

U.S. Policies Relevant to the Prescribing of Opioid Analgesics for the Treatment of Pain in Patients with Addictive Disease

Aaron M. Gilson, Ph.D. and David E. Joranson, MSSW

Pain & Policy Studies Group, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin, USA

Abstract:

Undertreatment of pain is likely to occur among patient with active addiction, or those who have a history of addiction. One of the factors that can contribute to the inadequate treatment of pain in this patient population is the presence of laws and regulations that, when implemented, could impede effective pain management. This article describes the current status of federal and state policy governing the medical use of opioid analgesics for pain management with patients who have an addictive disease. Three types of policy barriers are discussed: (1) those that can affect pain management in any patient, (2) those that can lead to patients in pain being classified as “addicts,” and (3) those that relate specifically to patients with a high risk of addiction. Also presented are recent policy initiatives that can improve the use of controlled substances to treat pain and, thus, ultimately enhance pain relief for patients with an addictive disease.

Key words: addiction - barriers - opioids - pain management - policy

Learning Objectives:

After reading this article, professionals should be able to

1. recall that patients who have an addictive disease are less likely to receive adequate pain management than patients in general, and discuss why this occurs;
2. identify three types of policies that have the potential to impede pain management in patients with addictive disease; and
3. identify three recent policy-related initiatives that have the potential to enhance pain management in patients with addictive disease.

Introduction

Among the many pharmacologic and non-pharmacologic approaches to pain treatment, the opioid analgesics are considered to be safe, effective, and even essential for the management of pain, especially for relief of moderate to severe pain.¹⁻⁸ Health-care practitioners must be confident in their ability to prescribe, administer, and dispense opioids when needed, based on an evaluation of the individual needs of each patient. Opioid analgesics are also classified as controlled substances because they have an abuse liability.

Despite the availability of effective analgesics, it is well-recognized that the inadequate treatment of pain is a serious public health issue in the U.S. Studies show that pain continues to be inadequately managed in many patient populations with a variety of diseases and conditions.⁹⁻¹² Patient populations for which there is a documented incidence of inadequate pain treatment include the elderly,¹³ minorities,¹³⁻¹⁷ children,¹⁸⁻²⁰ patients with terminal illnesses²¹⁻²⁵ or HIV/AIDS,²⁶⁻²⁷ and patients experiencing chronic non-cancer pain.²⁸ Undertreatment of pain also occurs at a relatively greater frequency in patients with pain who have a high risk for addiction.²⁹⁻³¹ For the purpose of this paper, patients who have a high risk of addiction or addictive disease are characterized as those who are currently addicted or who have a history of addiction or substance abuse (defined as the intentional use of drugs for non-therapeutic purposes).

Health-care professionals are often reluctant to use opioids to treat pain in patients with addictive disease, thus depriving this patient population of an important option for effective pain management. One reason for this undertreatment is physician concern about regulatory scrutiny and uncertainty about laws and regulations governing the use of opioids to treat pain. Indeed, national and international authorities have concluded that there are laws and regulations that impede the adequate availability and medical use of opioid analgesics.³²⁻³⁵ Organizations such as the Institute of Medicine, the United Nations, and the World Health Organization have called for efforts to identify and address legal and regulatory impediments to the use of opioids for pain relief.

In the United States, federal and state laws and regulations provide the legal parameters for the legitimate medical use of controlled substances for pain management. Policy evaluations have identified language in U.S. laws and regulations that, when implemented, could have the potential to impede effective pain management.^{34, 36-38} This potential appears to be greater when the patient in pain also has an addictive disease, due in part to the presence of some restrictive policies that are aimed specifically at this patient population.^{33, 39}

The objective of this article is to describe the current status of federal and state policy regarding the medical use of opioids for pain management with patients who are presently addicted to controlled substances or who have a history of addiction or substance abuse. To meet this objective, three types of policy barriers are discussed: (1) those that can affect pain management in any patient, (2) those that can lead to patients in pain being classified as “addicts,” and (3) those that relate specifically to patients with an addictive disease.

