
ARTICLE

Legal Liability Perspectives on Abuse-Deterrent Opioids in the Treatment of Chronic Pain

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ABSTRACT

Abuse-deterrent opioid analgesic formulations can help reduce the risk of opioid diversion and abuse. Not all opioid analgesics are available as both extended- and immediate-release dosage forms in abuse-deterrent formulations. Clinicians may have to balance the clinical benefit of a product that does not use abuse-deterrent technology versus the regulatory benefit of using a product with this technology. There is the possibility that a health care professional may be held legally liable when a product without abuse-deterrent qualities is used and a person suffers harm that would not have occurred had an abuse-deterrent formulation been provided. This article reviews legal precedents that inform an understanding of the need to reduce malpractice exposure by identifying patients who are at high risk of opioid diversion and/or abuse and considering the use of an abuse-deterrent formulation for these patients.

KEYWORDS. Abuse-deterrent opioid, malpractice liability, risk assessment

INTRODUCTION

Opioid analgesics are among the safest and most effective pharmaceutical products when used responsibly. Their adverse effects are generally avoidable or manageable, and they are valuable agents in reducing the suffering of many patients who otherwise would experience a greatly diminished quality of life. (1) On the other hand, when safe and effective opioid analgesics are used irresponsibly, they can contribute to adverse events and the well-documented problem of prescription drug abuse. (2) Pharmaceutical manu-

facturers, wholesalers, prescribers, and pharmacists accept a shared responsibility to reduce prescription drug abuse without adversely affecting access to medications by legitimate pain patients who need them. Under the central principle of balance, the goal of those responsible for controlling medication use is to develop tools and systems that both promote appropriate use of opioids and reduce their inappropriate use. (3) The principle of balance in pain policy has been articulated by the University of Wisconsin Pain & Policy Studies Group in the following terms:

The Central Principle of Balance represents a dual obligation of government to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability. (4)

It is important to note that with little or no formal discussion or debate within the health professions, the principle of balance has been imported from the policy domain to that of clinical practice. However, in doing so, prescribing professionals have taken on dual and potentially conflicting responsibilities: one to the well being of the individual patient and the other to public health and safety. In virtually every other aspect of clinical practice, the primary, if not the

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exclusive, responsibility of the health care professional is the interests of the patient.

This article examines the possibility that a health care professional might be held liable for malpractice if an available tool to reduce inappropriate opioid use is not utilized when the tool could have prevented harm to the user of a prescribed opioid. The focus of this article is on abuse-deterrent opioid formulations as a newly available risk reduction mechanism. The article first considers how health care practitioners have recognized and described their own responsibilities for the reduction of opioid abuse. Next, the article reviews the medical literature discussing the assessment and monitoring systems that health care professionals have developed to assist them in their pain management practices. The article then looks at the legal requirements for pain management practice, as determined by appellate courts in criminal, administrative, and civil cases. Activities undertaken by regulators and pain management professionals to reconcile medical practices and regulatory requirements are discussed. Finally, the article explains how the existing medical standard of practice could be adopted as the legal standard of care in a malpractice case alleging that an abuse-deterrent opioid should have been prescribed to a patient and could have prevented harm resulting from the provision of a product that did not have abuse-deterrent qualities.

RESPONSIBILITY AND OPIOID PRODUCT SELECTION

Various methods have been proposed and adopted in professional practice to assure appropriate patient selection when prescribing and dispensing opioid analgesics. These include validated screening instruments, (5) pain management agreements, (6) urine drug tests, (7) and prescription monitoring program reports. (8) Although perhaps relatively well recognized by pain management specialists, these methods have not necessarily been widely accepted by nonspecialists who prescribe a high percentage of the opioids used in the treatment of chronic pain. (9) Furthermore, prescription drug abusers acquire opioids from sources other than incautious prescribers, including legitimate patients who share or sell their drugs, (10) the Internet, (11) and drug dealers who sell drugs stolen from distributors, pharmacies, nursing homes, or patients. (12) A focus on greater care by practitioners in providing oversight of access to opioids is necessary but not sufficient to reduce prescription drug abuse. There will always be prescribing professionals who fail to screen patients appropriately, and there will always be sources of drug diversion other than

inattentive prescribers. For this reason, manufacturers, prompted by regulatory agencies in some cases, have begun to develop dosage forms that are considered abuse deterrent because they are manufactured with a quality intended to reduce product abuse regardless of how the product was acquired by a potential abuser. Many prescription drug abusers report that they abuse opioids in ways that can be addressed through product reformulation. (13) Dosage forms that diminish the appeal of opioid products have the potential to reduce drug abuse.

Several abuse-deterrent opioid formulations are now available. (14) However, not all opioid analgesic molecular entities are available as both extended- and immediate-release products in abuse-deterrent formulations. Interpatient variability in opioid receptor response and the great interpatient variability in pharmacokinetics and pharmacodynamics of opioids make it impossible to select a particular molecular entity or release mechanism as optimal for an individual patient simply because the formulation is abuse deterrent. The best choice of therapy for an individual patient will often be a dosage form that does not use abuse-deterrent technology.

Moreover, not all patients are at high risk for diversion and abuse, so it may not be desirable to provide abuse-deterrent formulations to all patients because of factors such as higher cost, the inclusion in the formulation of unnecessary ingredients that may be objectionable or otherwise problematic for the patient, or the offense that may be taken by a patient who perceives the prescribing of an abuse-deterrent formulation as a sign of distrust by the prescriber. Furthermore, the prescribing of an abuse-deterrent formulation may unintentionally label the patient as a drug abuser, subjecting the patient to a potentially inaccurate assessment by insurance companies, employers, or other health care professionals. This is particularly likely if third-party payers require documentation of the risk of abuse or diversion or perhaps even a diagnosis of addiction as a condition precedent to payment for an abuse-deterrent product.

Until all opioids, in both immediate- and extended-release formulations, become available only in abuse-deterrent dosage forms, the choice of which patients will receive abuse-deterrent formulations will be made on a case-by-case basis by health care professionals exercising sound clinical judgment in collaboration with patients and their family caregivers. The risks and benefits of various pharmaceutical options will be discussed at the clinical care level and the selection of the most appropriate dosage form will be made at that time. Third-party payers, government agencies, and consensus-driven guidelines may provide guidance in those decisions,

but ultimately the clinician will continue to make and be professionally responsible for the decision, in collaboration with the patient.

