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THE POLITICS OF PAIN: RHETORIC OR REFORM?

Ben A. Rich*

INTRODUCTION

A remarkable and disturbing phenomenon slowly crept into the collective consciousness of the American public in the last decade of the 20th Century: health care institutions and professionals, physicians in particular, did not take the relief of patient pain and suffering seriously. Documentary and statistical evidence of this phenomenon had been developing in the literature of the health professions decades earlier, but apparently without impact on individual practice or institutional policy.¹ Suffering patients and their families labored under the mistaken assumption that unrelieved pain, however significant or prolonged, was an unavoidable artifact of serious acute and chronic illness.² This was a reasonable assumption inasmuch as one of the core principles of medical ethics was beneficence, the duty of the physician to act only in the patient's best interest.³ Surely such a duty would include the professional responsibility to alleviate pain and suffering to the greatest extent possible.⁴ But as the documentation of a widespread pattern and practice of undertreating pain continued to mount, the existence of a genuine and pervasive public health problem of major proportions became undeniable.⁵

⁴ The fallacy of this assumption was initially posited by the physician Eric Cassel, who observed that the relief of pain and suffering was presumed to be among the highest priorities of clinical medicine by patients and lay persons, but not by physicians. Eric Cassell, The Nature of Suffering and the Goals of Medicine, 306 NEW ENG. J. MED 639, 640 (1982).

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The decade of the 1990’s proved to be a watershed, with a remarkable number and diversity of professional and policy initiatives directed at what had finally come to be recognized, at least by the cognoscente in pain and palliative medicine, as an epidemic of undertreated pain. Mid-way into the decade following this relatively frenetic period, a decade fortuitously identified by the Congress of the United States as “The Decade of Pain Control and Research,” it is appropriate to consider what improvements, if any, this activity has produced, and to seek to ascertain whether public policy is an effective means of changing health care professional and institutional practice.6

Section I of this article undertakes a form of root cause analysis of the phenomenon of undertreated pain in the healthcare setting, based upon the premise that an accurate assessment of the nature of the problem is essential to the formulation and implementation of any remedial measures, regardless of whether or not they take the form of law, regulation, public policy, or more clinically oriented approaches such as clinical practice guidelines or practice parameters. The particular focus will be on the “why” aspect of the problem.7 Section II reviews examples of legislative approaches to the problem, with particular focus on two types of statutes – those dealing with so-called “intractable pain” and those addressing inadequacies in physician education and training. Section III considers the approach of the Joint Commission for the Accreditation of Health Care Organizations (JCAHO), i.e., the incorporation of criteria for institutional pain management policies and protocols into its accreditation manual. Section IV discusses the formulation of model physician practice guidelines, in particular those developed by the Agency for Health Care Policy and Research (AHCPR) and the Federation of State Medical Licensing Boards (FSMLB). Section V considers the concept of balance that has become a widely accepted model for evaluating and reforming state and federal policies affecting pain management and drug diversion. The Conclusion will review the progress, or lack thereof, brought about by these policy initiatives, and propose modifications to existing approaches that might increase the likelihood of further improvements in the second half of the Decade of Pain Control and Research and beyond.

7 See, e.g., ABS GROUP, INC., ROOT CAUSE ANALYSIS HANDBOOK (1999).
I. ORIGINS OF THE CULTURE OF PAIN

Deeply embedded in the moral core of ancient medicine is the physician's responsibility to relieve pain and suffering. Interestingly, the duty of the health care professional to relieve pain and suffering is offered as a self-evident truism rather than analyzed or argued for through carefully crafted analysis. With the discovery of the miraculous powers of some naturally occurring substances to relieve even the most severe pain, particularly opium and its most important ingredient – morphine, physicians were almost always able to respond compassionately to alleviate suffering even when they could not cure or significantly affect the progression of disease. Yet by the final decades of the past century, a period in which advances in medical science and technology were being made at an unprecedented pace, pain relief seemed to be moving in the opposite direction. In order to understand this bizarre phenomenon, I consider the barriers to pain relief that have been consistently identified in the professional literature. Before doing so, however, it is important to understand the categories into which pain states are routinely divided.

In 1986, a National Institute of Health consensus conference recommended that pain be differentiated as either: acute pain, chronic pain not associated with malignant disease, and chronic pain associated with malignant disease (cancer pain). Acute pain is usually the result of trauma, surgery, or an acute episode of illness. Cancer pain is often considered the primary component of the entire range of conditions associated with terminal illness, even though modern therapies have enabled many patients to survive years and even decades after a cancer diagnosis. Chronic nonmalignant pain is pain that is not associated with cancer or other life-threatening conditions and which lasts for more

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8 Cassell, supra note 4.
9 Eric Cassel, for example, cites no authority for the proposition that "[t]he obligation of physicians to relieve human suffering stretches back into antiquity." Cassel, supra note 4, at 639. Similarly, in what appears to be one of the earliest articles devoted exclusively to the duty to relieve pain and suffering, the author, an academic philosopher, states without further authoritative reference that "there is a broadly based humanistic ethics which applies to the domain of medical care which gives patients a strong prima facie right to freedom from unnecessary pain ...." Rem B. Edwards, Pain and the Ethics of Pain Management, 18 SOC. SCI. & MED. 515, 517 (1984).
than six months. These categories of pain are to be distinguished from the classification of pain according to the mechanism involved in its generation. In such a classificatory scheme, nociceptive pain is that which arises from tissue injury. Nociceptive pain has the attribute of usually being commensurate in its severity with the demonstrable tissue damage, thereby lending an aura of authenticity to the pain levels reported by the patient. Neuropathic pain, caused by a disorder of the sensory processing of the central nervous system, is often inconsistent with the extent of physical injury. For reasons that will be made clear in subsequent sections of this article, this aspect of nociceptive pain poses serious problems for pain patients in securing treatment.

The categories (acute, chronic nonmalignant, cancer), to a greater extent than the classifications (nociceptive and neuropathic), have a greater pragmatic than clinical significance because of the attitudes many physicians have about them. Pain associated with surgery or trauma has a clear physiological basis and a time-limited duration in which strong analgesics may be required for effective management. Physicians have generally been more willing to acknowledge and address this type of pain. Pain whose source is cancer or terminal illness, while also associated with a clear physiological basis, has tended to be managed more tentatively and cautiously, even by oncologists who are presumed to be the most knowledgeable of physicians in the proper care of such patients. Chronic nonmalignant pain is the most problematic because, among other reasons, there are often no physiological findings that are considered by physicians to be commensurate with the patient’s reports of the nature, severity, and persistence of the pain. Chronic pain patients are most vulnerable to charges of “drug-seeking” behavior, and the most likely to be the victims of pseudo-addiction. While there is compelling evidence that all types of pain have been undertreated,

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15 Pseudo-addiction is an iatrogenic condition in which a patient with genuine pain that has not been adequately treated manifests behaviors similar to patients with addiction disorders. See David E. Weissman & J. David Haddox, Opioid Pseudoaddiction – An Iatrogenic Syndrome, 36 Pain 363 (1989).
chronic nonmalignant pain is by far the most problematic. In Section II of this article I will consider a type of legislation specifically targeted at this type of pain.

Remarkably, one of the most consistently cited barriers to effective pain relief in patient care is lack of physician knowledge and skill in the assessment and management of pain. It is remarkable because of the ostensible status of the relief of suffering among the core values of medicine, and because pain is the most common reason why patients seek out the care of physicians. Nevertheless, medical school curricula continue, as they have for decades, to be virtually devoid of required courses, as opposed to occasional lectures in more traditional courses, in the assessment and management of pain. When academic physicians cultivate their ignorance of the remarkable advances in pain pharmacotherapy, the result is the perpetuation, from one generation of physicians to another, of an incredible amount of myth and misinformation about the proper role of opioid analgesics in the management of pain. Among the more prevalent, persistent, and pernicious myths harbored by academic and nonacademic physicians alike are the following:

- opioid analgesics, even when appropriately prescribed to patients with moderate to severe pain, are highly addictive
- the risk of respiratory depression from opioids seriously outweighs the benefit of analgesia in many seriously ill patients, even with careful monitoring in the inpatient setting
- there is a maximum tolerable dose of morphine regardless of the severity of the pain
- unrelieved pain poses no risks of adverse outcomes that are commensurate with the risks of long-term opioid use

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In both Sections II and III, I will consider initiatives intended to address, in part, the persistent problem of clinician ignorance about state-of-the-art pain assessment and management strategies.

