AND LAW ENFORCEMENT PERSONNEL 1-3 (2004), available at <http://www.aapsonline.org/painman/deafaq.pdf>.

125. *Id.* at 1-2.

126. *Id.* at 3.

127. Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (Drug Enforcement Admin. Nov. 16, 2004) (notice).

128. *Id.*

four “misstatements” contained in the FAQ.¹²⁹ Acknowledging that the FAQ was not an official statement of the DEA, in part because it was not published in the Federal Register,¹³⁰ the end of the Interim Policy Statement addressed physician concerns in a parenthetical, citing the “significant questions DEA has received following the withdrawal of [the FAQ].”¹³¹ The Statement promised that the DEA would issue an official document in the Federal Register, aimed at “providing guidance and reassurance to physicians who engage in legitimate pain treatment.”¹³²

Two months later, the DEA set out to fulfill its promise, setting the bureaucratic wheels in motion with a round of notice and comment rulemaking.¹³³ In the notice, the DEA solicited comments from “physicians and other interested members of the public 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 the upcoming Federal Register document.”¹³⁴ The notice explained that the limited purposes of the document were to “stay within the scope of DEA’s authority by addressing . . . the [CSA], and the DEA regulations promulgated thereunder, as well as the pertinent court decisions.”¹³⁵

Eight months after issuing the notice, the DEA issued a “Clarification” at the request of “most” of the comments they received.¹³⁶ The DEA reiterated its Interim Policy Statement, which stated that a physician cannot write multiple prescriptions to the same patient for a Schedule II substance with “instructions to fill on different dates” because it is “tantamount to writing a prescription authorizing refills of a [S]chedule II controlled substance,” contrary to the CSA rules.¹³⁷ Apparently physicians were not the only concerned commentators; the Clarification also addressed patients who were understandably confused by the application of the aforementioned refill rule to their various situations, which might

129. *Id.* at 67,171-72.

130. *Id.* at 67,172.

131. *Id.*

132. *Id.* at 67,170-71.

133. See Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain, 70 Fed. Reg. 2,883 (Drug Enforcement Admin. Jan. 18, 2005) (notice).

134. *Id.*

135. *Id.*

136. Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances, 70 Fed. Reg. 50,408 (Drug Enforcement Admin. Aug. 26, 2005) (notice) (“Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of [S]chedule II controlled substances by physicians in view of [the Interim Policy Statement].”).

137. *Id.* (quoting Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170-71 (Drug Enforcement Admin. Nov. 16, 2004) (notice)).

involve only seeing their physician once every three months.¹³⁸ The Clarification acknowledged in its penultimate paragraph that physicians must adhere to state limitations on Schedule II prescriptions, such as the amount that can be prescribed, in addition to the CSA.¹³⁹

By addressing physician, patient, and federalism concerns separately, the Clarification did little to actually clarify what actions a patient should take if, for instance, he or she was living in a state that limits Schedule II prescriptions to one prescription, which may only last one month, but, contradictorily, only allows him or her to see his or her physician once every several months. Adding to the confusion is the lack of uniformity among states in limiting the amount that can be prescribed, which can range from a "30-day supply" to "100 dosage units."¹⁴⁰ Whereas the 2001 joint statement and the FAQ embraced informing and working with physicians in an admittedly murky area of the law,¹⁴¹ the three subsequent statements did away with this notion and confined the DEA's goals to regulation and enforcement.

Dr. Quill describes the disparate treatment of physicians by the DEA and state agencies: "For better or for worse, the DEA sets the tone and drives physicians' perceptions about the legal risk associated with prescribing Schedule [II] drugs . . . for seriously ill and dying patients."¹⁴² The federal government has made two attempts in the past decade to usurp state regulation.¹⁴³ The Pain Relief Promotion Act ("PRPA") would have amended the CSA by adding a provision directing the Attorney General to "give no force and effect to State law authorizing or permitting assisted suicide or euthanasia."¹⁴⁴ The bill had its benefits, such as "Title II: Promoting Palliative Care," which would have created a program to "[d]evelop and advance scientific understanding of palliative care,"¹⁴⁵ as well as a program to educate students and hospices and train healthcare professionals in palliative care.¹⁴⁶ However, had it been passed, PRPA, which was originally dubbed the Lethal Drug Abuse Prevention Act, would have effectively criminalized physician-

138. *Id.*

139. *Id.* at 50,409.

140. Weinman, *supra* note 34, at 537 (citation omitted).

141. *See* Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (Drug Enforcement Admin. Nov. 16, 2004) (notice); Press Release, A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, *supra* note 123.

142. Quill & Meier, *supra* note 1, at 2-3.

143. *Id.* at 3; *see* Pain Relief Promotion Act, H.R. 2260, 106th Cong. § 101(i)(2) (1999); Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Dep't of Justice Nov. 9, 2001) (interpretive rule) (the so-called "Ashcroft Directive").

144. H.R. 2260.

145. *Id.* § 201.

146. *Id.* § 202.

assisted suicide.¹⁴⁷ The Ashcroft Directive, discussed in Part V, would have similarly criminalized assisted suicide and invalidated Oregon's Death with Dignity Act by rejecting assisted suicide as a "legitimate medical purpose."¹⁴⁸ The distinctions between state and federal regulation exemplify the DEA's trend in narrowing their involvement with pain management while at the same time broadening their power over regulating physicians beyond the physicians' own state medical boards. Such regulation violates a patient's right to palliative care.¹⁴⁹

C. Criminal Prosecution

Criminal prosecutions of physicians who distribute OxyContin and other controlled substances illustrate how a lack of responsibility and training may lead physicians to irresponsibly distribute and administer Schedule II narcotics. A particularly egregious instance of physician irresponsibility is illustrated by *United States v. Moyer*,¹⁵⁰ where a physician was found guilty for tampering with a consumer product and obtaining a controlled substance through fraud in violation of the CSA.¹⁵¹ While the physician's patients were in the intensive care unit, the physician stole morphine from intravenous units and replaced it with a saline solution.¹⁵² Some other examples dealing with pain treatment have resulted in convictions where physicians conducted only a cursory assessment of the patients' pain.¹⁵³

IV. IMPACT ON PHYSICIANS, PATIENTS, AND OTHERS

In 2003 the DEA acknowledged and attempted to refute its critics' position that regulation ultimately leads to a "chilling effect" on effectively treating patients' pain.¹⁵⁴ Four years later it is clear that the refu-

147. Quill & Meier, *supra* note 1, at 3.

148. *Id.*; see *infra* Part V.