POLICIES RELEVANT TO THE PRESCRIBING OF OPIOIDS TO TREAT PAIN IN PATIENTS WITH ADDICTIVE DISEASE

Federal Policy

The prescribing, dispensing, and administering of opioid analgesics in the U.S. is governed by a combination of policies at both the federal and state levels. Under the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1962, the Food and Drug Administration (FDA) approves opioid analgesics and other drugs as safe and effective for commercial marketing and medical use. Once a drug has been approved for marketing under the FFDCA, a licensed physician can prescribe it for labeled uses, as well as for uses or patient populations that are not included in the approved labeling.⁴⁰ The FFDCA does not limit physicians’ prescribing either to recommended doses or to labeled indications, and does not restrict prescribing controlled substances for patients with addictive disease. In addition, the states, not the federal government, regulate medical practices, which is a principle that has been supported by the federal courts.⁴¹

Opioid analgesics, because of their potential for abuse, are additionally subject to controlled substances laws governed by the federal Controlled Substances Act (CSA). The CSA was adopted by Congress in 1970 and establishes a closed distribution system for controlled substances. This statute recognizes the medical value of controlled substances to public health, as well as their potential for abuse. Ensuring the control and availability of opioid analgesics is accomplished by registration of all individuals and businesses that import, manufacture, distribute, prescribe, or dispense controlled substances. To prevent diversion, the CSA establishes a system of security, record keeping, monitoring, and penalties for non-medical use. The CSA is not to interfere in medical

practice⁴² and the Drug Enforcement Administration (DEA) is to ensure that sufficient amounts of controlled substances are available to satisfy medical needs.⁴³ The CSA does not supersede the FFDCA⁴² and, thus, is not used to regulate the specific medical uses of controlled substances.

The CSA has the clear purpose of controlling the abuse and diversion of controlled substances, while not interfering with appropriate prescribing for medical and scientific purposes. It is lawful under federal policy to prescribe, administer, or dispense controlled substances for pain to patients, including those with addictive disease. This principle was upheld in 1993, when the DEA sought to revoke an Ohio physician's prescribing authority because controlled substances were being used for patients who were addicted or substance abusers. The DEA administrative law judge recognized that some of this physician's patients were substance abusers, but ruled that the physician had "issued controlled substances prescriptions for legitimate medical purposes, such as the relief of pain, muscle spasms, and anxiety."⁴⁴ The physician's prescribing for these patients was considered to be a legitimate medical purpose.

The ability of physicians to prescribe controlled substances to treat pain, even when the patient has an addictive disease, also extends to patients who are enrolled in a Narcotic Treatment Program (NTP), where methadone can be lawfully used to treat narcotic addiction. A statement from the DEA's Chief of the Liaison and Policy Section, Office of Diversion Control, supports this position (but does not constitute legal advice about particular cases):

Pain specialists may treat a chronic pain patient currently enrolled in a narcotic treatment program with narcotics. The Controlled Substances Act does not set standards of medical practice. It is the responsibility of individual practitioners to treat patients according to their professional judgement for a legitimate medical purpose in accordance with generally acceptable medical standards.⁴⁵

When considering the lawfulness of a particular prescribing practice, evaluation should be based on the purpose of prescribing, not on the type of patient being treated. It is critically important to distinguish whether the prescribing is for pain management or for the maintenance of addiction. Congress has ruled that prescribing controlled substances to maintain a person's addiction is not considered a legitimate medical practice, unless the physician is registered as an NTP. The purpose of an NTP is to allow maintenance or detoxification of narcotic addiction by use of methadone (also a pain medication) or levo-alpha-acetyl-methadol.

Federal narcotic treatment regulations have historically identified "narcotic dependence" as being the primary criterion for admission to an NTP. The use of this term has led to an interesting irony. Under past regulations "narcotic dependent" was defined as "an individual who physiologically needs...a morphine-like drug to prevent the onset of signs of withdrawal."⁴⁶ The use of this term perpetuated confusion between "addiction," which is associated with behavioral indicators such as compulsions to take the drug and a loss of self-control,³¹ and physical dependence, which is physiological and is characterized by the occurrence of withdrawal symptoms if opioid use is discontinued. As a result, according to the federal NTP regulations, any pain patient who was physically dependent as a result of the continued medical use of opioid analgesics for chronic pain could be considered "narcotic dependent." Such patients could be admitted to a detoxification or maintenance treatment program, designed specifically for addicts, solely for the purpose of using methadone to achieve effective pain relief.