This is not a unique or even novel situation for clinicians. New drugs and new formulations of old drugs are frequently marketed as superior successors to standard therapies. Seldom are new products immediately and uniformly adopted within clinical practice. (15) Rather, the diffusion of innovation is gradual, and during the time it takes for a new approach to become standard therapy, clinicians are appropriately cautious in the conversion from the existing standard to the new option. Ultimately the time may come when the new molecule or technology is known to be so vastly superior to the standard therapies that clinicians are compelled to adopt the more recently developed approach. The critical point in this evolutionary process is when the existing standard practice no longer constitutes a minimally sufficient standard of acceptable care. The failure to practice consistent with a newly evolved standard of practice is considered mismanagement within the field of medicine. It could also fall below the legal standard of care. (16)

As abuse-deterrent formulations become more prevalent, prescribers of opioid analgesics will face the prospect of liability for malpractice if they fail to select an abuse-deterrent product when the legal standard of care is to do so and causally related harm results. There may be good reasons not to select an abuse-deterrent product and the standard of care will support the selection of a product without abuse-deterrent qualities. The challenge for clinicians is to determine when the standard of care requires the use of an abuse-deterrent product and when there is flexibility to use a traditional formulation. Because the clinician is the ultimate decision maker in the choice of pharmaceutical product, it is the clinician on whom responsibility will fall when a decision is made below what is or might be deemed to be the standard of care. (17) In this context, it is essential that prescribing professionals carefully and thoroughly document their thought processes in considering available options and selecting the option that is the most appropriate treatment for the individual patient.

The standard of care for risk reduction strategies in opioid prescribing has been frequently discussed in both the medical (18) and legal (19) literature. Although the standard of care in the prescribing of abuse-deterrent formulations has been addressed only minimally, (20) it can be anticipated that this specific standard will incorporate the foundational principles developed over a decade of focused study in the area of opioid risk management. These general principles can be applied to the question of when an

abuse-deterrent opioid should be provided to a patient based on the assessment of risk and the patient's need for a particular course of therapy that may not be available as an abuse-deterrent formulation. Recognizing the substantially greater cost of abuse resistant dosage forms over traditional dosage forms of the same opioids, an assessment of high risk could warrant the use of an abuse-deterrent formulation, whereas an assessment of low risk likely would not.

STANDARDS OF PRACTICE IN PAIN MANAGEMENT

Prescription drug abuse not only leads to the disease of addiction, it increases health care costs, (21) it reduces worker productivity, (22) and it presents potential legal consequences to those who prescribe and dispense opioid analgesics. (23) As the problem of prescription drug abuse has escalated, health care practitioners responsible for providing access to abusable opioid products have developed risk management strategies. (24) These are not risk elimination strategies. The only way to eliminate the risk of prescription drug abuse is to eliminate abusable prescription drugs. Because opioid analgesics are a category of abusable prescription drugs that are the most effective treatment for many patients living and dying with moderate to severe pain, the risk elimination strategy is inappropriate. The sensible alternative is risk management, which accepts the reality that some prescription drugs will be abused despite the best preventive efforts.

There is error and risk inherent in all human activity, including the provision of health care, perhaps especially the provision of health care. (25) The error of providing drugs to patients who do not need them is necessarily correlated with the error of refusing to provide drugs to patients who do need them. In epidemiologic terms, this is referred to as Type I and Type II error. (26) The errors are logically and mathematically linked. As one error decreases, the other increases. Reliance on standard clinical judgment, in the absence of validated and systematic evaluation techniques, fails to reduce error. It just shifts error. Well-intentioned conservative practices that restrict access to opioids will reduce access both for those who do not need opioids and for those who do need them, unless the practices are evidence based. Empty admonishments that health care professionals "be more careful," or that they "use their best professional judgment" or "follow their gut instinct" are misplaced as ways to effectively reduce errors in prescribing opioids. Clinicians do not need platitudes and clichés. They need sound guidance. Evidence-based

systems to manage the risk of prescription drug abuse are necessary to actually reduce error in prescribing opioids rather than merely shift the error.

It is now well established among pain specialists that in prescribing opioid analgesics, the standard of medical practice requires careful patient selection and continued monitoring of opioid use. (27) Practice systems have been developed to screen patients for risk, stratify patients into categories of risk, and provide levels of care that reflect the identified risk. (28) These systems are not perfect. They are continually being modified to incorporate improvements developed over time based on observations of clinical practice. Opioid risk management systems do not mandate specific tasks that must be performed with every patient. They create a framework within which risk management tools can be used in an organized way. Within the system, risk management strategies must either be conducted, or the failure to perform them must be explained and documented. If risk management strategies are not used and no explanation is provided for not using them, the standard of practice has not been met. Providing opioids to a patient without assessing and managing the risk of abuse and/or diversion is unacceptable in the absence of a well-documented and reasonable explanation. (29)

Gourlay *et al.* have described how the approach of universal precautions that are now accepted practices for dealing with blood-borne pathogens can be applied to opioid risk management. (30) Those authors suggest a care plan that includes initial risk assessment, a treatment agreement, periodic assessment, and thorough documentation for every patient receiving opioids. Based on the assessment of risk, patients are placed into one of three groups. The largest group, Group I, includes patients with no past or present personal or family history of substance abuse. Group II patients have either a past history or family history, or problematic substance abuse but no active addiction. Patients with either active substance abuse disorder or major untreated psychopathology are assigned to Group III. After risk assessment and stratification, patients either are managed by their primary care professional (Group I), co-managed by the primary care professional with specialty support (Group II), or are referred to a pain specialist for treatment (Group III). Gourlay and Heit more recently described how universal precautions can be used to care for chronic pain patients who have been dismissed from primary care practices and are seeking pain relief through access to medications they no longer can obtain. (31) The “universal precautions” approach in prescribing opioids for patients with chronic non-cancer pain involves a requirement for medication use agreements and random urine drug screens on

all patients regardless of the risk of addiction or diversion that they pose. This approach is controversial and is not necessarily consistent with existing national guidelines and policies, such as that of the Federation of State Medical Boards of the United States, which recommend that such measures be considered when there is a good faith clinical basis for concern.

In a comprehensive review of risk management technologies, Katz *et al.* assert that “clinicians have a responsibility to embrace prudent approaches to prescribing and implementing the necessary controls to minimize opioid abuse and diversion.” (32) They suggest that there are specific factors provided in a patient’s history that are associated with substance abuse. These include a past history of substance abuse or a family history, a history of legal problems, nonparticipation in recovery programs, and poor family support. Factors that a clinician may observe include unsanctioned dose escalation, obtaining opioids from multiple sources, cigarette smoking, mental health problems, and a subjective report of lost control of prescribed medications. The authors caution that behaviors suggestive of opioid abuse may instead reflect the inappropriate treatment of pain, a phenomenon sometimes referred to as “pseudoaddiction,” (33) other health issues, or diversion of the patient’s medication by persons other than the patient.