149. See *supra* Part II.

150. 182 F.3d 1018 (8th Cir. 1999).

151. *Id.* at 1020.

152. *Id.*

153. See, e.g., *United States v. Polito*, No. 96-3022, 1997 U.S. App. LEXIS 7308 (6th Cir. Apr. 11, 1997) (affirming a doctor's conviction for the unlawful distribution of narcotics made outside the usual course of medical practice and without a legitimate medical purpose); *Konstantin v. Drug Enforcement Admin.*, No. 93-70385, 1995 U.S. App. LEXIS 3005 (9th Cir. Feb. 14, 1995) (affirming the DEA administrator's increased sanction upon a doctor for prescribing controlled substances without a legitimate medical purpose under the CSA, where the doctor performed brief physicals before prescribing controlled substances to undercover agents, none of whom complained of pain); *People v. Lonergan*, 267 Cal. Rptr. 887 (Cal. Ct. App. 1990) (affirming conviction for prescribing Schedule III drugs in violation of California Health and Safety Codes, where the physician prescribed the drugs to a known drug addict and two undercover agents who were not given physical examinations).

154. See Press Release, Drug Enforcement Admin., *supra* note 121.

tation has done little to reassure physicians that treating pain should be the greater goal.¹⁵⁵ Judging by its response to comments from physicians, the DEA's stance on pain relief has likely caused confusion and contention among physicians.¹⁵⁶ David Brushwood, Professor of Pharmacy Health Care Administration at the University of Florida, agrees that the DEA's attempts to clarify previous regulations have largely served to confuse doctors and pharmacists across the country.¹⁵⁷ The "chilling effect" is controversial because of its legal, medical, moral, and ethical implications. Fear of federal regulation goes beyond physicians and affects the patients as well, further limiting the ability of patients to obtain adequate treatment. Sandra Johnson agrees that there is a barrier to the effective treatment of pain, adding that other "obstacles . . . include financial restrictions, educational deficiencies, cultural challenges, and legal and regulatory concerns."¹⁵⁸

A. *Impact on Physicians: A Catch-22*

Physicians who overprescribe risk investigation, license revocation, sanctions, jail time, and a shattered reputation in the medical community.¹⁵⁹ Physicians who underprescribe, and as a consequence do not act

155. See Brody, *supra* note 6 ("[D]espite some physicians' commitment to treat pain . . . abundant evidence suggests that patients' fears of undertreatment of distressing symptoms are justified." (internal quotations omitted)).

156. See Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances, 70 Fed. Reg. 50,408 (Drug Enforcement Admin. Aug. 26, 2005) (notice).

157. David B. Brushwood, *Same Day Multiple Prescriptions: Clarifying the Bungled DEA Message*, PAIN & L., Mar. 14, 2005, http://www.painandthelaw.org/news/brushwood_031405.php.

158. Johnson, *supra* note 88, at 743.

159. See, e.g., Radley Balko, *Doctors, Patients, Latest Drug War Casualties*, FOXNEWS.COM, Sept. 23, 2004, <http://www.foxnews.com/story/0,2933,133204,00.html>. The well-publicized case against a Harvard-trained California physician, Dr. Frank Fisher, demonstrates this point. Fisher was mercilessly targeted for five years in, as one juror sitting for his trial described a "witch hunt." Prosecutors brought a variety of charges, including fifteen counts of murder that were immediately thrown out by the judge. Four years later, the judge also disposed of the felony charges of manslaughter and fraud. The jury acquitted Fisher of all remaining misdemeanor charges. As a result of five years of prosecution and persecution, Fisher was left with a shattered reputation, living with his parents and facing threats of license revocation.

Fisher's personal take on the DEA crackdown on physicians describes the new wave of prosecutions: "Law enforcement consistently seeks out rural solo practitioners to prosecute for suspected prescribing violations and the charges leveled are becoming increasingly exaggerated. In the past few years there have been a rash of murder and manslaughter charges leveled against well meaning physicians around the country and several doctors have been sent to prison." Frank Fisher, *Dr. Fisher's Story: The Anatomy of an Oxycontin Bust*, http://www.drfisher.org/the_story.asp?group=2 (last visited Mar. 14, 2007). For a review of the aftermath of Fisher's devastating tale, as well as an account of the pharmacists who were prosecuted for distributing Fisher's prescriptions for painkillers, see Sam Stanton, *Murder Case Dissolved, but So Did Doctor's Life*, SACRAMENTO BEE, May 23, 2004, available at <http://www.sacbee.com/content/news/story/9399329p-10323635c.html>.

in the patient's best interest, risk facing a malpractice lawsuit.¹⁶⁰ With the increasing numbers of both DEA raids and investigations on one hand and malpractice lawsuits on the other, physicians are placed in a difficult position. The result of the chilling effect based on physicians' fear of prosecution or DEA sanctions has also led to increasingly cautious measures that are costly and unnecessary.¹⁶¹ This fear of regulation physicians experience has been repeatedly acknowledged in literature.¹⁶²