Although it is not known how many chronic pain patients seek treatment for their pain in NTPs, there is evidence to suggest that this practice exists. Dr. Forest Tennant, a physician who operates methadone maintenance programs in California, estimates that nearly 200 patients have been treated for chronic pain conditions and have not otherwise evidenced behavioral or psychological characteristics of addiction.⁴⁷ In addition, results from surveys of convenience samples of health-care practitioners from Iowa, New York, and Pennsylvania indicate professional awareness of this issue.⁴⁸ The surveys were conducted to evaluate practitioner knowledge about the frequency of a variety of problems that patients encounter when obtaining Schedule II opioid analgesics. Respondents indicated that they occasionally (14.8%), often (2.5%), or always (1.5%) knew of pain patients who were admitted to NTPs only to obtain methadone for pain relief, not to obtain treatment for addiction. It seems ironic that, while most chronic pain patients would avoid being labeled as addicts, some accepted and perhaps sought such a diagnosis to obtain relief from their pain.

It seems, however, that admission of pain patients to NTPs will be largely curtailed. Effective May 18, 2001, the federal regulations for the treatment of addiction were modified extensively.⁴⁹ NTPs are now referred to as Opioid Treatment Programs (OTPs). Admission criteria for maintenance treatment have changed and now involve the use of accepted medical criteria, such as the Diagnostic and Statistical Manual for Mental Disorders⁵⁰ or the International Classification of Disorders,⁵¹ that characterize active "addiction" to an opioid drug and at least one year of addiction before admissions. OTPs will be required to make clinical distinctions between addictive disease

and physical dependence resulting from the prolonged administration of controlled substances for the relief of pain so that patients are not admitted to maintenance therapy to receive opioids only for pain (N. Reuter, personal communication, October 2000).

State Policy

State policies also address the use of controlled substances to treat pain in all patients; some policies directly address patients with active addiction or a history of substance abuse. It is the states, not the federal government, that have the authority to regulate medical, pharmacy, and nursing practice. Regulation of medical practice and opioid use is governed at the state level primarily by two sets of policies: (1) controlled substances laws and regulations, and (2) medical practice acts and guidelines. Although, like federal law, all state controlled substances laws prohibit the non-medical use of these drugs, many state policies do not recognize the medical value of controlled substances. For most states there are no provisions that recognize either the medical necessity of opioids for pain management or the importance of ensuring drug availability.

States also have policies that restrict prescribing and dispensing of opioids more so than federal policy; such policies have the potential to interfere with decisions about the care of individual pain patients, decisions that require medical expertise rather than government pronouncement. Many health-care and policy professionals have called attention to the presence of policy and regulatory restrictions, and their potential influence on physician prescribing and patient care.⁵²⁻⁵⁷ Such restrictions have been identified previously as barriers to the appropriate prescribing for pain management for any pain patient, not just those with addictive disease^{34, 38, 58} and will be briefly summarized here. When using controlled substances to treat pain, some state policies contain provisions that:

- Characterize the medical use of opioids as a treatment of last resort;
- Suggest that the medical use of opioids is outside legitimate professional practice;
- Perpetuate the belief that opioids hasten death;
- Require an evaluation of every patient by a specialist in the organ system believed to be the cause of pain;
- Require signed informed consents in every case;
- Require physicians and pharmacists to issue prescriptions for controlled substances in certain schedules using special government-issued forms;
- Limit prescribing based on quantity or duration; and
- Limit length of prescription validity.

Ironically, a number of these potential barriers to pain management have resulted from adoption of state legislation to improve pain management called Intractable Pain Treatment Acts (IPTA).^{34, 38, 59} Ten states currently have an IPTA.³⁴ The overall purpose of an IPTA is to legally recognize the legitimacy of using opioid analgesics for the treatment of “intractable” pain, and to protect physicians from discipline for providing such treatment that involves using opioids. Although state legislatures’ intentions were positive, a number of provisions in IPTAs place additional requirements and restrictions on physician practice and could ultimately hinder, rather than facilitate, good patient care. Such policies reflect greater, rather than less, government regulation over the use of controlled substances for pain management for all patients. It is encouraging that several IPTAs were amended to remove problematic provisions. In addition, the last IPTA was adopted in 1998, perhaps signaling the end of this phase of state pain policy development.

