

Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin

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Abstract

Interpretation of regulations establishing standards for prescribing opioids by government regulatory boards and drug-enforcement agencies is more restrictive for treatment of nonmalignant pain than for malignant pain. Authority to regulate opioids is provided by health practice acts enacted by state governments, and controlled substances acts, enacted by both state and federal governments. The methods used by boards/agencies to determine standards of practice for opioid use result in interpreting the language in these regulations based on myths, prejudices, and misinformation about opioids, and the unexamined belief that mere exposure of patients to these drugs causes psychological dependence (addiction) on them to all patients in all instances. Interpretation is also strongly influenced by a failure of regulatory and enforcement bodies to recognize their coequal obligation of making opioids readily available to those who need them for legitimate medical purposes, while simultaneously policing their diversion to illegitimate uses. Emphasis on the police function of preventing diversion is paramount. Disciplining practitioners using standards based on myths, prejudices, etc., reinforces physicians' fears of prescribing opioids for nonmalignant pain. Patients with nonmalignant pain who are not relieved if opioids are not provided will continue to suffer until regulatory boards/drug enforcement agencies define the standards of practice for opioid use for nonmalignant pain in clear and unequivocal terms. It is unlikely these standards will be developed until there is a consensus among pain specialists about opioid use for nonmalignant pain because boards/agencies have no consistent, reliable source of expert information. Pain specialists should initiate efforts to develop this consensus. J Pain Symptom Manage 1996;11:287-298.

Key Words

Pain, nonmalignant, opioid, regulate, prescribing, undertreatment, interpreting, standards, disciplinary, addiction

Introduction

Inadequate treatment of both acute and chronic pain¹⁻⁵ has been recognized as a signifi-

cant health care problem by a panel of pain specialists commissioned to evaluate pain treatment by the Agency for Health Care Policy and Research of the United States Public Health Service.^{6,7} Pain is most likely undertreated when relief requires the use of strong opioids because physicians are reluctant to prescribe these drugs, particularly if the doses required are considered outside the "usual" or "recommended" range,

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as defined by standard pharmacology texts, and if prolonged use is necessary.⁸ Similarly, nurses and pharmacists have reservations about administering and dispensing opioids under these circumstances. This reluctance is particularly compelling if the painful condition is of chronic, nonmalignant origin, and pain control will require prescribing, administering, and dispensing for months or years.

Three basic reasons have been proposed to account for this reluctance to prescribe opioids properly: (a) cultural and societal barriers to adequate and appropriate opioid use, (b) knowledge deficits about the pharmacology of opioids among health-care professionals, and (c) influence of disciplinary boards and drug-enforcement agencies, both state and federal, on the prescribing practices of physicians and dispensing practices of pharmacists.⁹ Government boards and agencies exert a subtle, and sometimes not so subtle, influence on treatment of pain and other symptoms through the real or perceived threat of loss of license or criminal prosecution felt by practitioners who prescribe, dispense, or administer controlled substances. The possibility of losing one's license or becoming the object of criminal prosecution, though only one of the three reasons cited above for inadequate pain and symptom treatment, is so serious that it has a profound, and disproportionate, influence on patient care, especially if the pain is of nonmalignant origin. Even if an accused practitioner is eventually exonerated, defending oneself against such charges is expensive.

This article explores the influence of licensing and disciplinary (regulatory) boards and drug enforcement agencies on the treatment of chronic nonmalignant pain. Distinction is made between pain of nonmalignant and malignant origin because use of opioids for the treatment of pain of malignant origin has greater acceptance than their use for treatment of pain of nonmalignant origin. The analysis is based on my experience with reviewing the Code of Federal Regulations,¹⁰ the federal and states controlled substances acts, and health practice acts in the states of Texas, Louisiana, Florida, and Washington, and on my personal experience providing advice and testimony for physicians charged with violations of acts in these states.

Source of Government Authority to Regulate

Government regulations on controlled substances are authorized by two legislative sources: (a) health-care practice acts (HPAs; including medical, nursing, pharmacy, dental, etc.), which set standards of practice for the use of controlled substances and all other aspects of professional practice, and (b) controlled substances acts (CSA), which mandate how such substances are to be handled when used for medical purposes. States exert influence on health-care practice through enactment of HPAs and the evaluation of practitioners' practices based on standards set forth in them. Federal influence is primarily through CSAs.