Physician malpractice suits have become standard and highly politicized talking points in the media. Recent cases have broken ground by awarding verdicts based on undertreatment of pain.¹⁶³ In *Bergman v. Chin* the family of the decedent sued the attending physician under California's Elder Abuse law.¹⁶⁴ Prior to the trial on April 30, 2001, Beverly Bergman, the decedent's daughter and one of the plaintiffs in the case, addressed the Mayday Scholars Press Conference and gave an emotional account of the background of this case.¹⁶⁵ The group Compassion in Dying and Kathryn Tucker helped the family find legal recourse for the pain that Mr. Bergman went through from age of eighty-five until his death.¹⁶⁶ The family filed suit for malpractice, elder abuse, and unlawful business practices.¹⁶⁷ Although the family's medical malpractice claim was dismissed, Dr. Chin was found liable for elder abuse

160. See, e.g., *Jury Decides Undertreatment of Pain Was Elder Abuse, Sets \$1.5 Million Damages*, 10 HEALTH L. REP. 982 (2001) [hereinafter *Jury Decides*] (discussing *Bergman v. Chin*, No. H205732-1 (Cal. Super. Ct. June 13, 2001), <http://www.alameda.courts.ca.gov/domainweb> (select "Case Summary" hyperlink; submit case number "CH205732")).

161. See Brody, *supra* note 6 ("The growing number of arrests of pain management specialists is exacting high costs for patients, physicians and medical insurers. Some doctors order costly but unnecessary diagnostic tests so they can show the D.E.A. a reason for prescribing strong pain medication.").

162. See Quill & Meier, *supra* note 1, at 1. Legal and medical scholars use the term "opiophobia" to describe the chilling effect. See, e.g., Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28 (2001) ("Physicians have long been accused of poor pain management for their patients. The term 'opiophobia' has been coined to describe this remarkable clinical aversion to the proper use of opioids to control pain."); Ben A. Rich, *The Politics of Pain: Rhetoric or Reform?*, 8 DEPAUL J. HEALTH CARE L. 519, 524-25 (2005) ("Because of what the DEA considers to be the high potential for abuse of drugs placed in Schedule II, there is a widespread belief among physicians that their prescribing practices with regard to them are carefully monitored. This perceived regulatory scrutiny, in combination with the myths and misinformation about the risks of opioids, has caused, or at least significantly contributed to, a phenomenon known as 'opiophobia.'"); Barth L. Wilsey, Scott M. Fishman & Christine Ogden, *Prescription Opioid Abuse in the Emergency Department*, 33 J.L. MED. & ETHICS 770, 779 (2005).

163. See *Jury Decides*, *supra* note 160.

164. See *id.*

165. *Transcript of Beverly Bergman from the Mayday Scholars Press Conference*, PAIN & L., Apr. 30, 2001, http://www.painandthelaw.org/malpractice/bergman_transcript.php.

166. *Id.*

167. *Id.*

and recklessness.¹⁶⁸ The family received a verdict of \$1.5 million because the physician administered inadequate pain management.¹⁶⁹ The verdict was subsequently reduced by the trial judge, who applied California's \$250,000 medical malpractice damage cap.¹⁷⁰ Interestingly, even though the medical malpractice claim was dismissed, and despite the verdict reduction under the medical malpractice cap, the case was later "characterized as one for elder abuse rather than malpractice."¹⁷¹ The court awarded the plaintiffs' attorney fees and enhanced the verdict amount by a 1.5 multiplier "in light of the importance of the case to the public interest."¹⁷² In another California case the next year, a similar elder abuse claim based on inadequate pain management was brought against the decedent's attending physician and nursing home.¹⁷³ Sandra Johnson notes that these cases illustrate the problems faced by physicians in treating terminally ill patients who are in a large amount of pain.¹⁷⁴

Despite the risk of tort liability, physicians continue to fear federal regulatory sanctions and often act in accordance with this fear, refusing to prescribe or administer opioids to terminally ill patients who suffer from chronic pain.¹⁷⁵ Statements like the Ashcroft Directive, although recently struck down by the Supreme Court,¹⁷⁶ heighten physicians' fears of "causing" a patient's death.¹⁷⁷ Physician intimidation will only

168. *Jury Decides*, *supra* note 160. Lawyers in the case focused on proving "reckless negligence." See Eric Warm & David E. Weissman, *Fast Fact and Concept #63: The Legal Liability of Undertreatment of Pain*, END OF LIFE/PALLIATIVE EDUCATION RESOURCE CTR., Mar. 2002, http://www.eperc.mcw.edu/fastFact/ff_63.htm ("By a 9 to 3 vote the jury decided that the physicians lack of attention to pain constituted elder abuse, awarding the family \$1.5 million (the amount was reduced to \$250,000). To win, lawyers convinced the jury that under-treatment of pain was 'reckless negligence.'").

169. *Id.*

170. *Undermedicating Cases*: *Bergman v. Chin*, No. H205732-1 (Alameda County Ct., June 13, 2001), PAIN & L. [hereinafter *Undermedicating Cases*], http://www.painandthelaw.org/malpractice/undermedicating_cases.php (last visited Apr. 18, 2007); see also CAL. CIV. CODE § 3333.2(b) (West 2006).

171. *Undermedicating Cases*, *supra* note 170.

172. *Id.*

173. Kathryn L. Tucker, *Medico-legal Case Report and Commentary: Inadequate Pain Management in the Context of Terminal Cancer: The Case of Lester Tomlinson*, 5 PAIN MED. 214, 215 (2004) (discussing the case of *Tomlinson v. Bayberry Care Center*); see *Parties Settle Elder Abuse Lawsuit over Refusal of Pain Medication*, 12 HEALTH L. REP. 1310 (2003).

174. Johnson, *supra* note 88, at 748-50 (discussing *Bergman* and *Tomlinson*).

175. See Quill & Meier, *supra* note 1, at 2 (discussing a case where, after consulting with ethicists and palliative care specialists, the medical staff members "remained unsettled about whether they might have been legally liable for 'causing' [the] death"); see also Johnson, *supra* note 88, at 753 ("Physicians' fear of regulatory scrutiny and intervention on the part of the state bureau of narcotics, the state medical licensure board, and the federal Drug Enforcement Administration (DEA) is a substantial barrier to access to effective pain relief for patients.").