Misuse of terminology relating to pain and addiction has the potential to mislabel pain patients as “addicts” and, thus, to interfere with their pain treatment. A number of states’ policies contain archaic addiction-related terms such as “addict” or “habitué,” or use the more current “drug-dependent person,” and define them according to antiquated standards. These terms and their definitions commonly assert that the presence of “physical dependence” alone is sufficient to characterize “addiction” or related terms. There are 11 states³⁴ that define “drug-dependent person” as follows:

...means a person who is using a controlled substance and who is in a state of psychic *or physical dependence*, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects *or to avoid the discomfort caused by its absence* (emphasis added).⁶⁰

Addiction-related definitions that include physical dependence as an essential feature create the potential for patients with pain who are using opioid analgesics to be incorrectly labeled as “addicts.” Such labeling can result in the denial of opioid prescriptions because the patients are perceived to be at high risk for using their controlled substances for non-medical purposes. In turn, undertreatment of pain can lead to patient request or demands for pain medication, which can be interpreted by health-care practitioners as drug-seeking behaviors. This phenomenon has been called “pseudoaddiction.”⁶¹

Misperceptions about the characteristics of addiction, which are present in state policy, can have profound implications for pain management and patient care. It is important to understand, however, that it is not necessary to use terms such as “addict” or “drug dependent person” to conform state policy with federal law – there is no federal restriction against prescribing opioids to patients with an addictive disease for the purpose of treating pain. In fact, the model for state drug law, entitled the Uniform Controlled Substances Act (USCA), does not include addiction-related terms. The USCA does contain a cautionary statement that, if a state uses such terms, the state legislature should ensure that the definition “cannot be construed to include a patient using a controlled substance pursuant to the lawful order of a practitioner.”⁶²

In addition, state policies can sometimes go so far as to exclude from controlled substances treatment pain patients who use drugs “for non-therapeutic purposes.” Such policy can have direct implications for patients who have addictive disease. For example, the Tennessee Medical Practice Act defines as misconduct “dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances...”⁶³ In addition, the North Dakota IPTA explicitly states that the policy “does not authorize a physician to prescribe or administer controlled substances to a person the physician knows is using controlled substances for nontherapeutic purposes.”⁶⁴ To correct this problem in Texas, the legislature recently modified the IPTA to eliminate the restrictive statutory language and replace it with language that specifically permits prescribing to a pain patient who currently abuses drugs or who has a history of drug abuse. Texas controlled substances regulations, however, have not been modified and continue to prohibit prescribing or dispensing to a “habitual user” of controlled substances.⁶⁵ Since neither of the terms “drug abuse” or “habitual user” are defined in state policy, these seemingly conflicting provisions create ambiguous parameters for medical practice and may contribute to inadequate pain management.

Restrictive language in state policy may have originated from the Federation of State Medical Boards of the U.S. (FSMB), in a model statute entitled “A Guide to the Essentials of a Modern Medical Practice Act” (MMPA). The MMPA recommended to states that prescribing controlled substances to a “habitué or addict or any person previously drug dependent”⁶⁶ be classified as unprofessional conduct and subject to license revocation. The MMPA has since been modified to recognize the legitimacy of prescribing to such patients when done “in compliance with rules, regulations or guidelines for use of controlled substances and the management of pain as promulgated by the Board.”⁶⁷ It is evident that provisions aimed at prohibiting prescribing to a broad class of persons, such as individuals who are addicts or drug dependent, could have a negative impact on patients with AIDS or other chronic conditions who may be experiencing pain from their disease but who also have a history of drug use.

Finally, some state laws that were on the books for many years have required physicians to report to the government the names and addresses of patients identified as “addicts” who were being treated with Schedule II controlled substances.³⁹ In New York, a state with such a reporting requirement,⁶⁸ “addict” was defined as “a person who habitually uses a narcotic drug and who by reason of such use is dependent thereon.”⁶⁹ Such an ambiguous definition could encompass a patient with chronic cancer or non-cancer pain who has developed physical dependence resulting from the medical use of opioid analgesics for a prolonged period of time. In 1998, however, the definition of “addict” in New York law was changed to exclude patients using controlled substances for legitimate medical use, but the general “addict” reporting requirement remains. Since the repeal of similar policies in California in 1985 and Montana in 2001, New York is currently the only state with an archaic policy that requires physicians to report patients who are “addicts.”

Initiatives to Improve Pain Management for Patients with Addictive Disease

A number of initiatives reflect increasing medical recognition that a patient’s current addiction or history of addiction is not an absolute contraindication to pain management using opioids. Such messages have the potential to open health-care professionals’ access to the interface between pain management and addiction, to improve state policies related to the use of controlled substances to treat pain, and ultimately to enhance pain relief for patients with addictive disease.