HPAs are administered and interpreted by boards created by the acts and composed of persons appointed by the state governor or some other government official. The quality of a board's actions is directly related to the quality of the members chosen by the governor. Although not invariably so, these appointments may be influenced more by political considerations than qualifications and merit. As a result, there is variation among these regulators in knowledge and attitudes about the issues that come before the board. Furthermore, some boards have lay, or so-called public members, who have no knowledge about technical medical conditions; these individuals have no knowledge of pain treatment or use of controlled substances. The rationale for including lay members on medical boards is to provide a presence that will instill confidence in the public that the board is functioning in an impartial manner and not allowing licensees to escape discipline when a violation of the MPA occurs because of colleague reluctance to discipline.

Because of the heterogeneity of state regulatory boards, variation in regulatory practices exists among them. Under the aegis of the Federation of State Medical Boards,¹¹ David Joranson et al. conducted a survey of regulatory board members in 49 states that assessed board members' perception of the legality and appropriateness of opioid use for treatment of pain. Results of this survey are shown in Tables 1 and 2. The number of regulators with negative views of opioid use in the treatment of pain in situations for which most practitioners

Table 1
Perceived Legality of Prescribing Opioids for an Extended Period

Level of perceived legality	Patient History			
	A. Cancer pain only	B. Cancer pain with history of opioid abuse	C. Chronic non-malignant pain only	D. Chronic non-malignant pain with history of opioid abuse
1. Lawful and generally acceptable medical practice	75%	46%	12%	1%
2. Lawful, but generally not acceptable medical practice; should be discouraged	14%	22%	47%	25%
3. Probable violation of medical practice laws and regulations; should be investigated	5%	14%	32%	58%
4. Probable violation of federal/state controlled substances laws; should be investigated	5%	12%	27%	50%
5. Don't know	7%	16%	7%	6%

Note: columns do not total 100% because respondents could give more than one response.

would consider such use an accepted standard of practice is of particular concern. A low percentage of board members considered the use of opioids appropriate for treatment of non-malignant pain. These findings validate the fear of disciplinary action all practitioners have when prescribing opioids, especially for nonmalignant pain. This fear significantly contributes to the inadequate use of opioids.

Determining and Applying Practice Standards

State legislatures are responsible for crafting HPAs, which create administrative bodies (examining and disciplining boards for medical nursing, pharmacy, etc.) responsible for

enforcing the acts. The purpose of such acts is to protect the public interest in matters of health care by licensing only qualified practitioners and monitoring their continued practice. Standards must be maintained that will, at the least, prevent practitioners from inflicting harm on their patients. However, the public interest must surely insist on standards that go beyond this negative requirement and actively ensure that modern, scientifically based, high-quality medical care be provided to all citizens of the jurisdiction. A criterion commonly used for monitoring practice is the practice of other comparable practitioners in the community. However, high-quality medical care should be measured against a standard that reasonable minds would agree is appropriate for qualified

Table 2
Physician Board Member Rankings of Analgesics for Treatment of Prolonged Moderate to Severe Cancer Pain

Ranked as 1, 2, or 3		Would not recommend	
1. aspirin/acetaminophen and codeine	47%	1. levorphanol	50%
2. aspirin/acetaminophen and oxycodone	35%	2. methadone	45%
3. morphine	25%	3. pentazocine	44%
4. aspirin/acetaminophen	21%	4. single entity codeine	42%
5. meperidine	18%	5. aspirin/acetaminophen	37%
6. propoxyphene	17%	6. Brompton's cocktail	34%
7. hydromorphone	13%	7. propoxyphene	33%
8. Brompton's cocktail	9%	8. hydromorphone	24%
9. single entity codeine	9%	9. meperidine	17%
10. methadone	7%	10. aspirin/acetaminophen and oxycodone	9%
11. pentazocine	6%	11. aspirin/acetaminophen and codeine	8%
12. levorphanol	2%	12. morphine	6%

practitioners, and not merely by customary community practice unrelated to any other applicable standard. Outcome should be an element of the standard of practice. This would require patient follow-up, a practice boards seem loathe to adopt.

In structuring the wording for practice standards, legislators try to avoid language that may inadvertently impede the highest standard of medical practice. In addition, as it is desirable that the standards be flexible enough to apply to a myriad of practice situations, the language contained in guidelines for determining standards is broad and general, and therefore subject to interpretation.