A second barrier to effective pain relief has been identified as the failure to make pain relief a priority in patient care. This barrier, as with the first, is highly paradoxical if the relief of pain and suffering is, in fact, a core value of medicine. Either it is a core value only in some ethereal, aspirational sense, or it is a core value that is routinely violated in everyday practice. To some extent, there may be a false dilemma posed by the persistence of the first, second, and fourth of the myths noted above. One of the ancient maxims of medical practice is *primum non nocere* (first do no harm). The phrase falsely suggests that a medical intervention may only be undertaken when it poses no material risk of harm to the patient. To the contrary, what is required is an appropriate risk-benefit analysis, in which the known risks are deemed to be outweighed by the anticipated benefits. A physician in the grip of the erroneous belief that opioid analgesia of more than a few days duration is highly likely to produce addiction, or that unrelieved pain poses no physiological risks and only negligible psychological ones, will believe that the primary duty to “do no harm” will justify the decision not to adequately relieve pain that requires the use of opioids.

In Section III of this article I will consider a regulatory approach to institutionalizing the duty to provide appropriate pain relief.

The last of the physician-centered barriers is the fear of regulatory scrutiny and/or legal liability. The nidus of this fear is the prescribing of opioid analgesics, particularly those identified by the United States Drug Enforcement Administration (DEA) as Schedule II narcotics by authority of the federal Controlled Substances Act. Schedule II drugs include those that are most effective in controlling moderate to severe pain such as Morphine and Oxycodone. Because of what the DEA considers to be the high potential for abuse of drugs placed in Schedule II, there is a widespread belief among physicians that their prescribing practices with regard to them are carefully monitored. This perceived regulatory scrutiny, in combination with the myths and misinformation about the risks of opioids, has caused, or at least significantly contributed to, a phenomenon known as

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"opiophobia." The DEA is not the only regulatory agency whose vigilance, real or imagined, has profoundly influenced physician practice in the prescribing of opioid analgesics. State medical licensing boards, in the very decades in which an epidemic of undertreated pain was being reported, established a pattern and practice of taking draconian disciplinary actions against their licensees for alleged instances of "overprescribing" opioid analgesics. Some physicians who have been the victims of such proceedings have successfully challenged them, and in doing so elicited from courts highly critical commentary about the prevailing attitudes of medical board members toward progressive efforts to manage moderate to severe chronic pain with opioids when weaker analgesics have demonstrably failed. These disciplinary proceedings sometimes reveal a failure of state medical board members to apprise themselves of recent developments in pain management and more enlightened views among pain medicine experts about the role of opioid analgesics in the management of moderate to severe pain, whether or not it is associated with a terminal or life-threatening illness. The result of widespread and highly publicized disciplinary proceedings against physicians for purported "overprescribing" has been the encouragement of the diametric opposite, or underprescribing. In Section II I will consider

27 One Executive Director of a state medical licensing board went so far as to describe an "ethic of underprescribing" that has come to characterize the attitudes of many state medical licensing boards. Ann M. Martino, In Search of a New Ethics for Treating Patients with Chronic Pain: What Can Medical Boards Do?, 26 J.L. MED. & ETHICS 332, 336 (1998).
28 See, e.g., Hoover v. Agency for Health Care Admin., 676 So. 2d 1380, 1385 (Fla. Dist. Ct. App. 1996), where the court, in reversing the board's disciplinary measures against Dr. Hoover, criticized the board's "draconian policy of policing pain prescription practice[s]" and found that the board had "once again engaged in the uniformly rejected practice of overzealously supplanting a hearing officer's valid findings of fact regarding a doctor's prescribing practices with its own opinion in a case founded on a woefully inadequate quantum of evidence."
state legislation specifically intended to address this phenomenon among state medical boards.

Before concluding Section I, it is important to anticipate the criticism that too much blame is being placed on physicians – either in their role as practitioners, medical school faculty, or as medical board members – as the sole or most significant source of the problem of undertreated pain. Certainly other barriers not directly linked to physicians have been identified. These include, among others, financial and insurance coverage considerations and the reluctance of patients and/or their families to consider the use of opioid analgesics on a sustained basis. However, with regard to financial or insurance coverage constraints, the pervasive phenomenon of undertreated pain pre-dates the rise of managed care or the imposition of cost containment mechanisms as a dimension of health care reimbursement policy. Furthermore, while it is true that opiophobia afflicts patients and their families, and indeed some cultures, there is no evidence to support the argument that knowledgeable, compassionate physicians cannot help patients and their families to appreciate the importance of effective pain management to good patient care. Practicing physicians have also maintained that the alleged hyperscrutiny of their opioid prescribing practices, particularly through the imposition of multiple copy prescription form requirements by some states on Schedule II drugs, justifies their practice of utilizing smaller doses and weaker analgesics in their efforts to manage the pain of their patients.

In portions of Section II and IV I consider the legitimacy and efficacy of legislative and regulatory measures to influence physician practice. In that context I will take note of the legal and ethical


33 Multiple copy prescription forms, often referred to as "triplicates" because the most common type requires the use of a special prescription pad that generates 3 copies, one of which goes to a designated state or law enforcement agency which can thereby monitor the prescribing practice of each physician. See H.I. SCHWARTZ, PSYCHIATRIC PRACTICE UNDER FIRE: THE INFLUENCE OF GOVERNMENT, THE MEDIA, AND SPECIAL INTERESTS ON SOMATIC THERAPIES (1994).
implications of a custom and practice among physicians that appears to countenance, indeed, to justify unnecessary suffering on the part of patients as a means of assuaging physicians’ anxiety and minimizing their perceived risk of liability.\textsuperscript{34}

II. LEGISLATIVE RESPONSES TO UNDERTREATED PAIN

The initial wave of legislation addressing the phenomenon of undertreated pain began in 1989 with the enactment by the Texas legislature of the first of what has come to be known generically as intractable pain treatment acts (IPTA).\textsuperscript{35} IPTA legislation was a direct response to the chilling effect on pain management produced by state medical licensing board disciplinary actions for so-called “overprescribing” of opioid analgesics. Intractable pain was defined as “a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.”\textsuperscript{36} The thrust of this definition is to reconceptualize chronic nonmalignant pain as a condition to be treated rather than a symptom of an underlying condition. The critical public policy component of an IPTA is the provision stating: “No physician may be subject to disciplinary action by the board for prescribing or administering dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.”\textsuperscript{37}

Following the lead of Texas, other states enacted similar statutes early in the decade of the 1990s.\textsuperscript{38} While hardly a trend that eventually made such legislation, or the public policy that such statutes espouse a majority view, IPTAs have fostered closer scrutiny of the problem of undertreated pain, the extent to which it is in part a product


\textsuperscript{35} TEX. REV. CIV. STAT. ANN. § 4495c (Vernon 1996).

\textsuperscript{36} Id. § 2(3).

\textsuperscript{37} Id. § 5.

\textsuperscript{38} CAL. BUS. & PROF. CODE § 2241.5 (West 1994); FLA. STAT. ANN. § 458.326 (West 1995); MO. ANN. STAT. § 334.105 (West 1995); NEV. REV. STAT. § 630.3066 (1995); N.D. CENT. CODE § 19-03.3-01 (1995); OR. REV. STAT. § 677.474 (1995); VA. CODE ANN. § 54.1-3408.1 (Michie 1995).
of medical board hyper-scrutiny of opioid prescribing practices, as well as other factors that influence the care of patients with pain. In addition to becoming the second state to enact an IPTA, California shortly thereafter convened a statewide summit on effective pain management that included participants from the health professions, professional education, legislative bodies and regulatory agencies. The summit report was both bold and sweeping in its recommendations. In addition to obvious reforms such as replacing the state imposed triplicate prescription form for Schedule II narcotics, it advocated the creation, by statute, of a positive legal duty on the part of physicians to effectively treat pain and suffering. Spurred by this new emphasis on the importance of pain management in patient care, the California licensing boards for physicians, nurses, and pharmacists promptly promulgated guidelines for the appropriate use of opioids in the treatment of pain.

IPTAs are not without potential problems. Typical provisions in such statutes either state or strongly imply that opioid analgesia is a treatment of last resort for serious chronic nonmalignant pain, with virtually no guidance to the physician (either in the statute or in other regulations or guidelines) as to what constitutes a reasonable effort to utilize non-opioid therapies. Even the choice of terms such as “dangerous drugs and controlled substances” sends a strong and somewhat misleading message that opioid analgesics are in a class by themselves in the risks of harm that they pose to patients. In 1995, under the sponsorship of the Mayday Fund and the Emily Davie and Joseph S. Kornfeld Foundation, The Project on Legal Constraints on Access to Effective Pain Relief developed a model Pain Relief Act. The model act recognizes the important role of state legislation in the empowerment of physicians to provide appropriate pain relief to their patients, while at the same time acknowledging serious limitations in the IPTA approach.