In 1998, the FSMB developed Model Guidelines for state medical boards to consider and adopt.⁷⁰ The purpose of the Model Guidelines is to address physicians’ concerns about regulatory scrutiny when using opioids to

treat pain. The document also includes a preface that contains many positive messages for medical practitioners. For example, pain management is recognized as part of quality medical practice, which includes the use of opioid analgesics when treating all types of pain. Physicians are also encouraged to become knowledgeable about effective methods for pain management, controlled substances requirements, and addiction when treating patients for pain. Modern definitions are provided for “addiction,” “physical dependence,” and “tolerance.”

The FSMB outlines a set of treatment guidelines that constitute good medical practice when using controlled substances to treat pain. There are seven specific guidelines: (1) evaluation of the patient, (2) treatment plan, (3) informed consent and agreement for treatment, (4) periodic review, (5) consultation, (6) medical records, and (7) compliance with controlled substances laws and regulations.⁷⁰ For patients who have an active addiction, or who have a history of addiction, the Model Guidelines recommend that physicians take advantage of consultation with addiction medicine specialists and undertake more intensive and consistent monitoring of prescription adherence, physical and psychosocial functioning, and treatment goals. The Model Guidelines are a substantial improvement over many past medical board policies because they accept opioid treatment for this patient population. As of October 2001, 19 states have adopted the Model Guidelines either in whole or in part.

A recent statement from the DEA recognizes the need for the appropriate use of opioid analgesics when treating patients with pain. A brochure developed to assist medical professionals in identifying the potential for patient drug abuse, and to address the situation appropriately, contains the following language:

The purpose of this guide is to inform and educate you, the healthcare practitioner, to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing their diversion into the illicit market. It is not the intent of this publication to reduce or deny the use of controlled substances where medically necessary.⁷¹

A letter from the DEA Office of Diversion Control substantiates the legality of pain management in patients who are enrolled in NTPs.⁴⁵

In 2001, the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) published a statement entitled “Definitions Related to the Use of Opioids for the Treatment of Pain.”⁷² Developed through a consensus process, the purpose of the statement is to promote universal agreement about the definitions for addiction-related terms, which is considered essential both to optimal pain management and the treatment of addictive disorders. Definitions are provided for addiction, physical dependence, and tolerance. Again, it is not necessary that state policy use addiction-related definitions as a means of compliance with federal policy. If a legislature considers such definitions necessary in their state’s drug policy, those provided by the AAPM/APS/ASAM consensus statement would reflect accurately the prevailing medical standard for defining “addiction” and other terms and be much less likely to erroneously exclude pain patients from necessary treatment with opioid analgesics.

It is encouraging that state policies that have the potential to place restrictions on prescribing to an entire class of patients (i.e., patients who have an addictive disease) are being reconsidered and repealed by state legislatures. Missouri, New York, and Texas have abolished policy provisions that prohibited prescribing controlled substances to patients with pain who use controlled substances for non-medical purposes. New York is the only remaining state that requires physicians to report patients with an addictive disease to a government agency. These modifications represent a significant improvement in state policy.

There is also evidence that state medical board members’ knowledge and attitudes are changing regarding issues of pain and addiction. A national survey of state medical board members was conducted in 1997 and was compared to responses from a 1991 sample.⁷³ Results showed that respondents in 1997 were more likely to correctly define addiction in behavioral, rather than physiological, terms. In addition, board members surveyed in 1997 were significantly more likely than in 1991 to consider the prescribing of opioids for more than several months to a patient with cancer pain and a history of substance abuse as both lawful and acceptable medical practice. A significant and positive difference was also demonstrated when the patient had non-cancer pain and a history of substance abuse. It should be noted that despite the greater willingness of board members in 1997 to judge the medical practice of prescribing for pain in patients with a history of abuse as legal and acceptable, such responses characterized a small percentage of the total sample. These results, however, represent encouraging improvement in the perceptions of medical regulators regarding the treatment of pain in patients with addictive disease, which by today’s standards would be considered legitimate medical practice.