One of the regulatory boards' functions is to interpret the broad language of the acts. Impediments to proper use of controlled substances usually arise in the process of interpretation. If interpretation is based on biases, prejudices, and misinformation, the licensee may be unjustly disciplined.

Interpreting Language

For practice standards to be flexible, the language must be broad in scope, and not rigid, directive, or prescriptive. This permits interpretation in light of a variety of clinical situations. An example from the Medical Practice Act (MPA) of Texas illustrates the wide latitude for interpretation these guidelines afford. The Texas act proscribes "prescribing or administering a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed" (Section 3.08(4)(E)), "prescribing, administering, or dispensing in a manner not consistent with public health and welfare dangerous drugs as defined by Chapter 425, (Section 3.08(4)(F)), and "professional failure to practice medicine in an acceptable manner consistent with public health and welfare" [(Section 3.08(18)].¹²

Guidelines for interpreting such phrases as "nontherapeutic," "prescribing medications not consistent with public health and welfare," and "practicing medicine in a manner not consistent with public health and welfare," are not provided in the acts. In addition, printed transcripts of hearings between the board and physicians charged with violating the MPA, under these sections, cannot be obtained easily. Very few cases ever reach the court system, and case law that

deals with interpretation of vague phrases in these acts is scarce. Therefore, a physician's access to information on how the board has interpreted these phrases in other cases is essentially nil. Unfortunately, health-care professionals must make treatment decisions regarding use of controlled substances without knowing the meaning of vague phrases or how a board will ultimately interpret them for the clinical situation facing the clinician.

Basing evaluation of treatment decisions on vague guidelines is problematic at best, but is valid only as long as the interpretation is based on sound scientific principles and is free from the influence of biases, prejudices, myths, and misinformation. Unfortunately, the reality is that societal biases, prejudices, myths, and misinformation about opioids do influence interpretation of these vague guidelines. Interpretation of appropriate use is especially severe and prejudicial in cases of long-term use of opioids for pain of nonmalignant origin. New guidelines are urgently needed for interpreting opioid use for this purpose.

Failure to Recognize

Competing Public Interests

It is in the public interest to prevent diversion of legal drugs from legitimate to illegitimate use. It is also in the public interest to assure that all citizens who suffer from painful medical conditions are relieved of their pain. Boards almost invariably fail to recognize competition between these public interests. When legal opioids are indicated for pain relief, they should be available to the patient at the appropriate time and in appropriate quantities.¹³ This is equally true for pain of both malignant and nonmalignant origin.¹³ This medical need, however, competes with the perceived police function of preventing diversion and the board's perception of its role in preventing addiction. More emphasis is given to the police function and preventing the maintenance of addiction than assuring availability of opioids for pain relief.

At present, there is considerable confusion about the definition of addiction. Physiological dependence on opioids is often equated with psychological dependence. It is imperative that a distinction be made between these two conditions when opioids are used for medical purposes. Persons who are psychologi-

cally dependent on a drug have a compulsive craving for the drug and take it despite predictable and consistent harm to the user.¹⁴⁻¹⁷ These persons are considered "addicts." Patients who are physiologically dependent on a drug that relieves pain do not exhibit these characteristics and are not addicts. When pain is relieved, these patients have no lingering desire to take the drug. Charles Schuster, former director of the National Institute on Drug Abuse, has stated, "We have been so effective in warning the medical establishment and the public in general about the inappropriate use of opiates that we have endowed these drugs with a mysterious power to enslave that is overrated."¹⁸

Determining Customary Community Standards

As stated previously, customary community practice is the usual criterion used by boards to determine standards of health-care practice. The community standard is almost universally characterized by the withholding of these drugs or prescribing inadequate doses for intervals that exceed the drug's period of effectiveness, and restricting the quantity supplied to only a few days' needs. Therefore, practitioners who prescribe adequate doses for proper time intervals and who provide adequate quantities of opioids to the patient for a reasonable number of days are often considered, *prima facie*, outside the standard of practice and are charged with violations of the act, such as "nontherapeutic (in this case, "overprescribing" and "inappropriate") prescribing," and "failing to practice medicine or prescribing in an acceptable manner consistent with public health and welfare." The patient's need for the opioid to treat a targeted symptom and the outcome of pain treatment are not considered vital parts of the community standard.