A key element of most prescription drug abuse assessment programs is a validated screening tool. The answers to these brief surveys are used to predict aberrant drug-related behaviors by chronic pain patients for whom opioid analgesics are indicated as therapy. A study by Moore *et al.* compared three of the available assessment instruments: the Opioid Risk Tool (ORT), the Screener and Opioid Assessment for Patients with Pain (SOAPP), and the Diagnosis, Intractability, Risk and Efficacy inventory (DIRE). (34) The results of the comparison show that each of these instruments provides useful information in classifying patients as being at low, medium, or high risk of aberrant behaviors. Depending on the characteristics of a health care clinic treating pain, one of the instruments may be of greater value than the others. The ORT is the shortest instrument, and may be the most useful in high-volume settings. The SOAPP is the longest, and it can measure more factors if additional information is desired. The DIRE is clinician-rated, rather than self-administered as are the other two instruments, and it has greater breadth of subject matter including factors beyond abuse prediction. Although this comparative study was small ($n = 48$), the results suggest that clinics of various types and sizes, with differing access to resources, will benefit from the use of a screening tool in the assessment of pain patients for prescription drug abuse.

It is well accepted by pain specialists that a standard of practice requires careful selection of patients before prescribing opioids followed by continuous monitoring of opioid analgesics that are prescribed and dispensed. Patient screening, risk stratification, and a level of care commensurate with the risk is also a standard of practice. How this standard can be reflected in primary care practice is less clear. To help nonspecialist clinicians understand their responsibilities in defining the line between risky and not-so-risky pain management practices, Passik and Kirsh have operationalized what is known about appropriate prescribing of opioids under conditions of risk for prescription drug abuse. (35) Those authors have developed a set of descriptive criteria from which a clinician can discern whether pharmacotherapy for a particular patient is “in the box” or “out of the box.” They explain that prescribing “in the box” is the “prescribing of opioids in a usual and customary fashion,” whereas prescribing “out of the box” refers to “prescribing opioids in a manner that deviates from the usual prescribing habits of physicians writing opioid prescriptions.” The authors take care to point out that there is nothing inherently wrong with prescribing “out of the box.” In fact, for some patients it may be necessary to deviate from what is usual and customary. This is how innovation in health care begins. However, precautionary steps could be appropriate when prescribing “out of the box,” because such prescribing may subject health care practitioners to a high level of scrutiny and may be interpreted as a practice that is below the applicable medical standard.

Based on their review of the literature, Passik and Kirsh define “in the box” as being applicable to a patient who is using opioids for a common indication (cancer or perioperative pain as opposed to headache), a daily dose of 180 mg or less of morphine equivalent, an older age patient, limited contact by the patient with nonmedical users of opioids, and a patient who lacks active psychiatric disorders or substance abuse issues. The authors recognize that health care professionals may make efforts to “get back in the box” to protect themselves from professional or regulatory criticism. There are various ways to do this, including opioid rotation, the use of adjuvant analgesics, or the addition of physical medicine treatments.

The concept of “in the box” is intended to assist opioid prescribers in their care of patients. It also has the potential to describe a professional standard of practice, although this is not the authors’ expressed intent. Prescribing high-dose opioids for a young headache patient with an active substance abuse issue and who is in frequent contact with non-

medical users of opioids is clearly “outside the box” according to Passik and Kirsh. This is the type of activity that a court could determine to be too risky. It might not only be perceived as below the professional standard of practice but also outside the legal standard of care unless steps are taken to “get back in the box” and conform to the standard. Although not mentioned by Passik and Kirsh, one such step could be rotation to an abuse-deterrent formulation. Otherwise, without taking steps to “get back in the box,” it is possible that involved health care practitioners will be considered to be practicing below the legal standard of care for pain medicine. Factors suggestive of inappropriate opioid use cannot be ignored by the prescribing professional. Indeed, turning a blind eye to such behaviors has been a common characteristic of physicians who have been convicted for violating the Controlled Substances Act.

The legal standard of care applied to the choice of opioid products when an abuse-deterrent formulation is an option will incorporate the professional standard of practice. According to the standard of practice currently described in the medical literature, risk assessment, stratification of risk, and the provision of a level of care based on the identified risk is a necessary prerequisite to the choice of appropriate therapy. This process need not be done pursuant to any specific rubric, but it must be done as component of the diagnostic procedure. Failing to address the risk of opioid abuse is unacceptable. Health care professionals will need to establish factors to consider in determining whether the risk of abuse warrants the provision of abuse-deterrent formulations based on the classification of a patient as high, medium, or low risk of abuse and/or diversion.

THE LEGAL STANDARD OF CARE FOR PAIN MEDICINE

Pursuant to the federal Food, Drug, and Cosmetic Act, prescription pharmaceutical products are defined as incapable of being labeled for safe use without medical supervision. (36) If a pharmaceutical product can be labeled for safe use without medical supervision, then it is placed in the over-the-counter drug category. (37) The regulatory challenge addressed through the prescription requirement for pharmaceuticals is information asymmetry. (38) Unlike a kitchen knife, or a toaster, or an automobile, all of which are risky products, the ordinary user of a prescription drug is unable to make a risk-benefit decision due to lack of information. Most patients can’t visualize a tablet or capsule of a prescription drug and reach a conclusion about risk and benefit,

because they lack the knowledge and experience necessary to understand the risks and benefits of the product. Discussing the product with other users only marginally increases the ability to decide about risks and benefits, because the experiences of others are not necessarily relevant to the safety and efficacy of a drug for an individual user. To address the problem of information asymmetry, the regulatory framework for prescription pharmaceuticals requires that a person who has studied the effects of drugs, and who has practical experience with their use in a large variety of patients, be the primary decision maker concerning access to drugs by prescription. The regulatory framework places trust in the professionally trained prescriber to select appropriate pharmaceutical products for patients, mindful of the risks involved.