Discussion

In a cogent letter to an editor, Passik recently commented that:

Because 6 to 15% of the US population abuses drugs, the history of pain management is marked by the undertreatment [of pain in] the other 85 to 94%.⁷⁴

We agree also that there is a need for pain relief for the other 6 to 15% of the population – a need that should be addressed with expertise and extra care, and that should not be precluded by law. Patients with addiction who have debilitating pain should not automatically be precluded from receiving effective opioid analgesia.

The medical community is increasingly acknowledging opioid therapy as an acceptable treatment, in some cases, of pain in patients who are currently addicted or who have a history of addiction. Support for this medical practice can be found in the FSMB's Model Guidelines,⁷⁰ a consensus document by the AAPM/APS/ASAM,⁷² a DEA statement,⁴⁵ reports of medical professionals' beliefs and attitudes,⁷³ and a number of recent policy changes.³⁴ To be effective and not contribute to further addiction or abuse, treatment with opioids should involve clinical arrangements that promote adherence to treatment plans and discourage illicit use.⁷⁵ Pain management in patients with a history of addiction requires extra care, monitoring, and documentation, which would include the careful evaluation of a substance abuse history, frequent review of physical and psychosocial functioning, and possible consultation with an addiction-medicine specialist. A written agreement between physician and patient outlining the patient's responsibilities during treatment can also be helpful. Conforming to these practice parameters can allow for adequate pain management and minimize risk of addiction and drug abuse.

Although effective pain management in patients with addictive disease is complex and demanding, opioid analgesics should be available and used when medically appropriate. We should also continue to identify and change those laws and regulations at both the federal and state levels that have the potential to interfere with the legitimate use of controlled substances to treat pain, including for patients who are at a high risk of addiction. Current standards of medical practice now recognize that the presence of addictive disease is not necessarily a contraindication to the use of opioids to treat pain. The essential task of both regulators and policy-makers is to create a policy environment that reflects these current standards.

Acknowledgments

The authors are grateful to Martha A. Maurer, BS, for her assistance with the collection of the current federal and state laws and regulations mentioned in this article. This project was supported by a grant from the Robert Wood Johnson Foundation.

Bibliography

1. World Health Organization. *Cancer pain relief*. Geneva, Switzerland; 1986.
2. Acute Pain Management Guideline Panel. *Acute pain management: Operative or medical procedures and trauma. Clinical practice guideline*. AHCPR Pub. No. 92-0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; February 1992.
3. Jacox A, Carr DB, Payne R et al. *Management of cancer pain. Clinical practice guideline. No. 9. AHCPR Publication No. 94-0592*. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; March 1994.
4. Portenoy RK. Opioid therapy for chronic nonmalignant pain: Clinicians' perspective. *J Law, Med & Ethics*. 1996;24(4):296-309.
5. World Health Organization. *Cancer pain relief with a guide to opioid availability*. Geneva, Switzerland; 1996.
6. American Academy of Pain Medicine and American Pain Society. *The use of opioids for the treatment of chronic pain: A consensus statement*. American Academy of Pain Medicine and American Pain Society; 1997.
7. American Medical Association Council on Scientific Affairs. *Report 11 of the Council on Scientific Affairs: Use of opioids in chronic noncancer pain*. Chicago, IL: American Medical Association; 1999.
8. American Pain Society. *Principles of analgesic use in the treatment of acute pain and cancer pain*. 4th ed. Glenview, IL; 1999.
9. Ferrell BR, Juarez G, Borneman T. Use of routine and breakthrough analgesia in home care. *Oncol Nurs Forum* 1999;26(10):1655-61.
10. Kruger M, McRae K. Pain management in cardiothoracic practice. *Surg Clinics North Amer* 1999;79(2):387-400.
11. Stevens DS, Edwards WT. Management of pain in intensive care settings. *Surg Clinics North Amer* 1999;79(2):371-86.
12. Tanabe P, Buschmann M. A prospective study of ED pain management practices and the patient's perspective. *J Emerg Nursing* 1999;25(3):171-7.
13. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. *JAMA* 1998;279:1877-82.
14. Todd KH, Samaroo N, Hoffman JR. Ethnicity as a risk factor for inadequate emergency department analgesia. *JAMA* 1993;269(12):1537-9.
15. Ng B, Dimsdale JE, Rollnik JD, et al. The effect of ethnicity on prescriptions for patient-controlled analgesia for post-operative pain. *Pain* 1996;66:9-12.
16. Cleeland CS, Gonin R, Baez L, et al. Pain and treatment of pain in minority patients with cancer. *Annals Internal Med* 1997;127:813-6.
17. Todd KH, Deaton C, D'Adamo AP, et al. Ethnicity and analgesic practice. *Annals Emerg Med* 2000;35(1):11-6.
18. Collins JJ, Grier HE, Kinney HC, et al. Control of severe pain in children with terminal malignancy. *J Pediatrics* 1995;126(4):653-7.