Among the limitations addressed in the model act is the failure to make the provisions applicable to all health care professionals who

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40 Id. at 11, 13.
42 Id.
43 See supra note 30.
may be involved in the process of prescribing and administering opioid analgesics, i.e., physicians, nurses, and pharmacists. While some states may have consistent policies in place that govern each of these professional groups, the more likely situation is that such policies may be inconsistent if they exist at all. In California recently, for example, the state medical board declined to take disciplinary action against a physician who replaced a patient's opioid analgesic with a placebo without informed consent, yet the state nursing board initiated disciplinary proceedings against nurses who administered the placebo pursuant to the physician's order.

A second limitation is the common failure of IPTAs or implementing regulations to clearly set forth the standards by which a physician's prescribing practices will be measured. Merely relying upon stock phrases such as consistent with what a "reasonably prudent physician would do under such circumstances" is particularly inadequate in the area of pain management with opioids because the well-established custom and practice has been undertreatment. The model act, by contrast, protects physicians who can demonstrate "substantial compliance" with an "acceptable guideline for pain management." Prime examples of such guidelines, which themselves have been referenced by state medical board pain policies as guides for physicians to follow, are those developed by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality).

The impact of the handful of IPTAs adopted by states is difficult to measure. States that have enacted them but continued to encounter problems of undertreatment have resorted to other legislative measures. A prime example is the State of California, which in the last 5-7 years has been particularly active on the pain policy front.

49 Agency for Health Care Quality and Research, Acute Pain Management: Operative or Medical Procedures and Trauma (1992); Agency for Health Care Quality and Research, Management of Cancer Pain (1994).
50 David E. Joranson and Aaron M. Gilson, State Intractable Pain Policy: Current Status, 7 APS BULL. 7 (1997).
Continuing the reform spirit engendered by the 1994 Pain Summit, in 1997 the California Assembly enacted the Pain Patients Bill of Rights. However, the title promises much more than the legislation delivers. While the importance of pain relief to patient care is emphasized, and the need to make opioid analgesia available to patients with serious chronic pain problems is reinforced, the act permits physicians to refuse to prescribe opioids, presumably even when medically indicated, so long as the patient is informed that there are physicians who specialize in the treatment of severe chronic pain from whom treatment may be sought. The legislation, rather than emphasizing the responsibility of all physicians to assess and treat pain promptly, effectively, and for as long as the pain persists," consistent with the guidelines of the California Medical Board, instead suggests that treatment of pain, particularly chronic nonmalignant pain that requires opioids for effective relief, is something that physicians may eschew without adverse consequences (to them).

In 2001, a jury verdict against a physician for elder abuse sent shock waves through the medical community and prompted further action by the California Assembly. The case involved an 85-year old man who was hospitalized with severe pain. He had multiple symptoms indicative of lung cancer. Throughout his 5-day hospital stay, nurses charted his pain in the moderate to severe range, yet his physician never changed the standing order for Demerol, 25-50 mg every 4 hours "as needed." Both in the Emergency Room prior to admission, and at home in the few days before his death while receiving hospice care, the patient achieved pain relief with administrations of morphine. Following his death, the family filed a complaint against the treating physician with the Medical Board of California. When the Board agreed with the family's expert that the pain management in the case

51 Pain Patients Bill of Rights, CAL. HEALTH & SAFETY CODE § 124960 (West 1997).
52 Id.
53 California Medical Board, Guideline for Prescribing Controlled Substances for Intractable Pain, 51 ACTION REPORT 1, 8 (1994).
55 A widely recognized approach to assessing pain is a 10-point scale with 0 being no pain and 10 being the worst pain one can imagine. Levels in the 1-3 range are characterized as mild, those in the 4-6 range are as "moderate," and levels above 6 as "severe". Richard H. Gracely & Patricia J. Wolskee, Semantic Functional Measurement of Pain: Integrating Perception and Language, 15 PAIN 389, 390 (1983).
had been inadequate but declined to take disciplinary action against the physician, the family filed suit alleging elder abuse. A jury ruled in the family’s favor and assessed $1.5 million in damages.

In what appeared to be a direct and immediate response to the Bergman case, and more particularly the marked disparity between the response of the California Medical Board and that of the jury, Assembly Bill 487 was introduced into the California Assembly in 2001. In its original form, the bill mandated the California Medical Board to, at a minimum, order a physician to complete continuing medical education in pain management whenever it concluded, upon complaint, investigation, and expert review, that a physician’s management of a patient’s pain had been inadequate. After significant revision at the behest of the California Medical Association, the enacted version mandated that all licensed physicians in California, with the exception of radiologists and pathologists, obtain a minimum of 12 hours of continuing medical education in pain management and treatment of terminally ill and dying patients by December 31, 2006.

The final version of the bill also charged the Division of Medical Quality to develop standards for the review of cases involving pain management.

The premise behind the original version of AB 487 in California was that the state medical board required legislative prodding in order to be as zealous in the handling of cases of underprescribing of opioids as it, and many other boards, had been in the handling of cases of overprescribing or inappropriate prescribing. The premise behind the version of AB 487 that ultimately became law was the quite different one that mandatory continuing professional education changes practice.

The lawsuit was filed as an elder abuse, rather than a traditional medical malpractice claim, because of the vagaries of tort reform legislation in the State of California. Pursuant to that legislation, damages for pain and suffering arising from medical negligence are capped at $250,000 and do not survive the death of the patient. However, the California elder abuse statute allows for the recovery of damages for pain and suffering resulting from elder abuse to be recovered by the survivors of the victim. It is also important to note that the California elder abuse statute, unlike some other states, does not explicitly exclude substandard medical care from the act or omissions that may constitute elder abuse. However, in order to establish a claim of elder abuse against a physician in California, it is not sufficient to show a mere departure from the applicable standard of care. Instead, the plaintiff must prove a gross departure from the standard.

The verdict was subsequently reduced to $250,000 by the trial judge pursuant to the statutory cap, but awarded attorneys fees to the plaintiff.

CAL. BUS. & PROF. CODE § 2190.5 (West 2001).

CAL. BUS. & PROF. CODE § 2241.6 (West 1994).
That premise is vulnerable to considerable critique. A wealth of data in the medical literature during the last 15 years reveals that the primary elements of continuing professional education programs – knowledge dissemination and attitude adjustment (motivation to change) – do not consistently, indeed rarely lead to widespread change in clinical practice. The belief that it does has been characterized as "a grand and prevalent delusion." Theories abound as to what the missing element or elements are that must be included in order to consistently translate the dissemination of knowledge and the appropriate adjustment of attitude into improved professional practice. A vivid example of what does not work has been provided by a massive project funded by the Robert Wood Johnson Foundation ten years ago.

The Study to Understand Prognosis, Preferences for Outcome and Risks of Treatment (SUPPORT) was a multi-million dollar, multi-year, multi-institutional review of the quality of intensive care provided in the United States. The stated purpose of SUPPORT, particularly its second phase, was to "improve end-of-life decisionmaking and reduce the frequency of a mechanically supported, painful, and prolonged dying process." Phase I of SUPPORT collected and analyzed data on over 9000 patients who died in the intensive care unit (ICU) of one of the five academic medical centers participating in the study over a four-year period. Among the most significant findings of the investigators based upon the Phase I data were that Do Not Resuscitate (DNR) orders were often too late in the trajectory of the patient’s illness or were inconsistent with the expressed wishes of the patient, discussion between treating physicians and patients or their families was inadequate, and 50% of patients experienced moderate to severe pain in the last three days of life. With both an intervention and control

62 Ferris, von Gunten, and Emanuel, supra note 58, at 145.
63 SUPPORT Principal Investigators, A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients, 247 JAMA 1591, 1592 (1995).
64 Id. at 1593-4.
group, Phase II sought to remediate the deficiencies identified in Phase I by utilizing a cadre of experienced and specially trained nurses. Their objective was to facilitate physician-patient and physician-family communication about prognosis, treatment plans, patient directives and values, and prompt assessment and management of pain and other symptoms of distress. In order to address the particularly difficult task of prognostication in the ICU setting, a state-of-the-art prognostic instrument was developed by the investigators to be utilized by the intervention group. When SUPPORT investigators analyzed the data from Phase II, they found no demonstrable improvement in the care patients in the intervention group received. Merely providing more information to treating physicians, and seeking to facilitate the kind of interpersonal interactions with seriously ill patients or their families in which such physicians are not naturally inclined to engage, had no practical impact on deeply ingrained and embedded practices of critical care professionals. Among the realizations of the SUPPORT investigators was that the barriers to change transcend knowledge and attitudes, and that the target for change in settings such as hospital ICUs should be systems rather than individual practitioners.