In general, health care practitioners who provide access to prescription opioid analgesics must exercise due care in selecting appropriate products for individual patients. (39) They must inform patients of the risks associated with the products, (40) and practitioners continue to be responsible for a patient's use of a product throughout the time during which the supply of prescribed product is expected to be used. (41) Failure to meet the standard of care may lead to liability for malpractice, it may lead to administrative discipline by the practitioner's licensing agency, and it may also lead to criminal prosecution. The standard of care to which a health care practitioner is held is not a unitary standard. Rather, there are multiple standards of care that apply in most health care professions, and individual health care practitioners must conform to one of them. (42) There is more than one acceptable approach to caring for a patient who presents with chronic pain. Meeting the standard of care requires practice in accordance with one of the acceptable approaches, while avoiding all of the many unacceptable approaches. The majority does not establish a single approach that the minority must use. Rather, there is recognition of a respected minority rule so practitioners who care for patients in way that differs from the mainstream approach may still be practicing within the standard of care if the majority of practitioners respect the unconventional approach even though they choose not to use it. (43) There is considerable controversy about the standard of care in prevention of misuse of prescribed opioid analgesics. Generally, prescribers are held responsible for foreseeable misuse, but not for misuse that was unpredictable at the time of prescribing. (44) Expert witness testimony is necessary in most jurisdictions to support a claim that a health care practitioner has violated the legal standard of care. (45) In most jurisdictions, this testimony must be both relevant and

reliable for it to be admitted into evidence for jury consideration.

Within the context of criminal liability for inappropriate opioid prescribing, practices that conform to a standard of care are exculpatory, whereas the failure to conform does not necessarily support a conviction. (46) Criminal liability extends to those practitioners who are not practicing within their profession, but instead are selling drugs that have not been prescribed for a legitimate medical purpose or have been ordered outside the usual course of professional practice. (47) Criminal liability does not extend to those who are practicing with their profession but are practicing below the standard of care. Although this latter type of activity may be malpractice, and subject the practitioner to licensure revocation and liability for negligence, it is not a crime to be a substandard practitioner. Nevertheless, evidence that a practitioner has practiced within the standard of care is an effective defense to a criminal charge.

The leading case on criminal liability is *United States v. Hurwitz*. (48) In this case, the defendant physician was prosecuted because he prescribed opioids for people who he allegedly knew were selling their drugs or were abusing them. The physician's defense was that he prescribed opioids in good faith and that he did not know the drugs were being sold or abused. He was convicted at a trial and from this conviction he appealed. A key issue on appeal was the trial court's refusal to permit the jury to consider the "good faith" argument asserted by the physician. The appellate court reversed the conviction, ruling that the physician had a right to assert the "good faith" defense. The trial court had erred in not allowing it.

The appellate court noted, however, that "a practitioner is not free deliberately to disregard prevailing standards of treatment." The court said that, "To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area." The court adopted an objective standard of "good faith," as opposed to a subjective standard. In effect, this means that a prescriber of opioids must adhere to standards expressed by the profession and not to personal beliefs that materially differ from professional standards, no matter how fervently and honestly those beliefs may be held. Standards of a profession are constantly evolving and must be evaluated within that evolutionary background. The court said that simply because the physician may have practiced "outside the bounds of an out-of-step medical board's view of proper medical practices does not necessarily mean that his actions were beyond the bounds of

generally accepted medical practices.” Expert witnesses supportive of the physician testified that his approach to opioid therapy was medically appropriate and that he ran a legitimate medical practice. A new trial was ordered by the appellate court. At the new trial, the physician was allowed to assert the objective “good faith” defense. He was again found guilty, but of far fewer charges than in the original trial. (49)

Federal Drug Enforcement Administration (DEA) administrative actions against a registrant also demonstrate how the standard of care plays a role in expert testimony and determining whether the granting of a registration is inconsistent with the public interest. In February 2010, DEA published its opinion evaluating the evidentiary record in the matter of *Ferri Hassman, MD (Notice of Denial of Application)*. (50) In 2002, the DEA suspended Hassman’s DEA Registration on the grounds that she “regularly engaged in the practice of prescribing excessive amounts of controlled substances to patients for no legitimate medical purpose.” Some patients overdosed and died; others diverted the medications prescribed. Hassman was indicted on federal charges in 2003, pleaded guilty to four felony violations involving controlled substances in 2004, and entered into a Consent Agreement with the Arizona Board of Medicine in 2005. The Consent Agreement stated that Hassman failed, among other things, to conduct physical examinations, obtain adequate patient histories, and did not provide sufficient information (documentation) to support the diagnoses, justify the treatments, or indicate advice and cautionary warnings to patients. The evidentiary record in the Hassman case is extensive and relied on the testimony of several physicians. This testimony established that the appropriateness of prescribing controlled substances depends on the level of medical documentation, and without adequate documentation, it is inappropriate to prescribe.

A significant part of the Hassman opinion reviews expert testimony regarding patient assessment and monitoring, including the use of assessment tools, drug testing, and the reasonable choice of medication type and amount based on the assessed risk. The case concludes that prescribers have a duty to ensure that the issuance of controlled substance prescriptions does not create an undue risk of abuse and diversion. DEA’s authority to revoke a registration or deny an application is not limited to those instances in which a practitioner intentionally diverts. Rather, a practitioner who ignores the warning signs that patients are either personally abusing or diverting to others commits acts inconsistent with the public interest even if the practitioner’s conduct is merely negligent. (51) The case report says:

“Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration or the denial of an application for a registration. A practitioner’s failure to properly supervise her patients to prevent them from personally abusing controlled substances or selling them to others constitutes conduct ‘inconsistent with the public interest.’” (52)

The Hassman case clarifies that practitioners must consider their prescribing choices (medication, dosage, quantity, and term) in light of patient conduct and other factors, and must document completely their rationale for prescribing else they risk loss of their DEA registration.

Within the framework of a state licensing agency administrative disciplinary action, the leading case is *Hoover v. The Agency for Health Care Administration*. (53) The physician against whom disciplinary action was taken was a pain management specialist treating primarily chronic pain. She appealed from an order of the Florida Board of Medicine penalizing her and restricting her medical license. The state agency bringing the charges against her asserted that she “provided care that fell below that level of care, skill and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.” At a hearing, the agency presented the testimony of two physicians retained as expert witnesses. Neither witness had examined any data on the defendant physician’s prescribing, other than computer printouts from pharmacies showing the volume of drugs prescribed. Neither witness treated chronic pain in his own practice. Both referred chronic pain patients to specialists. Yet, despite not having seen any patient records, and despite their seeming lack of expertise, the witnesses testified that the defendant physician “had prescribed excessive, perhaps lethal amounts of narcotics, and had practiced below the standard of care.” The appellate court reversed the discipline of the defendant physician, explaining that the case against her was “founded on a woefully inadequate quantum of evidence.”