When interpreting the validity of practitioners' actions, decisions about dosing should be based on current, scientific information derived from studies of opioid pharmacology in patients experiencing pain. The cancer patient in pain has provided a new model for studying long-term administration of opioid pharmacology in the setting of chronic pain, and this has provided new knowledge about opioids. Principal among this new knowledge

is that pain itself influences the dose of drug required to relieve it.¹⁹ The more intense the pain, the higher the dose of analgesic needed for relief. A "proper" dose, therefore, is whatever dose is required to relieve the pain and is limited only by demonstrable side effects. Recommended or usual starting doses found in pharmacology texts, and other generally accepted authoritative sources, are merely guidelines and should be hastily abandoned if they are inadequate. Doses recommended as "usual" in most sources of dose information were determined by single-dose studies using an older pain model, the postoperative pain patient, and single-dose studies in selected cancer patients.²⁰ The intensity of pain in patients suffering chronic pain, of both malignant and nonmalignant origin, is usually greater than that of patients experiencing postoperative pain, and doses must be adjusted accordingly. For example, in a multicenter study of cancer pain treatment, the mean daily dose of morphine was 240 mg, with a range of 60-1800 mg/day.²¹

Opioid use for pain of nonmalignant origin is controversial, and no consensus exists among experts.²²⁻²⁵ This is especially true of back pain with no demonstrable cause and chronic headaches.^{26,27} Recommendations for opioid use in treatment of pain for these conditions and all pain of nonmalignant origin range from an emphatic rejection under any circumstances to use in selected cases. Many patients with back pain have had multiple surgical procedures, and, unfortunately, a significant number have symptoms that either persist or are worse following the surgical procedure. Almost invariably, these patients are ultimately cared for by a generalist, such as a family practitioner or an internist. The only effective option remaining for pain relief for a subpopulation of these patients is systemic opioid therapy. Because of the frustrating and debilitating nature of their symptoms, these patients frequently exhibit emotional disturbances that require the use of psychoactive drugs. Practitioners who use opioids and psychoactive drugs to treat these patients for what they consider legitimate medical complaints are often accused by boards of perpetuating an "addict's" drug abuse habits. The lack of consensus about the proper use of opioids for pain of nonmalignant origin among pain

experts makes determining a community standard extremely difficult. Indeed, the standard is likely to be determined based on prejudices and misinformation about the drugs involved and about the patients experiencing these problems. Doses outside of the usual range are likely to be considered as "excessive" prescribing and in violation of the MPA. Physicians faced with treating these patients are reluctant to risk this possibility, and the result is undertreatment or refusal to treat the patient effectively. In the absence of practice standards, board investigators and board members may arbitrarily rule that extensive consultations with a variety of specialists should have been done.

Boards should not rely uncritically on community standards for determining the use of these drugs in a given community. Targeted symptoms and outcome of treatment should also be considered. Community standards should not be allowed to perpetuate inadequate treatment of valid medical complaints. Statutory remedy may be necessary to establish appropriate community standards for treatment of pain.

Failure to Appreciate Pharmacokinetics and Pharmacodynamics

Investigators for boards and agencies are unlikely to have an adequate understanding of the pharmacokinetics of opioids. For example, biotransformation in the liver is not often understood and "larger" oral than parenteral doses are not understood to be equianalgesic. The "larger" oral dose is frequently considered outside the standard of practice and therefore a violation of the HPA, whereas the "smaller" parenteral dose is considered to be within the standard of practice.

Being unaware of or ignoring pharmacokinetics commonly causes regulators to consider only the absolute number of milligrams, tablets, or dose units without regard for clinical circumstances. For example, practitioners who use opioids intraspinally are rarely investigated because regulatory investigators considers the "smaller" dose required by this route not only acceptable but desirable compared with equianalgesic oral doses. In contrast, physicians who must assume treatment of patients who have failed intraspinal opioid therapy and must use oral opioids are vulnerable to

charges of violating the standard of practice for opioid use because the oral dose is considered "excessive," even though the ultimate, effective dose is essentially identical.

Faulty Definition of Addiction Results in Unjust Discipline

As mentioned earlier, boards often make decisions about addiction based on a faulty definition. Again, this is especially true when opioids are prescribed to treat nonmalignant pain. The common societal definition of addiction is equated with the physiological dependence on a drug that results from chronic use. Unfortunately, many regulators accept this definition without critical evaluation. Because of this, practitioners who prescribe opioids for patients with chronic painful conditions over the protracted course of their diseases consider themselves vulnerable to discipline because regulators may judge them to be creating drug addicts, a practice that is not in the public interest and, therefore, a violation of the practice act.