The data discussed above strongly suggests that while professional education is a necessary element of changing physician practice, it is not sufficient. This is particularly true when physician practice is driven not just by previous medical training, but also by deeply entrenched concerns about potential risk and liability arising out of any material deviation from that custom. The perennial debate about the optimal approach to improving physician practice has a multiplicity of issues. Among them are whether change can be achieved in the short-term or whether it is inevitably incremental, and whether positive change requires positive reinforcement, or whether negative

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65 Id.
67 SUPPORT, supra note 60, at 1595-6.
reinforcers can sometimes be efficacious. The majority view has been that such change comes slowly and by a system of rewards rather than punishment. This view criticizes lawsuits and disciplinary proceedings for alleged instances of undertreating pain.

There is at least one area, however, in which negative reinforcement precipitously changed physician practice on a large scale. That area is the adoption of multiple copy prescription form (MCPF) requirements by some states for certain types of narcotics. While about 20% of the states have had some type of MCPF requirement at some time during the last 50 years, there has been a general trend away from those toward electronic monitoring in the last 10-12 years.\textsuperscript{71} One of the reasons supporting the transition to electronic monitoring is that they are perceived to be less intrusive and intimidating to physicians, and hence less of a barrier to appropriate prescribing. The evidence of the chilling effect of MCPF's is compelling, and relates directly to the question of what, from a public policy standpoint, prompts changes in physician behavior. A number of studies compared physician prescribing practices in the period immediately before and after the adoption of a MCPF requirement or the addition of a particular narcotic to a pre-existing requirement.\textsuperscript{72} The remarks were striking and consistent: the volume of prescribing of the drug or drugs covered by the new MCPF requirement was reduced by half.\textsuperscript{73} Unless one assumes that such a substantial percentage of these narcotics was being prescribed inappropriately by physicians, then the logical conclusion is that physicians began to prescribe less appropriate or effective narcotics to their patients in order to avoid the regulatory scrutiny that they believed was made possible by the MCPF policy.\textsuperscript{74} In either case, the data strongly suggests that the perceived threat of

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regulatory scrutiny can rapidly and significantly alter a critical aspect of physician practice, i.e., prescribing medications for patients.

A quite different approach is one that provides institutional impetus and support for changes in practice patterns in pain and symptom management. In section III I consider one of the most recent and significant.

III. THE JOINT COMMISSION PAIN STANDARDS

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the pre-eminent national organization that monitors and certifies the quality of care provided by hospitals in the United States. So pervasive and dominant is its role that JCAHO accreditation constitutes compliance with most requirements for Medicare reimbursement. As a private, not-for-profit entity, JCAHO offers a kind of self-regulation in that its governing board consists of individuals appointed by the American Medical Association, the American Hospital Association, the American College of Surgeons, the American College of Physicians, and the American Dental Association. Thus, when JCAHO introduces new standards or priorities for evaluating institutions in its survey process, health care organizations take notice.

In 1998, JCAHO responded positively to a proposal by certain faculty of University of Wisconsin to explore what role it might be able to play in making quality pain management more of a priority in patient care. With financial support from the Robert Wood Johnson Foundation, they began a joint project entitled "Institutionalizing Pain Management." As a part of this project, a panel of national pain experts began working in conjunction with the JCAHO Professional and Technical Advisory Committees, Standards and Survey Procedures Committee, and the Board of Commissioners. In March of 1999, the new pain standards were officially approved by JCAHO. The standards first appeared in the Accreditation Manual in its 2000-2001 edition, and began to be part of the compliance scoring in 2001.

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78 Id.
An important and quintessentially American message emerges from the decision to place one element of the pain standards in the chapter of the Accreditation Manual entitled "Patient Rights and Organizational Ethics." Standard RI.1.2.9 states: "Patients have the right to appropriate assessment and management of pain." Perhaps more importantly, the new priority for pain management in patient care is stressed in other chapters of the JCAHO standards as well, including those pertaining to the assessment and care of patients, rehabilitation, patient education, continuum of care, and improving organizational performance. Accredited institutions are expected to meet this obligation to patients by insuring that each of the following takes place:

1. Assess the existence and nature of pain in all patients
2. Document the results of the assessment in a manner that facilitates regular reassessment and follow-up
3. Determine and assure staff competency in pain assessment and management
4. Establish policies and procedures which support the appropriate prescribing of effective pain medications
5. Educate patients and their families about effective pain management
6. Address patient needs for symptom management in the discharge planning process

The JCAHO standards are not merely a means by which institutions can improve their patient satisfaction surveys. Rather, these standards are essential to quality patient care because unrelieved pain produces a plethora of adverse effects of both a psychological and physiological nature. If each of the six items listed above were to become a vital part of the institutional culture, then they might provide the missing elements in professional education, which are the modeling and

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79 See JCAHO, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS (2000).
80 Id.
81 JCAHO, Joint Commission Focuses on Pain Management, at http://www.jcaho.org/news=room/health=care=issues=jcaho+focuses+on+pain+management
mentoring of new knowledge and attitudes so that skills in delivery can be practiced, refined, and reinforced in actual clinical settings.\textsuperscript{83}

Remarkably, for decades prior to the recent development and implementation of the JCAHO pain standards, the typical hospital had been a wasteland in the assessment and management of pain. A major 1977 study, for example, contains the following bleak assessment:

Chief among the difficulties facing anyone who would reform current practices of pain management in our hospitals is the far from obvious fact that most aspects of pain work are peripheral to the attention and the responsibilities of the staff. By responsibilities we mean not merely the staff's perceived responsibilities, but also its actual legal and organizational ones. We are asserting, in other words, that \textit{the staff is not genuinely accountable for much of its interaction with or behavior toward patients in pain.}\textsuperscript{84}

Further confirmation of the blind eye the typical hospital clinical staff member turned to pain relief appeared five years later in the \textit{New England Journal of Medicine} when Marcia Angell observed that pain in hospitals was not just occasionally, but "systematically" undertreated.\textsuperscript{85}

At about the same time as the JCAHO standards were being developed, a new initiative developed under the banner of "Pain: The Fifth Vital Sign."\textsuperscript{86} The American Pain Society (APS), a national interdisciplinary pain advocacy organization, offered the following rationale for its significance: "Vital signs are taken seriously. If pain were assessed with the same zeal as other vital signs, it would have a much better chance of being treated properly. We need to treat pain as a vital sign. Quality care means that pain is measured and treated."\textsuperscript{87} Critics of the initiative, many of whom are physicians, argue that because pain is a subjective human experience, and there are no completely objective means of measuring the pain that someone is experiencing, then pain can never be legitimately characterized as a

\textsuperscript{83} Ferris, von Gunten, Emanuel, \textit{supra} note 58, at 146-147.

\textsuperscript{84} SHIZUKO Y. FAGERHAUGH & ANSELM STRAUSS, POLITICS OF PAIN MANAGEMENT: STAFF-PATIENT INTERACTION 26 (1977).

\textsuperscript{85} Marcia Angell, \textit{The Quality of Mercy}, 306 NEW ENG. J. MED. 98, 99 (1982).

\textsuperscript{86} The American Pain Society appears to have secured a trademark on the phrase in the mid-1990's. \textit{See} the APS website at http://www.ampainsoc.org/advocacy/fifth.htm.

\textsuperscript{87} Id. James Campbell, Presidential Address, American Pain Society, November 11, 1995, \textit{available at} www.ampainsoc.org/advocacy/fifth.htm.
vital sign. However, a close reading of the language above indicates that the thrust of the APS assertion is not that pain is or should be considered a vital sign (the 4 classic vital signs are: temperature, pulse, respiratory rate, and blood pressure), but only that it be assessed with the same level of concern and consistency as vital signs, because important information about the patient's condition can thereby be obtained and utilized. Pain as a fifth vital sign has found its way into some recent state legislation. The most thorough and expansive adoption of the "pain as fifth vital sign" initiative is that of the Veterans Health Administration (VHA). As a part of the VHA National Pain Management Initiative, a detailed manual ("toolkit") was issued.

An open question is whether such initiatives as "Pain as the 5th Vital Sign" can, in the absence of education, training, monitoring, and appropriate sanctions for noncompliance, motivate a significant and sustained change in professional practice. One study of the VHA system following the initial phase of the initiative indicated significant progress toward the target goals. The remarkable improvement produced by the initiative was attributed in significant part to the comprehensive and systematic way in which the initiative was developed and implemented, utilizing team formation, goal identification, testing and adaptation of recommended system changes, and sharing and feedback of outcome information.