There are many cases from which to choose an example of how the law of medical malpractice applies to the field of pain management. One illustrative case is the Florida case of *Posner v. Walker*. (54) In this case, the patient’s survivors sued a physician for malpractice in providing opioid analgesics to the patient, allegedly resulting in her addiction, which caused her to die from using opioids that had been illegally provided by another physician. An expert witness’ testimony at trial asserted that the defendant physician had fallen below the standard of care in four specific ways: (1) failing to have an exit strategy so the patient would not use opioids forever; (2)

continuing to prescribe opioids when they were no longer indicated; (3) not referring the patient to an addiction medicine specialist; and (4) failing to order a urine drug test. At trial, the defendant physician was held liable for almost \$2 million. The appellate court reversed the verdict, concluding that the plaintiffs had “failed to establish any breach of the standard of care” in treatment of the patient. Based on the evidence, each of the allegations against the physician was refuted by the appellate court. The physician had repeatedly discharged the patient from his practice when he believed she had reached her maximum medical improvement and her pain was controlled, but she would always return in unbearable pain. The physician repeatedly referred the patient to a specialty clinic, but the patient refused to be seen there. The court found no evidence that urine drug tests would have provided the physician with any information he did not already know. Since the objective evidence established that the physician had met the standard of care, he could not be held liable for malpractice.

As these four cases show, regardless of whether the situation is one of alleged criminal liability, administrative discipline, or malpractice litigation, the approach taken is to determine the legal standard of care primarily by referring to expert testimony, and to then evaluate the conduct of the subject health care professional by considering the persuasiveness of the expert testimony and comparing the relevant standard against the actual conduct. It is an objective exercise based on evidence of actual practice standards and not on personal beliefs about what is or could be the best practice. The legal issues faced by health care professionals who provide opioid analgesics invariably relate to the provision of too much drug and not too little. Suggestions that health care professionals may also be exposed to legal problems for providing too little pain medication are largely an academic exercise with very few meaningful practice-based examples. Those few examples related to patients who were at or near the end of life. (55) Drawing the conclusion from these cases that physicians are equally at risk of legal sanction for both over- and underprescribing opioid analgesics, particularly with regard to chronic noncancer pain, would be inadvisable. (56) The overriding emphasis on legal responsibility for providing too much drug contradicts the central principle of balance, and it may place practitioners in the difficult position of being tempted to opt for a conservative risk management strategy that reduces the risk of legal consequences for them, but increases the risk of undertreatment for patients. To counter this understandable inclination for self-preservation at the expense of patient welfare, practice guidelines have been developed in an effort to specify the expect-

tations of health care professionals providing opioid analgesics to patients in pain.

To comply with the legal standard of care, practitioners who provide patients with opioid products that lack abuse-deterrent characteristics must do so in good faith. Courts conduct this analysis with deference to the professional standard of practice as interpreted by expert testimony. Practice guidelines reflect these professional standards and they provide a vehicle for regulators and practitioners to explore together the balance that must be struck between the responsibility to effectively manage a patient’s pain and the correlative responsibility to restrict access to abusable drugs.

THE SIGNIFICANCE OF PRACTICE GUIDELINES IN PAIN MANAGEMENT

Variability in the quality of health care has produced efforts to standardize therapies through the creation and dissemination of treatment guidelines that describe best practices in a field of health care. (57) Guidelines are intended to elevate the quality of practice by those whose skills or knowledge in an area of therapeutics are less than optimal, and whose patients have experienced unfavorable therapeutic outcomes. Health care professionals who make a conscientious effort to improve the quality of their care, based on information provided in a clinical practice guideline, will theoretically reduce their errors in practice and will improve the quality of therapeutic outcomes for their patients. Practice guidelines must be sufficiently flexible so that innovative clinicians using new and potentially controversial treatments will not be unnecessarily restricted. Innovators will turn to practice guidelines to carefully consider the evidence supporting widely accepted approaches to care before concluding that a particular patient’s unique needs require nonstandard treatment. The purpose of clinical practice guidelines is not to homogenize health care to the equivalent of mechanically preparing meals from a recipe in a cookbook. Guidelines promote evidence-based practice that provides therapies to patients, with a realistic expectation that the therapies will succeed based on data reported from successes and failures of the past. Nevertheless, some commentators argue that there are both conceptual and pragmatic reasons why guidelines cannot and should not definitively set the standard of care. (58)

Clinical practice guidelines are always controversial. Although such guidelines are increasingly evidence based, most are developed through a consensus process due to insufficient evidence, resulting in a document that everyone has compromised to

achieve. For therapies that are unmistakably superior to every alternative, based on definitive clinical trials, there is seldom a need for clinical practice guidelines, because there is no need to convene an expert panel to consider answering a question that has already been clearly answered. Instead, clinical practice guidelines deal with the more difficult therapeutic choices, where the evidence is capable of alternative interpretations and where those with a high level of expertise in a medical specialty can deduce from the evidence how practitioners can optimally manage their patients. Despite the controversy that frequently is associated with clinical practice guidelines, due to their perceived lack of solid scientific foundation, they are the best practices that experts have determined will guide practitioners to use therapies that are within the standard of care. (59)

In addition to providing assistance to clinicians in determining appropriate health care practices, clinical practice guidelines may provide protection from legal liability for allegedly inappropriate clinical care. The value of guidelines is that adherence to them is persuasive evidence of conformance with a standard of practice. (60) Departure from guidelines, with a well-documented explanation, does not necessarily equate with legal liability, because there are alternative standards of care against which a practitioner's chosen therapeutic approach may be compared. (61) The most useful clinical practice guidelines are those that combine an evidentiary basis for a recommended plan of care with flexibility to depart from the recommendation when circumstances warrant. In pain management, the health care community and the regulatory community have attempted to work together in developing clinical guidelines that flexibly permit the clinician to meet the needs of patients for opioid therapy, while at the same time imposing risk management strategies that protect the public from the consequences of unrestricted access to drugs of abuse. These collaborations between health care practitioners and drug regulators, though well intentioned, have met with only mixed success.