176. See *Gonzales v. Oregon*, 126 S. Ct. 904 (2006); *infra* Part V.

177. See Quill & Meier, *supra* note 1, at 1.

increase as the DEA increases its regulation of prescriptions. Using a three-patient illustration, Dr. Quill notes this very real intimidation, as well as its unfortunate consequence: a decline in quality pain management for patients suffering from intractable pain.¹⁷⁸ While many states have legislation that, to varying degrees, criminalizes assisted suicide, most of these statutes contain companion provisions that emphasize the state's interest in palliative care and serve to distinguish assisted suicide from aggressive pain management.¹⁷⁹ Additional state regulations, such as MCPs, can often serve as a nuisance and even a hindrance to effectively treating patients' pain.¹⁸⁰ In her address at the Mayday Scholars Press Conference, Beverly Bergman noted that the defendant physician's excuse for not writing a prescription sooner was because "he didn't have his triplicate pad."¹⁸¹ The deterrent effects of mandatory triplicate programs have been heavily criticized.¹⁸²

The CSA's purpose is to curb drug abuse and addiction.¹⁸³ DEA regulation of physicians' distribution of Schedule II narcotics, therefore, creates the inference that drugs such as OxyContin are typically used by drug addicts rather than by patients to relieve chronic, intractable pain. This inference increases the reluctance on the part of physicians to prescribe opioids, which in turn prevents more patients from receiving proper treatment. In Part II of this Note, there is a list of several states, including Tennessee and Hawaii, that essentially acknowledge physician reluctance to prescribe opioids and provide an alternative: patient referrals to other specialists who do prescribe opioids.¹⁸⁴ However, at least one author expresses skepticism at this alternative, noting that such specialists are not typically covered by insurance policies and may not even be accessible to pain patients.¹⁸⁵

B. *Impact on Patients: Sensationalism Breeds Fear*

Beth Packman Weinman attributes patients' fear at least in part to

178. *See id.* at 2-3.

179. *See, e.g.*, § 782.08, FLA. STAT. (2006) ("Every person deliberately assisting another in the commission of self-murder shall be guilty of manslaughter, a felony of the second degree . . ."); § 765.102, FLA. STAT. (2006).

180. *See* Weinman, *supra* note 34, at 532.

181. *Transcript of Beverly Bergman from the Mayday Scholars Press Conference, supra* note 165; *see* Weinman, *supra* note 34, at 532 ("Triplicate prescription programs require prescribing physicians to complete, official, government-provided, detailed prescription forms that contain three copies.").

182. *See, e.g.*, Weinman, *supra* note 34, at 532-36.

183. *See* 21 U.S.C.A. § 801(2) (West 2006) ("The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.").

184. *See supra* Part II.

185. Weinman, *supra* note 34, at 511.

cultural attitudes toward pain relief, such as a Christian-based belief system which rewards physical suffering and the Western notion that "pain builds character."¹⁸⁶ But not all patient fear is so psychosocial in nature, as insurance coverage may also be a practical deterrent from pain patients seeking relief,¹⁸⁷ and perhaps the most pervasive deterrent for patients is the federal regulation of prescription practices.¹⁸⁸ Patients who suffer chronic pain experience a twofold fear: their pain will go undertreated, and they will become addicted if they take narcotic drugs for pain.¹⁸⁹

V. RECENT DEVELOPMENT: *GONZALES V. OREGON*¹⁹⁰

On April 17, 2002, the District Court of Oregon permanently enjoined¹⁹¹ the so-called "Ashcroft Directive,"¹⁹² which construed the CSA.¹⁹³ The Ashcroft Directive expressly stated that physician-assisted suicide was not a "legitimate medical purpose" under the CSA,¹⁹⁴ an interpretation that directly conflicted with Oregon's Death with Dignity Act ("ODWDA").¹⁹⁵ Enacted by ballot measure in 1994, ODWDA sought to "protect vulnerable patients and ensure that their decisions are reasoned and voluntary" by allowing attending physicians of terminally ill patients to prescribe lethal doses of controlled substances.¹⁹⁶ Had it been enforced, the Ashcroft Directive would have effectively preempted the ODWDA by enforcing its construction of the CSA, "regardless of whether state law authorizes or permits such conduct by practitioners."¹⁹⁷

In *Ashcroft v. Oregon* The Ninth Circuit framed the issue as "whether Congress authorized the Attorney General to determine that physician assisted suicide violates the CSA."¹⁹⁸ While the court ultimately held that "[t]he Ashcroft Directive violates the 'clear statement' rule, contradicts the plain language of the CSA, and contravenes the

186. *Id.* at 518-19 (citations omitted).

187. *Id.* at 519-21 (citations omitted).

188. *Id.* at 520.

189. See Quill & Meier, *supra* note 1.

190. 126 S. Ct. 904 (2006).

191. See *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002), *aff'd*, 368 F.3d 1118 (9th Cir. 2004), *aff'd*, *Gonzales v. Oregon*, 126 S. Ct. 904 (2006).

192. Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Dep't of Justice Nov. 9, 2001) (interpretive rule).

193. 21 U.S.C.A. §§ 801-904 (West 2006).

194. Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. at 56,607.

195. See OR. REV. STAT. ANN. §§ 127.800-897 (West 2006).

196. *Ashcroft*, 368 F.3d at 1122.

197. Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. at 56,607.