The ability of an accredited institution to, and the consistency with which it actually does, comply with JCAHO standards can be measured, at least to some degree, by the extent to which the standards have been incorporated into the daily operations of the facility through official policies, protocols, rules and regulations. The process of demonstrating, in this instance to JCAHO surveyors, that the timely and effective assessment and management of patient pain has actually

89 See, e.g., CAL. HEALTH AND SAFETY CODE § 1243.7 (West 2000), providing that every licensed health facility shall "as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken ... and noted in the patient's chart in a manner consistent with other vital signs."
92 Id.
been “institutionalized” through policies that require it can in turn have the effect of creating an institutional standard of care. Medical malpractice cases in many jurisdictions have held that an institution’s own internal policies, procedures, and regulations may serve as a source of the applicable standard of care. Although the duty to assess and manage a patient’s pain is that of the physician, the JCAHO pain standards charge the institution with the responsibility of insuring that its medical and nursing staffs possess, maintain, and consistently apply the requisite competencies. Under well-established principles of corporate negligence or vicarious liability, health care institutions and organizations may be held accountable for the failure of their professional staffs to provide effective pain management.

While the JCAHO standards appear to have the potential to produce real changes in knowledge, skills, and attitudes (both individual and institutional), they will not be realized unless regular institutional surveys continue to convey the need for compliance. The seriousness with which institutions view JCAHO accreditation, and the consequent motivation to insure the ability of the clinical staff (physicians, nurses, pharmacists) to fulfill this particular patient care obligation, could provide the otherwise missing link between professional education and changes in practice patterns.

IV. CLINICAL PRACTICE GUIDELINES

Among the earliest nationally recognized clinical practice guidelines in the field of pain management were issued in the 1980’s by the American Pain Society. Now in their fifth edition, these guidelines focus on acute and cancer pain. In 1990, the newly established Agency for Health Care Policy and Research (AHCPR) convened an interdisciplinary panel of national experts on pain management. They were charged with the responsibility for developing detailed and comprehensive clinical guidelines for the assessment and management of various types of pain. The impetus for these guidelines was the

94 The seminal case on hospital corporate negligence principles is Darling v. Charleston Cmty Mem’l Hosp., 211 N.E.2d 253 (Ill. 1965).
96 For a list of the initial panel members and the process by which they undertook the task before them see Agency for Health Care Quality and Research, Clinical Practice
continuing data that currently prevailing custom and practice among physicians "fail[ed] to relieve pain in about half of postoperative patients," resulting not only in unnecessary patient discomfort, but also protracted recovery periods and suboptimal patient outcomes. These guidelines were followed two years later with similarly detailed guidelines on the management of cancer pain. Publication of the cancer guidelines coincided with some of the early state initiatives by medical boards to foster improved pain management among physicians. In conjunction with its own efforts, for example, the California Medical Board promulgated a policy and more general guidelines on the assessment and management of pain, incorporated the AHCPR guidelines by reference, and even sent a copy of the AHCPR cancer guidelines to every licensed physician in California. California continues to be in the vanguard of state medical boards, having recently revised the pain management guidelines, expanding them to cover all patients with pain, and not merely those with “intractable pain.”

The obvious and significant element missing in the proliferation of pain management clinical practice guidelines in the decade of the 1990’s was chronic nonmalignant pain. This was not mere happenstance. Chronic pain patients are the bane of many physicians because they often epitomize the “difficult patient” who inordinately consumes physician and health system resources and energy, and for whom demonstrable improvement is very difficult to achieve.

Despite the seemingly wide distribution of these clinical practice guidelines, and their endorsement by a number of state medical boards, survey and anecdotal data continued to suggest that undertreated pain was widespread, serious, and constitutive of a major

Guideline No. 1, Acute Pain Management: Operative or Medical Procedures and Trauma (1992).
97 Id.
98 Id.
100 Medical Board of California, A Statement by the Medical Board, 50 ACTION REPORT 1, 4 (July 1994); Medical Board of California, Guidelines for Prescribing Controlled Substances for Intractable Pain, 51 ACTION REPORT 1, 8 (October 1994).
101 Medical Board of California, Revised Pain Management Guidelines, 87 ACTION REPORT 1, 1 (Oct. 2003).
102 For an in-depth and insightful examination of medicine’s profound ambivalence toward patients with chronic illness, particularly chronic pain, see ARTHUR KLEINMAN, THE ILLNESS NARRATIVES: SUFFERING, HEALING, AND THE HUMAN CONDITION (1988).
public health problem. Moreover, one of the most significant barriers to the consistent delivery of effective pain management was the widespread fear on the part of physicians that state medical licensing boards routinely took disciplinary action against those who prescribed opioid analgesics to patients who were not in the final stages of a terminal illness.

In response, at least in part, to the mounting criticism that state medical licensing boards continued to be part of the problem of, rather than part of the solution to the epidemic of undertreated pain in the United States, the Federation of State Medical Licensing Boards developed and issued model guidelines for the use of controlled substances for the treatment of pain. These guidelines, from a substantive perspective, were modest indeed. Unlike the AHCPR guidelines, they provided neither specific guidance to physicians on techniques and strategies for assessing and monitoring pain, nor recommendations of analgesics, dosages, or routes of administration for particular types of pain. For such guidance, physicians are referred to the AHCPR Clinical Practice Guidelines. Instead, the Federation guidelines set out requirements that physicians must meet in order to demonstrate that their use of opioid analgesics (controlled substances) for pain management was justified and consistent with sound medical practice. Those requirements included: evaluation of the patient, development of a treatment plan, informed consent of the patient, periodic review of the patient's progress (or lack thereof), consultation with other physicians as appropriate, detailed and accurate medical records, and compliance with controlled substances laws and regulations. If these appear to be quite basic and generic in nature, that is because they are. Such "requirements" apply to virtually every aspect of patient care. They have no unique application to the prescribing of controlled substances in the management of pain. Arguably, the significance of the guidelines was the policy message that was not merely implicit, but rather overtly articulated in the Preamble of the document:

102 N.Y. Public Health Council, supra note 5.
103 See, e.g., C. Stratton Hill, Jr., supra note 27, at 293.
105 Id.
- Principles of quality medical practice dictate that patients have access to appropriate and effective pain relief
- Physicians should view effective pain management as a part of quality medical practice for all patients with pain
- All physicians should become knowledgeable about effective methods of pain treatment
- Pain should be assessed and treated promptly, and the quantity of doses should be adjusted according to the intensity and duration of the pain

The implicit message of the Federation guidelines, at least when adopted by a state medical board, is that physicians will not be at risk of disciplinary action if they prescribe controlled substances to patients in compliance with the guidelines. What was not clear was whether the manifest failure of a physician to provide "appropriate and effective" pain relief to a patient would be deemed to constitute substandard medical practice and hence render the physician vulnerable to disciplinary action. The proposition, at least on its face, appears straightforward: if there can be such a phenomenon as inappropriately excessive prescribing of opioid analgesics that leads to medical board disciplinary action (e.g. the Hoover case), then with the adoption of the Federation Guidelines there should also be a recognized phenomenon of inadequate prescribing of opioid analgesics that also leads to medical board disciplinary action. Both should amount to substandard patient care and unprofessional practice. In the absence of such a balanced medical board approach, the actual message to physicians would likely be that while you can continue to be subject to disciplinary action for so-called "overprescribing" of opioid analgesics, there will be no commensurate risk for the converse. In other words, there is no such thing as "underprescribing" insofar as medical boards are concerned. If that were the case, the guidelines would be highly unlikely to materially alter the extremely conservative approach to opioid prescribing that had produced the epidemic of undertreated pain.

The first state medical board to signal that allowing patients to experience unnecessary suffering would merit disciplinary action was Oregon. In March of 1999, the Oregon Board of Medical Examiners (OBME) filed a complaint against Paul Bilder. The complaint

106 Id.
alleged six instances of conduct that constituted unprofessional or dishonorable conduct and gross or repeated negligence in the practice of medicine. The episodes of misconduct spanned a period of time from 1993-1998. Bildner's alleged misconduct in these cases fell into one of two categories: 1) failure to provide adequate pain relief to dying patients, and 2) administering paralytic agents to ventilator-dependent patients without also providing anxiolytic agents. One of the bitter ironies of the Bildner case was that five out of six episodes involved care at a facility by the name of Mercy Medical Center. In September of 1999, Bildner and the OBME entered into a Stipulated Order pursuant to which he was required to enroll in a program of peer evaluation and education under the auspices of the Oregon Medical Association, complete a course on physician-patient communication, and continue to receive psychiatric treatment. The painful saga of Paul Bildner continues. According to the OBME website, another Stipulated Order was entered in April of 2003, pursuant to which Bildner received a public reprimand, 10 years of probation, and was required to receive continuing medical education, make quarterly reports to the OBME, submit to monitoring of his practice, and continue with psychological counseling.