The first group to promulgate guidelines that strike a balance between the need for access to opioids by pain patients and the need for restrictions on access to prevent abuse was the Federation of State Medical Boards (FSMB). In 1998, that group adopted what was then called the Model Guidelines for the Use of Controlled Substances in the Treatment of Pain. (62) These guidelines were "not meant to constrain or dictate medical decision-making," but they did note that a medical board will consider "the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations." The guidelines described a process of pa-

tient care that reflected criteria to be followed by a licensing agency in evaluating a physician's treatment of pain with controlled substances. In one form or another, these guidelines were incorporated into the licensing laws of just under half of the states. When reissued in 2004, the guidelines were instead labeled as a "Model Policy." The general approach within health care is to recognize that the FSMB Model Policy can be used by experts to establish a standard of practice, but that "physician/practice/documentation will have to be weighed individually case by case." Although the Model Policy describes objective standards, the application of those standards is done subjectively. Ultimately, it is state medical boards, comprised of experienced practitioners who understand the challenges of medical practice, who will apply the standards to the facts of each disciplinary case. The Model Policy requires that this judgment be done mindful of how difficult it can be in clinical practice to accurately screen patients for abuse and diversion. Fishman has interpreted the Model Policy to say that "Whenever a clinician considers treating pain with a controlled substance, such as an opioid, risk of abuse or diversion is always a possibility, no matter how remote, and must be assessed." (63)

A large number of health profession organizations and a relatively small number of drug regulatory agencies collaborated in 2001 to create a one-page joint statement, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act." (64) Referring to itself as a "consensus statement," the document acknowledged that both drug abuse and the inappropriate treatment of pain are serious problems. The document recognized that for many patients opioid analgesics are the most effective way to treat pain, and that efforts must be made to prevent their becoming a source of harm or abuse.

Two years later, a much more detailed document was published by a much smaller group of organizations. Known as the Prescription Pain Medications Frequently Asked Questions (FAQ), (65) the document was ill fated. Released with extensive fanfare, and touted as evidence that health care professionals and drug regulatory agencies can, in fact, work in harmony, the document was within weeks denounced by the Drug Enforcement Administration (DEA) as the product of an unauthorized regulatory process. This turnabout was greeted with huge disappointment in the pain management community, where the sensible and balanced approach of the document had been warmly embraced. Instead of providing a higher level of comfort to conscientious pain management practitioners, the Pain Medicine FAQ debacle led to greater suspicion and mistrust of regulators. For 3 years a series of Federal Register postings attempted to explain

some of the DEA's concerns with the substance of the document, leading eventually to the clarification of one small issue that the document had raised. (66) But the opportunity for a comprehensive understanding of mutual responsibilities held by health care professionals and drug regulators was lost.

Filling the void left by the retraction of the FAQ, and reflecting the absence of evidence-based guidelines for the treatment of chronic noncancer pain (CNCP), the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) undertook a massive project to develop useful and detailed practice-oriented guidelines that could serve as a roadmap for effective pain management and successful risk management. Published in 2009, these guidelines recognize the appropriateness of chronic opioid therapy in CNCP for carefully selected and monitored patients, but only when strategies are used to limit the risks associated with opioid use. (67) The guidelines note that clinicians are more vulnerable to regulatory investigation or discipline if they fail to comply with practice standards or regulations. The APS/AAPM guidelines assert that "clinicians and regulators must jointly seek a balanced approach to opioid use, acknowledging the legitimate medical need for opioids in some patients with CNCP, while concurrently recognizing the serious public health problem of abuse, addiction, and diversion, and implement procedures to reduce these risks."

Although the APS/AAPM guidelines were developed entirely by health care professionals, without input from drug regulators, the principle of balance they reflect can serve as a standard both for clinical care and for risk management. Health care practitioners don't have to be perfect clinicians and they don't have to be perfect risk managers. They do have to show that their clinical activities were conducted with knowledge, skill, and care. As a benchmark against which practitioner activities can be measured, the APS/AAPM guidelines are clearly stated so as to put practitioners on notice of the expectations established for them, and they provide a roadmap for regulators in evaluating the conduct of a practitioner who is under investigation. They make it possible to discern the difference between a practitioner whose actions produced an undesired outcome despite the best efforts to prevent it, and the practitioner whose activities led to bad outcomes while failing to use any standard strategies designed to reduce the risk of bad outcomes.

The APS/AAPM guidelines do not reference abuse-deterrent formulations, and this could be a significant omission as the availability of these products expands and as clinicians face the choice of when to use them. Yet, the principle of balance expressed in

the guidelines can be applied to abuse-deterrent formulations just as it is to other risk management tools. That principle will guide clinicians to choose abuse-deterrent formulations when, on balance, a determination is made that the risks of abuse outweigh the benefits of providing an opioid in a dosage form that clinically superior but is not abuse deterrent. On the other hand, when the balance tips in favor of therapeutic benefit of the product that is not abuse deterrent, in light of low risk for abuse, the clinician will be guided to authorize an opioid that does not use abuse-deterrent technology. The current guidelines are supportive of this approach.

STANDARDS OF PRACTICE AND ABUSE-DETERRENT OPIOIDS

To avoid malpractice liability for negligently allowing access to prescription opioid analgesics, health care practitioners must meet the legal standard of care in the provision of pharmaceutical products to chronic pain patients. (68) Determination of whether the standard of care has been met will invariably require a comparison of the practitioner's actions with the standard of practice in the relevant profession. This is also often the approach that is taken in cases considering exculpation from alleged criminal misconduct and in disciplinary cases brought against a licensee by a state professional licensing board. Thus, the malpractice standard is relevant in criminal and disciplinary cases. In malpractice cases, there will be liability only when the standard of care has not been met. Health care practitioners do not guarantee good outcomes. The law requires that practitioners provide assurance that they will make their best effort to use accepted practices and available resources to produce a desirable result. Similarly, there is no malpractice liability for a mere error in the exercise of clinical judgment, so long as the clinician gave due consideration to all the relevant medical options that would be taken into account by a reasonably prudent professional of similar training and experience under similar circumstances. To hold otherwise would be to demand error-free performance, i.e., perfection, a patently unreasonable expectation. Even when the standard of care has not been met, there will be no liability if the failure by the practitioner has not caused the harm suffered by the affected party. (69) Furthermore, chronic pain patients must meet their responsibilities to control access to prescribed medications, and there are limits on the sequence of events following prescribing and dispensing of medication for which health care practitioners will be held liable.