198. *Ashcroft*, 368 F.3d at 1123.

express intent of Congress,”¹⁹⁹ the opinion contains a lot of language focusing on federalism. Quoting a Ninth Circuit case to support his federalism argument, Judge Tallman wrote: “The principle that state governments bear the primary responsibility for evaluating physician assisted suicide follows from our concept of federalism, which requires that state lawmakers, not the federal government, are ‘the primary regulators of professional [medical] conduct.’”²⁰⁰ Additionally, he cites a 1925 Supreme Court decision for the principle that “‘direct control of medical practice in the states is beyond the power of the federal government.’”²⁰¹ Judge Tallman uses federalism to bolster the notion that it is imperative to ascertain congressional intent before assuming that a federal actor has the authority to preempt state law.²⁰² The opinion also contains references to the Supreme Court’s right-to-die cases that support Oregon’s right to enact ODWDA without federal government interference.²⁰³

After the Ninth Circuit’s 2004 decision in *Oregon v. Ashcroft*, commentators eagerly awaited the outcome of this “right-to-die” case in the Supreme Court. Before certiorari was granted, one author suggested that the Ninth Circuit might be overturned.²⁰⁴ Proponents of the “right to life” movement viewed the case as an “opportunity for the high court to address the right to life,”²⁰⁵ while proponents of “death with dignity” feared not only the end to physician-assisted suicide but also the aforementioned “chilling effect” on effective palliative care.²⁰⁶ One commentator expressed the concern that “[s]hould the court rule against Oregon, the D.E.A. could turn to all physicians whose patients die while getting prescribed opioids or barbiturates, even if the drugs were administered only to relieve intractable pain, not to hasten death.”²⁰⁷ Dr. Quill

199. *Id.*

200. *Id.* at 1124 (quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002)) (additional citation omitted).

201. *Ashcroft*, 368 F.3d at 1124 (quoting *Linder v. United States*, 268 U.S. 5, 18 (1925)) (additional citation omitted).

202. *See id.* at 1124-25.

203. *See id.* at 1123-24 (“We begin with instructions from the Supreme Court that the ‘earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide’ belongs among state lawmakers.”) (quoting *Washington v. Glucksberg*, 521 U.S. 701, 735 (1997) (O’Connor, J., concurring)); *id.* at 1126 (“Physician assisted suicide is an unrelated, general medical practice to be regulated by state lawmakers in the first instance.”) (citing *Glucksberg*, 521 U.S. at 735 (O’Connor, J., concurring)).

204. Marya Lucas, *Government Looks to Undo Death with Dignity Act*, LEGAL TIMES, Feb. 18, 2005 (“[T]he justices have a history of taking up controversial decisions out of the Ninth Circuit and overturning them.”).

205. Warren Richey, *High Court Takes up Physician-Assisted Suicide*, 97 CHRISTIAN SCIENCE MONITOR 3-3 (2005).

206. *See supra* Part IV.

207. Brody, *supra* note 6.

similarly warned, "[j]ust beneath the surface, however, lies the risk of empowering agents of the [DEA] – whose traditional role is to prevent drug abuse and diversion – to evaluate the end-of-life practices of physicians whose patients die while receiving prescribed opioids or barbiturates."²⁰⁸

The expectations of an explosive decision were not realized when the Supreme Court decided *Gonzales v. Oregon* in early 2006.²⁰⁹ Although the case was a relief to "death with dignity" proponents because it affirmed the Ninth Circuit's decision, it was decided on technical administrative law grounds rather than on a moral, political, or federalism basis. Justice Kennedy's opinion quickly sweeps aside the "political and moral" aspects of the case and immediately hones in on "interpreting a federal statute to determine whether Executive action is authorized by, or otherwise consistent with, the enactment."²¹⁰ The opinion is void of politically or morally charged rhetoric and instead opts for a basic administrative law analysis: how much deference the Ashcroft Directive deserves and whether it had congressional authorization.²¹¹ The opinion relies on the Court's prior decisions in *Chevron*,²¹² *Auer*,²¹³ *Mead*,²¹⁴ and *Skidmore*,²¹⁵ to hold that the Ashcroft Directive was not entitled to *Chevron* deference because Congress did not delegate the authority to the Attorney General to criminalize the issuance of controlled substances for physician-assisted suicide.²¹⁶ Instead, the Ashcroft Directive warranted only persuasive *Skidmore* deference, under

208. Quill & Meier, *supra* note 1, at 1.

209. *Gonzales v. Oregon*, 126 S. Ct. 904 (2006).

210. *Id.* at 911.

211. *Id.* at 914 ("The parties before us are in sharp disagreement both as to the degree of deference we must accord the Interpretive Rule's substantive conclusions and whether the Rule is authorized by the statutory text at all.").

212. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (formulating the following two-pronged analysis for determining the amount of deference that a reviewing court should afford to an agency's construction of the statute it administers: first, whether Congress has spoken directly to the issue; and second, if the statute is silent or ambiguous on the issue, whether the agency or executive interpretation is a reasonable one).

213. *Auer v. Robbins*, 519 U.S. 452, 463 (1997) ("A rule requiring the Secretary to construe his own regulations narrowly would make little sense, since he is free to write the regulations as broadly as he wishes, subject only to the limits imposed by the statute.").

214. *United States v. Mead Corp.*, 533 U.S. 218, 229-31 (2001) (adding a "step zero" to the *Chevron* test: before determining whether Congress has spoken directly to the issue at hand, a court should determine whether Congress has delegated the assumed authority to the agency, and if so, whether the agency has acted in accordance with that authority).

215. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (suggesting a rule of judicial deference to agency action based on the "thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control").