Another popular misconception about the addictive potential of these drugs is that mere exposure to them will cause addiction. Studies in patients who must take narcotics over prolonged periods for relief of painful medical conditions demonstrate that psychological dependence is a rare outcome.^{28,29} Similarly, experience with veterans of the Vietnam War who returned home psychologically dependent (addicted) on heroin revealed that only 25% remained psychologically dependent (addicted) on it after 2 years.^{30,31}

Treating patients with opioids for chronic pain is not a threat to the public interest. Rather, such treatment is in the best interest of the public health and welfare of the citizens of the jurisdiction. Discipline based on a faulty definition of addiction (physiological dependence) is unjust.

Inequitable Enforcement Practices

Health-care professionals may be reported to boards and agencies by a wide variety of sources, including anonymous complainants. Most boards and agencies are obligated to investigate such complaints regardless of their apparent merit. In some instances, the same patient has been treated with opioids, psychoactive drugs, and other categories of drugs by

a succession of practitioners, all of whom have prescribed in essentially the same way, but the complainant, who may be a disgruntled patient or a colleague who is prejudiced against these drugs or disagrees with how the treating physician is using them, only is familiar with one of the physicians and charges that practitioner with a violation. The charged practitioner may be disciplined while the others are not.

Another inequitable enforcement practice arises from the treatment of chronic back pain of nonmalignant origin. Surgical correction of the cause is possible in some patients; however, in others, severe, chronic pain persists and indeed may worsen after multiple surgical attempts to treat the alleged cause. The indications and justification for multiple surgical procedures may be vague and problematic, and, after these multiple surgeries, many patients are nonfunctional because of constant pain. Opioids are useful in controlling pain and restoring functional status to a selected subpopulation of these patients. However, physicians who prescribe opioids for these patients are vulnerable to charges of "nontherapeutic" or "excessive" opioid use and therefore in violation of the standard of practice. In contrast, the surgeon who performed the multiple "nontherapeutic" or "excessive" surgeries is seldom, if ever, vulnerable to being charged with violating the standard of practice. In applying the term "nontherapeutic" to opioid use in this context, confusion exists between pharmacological and social definitions of nontherapeutic. Certainly, using an analgesic to treat pain is pharmacologically therapeutic. However, society is reluctant to accept treatment of pain of nonmalignant origin with opioids, especially long-term treatment, as a valid use for them and consequently labels such use "nontherapeutic" or "excessive."

Questionable Disciplinary Techniques Used By Boards

The disciplinary actions of boards reflect the confusion about legitimate and illegitimate uses of opioids. Some of these actions are as follows:

Required courses in opioid prescribing. A physician who has been charged with a violation of the MPA because of inappropriate use of opioids may be required to enroll in an educational course to learn how to "properly" use

them. "Proper" use in these courses is characteristically defined as not using opioids at all for the clinical condition the practitioner was treating. Although pain relief may be impossible without using opioids, the undesirable outcome of unrelieved pain seems irrelevant to the disciplinary board. Indeed, most courses have no relevance to the realities of the medical situation the charged physician was treating, nor is the faculty for such a course likely to have had experience with clinical situations similar to those the charged physician faced. When other practitioners hear of professionals they respect and consider competent and compassionate being subjected to such irrational discipline, this reinforces their reluctance, and indeed unwillingness, to use opioids, even when they feel these drugs are indicated, because of fear of being subjected to a similar, or worse, fate.

Required use of all alternative treatments. Regulators assume that if opioids are to be used at all for the treatment of pain, especially pain of nonmalignant origin, they must be used only for brief periods and only as a last resort. Boards, therefore, require a practitioner to subject a patient to all alternative modalities of treatment before considering opioid use, often regardless of whether these modalities are medically indicated and despite evidence that multiple attempts to remove the cause of the pain have failed. Psychiatric consultation for all patients is usually a minimum requirement. The presumption seems to be that anyone who potentially requires extended treatment with opioids for pain relief has a psychiatric disorder until proven otherwise. Requiring patients to undergo such an arbitrary and problematic succession of treatment modalities is degrading, irrational, and expensive. Additionally, it represents an arbitrary, nonproductive intrusion into the doctor-patient relationship by disciplinary boards.