For decades drug researchers have devoted their careers to producing safer and more effective agents. The goal of new drug development is to either discover a molecular entity with enhanced therapeutic effect and reduced toxicity when compared with existing modalities, or to modify the dosage form of an existing molecular entity for the same purpose. Opioid analgesics have been the subject of many scientific investigations intended to improve pain relief and reduce abuse potential. The results have been disappointing. Heroin was at one time considered to be a molecular entity that would produce such an advance. (70) These hopes were quickly dashed. A century later, a pentazocine/naloxone formulation was considered promising, but its value has been questioned. (71) Extended-release opioids were initially thought to be more efficacious and less prone to abuse than their immediate-release predecessors, but that dream has turned to a nightmare. (72) The challenge for researchers dealing with opioid analgesics is that they seek pharmacologic and pharmaceutical solutions to social adverse effects, rather than solutions to the pharmacologic adverse effects with which they are generally more familiar. As difficult as it is to conduct research that deals with human physiologic uncertainty, research that addresses the uncertainty of social problems such as substance abuse is much more complicated. The unknown variables of physiologic problem identification pale in comparison with the variables dealt with by those who seek solutions to social problems.

Despite the many challenges researchers face, new abuse-deterrent opioid formulations have recently been developed and others are currently under development. They generally fall into one of three categories. (73) One approach is to formulate opioid products with physical barriers to manipulation, such as a viscous gel matrix or a rate-controlling membrane. A second approach is to combine the opioid component with an opioid antagonist such as naltrexone that releases only when the product is subjected to tampering. A third approach is to incorporate into the opioid product a drug like niacin that is harmless in low doses but causes unpleasant effects when the product is used at high doses. With all of these technologies, the patient who uses the product as prescribed can derive the benefit from its use without experiencing any untoward effect. Persons attempting to tamper with the products, or who ingest far more product than is intended for ingestion to obtain a euphoric effect, will not achieve that effect. Ideally, the result will be that disappointed abusers will learn to avoid the dosage forms because they do not produce the desired result. There is no claim made that these formulations will reduce overall substance

abuse; only that the abuse of opioid analgesics will be reduced, and that the confounding of legitimate pain management with fraudulent acquisition of abusable drugs will diminish. (74)

Currently some, but not all, opioid molecular entities are available in abuse-deterrent dosage forms, and in both immediate- and extended-release formulations. Questions will inevitably arise regarding the legal liability of a practitioner who opts to use a non-abuse-deterrent product because it is deemed to be the best choice for a patient. These questions will likely be asked after the product has been used irresponsibly and unlawfully either by the patient or by a person who has acquired the product following its diversion from legitimate channels. The person allegedly harmed, or the survivors of that person, will contend that had an abuse-deterrent formulation been prescribed the person would not have been harmed, therefore the practitioner is legally responsible for the harm done. If this litigation were to result in a determination that the legal standard of care is to always choose an abuse-deterrent product, then the practitioner will be in a vulnerable position. If, on the other hand, the legal standard of care is more flexible, allowing for the choice of a product that does not use abuse-deterrent technology when such a product is considered more appropriate for the patient based on accepted clinical rationale, then the practitioner will be in a much more secure posture. In predicting how this issue will be addressed, it is important to consider two questions: When does a good idea become a practice standard and ultimately a standard of practice? Must an available technology be used simply because it is available?

Guidance from the pain management literature and from consensus-driven guidelines based on evidence in the literature clearly supports a three-step process of care in deciding what opioid analgesic to prescribe. (75) It is a practice standard for practitioners to assess each patient for risk of abuse, stratify the patient into a category of risk based on the assessment, and manage patients more carefully when the risk of abuse is high. Not all patients are appropriate for a trial of opioid analgesics. Patients who are selected as suitable for opioid therapy must be monitored while they are using opioids. (76) These practice standards, through their support in the literature and in practice guidelines, have become standards of practice. How to apply these standards when considering risks to nonpatients is a problem that has not always been incorporated into the process. It is one thing to select patients, assess and manage the risk of abuse, and monitor therapy when the abuse of drugs by the patients is the critical factor. When the abuse of drugs by someone other than the

patient is the relevant consideration, the process still can be done but it requires reflection on a separate set of parameters. Factors that lead to concern over potential abuse by a patient will not necessarily be the same as factors leading to concern over abuse by nonpatients. Furthermore, policy considerations may arise if health care professionals were to begin focusing on risks and benefits for nonpatients rather than risks and benefits for a specific patient who is being treated for pain. (77)

In determining whether a practitioner's conduct has met the standard of care, courts generally look to the profession to discern the standard of practice as defined by those within the profession. (78) This approach is complicated when there are competing standards in the literature and when there is conflicting expert witness testimony, but it is an exercise that is familiar to courts. Denied the luxury of mulling over scientific data and clinical case studies for years as some professional groups may do, courts must decide how to apply facts to standards and resolve a controversy relatively quickly once discovery has been completed and the evidence has been developed. That is a subjective activity undertaken at the trial level and it is open to appellate review. Although there are many formulations of this judicial activity, an approach that is often taken by appellate courts in reviewing the appropriateness of the application of standards to facts by trial courts is to examine three issues: (1) The relationship of the practitioner to the plaintiff; (2) the foreseeability of harm to the plaintiff at the time professional services were provided by the practitioner; and (3) the public policy considerations of holding the practitioner responsible for harm to the plaintiff. (79)

A legal duty to act on behalf of another, based on a standard of care by one toward the other, arises out of the relationship between the two parties. (80) The law clearly recognizes a relationship between a licensed health care practitioner and a patient. The time at which the relationship ends and begins is often far less clear. (81) The extent of the relationship may be determined by whether the practitioner is a primary care professional or a consultant. (82) Within the context of a pain patient seeking medical care from a practitioner who treats pain, the law recognizes a relationship sufficient to incorporate a standard of care that includes a responsibility to take such steps as are taken by other similarly qualified practitioners, as reflected in the relevant professional literature and practice guidelines, to prevent abuse of opioid analgesics by the patient.

A health care practitioner's relationship with unknown strangers who may acquire prescribed opioids from a patient, either with or without the patient's

knowledge, is very much open to question. There is some precedent for judicial recognition of a relationship between a health care practitioner and a stranger. (83) Courts have held, for example, that a health care practitioner has a sufficient relationship with an unknown nonpatient who is put in jeopardy by the practitioner's treatment of a patient. A motorist who is harmed by a patient driving under the influence of opioids may be able to maintain a legal action against a practitioner who negligently allowed the patient access to the opioids. (84) There may be a responsibility by a practitioner to a stranger who is in a "zone of danger" and is likely to be harmed by a patient's inadequately treated violent outbursts or infectious diseases. (85) Extending this logic, one might consider the well-known public health problem of prescription drug abuse to place all potential users of a patient's diverted controlled substances in a "zone of danger" and therefore to have a sufficient relationship with a practitioner to warrant prescribing of abuse-deterrent formulations of opioids for the patient. Although it may be a stretch to consider a relationship between a practitioner and a nonpatient prescription drug abuser to be a legal relationship, courts have made similar stretches before, and this idea is not as far-fetched as it may initially seem. The relationship issue is not an automatic bar to a judicial finding that the standard of care requires the use of an abuse-deterrent opioid, in a case brought against a practitioner by a person who alleges harm to a nonpatient from abuse of an opioid prescribed for another person.