216. *Gonzales*, 126 S. Ct. at 918.

which it did not pass muster.²¹⁷

Despite sidestepping federalism issues, the opinion contains language that does suggest approval of a physician's right to administer effective palliative care. The Court rebuts the Government's argument that the Attorney General was within his authority by saying,

[i]t is not enough that the terms "public interest," "public health and safety," and "Federal law" are used in the part of [the CSA] over which the Attorney General has authority. The statutory terms "public interest" and "public health" do not call on the Attorney General, or any other Executive official, to make an independent assessment of the meaning of federal law.²¹⁸

This statement expresses a "hands off" mentality, allowing the states to make their own decisions about the public interest of their own citizens unless a congressional act expressly delegates such authority to an executive official. The Court emphasizes this approach by noting that the CSA "conveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise."²¹⁹ The last sentence of the opinion also expresses the state's right perspective: "The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance"²²⁰ Regarding palliative care in particular, the Court highlights the Ashcroft Directive's own "distinctions between assisting suicide and giving sufficient medication to alleviate pain."²²¹

Perhaps the most useful analysis in establishing a right to palliative care arises in the Supreme Court's analysis of the CSA. The Court cites its previous decision in *United States v. Moore* for the proposition that "we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician."²²² The Court concludes that the CSA is a "statute combating recreational drug abuse,"²²³ rather than regulating every possible usage of the drugs which are regulated by the statute.

Although the Ninth Circuit's discussion of the federalism issue was technically left unresolved by the Supreme Court, the reasoning behind Judge Tallman's discussion is sound. He relies on *Linder v. United States*, which clearly states that the regulation of medicine belongs in the

217. *Id.* at 922.

218. *Id.* at 919 (emphasis supplied).

219. *Id.* at 921.

220. *Id.* at 925.

221. *Id.* at 921 (citing Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Dep't of Justice Nov. 9, 2001) (interpretive rule)).

222. *Id.* at 922 (citing *United States v. Moore*, 423 U.S. 122, 143 (1975)).

223. *Gonzales*, 126 S. Ct. at 924.

hands of state lawmakers, not federal agencies like the DEA.²²⁴ However, this delineation is not always so easy to define, as the CSA regulates both illegal and legal drugs. To remove any regulation of prescription drugs from the DEA's control would require a restructuring of federal law, one that would not likely be desirable for federal or state lawmakers. The CSA itself, however, is not the problem; rather, it is the DEA's broad interpretation of its own statutory authority that creates cases like *Gonzales*, where the federal government undermines principles of federalism by usurping the states' regulation of physicians. Staying within the bounds of the CSA is necessary to prevent the federal government from intruding on state lawmakers' functions and, ultimately, states' rights.

It is hard to say what the fallout from *Gonzales* will be. One author writes, "[m]ost commentators characterized [*Gonzales*] . . . as a narrow administrative law ruling . . . telling us little about whether other states should follow suit or Congress should make a federal rule."²²⁵ Although language in the opinion may be supportive of right-to-die advocates, it leaves room for Congress to enact a statute that would allow preemption of ODWDA or even a state's palliative care law. Right-to-life proponents latch onto this hope, saying that "the Court merely said the Administration had incorrectly interpreted the [CSA], and made clear that if Congress chooses, it has the constitutional authority to act to bar the use of federally controlled drugs to assist suicide."²²⁶ The effect of the decision on physicians' administration of palliative care is still unclear. To be sure, *Gonzales* did very little to alleviate the fears of death-with-dignity advocates.

VI. SOLUTIONS TO PHYSICIAN AND PATIENT FEAR AND CONFUSION ABOUT PAIN RELIEF

Proponents of aggressive pain management would agree that *Gonzales v. Oregon* was a blessing to their cause in that it refused to allow the executive branch to overstep its bounds. However, these same proponents would likely contend that the case had little impact on remedying the ignorance and fear of the executive's regulation of prescription practices. This Part discusses various methods – some already initiated, others only suggested in scholarly articles – of ensuring that the pain management crisis in the United States is recognized, addressed, and

224. *Linder v. United States*, 268 U.S. 5, 18 (1925).

225. Susan M. Wolf, *Court Ruling Doesn't Answer Assisted Suicide Questions*, ST. PAUL PIONEER PRESS, Jan. 29, 2006, at 11B.

226. Burke J. Balch, *Supreme Court Allows Use of Federally Controlled Drugs to Assist Suicide*, 33 NAT'L RIGHT TO LIFE NEWS (2006), available at <http://www.nrlc.org/news/2006/NRL02/HTML/AssistedSuicideBackCover.html>.

actively rectified. By implementing such solutions, American institutions ranging from Congress and the federal judiciary to state legislatures and universities can force our culture to confront the frequently downplayed issues associated with end-of-life care.

A. *Physicians: Education, Training, and Documentation*

Dr. Quill recognizes that, although lack of education is not the primary factor, physicians' lack of awareness and proper training with regard to prescribing opioids contributes, in some part, to the undertreatment of pain.²²⁷ If physicians are educated by palliative care experts, they will be assured that their fears of hastening death or initiating an addiction are unfounded as long as they follow various protocol and cautionary measures.²²⁸ Continuing education is especially important considering the lack of pain management education that physicians receive in their schooling. One study found that not only did none of the New York schools surveyed have a formal pain management curriculum, but the amount of time spent educating students about pain assessment was "usually under 20 hours."²²⁹ In addition to the lack of education and training in treating pain, it is imperative for physicians to be educated and trained in diagnosing pain. A physician's fear of regulation is based partly on a lack of trust that the patient is truly in pain and not just an addict disguised as a pain patient.²³⁰ One author agrees that lack of trust is a barrier to effective palliative care, referencing calls that urge "doctors and nurses [to] 'trust the patient's report of pain.'"²³¹

An obvious solution to the lack of initial pain management education that physicians receive is for medical schools to refocus their attention, to some degree, on pain management and the actual effects of opioids. Another solution is to require physicians to devote some of their post-scholastic time to remain up-to-date on developments in pain management and palliative care. Finally, by enacting strict standards under elder abuse statutes, states such as California open the door for patients' surviving family members to sue physicians for undertreating

227. Quill & Meier, *supra* note 1, at 1.

228. *See id.* at 2 ("Ethics and palliative care consultants were called in, and they refocused the [medical] team on the professional obligation to relieve pain and suffering."); *supra* Part IV (discussing the impact of federal regulation on physicians).