Controlled Substance Laws

Federal and state laws exist to control any drug that may be dangerous to the user with unsupervised use. All prescription drugs fall into this category and are designated "dangerous drugs." Drugs that have mind-altering potential, may cause psychological dependence (addiction), and have a high abuse potential are sub-

ject to additional laws that further control their legal use. These drugs are designated "controlled substances" by both federal and state governments. Controlled substances may be legally used to treat medical conditions for which their pharmacological properties, including mind alteration, are beneficial to the afflicted individual. Individuals who use these drugs for their intended medical purposes are called patients and are not drug abusers or criminals. Individuals who use these drugs for recreational, illegal, and nonmedical purposes are drug abusers. Such persons commonly engage in other criminal activity, such as robbery, assault and battery, and sometimes murder, that violate not only controlled substances laws but other laws; they are criminals. Unfortunately, society does not always distinguish between patients, who have legitimate needs for these drugs, and individual drug abusers or criminals, who have no legitimate medical need for them. Patients who must have opioids for treatment of medical conditions requiring their use may find their disease is "criminalized," and they are stigmatized.

Controlled substances laws are enacted by both federal and state governments. Title 21 of the Code of Federal Regulations is the federal law that details how a practitioner may use opioids.¹⁰ Enforcement of federal laws is the responsibility of the Diversion Control Division of the Drug Enforcement Administration of the United States Department of Justice. States' controlled substances laws are enforced by narcotics or controlled substances divisions of state law enforcement agencies, as well as state and local police agencies. State and federal agencies have police powers that generally parallel one another, i.e., both can file criminal charges that can lead to imprisonment. One difference between federal and state laws is that Title 21 specifically recognizes that opioids have legitimate medical uses, whereas most state statutes do not.

Texas and California have passed "Intractable Pain Treatment Acts." These acts recognize the legitimate use of controlled substances. California's act differs from Texas's in that California requires a second opinion to substantiate the diagnosis of "intractable pain." Both laws permit the use of controlled substances for the treatment of intractable pain due to any etiology. Although both laws have been on the books for

several years, neither seem to have made an appreciable difference in physicians' prescribing practices. This is probably true because the act in both states failed to provide specific standards for opioid use. Subsequently, the Medical Board of California adopted specific guidelines for prescribing controlled substances for intractable pain,³² and the Texas State Board of Medical Examiners adopted rules providing for authority of physicians to prescribe for the treatment of pain.³³ In both instances, the net effect is a clearer picture for the practicing physician as to what the standard of practice is for the use of opioids in treating pain of both malignant and nonmalignant origin. The action by the Texas Board is stronger because rules have the same force as law. Succeeding boards will be bound by these rules, whereas succeeding boards will not be bound by the guidelines adopted by the present California Board because there is no legal requirement to follow guidelines. Hopefully, physicians in both of these states will feel more comfortable prescribing opioids for intractable pain, especially of nonmalignant origin.

How Controlled Substance Laws Contribute to Inadequate Pain Relief

Scheduling of drugs. Controlled substances are categorized into "schedules" based upon their potential for abuse. Elaborate tracking procedures monitor the drugs' movement in pharmaceutical and medical channels, beginning with international treaties that govern the importation of raw materials for their manufacture and concluding with their distribution through wholesale and retail sales channels.³⁴ An example of how scheduling may negatively influence patient care is illustrated by recent action of the Texas Board of Pharmacy. In collaboration with law enforcement officers, the board requested the Texas Commissioner of Health to reschedule all products containing hydrocodone from schedule III to schedule II because of alleged diversion and prescription forgery. As Texas requires that all schedule II drugs be written on a triplicate prescription, with one copy going to the state police, rescheduling hydrocodone would then require that prescriptions for these products be written on triplicate prescription forms. Experience in states requiring triplicate prescriptions demonstrates that a significant decline in prescribing occurs when a drug must