The OBME prosecution of Bildner cannot be attributed to the formal adoption of the Federation Guidelines. However, one month after the filing of the complaint against Bildner, the OBME did issue a policy statement on pain management that was consistent with the philosophy and policy behind the Federation Guidelines. It is

108 Id.
109 The Oregon Board of Medical Examiners might appear to be vulnerable to the critique that it should not have required a critical mass of 6 suffering patients over a period of 5 years before it was moved to take action against Dr. Bildner. However, such a critique misses the more fundamental question of why the medical staff of Mercy Medical Center did not take action much earlier. It strains credulity to suggest that the medical staff, nursing staff, and hospital administration did not know about the threat to patient care this physician posed. Given the well-known limitations of financial and human resources all state medical boards face, they cannot reasonably provide the first line of defense against substandard medical practice. That responsibility must fall upon the local community of health care institutions and professionals.
112 Oregon Board of Medical Examiners, Statement of Philosophy on Pain Management, BME REPORT, Fall 1999.
interesting, although for the most part speculative, to consider the role that Oregon’s legalization of physician-assisted suicide has had on its public policy of advocating for improved pain management by physicians. Concerns have been raised that undertreated pain and substandard symptom management are major factors in patient requests for physician-assisted suicide. These concerns have persisted despite six years of data on the experiment with physician-assisted suicide indicating that unrelieved pain is far down on the list of reasons most often given by patients who request and receive physician-assisted suicide. In 2003, the California Medical Board (CMB) became the second state licensing board to take disciplinary action against a physician for failure to provide appropriate pain relief. While the charges against the physician suggested multiple instances of failing to provide appropriate pain relief to a patient dying of mesothelioma in a skilled nursing facility, the stipulated decision and order was very narrowly crafted and focused entirely on the demonstrable failure to know the form in which certain analgesics were available. The CMB action against Dr. Whitney also indicates that medical boards can take appropriate disciplinary action based upon a single instance of substandard or unprofessional practice. One of the justifications that had been offered for the failure of the CMB to take any disciplinary action against Dr. Chin, despite the negative review of his care by the CMB expert, was that it involved only a single instance, rather than an established pattern and practice.

In 2004, the Federation issued revisions to its Model Guidelines, in an apparent effort to reinforce the fundamental proposition inherent in the original document of 1998 that the prompt, effective, and consistent assessment and management of pain is an integral component of quality patient care. But the 2004 revisions also sought to transform the very nature of the document — from model guidelines to model policy. Indeed, the “Model Policy” now contains the disclaimer that it is “not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled

115 In the matter of the accusation against Eugene B. Whitney, M.D., Case No. 12 2002 133376, filed March 13, 2003.
117 See supra note 51 and accompanying text.
THE POLITICS OF PAIN

substances laws and regulations."\(^{118}\) Of particular note is language indicating that the inappropriate prescribing of analgesics can constitute substandard practice regardless of whether it consists of overprescribing or underprescribing.\(^ {119}\) The Federation reports that as of January of 2004, 22 state medical boards had adopted all or part of the guidelines.\(^ {120}\)

Changing medical board thinking about the place of pain relief in patient care, and the role of medical boards in insuring that physicians have the requisite knowledge, skills, and attitudes to respond appropriately to the pain and suffering of their patients, is a monumental task.\(^ {121}\) The myths, misinformation, and phobias related to controlled substances and the "untestable hypothesis" of a patient's subjective experience of pain are deeply embedded in the culture of medicine and the minds of many of its current practitioners.\(^ {122}\) Further confirmatory evidence of the remarkable persistence of this phenomenon was provided by the results of a recent study of medical board disciplinary attitudes and practices.\(^ {123}\) The details of the Bilder case in Oregon were described to state medical board members and staff. When asked how likely the respondent's board would be to take disciplinary action against a physician if similar complaints were corroborated upon investigation, 11 respondents believed action would be almost certain (a likelihood of greater than 90%); 14 respondents thought it would be probable (a 60-90% chance); 3 considered it to be possible (40-60%); 2 thought it was unlikely (10-40%); 3 offered other broad ranges 60-100% and 40-90%), while 5 were unable to offer any prediction.\(^ {124}\) Such data, particularly the regulators who believed there was a less than 50% chance that the clinical facts of a Bilder-type case

\(^{118}\) Federation of State Medical Boards of the United States, Inc., Model Policy for the Use of Controlled Substances for the Treatment of Pain, May 2004.
\(^{119}\) Id.
\(^{120}\) Federation of State Medical Boards of the United States, Inc., Prescription for Change: Federation to Strengthen Pain Treatment Policy, March 2004. For a more detailed description and analysis of the use of these model guidelines by the states see Aaron M. Gilson, David E. Joranson, & Martha A. Maurer, Improving State Medical Board Policies: Influence of a Model, 31 J.L. MED. & ETHICS 119 (2003).
\(^{121}\) For a glimpse into the mindset of the average physician and medical board member, one which has fashioned and defended an "ethic of underprescribing," see Ann M. Martino, supra note 24.
\(^{122}\) See Joranson and Gilson, supra note 26, and accompanying text.
\(^{124}\) Id. at 31.
would not prompt their board to undertake any disciplinary action, not even so much as a letter of reprimand or a demand for completion of a continuing medical education program in the relief of pain and suffering, tends to offer strong corroboration to a charge that physician Eric Cassell made against the medical profession well over a decade ago:

> The test of a system of medicine should be its adequacy in the face of suffering: this book starts from the premise that modern medicine fails that test. In fact, the central assumptions on which twentieth-century medicine is founded provide no basis for an understanding of suffering. 125

Perhaps in recognition of these realities, the Federation has announced yet another series of “workshops” for members of the “medical regulatory community” for 2004-2005. Among the objectives of the educational program are:

- Creating a regulatory environment that encourages accessible and appropriate pain care;
- Identifying policy/legislative barriers to appropriate pain care;
- Gaining an understanding of abuse, diversion and the appropriate regulatory responses;
- Distinguishing criminal vs. negligent/incompetent vs. acceptable practice;
- Defining key terms and concepts related to pain and addiction. 126

The second, third, and fourth items above relate directly to another important change in the 2004 Model Policy, i.e., the invocation of the state attorney general as a potential agent of change in the regulatory law and policy of pain management. The Model Policy encourages state medical boards to work cooperatively with their state attorney general to review state policies and regulations that may impede the effective use of opioids to relieve pain.

126 Federation of State Medical Boards, Promoting Balance and Consistency in the Regulatory Oversight of Pain Care, *available at* http://www.fsmb.org/Education/Pain/Pain_Main.dwt.
Traditionally, state attorneys general, as the chief law enforcement officer, were focused on waging the war on drugs, i.e. investigating and prosecuting instances of drug diversion. There has never been a declared war on pain, and even if there had been, as there has been with the war on cancer, it would in all likelihood be viewed as entirely within the domain of medicine, with no recognized legal implications whatsoever. Even as the evidence of the epidemic of undertreated pain became overwhelming in the decade of the 1990’s, strongly implicating drug control policies as one of the barriers to pain relief, only a small number of state attorneys general demonstrated any awareness that their office might have a role and a responsibility in addressing the problem. Quite recently, however, a former President of the National Association of Attorneys General (NAAG), Oklahoma Attorney General Drew Edmondson, made improving end-of-life care the presidential initiative for the organization in 2002-2003. As part of this initiative, NAAG sponsored a series of regional “listening conferences” throughout the country at which members of the organization and/or their staff could hear from leaders in the movement to improve end-of-life care. Three questions were the focus of the listening conferences:

- Will my pain be managed?
- Will my wishes be known and honored?
- Will I receive competent care?

Sections of the NAAG report written by contributing specialists discuss the barriers to a favorable response to these questions and prospects for their removal. What is significant about this aspect of the report is not that any new and different information is available, but that a new audience is, at least in theory, receiving it with some limited expectation of a response. The political reality, of course, is that no state attorney general is likely to be held accountable by voters for not vigorously seeking to overcome state legal and regulatory barriers to pain management, advance care planning, or quality end-of-life care. Consequently, the role of the attorney general in breaking down these well-known and long-standing barriers will be highly idiosyncratic,

depending on the personal perspective and motivation of the office holder.  

The other major player in the regulatory barrier to effective pain management is the federal Drug Enforcement Administration (DEA). Pursuant to authority conferred by the Uniform Controlled Substances Act (CSA), physicians in the United States are required to obtain DEA registration in order to prescribe, dispense, or administer any controlled drugs to their patients, and they must do so only for "legitimate medical reasons."

Controlled substances are divided into five schedules depending upon their potential for abuse. Schedule I drugs have been deemed to have a high abuse potential and no accepted medical use in the United States. They include heroin, marijuana, LSD, peyote, and mescaline. Schedule II drugs are those that are most effective in the treatment of moderate to severe persistent pain, e.g., morphine, meperidine (Demerol), oxycodone, and fentanyl.