229. Weinman, *supra* note 34, at 517 (citation omitted).

230. *See* Johnson, *supra* note 88, at 746 (citing a study speculating that physicians' assumptions about a patient determine whether they will diagnose him as one in severe pain or rather one who is seeking drugs); *id.* at 747 (distinguishing between an ethical physician who uses "red flags" to identify a possible addict who falsifies his symptoms and a "hypervigilant" physician who denies the patient access to pain relief based on prejudices and profiling).

231. *Id.*; *see id.* (asserting that "physician distrust of patients is a core issue in the effective treatment of patients in pain").

their relative's pain.²³² The *Bergman* and *Tomlinson* cases, discussed in Part III, exemplify the effectiveness of such statutes.²³³ Even though they are less direct than medical board sanctions, such elder abuse laws are likely to deter physicians from withholding pain treatment.

Although the risk of addiction and recreational use of opioids is real (which is why they are classified as a Schedule II narcotic), the benefits they provide in relieving intractable pain cannot be overstated. Thus, while it is certainly important for physicians to be educated about the adverse effects of the drugs they administer, medical schools and licensing boards need to encourage and require a certain amount of training and exposure to the benefits of opioids. To refrain from such training is to jeopardize a terminally ill patient's right to palliative care.

B. Congress: Legislation

The Project on Legal Constraints on Access to Effective Pain Relief has produced a Model Pain Relief Act that aims at protecting healthcare providers and, as a result, allows patients to receive the best possible pain treatment.²³⁴ This Act prohibits disciplinary action "against a health care provider for the prescription, dispensing, or administration of medical treatment for the therapeutic purpose of relieving intractable pain," subject to compliance with guidelines and standards of practice.²³⁵ The Model Act makes a clear distinction between discipline of the physicians who prescribe drugs lawfully under established guidelines, and those who fail to conduct proper checks before prescribing or who purposely provide drugs for the patients' or the physician's personal use.²³⁶

In June 2001, the Senate introduced the Conquering Pain Act.²³⁷ Among the Act's findings was that "despite the best intentions of physicians, nurses, pharmacists, and other health care professionals, pain is often under-treated because of the inadequate training of clinicians in pain management."²³⁸ The bill included a definition of palliative care and gave examples of how it could best be administered.²³⁹ The bill, had it been passed, would have encouraged educating and protecting

232. See Johnson, *supra* note 88, at 748.

233. See *supra* Part III.A.

234. Project on Legal Constraints on Access to Effective Pain Relief, *The Pain Relief Act*, 24 J.L. MED. & ETHICS 317-18 (1996), available at http://www.painandthelaw.org/aslme_content/24-4c/painact.pdf; see Sandra H. Johnson, *Disciplinary Action and Pain Relief: Analysis of the Pain Relief Act*, 24 J.L. MED. & ETHICS 319 (1996).

235. Conquering Pain Act of 2001, S. 1024, 107th Cong. (2001).

236. *Id.* § 3(1).

237. *Id.* §§ 3-4.

238. *Id.* § 2(6).

239. *Id.* § 3(7).

physicians and thrust pain management and palliative care issues to the forefront.²⁴⁰ The proposed bill addressed physician training,²⁴¹ patient and community support,²⁴² and even insurance issues regarding the coverage of palliative care.²⁴³

C. *Executive Branch: Clarification*

Part IV briefly discussed the confusion that arose when the DEA revoked the FAQ it had previously supported.²⁴⁴ Pharmacist and Professor David Brushwood's commentary on the DEA's revocation of the FAQ two months after it was issued paints a mystifying picture. His editorial concludes that the DEA's notion that "multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a [S]chedule II substance"²⁴⁵ was "obviously a preposterous position."²⁴⁶ Brushwood also questions the DEA's motives in rescinding its document, issued only two months earlier, because it only propounded a couple of "misstatements" of the law as its reason for revocation,²⁴⁷ and the ideas expressed in the FAQ had already been articulated prior to its issuance.²⁴⁸ If the problem of confusion is as prevalent as Professor Brushwood's article and the DEA's own acknowledgement of "confusion"²⁴⁹ indicate, then the executive branch must act. Instead, the DEA has let time pass while physicians, pharmacists, and healthcare practitioners scratch their heads trying to figure out a way to treat patients under a regulatory regime that sends mixed messages. While more regulation to clarify current regulation can sometimes have the backfiring effect of more federal interference, the DEA needs to step up its efforts to "clarify" beyond the ineffective documents that have already been released.

D. *States: Medical Board Correction*

Commentators agree that under the current federal regulatory sys-

240. *Id.* § 101 (requiring a Web site for quick reference by healthcare practitioners as well as patients and caregivers and providing "alternative means" of such guideline information in rural areas with limited access to the Internet).

241. *Id.* § 502.

242. *Id.* § 102.

243. *Id.* § 302.

244. *See supra* Part IV.

245. Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances, 70 Fed. Reg. 50,408 (Drug Enforcement Admin. Aug. 26, 2005) (notice).

246. Brushwood, *supra* note 157.

247. *Id.*; *see* Dispensing of Controlled Substances for the Treatment of Pain, *supra* note 127.

248. Brushwood, *supra* note 157.

249. *See* Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances, 70 Fed. Reg. 50,408.

tem, state legislatures and medical boards have taken commendable strides to "lessen[] the adverse effects of regulatory constraints on symptom management."²⁵⁰ Model pain statutes are one such initiative. These statutes serve to protect law-abiding physicians who properly follow established guidelines from investigation.²⁵¹ MCPPs have largely been abolished. Many states recognize the importance of palliative care,²⁵² and some states allow a malpractice claim to be brought against a physician for undertreating pain, such as in the *Bergman* and *Tomlinson* cases.²⁵³ Even though states are going in the right direction in improving pain management for their citizens, there is room for more rigorous and explicit statutory regimes. If state legislatures explicitly recognize a fundamental right to palliative care, this could have a diminishing effect on interference by the executive branch. More importantly, it would support a decision by the Supreme Court, in its next inevitable case relating to end-of-life issues, to recognize the fundamental right to palliative care implicit in its prior cases.