The legal standard of care applies only when a reasonably foreseeable victim is injured by reasonably foreseeable harm. (86) It stands to reason that prescription drug abuse is reasonably foreseeable from the prescribing of opioid analgesics. (87) With the exception of circumstances of restricted distribution, periodic audits, and constant professional oversight, the data on prescription opioid abuse would belie any explanation by a practitioner that opioids were prescribed with every reasonable expectation that they could not possibly end up in the hands of anyone other than the person for whom they were intended. The package insert of these products warns of diversion and abuse, (88) the practice guidelines instruction on techniques to avoid diversion and abuse, (89) and the medical literature indicates that there is a known but not precisely quantifiable risk. (90)

Nevertheless, a body of law exists that limits liability for misuse of prescribed drugs unless the misuse was foreseeable. (91) In many ways this is a causation question. Even if a practitioner prescribes opioids in a negligent way, that practitioner may escape liability for harm suffered by the plaintiff if the harm

was caused by unforeseeable misuse. For example, if a patient's friend or family member intentionally ingests the patient's medication, this may be considered a "superseding, intervening" cause of harm to the friend or family member. The cause of the harm is the drug user's act of intentionally ingesting the medication, and not the practitioner's act of prescribing the medication. It does not matter that the medication would never have been available but for the prescribing of it. The chain of causation is broken. There is one caveat. If the misuse was reasonably foreseeable, then the chain remains unbroken. In the circumstance of opioid analgesic misuse, a practitioner's argument of unforeseeability could be weak. The misuse of opioids is well documented. In most situations of clinical care, it is probably not reasonable to contend that misuse of prescribed opioids was unforeseeable. This is not an argument on which practitioners who allow access to opioids should rely in defending an allegation that an abuse-deterrent opioid formulation should have been prescribed.

Public policy is the third factor to consider in determining whether a standard of care applies to a particular situation. In many ways this is a model that incorporates economic efficiency. One calculus of professional liability suggests that actionable negligence occurs if there is a failure to take preventive measures that cost less than their expected benefit. (92) With the high cost of prescription drug abuse, it is likely that public policy considerations would weigh in favor of using an abuse-deterrent opioid formulation given the economic benefits of reduced prescription drug abuse, unless economic costs can be shown to exceed those benefits. The prevailing practice within the profession may not always support a practitioner's actions if there is evidence that the profession conspired, either intentionally or unintentionally, to maintain a low expectation of itself for purposes of avoiding liability. Courts may judicially recognize a legal standard of care reflecting economic efficiency, despite a professional standard of practice that has not taken that step. (93) This is a relatively rare occurrence in malpractice law, but it cannot be ruled out, particularly when the harm to be addressed is as socially costly as prescription drug abuse. (94)

Public policy considerations may also favor a legal standard of care that supports the use of an innovative technology, under the deterministic principle sometimes known as the "technological imperative," which teaches that the use of a new technology is the inevitable result of its introduction into society. (95) There is a strong public policy favoring a reduction in drug abuse. There may be disagreement over policy in solving the problem of drug abuse, with some advocating stronger criminalization and

some advocating legalization or medicalization, but public support of policy favoring a reduction in drug abuse by some means is well established. It could be difficult for a practitioner to defend the use of a non-abuse-deterrent opioid formulation on public policy grounds, when an abuse-deterrent technology is available and the failure to use it cannot be clinically justified.

A final factor to consider in predicting potential exposure to legal liability for the failure to prescribe abuse-deterrent opioids is the familiar central principle of balance. This is not just a principle incorporated in clinical practice guidelines for pain management practice; it is the foundation of American justice. (96) There are limits to what regulation can and should do. People who choose to abuse drugs cannot be protected by government from all consequences of their own risky choices. In considering the responsibilities of health care professionals, courts will also consider the responsibilities of people who use and abuse prescription drugs. In striking that balance, courts are likely to turn to professional standards for guidance on the specific issue of abuse-deterrent formulation use. It would be productive for the health care professions involved with opioid use in the treatment of pain to develop explicit standards for the use of abuse-deterrent formulations, as they have for other approaches to risk minimization in pain management practice. Courts are likely to be swayed by the logic of these standards if they are consensus driven and evidence based.

Professional standards in pain management describe a system of risk assessment, risk stratification, and individualized treatment based on the identified risk. This can be done very quickly and informally, or it can be done deliberately pursuant to a structured process. Either way, it must be documented, as is the case with all risk management activities. (97) Health care professionals who can point to their documentation and justify the choice of an opioid product that does not use abuse-deterrent technology when the risk of abuse was determined to be low will be in a strong position to defend allegations of malpractice following harm caused by the prescribed product. Those who either fail to conduct a risk assessment, or who fail to choose an abuse-deterrent product when the risk is assessed as high, will find they are in a position of exposure to potential malpractice liability.

CONCLUSION

Managing some types of moderate to severe pain with opioids is an important aspect of quality patient care. In utilizing this approach prescribing professionals

must comply with the standard of care as well as all relevant state and federal laws and regulations pertaining to controlled substances. As with all other aspects of patient care, responsible opioid prescribing involves pursuit of the patient's best interests by taking into account the potential benefits and risks of opioid analgesia. However, because of the concurrent epidemics of both undertreated pain and escalating abuse and diversion of prescription medications, prescribing professionals are also being admonished to balance the need of patients with pain to appropriate analgesics with the need of society to minimize the risk that these medications might be abused or diverted. The introduction of abuse-deterrent pain medications adds a new consideration for prescribing professionals. Given the recognized challenges in assessing the risk of abuse or diversion posed by any particular patient, there may be considerable pressure on prescribing professionals to default to abuse-deterrent formulations when medications with a high abuse potential are prescribed, regardless of competing clinical and other considerations based upon the unique situation of an individual patient. Policies and guidelines that address the utilization of abuse-deterrent formulation in the management of pain must reflect the overarching responsibility of the clinician to pursue the best interests of the patient. Other factors may be important considerations, but should never be allowed to materially compromise the well-being of the individual patient.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

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