be prescribed using these forms. It could be predicted that the same would occur if hydrocodone were rescheduled. Many patients currently treated with hydrocodone have pain of such severity that it should be treated with a more potent opioid. Because the more potent opioid requires a triplicate prescription, however, they are not. It could be predicted, therefore, that if hydrocodone were rescheduled and a triplicate required, those patients already undertreated with hydrocodone would be treated with an even "weaker" opioid, or a nonopioid that did not require a triplicate prescription. This would result in further undertreatment of pain in these patients. The amount of hydrocodone involved in this alleged diversion and forgery problem was interesting from its possible impact on the street availability of the drug. Figures obtained from the Drug Enforcement Administration showed that the percentage of hydrocodone considered diverted amounted to 0.08% of all the hydrocodone entering the state of Texas during the time period in question! It hardly seems warranted to cause a negative impact on the quality of patient care to attempt to prevent diversion of such an insignificant amount of a controlled substance. This is not to minimize the crime of forgery and diversion, but crimes should be dealt with by police tactics, not by restricting access to a legal, effective drug. The reluctance of physicians to use triplicate prescriptions is not the only reason schedule II drugs are not prescribed when they are indicated. There are also restrictions on refills and delivery. Additionally, prescriptions for such drugs cannot be phoned into a pharmacy except in emergency conditions. The individual receiving the drug must be the patient, appear in person, or someone with a legitimate relationship to the patient, and be identifiable by the pharmacist filling the prescription. Physicians practicing in rural areas who have patients living in surrounding communities have difficulty getting schedule II drugs to their patients because of restrictions on prescriptions. The impact of regulations to control diversion and methods to address prescription forgery on patient care should be carefully studied before they are implemented. Unfortunately, there is seldom a spokesperson for patients participating in the deliberations of members of bureaucratic agencies considering these regulations.

Numerical restrictions. Controlled substances laws may limit the number of dose units, usually for schedule II substances only, that can be prescribed for a patient for a given time period. The number designated in the law is arbitrary and not related to the number of dose units required to effectively treat a medically targeted symptom or condition. For example, a number frequently contained in statutes is 120 units, or a 1-month supply, whichever is less. This could be 120 units of 15-, 30-, 60-, 100-mg morphine tablets. The range of total milligrams for this number of tablets is 1800 to 12,000 mg, depending on the dose size of the unit prescribed. A restriction of this type is irrational. No data are available to substantiate the premise that restricting quantities is effective in addressing the problem of drug diversion, but it is a significant disadvantage and inconvenience for the patients who have a legitimate need for them. This limitation forces the patient to make frequent requests for prescription refills and possibly requires otherwise unnecessary office visits, resulting in increased costs, intimidation of the patient, and even deterioration of the doctor-patient relationship because the doctor may insinuate the patient is a drug abuser. The pseudo-rationale for legal limitation of dose units stems from illegal prescribing by so-called "script doctors" being characterized by prescribing large quantities of drugs.³⁵ This is a further example of confusing the legal and illegal uses of these drugs, with an imprudent judgment in favor of an alleged prevention of illegal use.

Medical indication restrictions. Medical indications for prescribing controlled substances may also be limited by regulatory boards. For example, until recently, prescribing psychostimulants to counteract the sedation caused by opioids prescribed for pain treatment was prohibited in Wisconsin. Thanks to efforts by the Wisconsin Cancer Pain Initiative, this restrictive rule was changed.³⁶ Many states have laws and rules that arbitrarily limit medical indications for controlled substances and are out of touch with clinical reality. For example, laws may summarily prohibit persons who are psychologically dependent on (addicted to) controlled substances, or who have a history of drug abuse, from having these drugs prescribed, regardless of a current, legitimate medical indication for their use. Clinical reality is that persons falling into these cat-

egories may develop chronic painful medical conditions such as cancer; denying pain relief to them is inhumane. Admittedly, such patients are likely to be more difficult to manage, but health-care professionals have an obligation to provide them care.

Record-keeping requirements. Pharmacists and physicians who stock controlled substances are subject to strict record keeping regarding the dispensing, delivering, and administering of these drugs. Failure to do so can result in disciplinary action and criminal prosecution. Record keeping for pharmacists is a fact of life that is fundamentally accepted. However, physicians who provide these drugs for their patients may find the record keeping requirements onerous. Therefore, it is unlikely that many will be willing to meet the requirements to make controlled substances available for the usually small number of patients requiring them. This may be a serious problem in rural areas or other areas that are medically underserved, thus causing these patients to be inadequately treated.