Both the language and the legislative history of the CSA indicate that it was not intended to confer upon the DEA any authority to regulate medical decisions such as when to prescribe a particular controlled substance for a patient, or at what dosage or for what duration. The DEA’s representation to physicians has been: controlled substances have legitimate clinical usefulness, and the prescriber should not hesitate to consider prescribing them when they are indicated.

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129 The Attorney General of Maine, for example, co-sponsored with the Maine Hospice Council, their own "Listening Conference" in September of 2004 entitled Consumer Protection and End-of-Life Care in Maine, described at www.MaineHospiceCouncil.org.
132 Id.
133 The extent to which the CSA may, explicitly or implicitly, empower the Department of Justice to regulate any aspect of medical practice related to the prescribing of controlled substances has now become a major issue in the federal courts. The State of Oregon has challenged a directive of Attorney General Ashcroft that would sanction any physician who provided a lethal prescription of a controlled substance pursuant to the Oregon Death with Dignity Act. Ashcroft contends that writing a prescription for a controlled substance for the purpose of assisting a patient in committing suicide is against the public interest and can never be for a legitimate medical purpose. At the heart of the State of Oregon’s successful challenge of the Ashcroft directive is the argument as a matter of both reasonable statutory construction of the CSA, as well as sound constitutional principles, regulation of medical practice is the responsibility of the states, not the Attorney General of the United States. See Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004).
are indicated for the comfort and well-being of patients. In what appears to be a response to the charges that DEA practices constitute one of the barriers (physicians’ fear of regulatory scrutiny) to pain relief for patients, the DEA issued a news release in October of 2003, posted on its website, entitled “The Myth of the ‘Chilling Effect’.” In this press release the DEA states that since FY 1999, the DEA has pursued sanctions for violations of the CSA on less than one tenth of one percent of the physicians with DEA registrations.

In 2001, the DEA issued a joint statement in conjunction with 21 health organizations entitled “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.” The concept of “balance” has become prominent in recent efforts to address the epidemic of undertreated pain. I will consider it in the next section. The most direct and immediate impetus for issuing the joint statement, and the compelling need to persuade the DEA to join in its issuance, was the media frenzy surrounding recent reports of a growing problem of the abuse and diversion of a particular Schedule II drug – Oxycontin.

Oxycontin is a timed-release form of oxycodone that was developed and marketed by Purdue Pharma L.P. for patients with moderate to severe chronic pain. It was approved by the FDA in 1995, and soon thereafter became the most profitable item in the Purdue pharmacopia. Beginning in 2000, reports began to surface that in certain parts of the country (e.g., Maine, West Virginia) Oxycontin was being abused and diverted to a disproportionate degree. The reason was that by merely crushing the capsule, the timed-release feature could be circumvented, and a dosage of Oxycontin intended for a 12-hour period could be ingested at one time. The U.S. General Accounting Office was asked to investigate, and in doing so focused on three issues: 1) how Oxycontin was promoted; 2) what factors contributed to the abuse

134 Id at 1124.


138 General Accounting Office, Oxycontin Abuse and Diversion Efforts to Address the Problem, GAO-04-110 (December 2003).

139 For a journalist’s extensive, detailed, and controversial account of the Oxycontin abuse phenomenon see BARRY MEIER, PAIN KILLER: A “WONDER” DRUG’S TRAIL OF ADDICTION AND DEATH (2003).
and diversion of Oxcontin; and 3) what actions had been taken to address Oxycontin abuse and diversion. The GAO essentially declined to blame any particular party, including Purdue, for the abuse of Oxycontin. Indeed, the GAO found that the data on abuse and diversion were not reliable, complete, or timely. It also noted, in a commendatory fashion, the collaborative efforts by Purdue and the FDA to address the problem of Oxycontin abuse and diversion once it was recognized.

The genuine concern on the part of the advocates for improved pain management that the availability of a valuable opioid analgesic for chronic pain patients might be severely curtailed because a small group of non-patients was illegally obtaining and abusing it reflects the perception that law and public policy have been highly supportive of the “War on Drugs” and historically indifferent to the need for a “War on Pain.” Advocates for improved pain relief have not sought to trivialize the legitimacy of the first, but they have sought a genuine acknowledgement of the legitimacy of the latter. The new watchword in this movement has become the concept of “balance.”

V. THE CONCEPT OF BALANCE IN PAIN POLICY

The pursuit of balance in any domain of human endeavor presupposes a prior state or condition of imbalance. In the case of pain and its relief, the preexisting imbalance was largely attributable to the “War on Drugs”, in particular those controlled substances that are integral to the management of moderate to severe pain, i.e., opioid analgesics. In the absence of a countervailing “War on Pain”, federal and state policy compromised both the willingness and the ability of physicians to make pain relief a priority in patient care, and physician fear of regulatory scrutiny by both state and federal agencies became one of the well-recognized barriers to pain relief. This was so despite the clear legislative intent of the Controlled Substances Act that the legislation provided no authority for the DEA to regulate medical decisions, and the explicit recognition that controlled substances have important medical uses in the relief of pain and other distressing symptoms of illness. Because state medical boards routinely disciplined physicians for over-prescribing opioid analgesics, while turning a blind eye to a burgeoning epidemic of undertreated pain, it appeared that physicians and their licensing boards had become conscripts in the “War on

140 GAO, supra note 124, at 3.
141 Id. at 32.
Drugs”, pain patients had become the noncombatant casualties of that war, and a core value of medicine, the duty to relieve pain and suffering, thereby suffered grave collateral damage. Although the term “balance” was not invoked, both national and international organizations began, within the last ten years, to call upon governmental agencies at all levels to recognize the manifestly negative impact that some drug control policies have upon legitimate patients and the health care professionals responsible for their care. The pendulum had swung far in the direction of detecting and punishing drug diversion, and away from concerns about the availability and utilization of controlled substances for legitimate medical purposes.

In 2000, the Pain and Policy Studies Group (PPSG) of the University of Wisconsin Comprehensive Cancer Center published an extensive analysis of federal and state policies related to or significantly impacting pain relief. The elusive ideal of balance in such policies is between control, i.e., prevention or detection of drug abuse or diversion, and availability, i.e., ensuring both the adequate supply and distribution (the prescribing, dispensing, and administering) of controlled substances for legitimate medical needs. The federal CSA embodies the need for and the appropriateness of a balanced public policy, explicitly noting as it does the multiplicity of legitimate medical purposes for which the scheduled drugs might be prescribed. Many state laws regulating the availability and distribution of controlled substances are more restrictive than the CSA and lack the explicit recognition that such laws, as a matter of sound public policy, must not prevent diversion of controlled substances at the cost of insuring their availability for patients whose proper treatment is dependent upon them. These state laws are based upon the Uniform Controlled Substances Act (USCA) drafted at about the same time as

142 See, e.g., the International Narcotics Control Board, Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs, available at http://www.incb.org/e/ind_ar.htm, calling upon national governments to ascertain whether national narcotics laws create impediments to the prescribing of narcotic drugs to patients; the Institute of Medicine Committee on Care at the End of Life, Approaching Death: Improving Care at the End of Life (1997) calling for reform of drug prescription laws, burdensome regulations, and state medical board policies that impede effective use of opioids to relieve pain and suffering.


144 Id. at 13.

the federal CSA. The USCA, unlike the CSA, does not specifically charge states with the responsibility to insure the availability and accessibility of controlled substances for legitimate medical purposes.\textsuperscript{146}

The goal of the PPSG criteria for evaluating state law and policy was to identify provisions with a tendency to either enhance or impede pain management.\textsuperscript{147} The premise underlying this approach would appear to be that such laws and policies had as their primary, if not their sole consideration, the prevention of drug diversion and the achievement of control. The open question the development and application of the evaluational criteria sought to answer was whether any semblance of balance had been forfeited in the zealous pursuit of that control. The PPSG criteria intended to identify provisions that may enhance pain management are as follows:

- Controlled substances are recognized as necessary for the public health
- Pain management is recognized as part of general medical practice
- Medical use of opioids is recognized as legitimate professional practice
- Pain management is encouraged
- Practitioners' concerns about regulatory scrutiny are addressed
- Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
- Physical dependence or analgesic tolerance are not confused with "addiction"
- Other provisions that may enhance pain management\textsuperscript{148}

One general observation about this set of criteria is that it strongly reflects the modern, "enlightened" view of pain management in patient care. With regard to the first criteria, for example, it was really only at the point that an epidemic of undertreated pain was deemed to constitute a major public health problem that the use of controlled substances in the management of moderate to severe chronic pain was directly linked to public health. Similarly, the second, third,

\textsuperscript{146} Joranson and Gilson, supra note 30, at 183.
\textsuperscript{147} University of Wisconsin Pain and Policy Studies Group, supra note 140, at 17.
\textsuperscript{148} Id. at 17.
and fourth criteria rarely found their way into law and public policy until the decade of the 1990's, between 10 and 20 after the barriers to effective pain management had been consistently established in the literature of the health professions. The sixth criteria relates to the purpose of state intractable pain legislation, which as previously noted, sought to constrain the propensity of state medical boards to discipline physicians solely on the basis that they had prescribed opioid analgesics to their patients with chronic nonmalignant pain. The seventh criteria is based upon the widespread confusion, not only among those involved in efforts to control drug diversion, but also among practicing physicians and state medical board members, that drug addiction is not limited to psychological dependence, but rather includes physiological dependence and the phenomenon of analgesic tolerance.