19. Bossert EA, Van Cleve L, Savedra MC. Children with cancer: the pain experience away from the health care setting. *J Pediatric Onc Nursing* 1996;13(3):109-120.
20. Wolfe J, Grier HE, Klar N, et al. Symptoms and suffering at the end of life in children with cancer. *N Engl J Med* 2000; 342:326-333.
21. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med* 1994;330:592-6.
22. SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously ill hospitalized patients: The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). *JAMA* 1995;274:1591-98.
23. Whipple JK, Lewis KS, Quebbeman EJ, et al. Analysis of pain management in critically ill patients. *Pharmacotherapy* 1995;15(5):592-9.
24. Zhukovsky DS, Gorowski E, Hausdorff J, et al. Unmet analgesic needs in cancer patients. *J Pain Symptom Manage* 1995;10(2):113-9.
25. Nowels D, Lee JT. Cancer pain management in home hospice settings: a comparison of primary care and oncology physicians. *J Pall Care* 1999;15(3):5-9.
26. Breitbart W, Rosenfeld BD, Passik SD, et al. The undertreatment of pain in ambulatory AIDS patients. *Pain* 1996;65(2-3):243-9.
27. Breitbart W, Kaim M, Rosenfeld B. Clinicians' perceptions of barriers to pain management in AIDS. *J Pain Symptom Manage* 1999;18(3):203-12.
28. Smith BH, Hopton JL, Chambers WA. Chronic pain in primary care. *Fam Prac* 1999;16(5):475-82.
29. Portenoy R, Dole V, Joseph H, et al. Pain management and chemical dependency: Evolving perspectives. *JAMA* 1997;278:592-3.
30. Sees KL. Pain management in a patient with an addiction history. *JAOA* 1999;99(6: Suppl):11-5.
31. Scimeca MM, Savage SR, Portenoy R, et al. Treatment of pain in methadone-maintained patients. *Mount Sinai J Med* 2000;67(5-6):412-22.
32. International Narcotics Control Board. *Report of the International Narcotics Control Board for 1995: Availability of opiates for medical needs*. United Nations, Vienna; 1996.
33. Institute of Medicine. *Approaching death: Improving care at the end of life*. Washington, D.C.: National Academy Press; 1997.
34. Joranson DE, Gilson AM, Ryan KM, et al. *Achieving balance in federal and state pain policy: A guide to evaluation*. The Pain & Policy Studies Group, University of Wisconsin Comprehensive Care Center. Madison, WI; 2000.
35. World Health Organization. *Achieving balance in national opioids control policy: Guidelines for assessment*. World Health Organization, Geneva; 2000.
36. Joranson DE. Federal and state regulation of opioids. *J Pain Symptom Manage* 1990;5(1: Suppl):12-23.
37. Joranson DE. A new drug law for the states: An opportunity to affirm the role of opioids in cancer pain relief. *J*

Pain Symptom Manage 1990;5(5):333-336.

38. Joranson DE, Gilson AM. State intractable pain policy: Current status. *APS Bull* 1997;7(2):7-9.

39. Joranson DE, Gilson AM. Policy issues and imperatives in the use of opioids to treat pain in substance abusers. *J Law, Medicine, Ethics* 1994;22(3):215-223.

40. Federal Register 2673, 1983.

41. United States vs. Evers, 643 F2d 1043 5th Circuit, 1981.

42. United States House of Representatives. *Comprehensive Drug Abuse Prevention and Control Act of 1970*. House Report No 91-1444, September 1970.

43. Federal Register 50591-97; 1988.

44. Federal Register, Vol. 58, No. 131, July 1993, p. 37507.

45. Good P. *DEA: Pain management in addiction medicine*. Drug Enforcement Administration: U.S. Department of Justice; March 2000.

46. Code of Federal Regulations. Title 21. §291.505(a)(5).

47. Tennant F. *The dilemma of severe incurable, narcotic-dependent pain patients referred to narcotic treatment programs: Need for administrative, regulatory, and legislative relief*. West Covina, CA: Research Center for Dependency Disorders and Chronic Pain Community Health Projects Medical Group; October, 1996.