Multiple-copy prescriptions. In nine states, schedule II controlled substances must be prescribed using multiple-copy prescription forms (usually three copies, commonly referred to as "triplicates"), with one copy going to a state police agency. In New York, benzodiazepines must also be prescribed using a triplicate prescription form. No studies have been done in any of these states to determine whether unthoughtful and unnecessary prescribing was a problem or whether diversion was diminished or eliminated by this requirement. Triplicate prescriptions do have a chilling effect on physicians' prescribing of schedule II controlled substances, resulting in less prescribing of the regulated drug. However, less prescribing does not mean that patients' needs for the drugs have diminished or disappeared, or that prescribing of them was frivolous. Generally, less-effective drugs are prescribed and patients suffer from inadequately relieved pain.^{37,38} Proponents of multiple-copy prescriptions take the rather naive view that if a physician is "competent," he or she will prescribe schedule II substances when they are really necessary for a patient regardless of the triplicate requirement. This view assumes the physician is confident that the enforcement agency has a clear and undisputed concept of what is proper prescribing, free of biases, preju-

ices, myths, and misunderstandings. Examination of the record of enforcement in the cases I have been involved with, especially in cases of pain of nonmalignant origin, does not substantiate such an interpretation.

Discussion

The foregoing presents how the HPAs and CSAs are administered, and how the process of administration is often done in such a way as to negatively influence proper prescribing of opioids, especially for the treatment of pain of nonmalignant origin. Practitioners' fear of unwarranted discipline and/or criminal prosecution by regulatory/disciplinary boards and drug enforcement agencies can be removed only if the HPAs (and rules and regulations interpreting them) and the CSAs clearly define standards for opioid use. These standards must be understood by both the prescribers and the disciplinary boards/drug enforcement agencies and then be enforced fairly and consistently. This will allow practitioners to know how to conduct themselves in such a way as not to provoke charges by government authorities. Once standards and consistent enforcement practices are in place, the board/drug enforcement agency, through their investigative arms, can determine whether the charges made against a practitioner are outside the standards of acceptable practice and require further investigation or whether no further proceedings are necessary. This would restore practitioners' confidence in the system and encourage proper prescribing.

A major hindrance to developing these standards is, unfortunately, a lack of consensus among pain specialists about opioid use for nonmalignant pain which contrasts to the consensus for their use in treating pain of malignant origin.^{22,23} Four reasons probably account for this lack of consensus: (a) data is lacking on the long-term effectiveness of treatment with opioids versus alternative modalities, (b) lack of data on whether long-term opioid use interferes with other goals of treatment (e.g., improved function) in chronic pain patients, (c) application of confusing definitions of addiction, and (d) strong emotional feelings about opioids resulting from their overwhelmingly negative image in our society.

Lacking this consensus, regulatory/drug enforcement agencies have no consistent, reli-

able source of expert information regarding opioid use for these conditions. This results in inconsistent disciplinary actions, which practitioners find patently unfair, and scary practice-threatening and criminal prosecution actions by drug enforcement agencies for opioid use that practitioners consider appropriate. Pain specialists could make a major contribution by developing clearly defined standards through consensus guidelines for opioid use in the treatment of chronic pain of nonmalignant origin. This would require a dispassionate review of goals and outcome of treatment. Portenoy has made a significant beginning in this regard.²² Guidelines should also operate from the viewpoint that where evidence for recommendations is tenuous, practitioners should not be denied access to modalities they consider appropriate, and certainly should not suffer severe disciplinary consequences as a result of the treatment they choose.

Developing this consensus is likely to take time. In the meantime, consideration and adoption of elements of the standards about which there is no controversy should proceed. The ultimate standards will, of necessity, be broad but should achieve the following goals: (1) Recognize that opioids have legitimate medical uses, and encourage their use for these purposes. (2) Distinguish between drug abusers and legitimate drug users by defining a drug abuser. (3) Relate the term "drug addict" to drug abuse, and define addiction. (4) Distinguish between "physiological dependence" and "psychological dependence." (5) Recognize that "physiological dependence" is not synonymous with "addiction." (6) Recognize that there are no data to support the belief that large dose size and long duration of exposure to opioids invariably cause psychological dependence on them. (7) Recognize that intent to relieve a targeted symptom is a valid use of an opioid as long as the opioid is pharmacologically appropriate for the symptom. (8) Recognize that as long as there is lack of convincing data that support a deleterious outcome, either for the patient or society, for prescribing opioids to patients with nonmalignant pain, disciplinary action should be precluded merely on the basis of such prescribing.

Physicians and all health-care professionals must be proactive in determining whether the HPAs and CSAs in their states are unclear and ambiguous, and, if they are, in working to cor-

rect them. Also, health-care practitioners must be active in ensuring that the proceedings of regulatory boards are consistent and fairly applied.

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