Unlike the DEA, medical boards have made an effort to bring uniformity to the otherwise enigmatic realm of treating pain using controlled substances. The Federation of State Medical Boards of the United States, Inc., adopted the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain in May 1998.²⁵⁴ The guidelines aim at quelling physicians' fear of disciplinary action both on the state and federal level.²⁵⁵ Despite the steps toward clarity and uniformity, the Model Guidelines only briefly discuss physicians' compliance with federal law, referring physicians to the Physicians Manual of the U.S. Drug Enforcement Administration and applicable state documents "for specific rules governing controlled substances."²⁵⁶ These guidelines, and successors, could be vastly improved if they further clarified both allowed and prohibited practices. Ann Martino addresses the conflict between IPTAs and state medical board rules, regulations, and guidelines, which stems from the fact that most of the IPTAs provide protection to physicians while state medical boards merely impose new

250. Quill & Meier, *supra* note 1, at 1; see Johnson, *supra* note 88, at 754.

251. Quill & Meier, *supra* note 1, at 1.

252. See, e.g., MO. REV. STAT. § 192.350 (2006); N.H. REV. STAT. ANN. § 126-A:15(I-a)(b) (2006); N.J. STAT. ANN. 52:9U-5(d)(2) (West 2006); N.Y. PUB. HEALTH LAW § 230(1) (McKinney 2007); see also *supra* Part II (discussing these cited statutes).

253. See Johnson, *supra* note 88, at 748.

254. MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (Fed'n of State Med. Bds. of the United States, Inc. 1998), available at <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>.

255. *Id.* § I.

256. *Id.* § II(7).

sets of requirements on physicians.²⁵⁷ These, and similar guidelines, were initially praised, but Martino cautions that studies and anecdotal evidence suggest that guidelines and regulations – even those with the best of intentions – have not quelled physician fear of regulatory repercussions and have consequently done little to improve adequate treatment of pain.²⁵⁸

Keeping in mind the strides that state medical boards have made, as well as the goals that they aim to accomplish, further initiatives could include taking disciplinary action against a physician who is accused of administering inadequate pain treatment.²⁵⁹ Martino's article provides models of a formal rule that would make underprescribing a ground for punishment.²⁶⁰ The models range from direct and aggressive²⁶¹ to cautious.²⁶²

E. *Patients: Education and Awareness*

"While the idea of establishing a policy against under-prescribing makes good sense, guidelines or rules alone are not going to change behavior. Board members and licensees have to change the way they think about prescribing to chronic pain patients. Eventually, the patients too will have to be more aware."²⁶³

Education is an important tool in dispelling the nationwide frenzy in reaction to the prescription of opioids. Thus, it is important that the general public's fear of addiction is quelled by actual facts about pain management. The media's increased sensationalizing of drug abuse scandals only serves to discourage patients from taking such medication, even if their physicians think it would be in the patients' best interest to take a controlled substance, such as OxyContin, to reduce pain. If the treating physician does her part by discussing the medication's effects and by working with the patient to taper off of the drug when necessary, rather than just leaving the patient in the dark, the patient's fears will at least be diminished if not dispelled.

257. Martino, *supra* note 26, at 332.

258. *Id.*

259. *See id.* at 333.

260. *Id.* at 343-44.

261. "Failure to adequately prescribe, order, administer, or dispense controlled substances, including opioid analgesics, for the relief or modulation of chronic pain in accordance with accepted knowledge and prevailing clinical practice for pain treatment and the standard for chronic pain management established in [*IPTA* or *rule*]." *Id.* at 343.

262. "Nothing in this subrule shall be construed to be an advocacy of the imprudent or improper use of opioid analgesics. Further, this subrule shall not relieve a licensee of the obligation to comply with state and federal laws governing the lawful prescribing, ordering, administering, or dispensing of controlled substances." *Id.* at 344 (citation omitted).

263. *Id.* (citation omitted).

As mentioned earlier, the notion that pain is a test of endurance and will permeates Western culture. Until this cultural attitude changes, it is likely that at least some patients who are suffering treatable pain will not receive relief. Changing a culture takes time, effort, and patience, but there is hope of doing so.

CONCLUSION

There is no shortage of anecdotal and statistical evidence that the DEA is increasingly targeting physicians as a means to eradicate substance abuse. Although investigations are warranted in some cases, some physicians can lose their entire reputation and career based on an unjust accusation.²⁶⁴ The culture of fear among physicians ultimately leads patients to experience unbearable pain at the end of their lives, and fear may ultimately result in a lawsuit for elder abuse against the non-prescribing physician.²⁶⁵ Scholars and public interest groups like the American Pain Society can only do so much to establish a concrete right to palliative care. All three branches of federal government, as well as state governments, need to take the next step toward establishing a right to palliative care in order to protect citizens from living their last days in unbearable pain.

This Note acknowledges the legitimate problem of prescribing addictive narcotics to patients who use the drugs recreationally. However, the equally legitimate goal to provide pain relief to terminally ill patients should not fall to the wayside of regulating overprescription. A patient who is in the advanced stages of terminal cancer is left with a predictable fate. Depriving this patient of adequate pain relief seems not only unjust, but cruel and dehumanizing. When this picture of looming death and intractable pain is painted against a background of fear and of government regulation, however, it morphs into a disturbing portrait: the War on Drugs extends beyond illegal drug trafficking to diminution of legitimate pain relief. Without stepping back to view the picture as a whole, our nation fixates on ending drug abuse and addiction, losing sight of its interest in providing relief to people who are suffering extreme pain.

264. Dr. Frank Fisher's story is an unfortunate example of such a "witch hunt." See discussion *supra* note 159.

265. See discussion *supra* Part IV.A.