48. Joranson DE, Gilson AM, Nelson JM. *Perceived barriers to the use of Schedule II pain medications: A survey of health-care professionals in three states*. Poster presented at the 17th Annual Meeting of the American Pain Society. San Diego, CA; November 1998.

49. Code of Federal Regulations. Title 42. §8.12.

50. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 4th ed. Washington, DC: APA; 1994.

51. World Health Organization. *The ICD-10 classification of mental and behavioural disorders: Clinical descriptions and diagnostic guidelines*. Geneva, Switzerland: WHO; 1992.

52. Angarola RT, Wray SD. Legal impediments to cancer pain treatment. In: Hill CS, Fields WS, eds. *Advances in pain research and therapy, Volume 11*. New York, NY: Raven, 1989:213-31.

53. Foley KM. The “decriminalization” of cancer pain. In: Hill CS, Fields WS, eds. *Advances in pain research and therapy, Volume 11*. New York, NY: Raven, 1989:5-18.

54. Max MB. Pain relief and the control of drug abuse: conflicting or complementary goals? In: Hill CS, Fields WS, eds. *Advances in pain research and therapy, Volume 11*. New York, NY: Raven, 1989:241-5.

55. Portenoy RK. Chronic opioid therapy in nonmalignant pain. *J Pain Symptom Manage* 1990;5(Suppl):46-62.

56. McIntosh H. Regulatory barriers take some blame for pain undertreatment. *J Nat Cancer Inst* 1991;83(17):1202-4.

57. Joranson DE, Cleeland CS, Weissman DE, et al. Opioids for chronic cancer and non-cancer pain: A survey of state medical board members. *Fed Bull* 1992;79(4):15-49.

58. Joranson DE, Gilson A. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. *Psychiatric practice under fire: The influence of government, the media, and special interests on somatic therapies*. Washington, DC: American Psychiatric Press, 1994:173-94.
59. Joranson DE. Intractable pain treatment laws and regulations. *APS Bull* 1995;5(2):1-3, 15-7.
60. Arizona Revised Statutes. §36-2501(A)(5).
61. Weissman DE, Haddox JD. Opioid pseudoaddiction - An iatrogenic syndrome. *Pain* 1989;36:363-366.
62. National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. Chicago, IL: NCCUSL; July 29-August 5, 1994, p. 13.
63. Tennessee Code Annotated. §63-6-214(13).
64. North Dakota. §19-03.3-05
65. Texas Annotated Code. §13.66(j)(1).
66. Federation of State Medical Boards of the United States. *A guide to the essentials of a Modern Medical Practice Act*. 5th ed. A policy document of the Federation of State Medical Boards of the United States, Inc. Euless, TX: FSMB; 1988, p. 15.
67. Federation of State Medical Boards of the United States. *A guide to the essentials of a Modern Medical Practice Act*. 9th ed. A policy document of the Federation of State Medical Boards of the United States, Inc. Euless, TX: FSMB; April, 2000.
68. New York CLS Public Health, §3372.
69. New York CLS Public Health, §3302(1).
70. Federation of State Medical Boards of the United States. *Model guidelines for the use of controlled substances for the treatment of pain*. A policy document of the Federation of State Medical Boards of the United States, Inc. Euless, TX: FSMB; May, 1998.
71. Drug Enforcement Administration. *Don't be scammed by a drug abuser*. An informational brochure produced by the Drug Enforcement Administration, U.S. Department of Justice; December, 1999, p. 1.
72. American Academy of Pain Medicine/American Pain Society/American Society of Addiction Medicine. *Definitions related to the use of opioids for the treatment of pain*. A consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine; 2001.
73. Gilson AM, Joranson DE. Controlled substances and pain management: Changing knowledge and attitudes of medical regulators. *J Pain Symptom Manage* 2001;21(3):227-237.
74. Passik SD. Letter to the editor: Responding rationally to recent reports of abuse/diversion of Oxycontin. *J Pain Symptom Manage* 2001;21(5):359-360.
75. Passik S, Portenoy R. Substance abuse issues in palliative care. In: Berger A, Portenoy RK, Weissman D, eds. *Principles and practice of supportive oncology*. Philadelphia, PA: Lippincott-Raven, 1998:513-30.