The criteria that are believed to have the potential to impede pain management are the following:

- Opioids are implied to be a last resort
- Medical use of opioids is implied to be outside legitimate medical practice
- The belief that opioids hasten death is perpetuated
- Physical dependence or analgesic tolerance are confused with “addiction”
- Medical decisions are restricted
- Length of prescription validity is restricted
- Practitioners are subject to additional prescription requirements
- Other provisions that may impede pain management
- Provisions that are ambiguous

All but the last of the second set of criteria constitute efforts on the part of public policy makers to infringe on medical judgment and decision making in patient care in pursuit of the goal of constraining drug diversion. Such policies are in conflict with the thrust of the federal CSA, as well as with the generally accepted proposition that non-physicians are ill-equipped to critique or regulate medical practice.

149 See supra notes 14-21 and accompanying text.
150 See supra notes 32-38 and accompanying text.
151 See Joranson and Gilson, supra note 26.
152 University of Wisconsin Pain and Policy Studies Group, supra note 140, at 17.
The bulk of the PPSG guide to evaluation of pain policy is devoted to a detailed jurisdiction-by-jurisdiction (including federal legislation and regulation) analysis of law and policy. For example, in the examination of the Rhode Island Intractable Pain Treatment Act, five of the criteria are found to be applicable.\textsuperscript{153} The act's definition of intractable pain is found to exemplify two of the criteria that may impede pain management, in that it implies that opioids are a last resort after all other measures have demonstrably failed, and it also implies that opioids are not an integral aspect of professional practice.\textsuperscript{154} The act's definition reads as follows:

“Intractable pain,” a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the physician’s medical records.\textsuperscript{155}

The total number of positive and negative provisions identified for each state using the evaluation criteria provided the basis for an overall grade (ranging from high A or B+ to low D+, D, or F, with no minus grades utilized). Equal weight was given to positive and negative provisions.\textsuperscript{156} When the final calculations were completed, no state received a grade of A or F. Nine states received a grade of B or B+ in 2000, whereas 20 received D+ or D. The remaining received a grade of C or C+.\textsuperscript{157} A lower grade indicates a disproportionate number of law or policy provisions that may impede pain management. No necessary connection should be presumed between a low overall grade and the effectiveness of the jurisdiction’s drug diversion control policy. The PPSG does not endorse the proposition that erecting or maintaining barriers to effective pain management in any way constitutes a plausible or a legitimate drug diversion control strategy.\textsuperscript{158}

In 2003 the same evaluation criteria were again applied to the states. Fourteen states (Hawaii, Idaho, Iowa, Kansas, Kentucky,  

\textsuperscript{153} R.I. GEN. LAWS § 5-37.4-3 (1997).
\textsuperscript{154} University of Wisconsin Pain and Policy Studies Group, \textit{supra} note 140, at 364.
\textsuperscript{155} See \textit{supra} note 150, at § 5-37.4-2(B).
\textsuperscript{157} \textit{Id.} at 13.
\textsuperscript{158} \textit{Id.} at 7, noting that a system of controls is necessary to prevent drug diversion and abuse, but should not be intended to achieve this objective by interfering with the legitimate medical uses for which they are intended.
Massachusetts, Michigan, Missouri, Nevada, New Mexico, South Carolina, Tennessee, West Virginia, Wisconsin) raised their grade, whereas one (Ohio) went down. The major factors contributing to an improved grade were the adoption of model board guidelines for pain management or board policies encouraging the use of opioids as appropriate for the relief of moderate to severe pain. Ohio’s lower grade was the result of the addition of language to state law suggesting that the use of opioids at the end of life may hasten death.

The concept of balance has permeated other efforts to shape public policy in the areas of promotion of pain management and the prevention of drug diversion and abuse. For example, in 2001, 21 health care organizations and the DEA issued a joint statement calling for the need to balance the promotion of pain relief and the prevention of abuse of pain medications. The general thrust of the joint statement, developed through a collaboration of the DEA, the Last Acts Partnership, and the Pain & Policy Studies Group of the University of Wisconsin, was that health care professionals and those involved in law enforcement and regulatory agencies have a shared responsibility “for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse.” Similarly, the American Alliance of Cancer Pain Initiatives issued a statement on state prescription monitoring programs in 2002 that expressed the organization’s commitment to “assuring their [opioid analgesics] availability for legitimate medical purposes as well as preventing their diversion and abuse.” More recently, the collaboration that produced the “joint statement” in 2001 produced a compendium of frequently asked questions on prescription pain medications, and responses to them, for health care professionals and law enforcement personnel. The stated goal of this document was “to

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159 Id. at 13.
160 Id. at 15.
161 Interestingly, similar language can be found in Justice O’Connor’s often-quoted concurring opinion in Washington v. Glucksberg, 117 S. Ct. 2302 (1997), wherein she seeks to reassure physicians that such a “double effect” of strong pain medications in the care of dying patients is not proscribed by law and ought not to be confused with physician-assisted suicide or euthanasia.

achieve a better balance in addressing the treatment of pain while preventing abuse and diversion of pain medications.  

The concept of balance is not without its critics among advocates for improved pain management. One of the most vociferous critiques argues that the concept of balance overtly, or at least tacitly accepts the validity of the proposition that physicians and other healthcare professionals with prescribing authority for controlled substances have a responsibility to balance the needs of their patients for pain medication with some societal interest in preventing drug diversion. The insinuation of the concept of balance into the patient-professional relationship as a side constraint, so the argument runs, corrupts the health professional's singular responsibility to act only so as to pursue the best interests of the patient. From this perspective, the concept of balance demands more of prescribing professionals than merely providing competent pain relief within the scope of legitimate clinical practice. It imposes the additional responsibility, for example, to assess whether prescribing an opioid analgesic to a patient who requires one might, in the context of the patient's living situation, increase the risk that the controlled substance is diverted to non-clinical and hence illegitimate use. If that were the case, so the principle of balance seems to maintain, the prescriber might properly elect not to provide the needed medication.

VI. CONCLUSION

The barriers to effective pain relief, particularly when relief requires the use of prescription analgesics, lie mostly within the medical domain in that they relate to the knowledge, skills, and attitudes of physicians. Even those barriers pertaining to the regulatory scrutiny of prescribing practices (real or perceived) produce their impact on patient care because of the negative attitudes they engender in physicians with regard to the duty to provide effective pain relief. The focus on

165 Id. Shortly after this document was posted on the DEA website, it was removed and replaced with a notice that stated, in pertinent part: "The document contained misstatements and has therefore been removed from the DEA website. DEA wishes to emphasize that the document was not approved as an official statement of the agency and did not and does not have the force and effect of law." The notice goes on to state that "DEA recognizes that the proper use of controlled substances in the treatment of pain remains an extremely important issue. Accordingly, DEA intends to address this matter in the future."

attitudes is particularly important because of the data strongly suggesting that they are the most resistant to change through continuing professional education. Among the policy initiatives I have considered, IPTAs, statutory mandates for physician education, and model guidelines or medical board policy statements are all directed, in large measure, to modifying physician attitudes. At the present time there is no real evidence confirming that these initiatives have had any effect upon the custom and practice of most physicians. The emphasis on "balance" in state and federal policies is directed primarily at legislators and regulators, not health care professionals.

The JCAHO accreditation standards related to the assessment and management of pain, at least in theory, hold the most promise for changing physician attitudes and practice. Accredited institutions, particularly hospitals through their medical and nursing staffs, can become the crucibles of change. These institutions, in order to secure or maintain JCAHO accreditation, are charged with insuring that their professional staffs have up-to-date knowledge and skills in the assessment and management of pain. Perhaps even more importantly, those with leadership roles on the professional staffs can and should become models for and mentors of their colleagues, using both example and moral suasion to motivate their colleagues who are deficient in knowledge, skills, and/or attitudes to improve their performance. It is at the institutional level that standards of professional practice can be most effectively established and enforced. If JCAHO continues through its survey process to hold accredited institutions responsible for insuring that patients receive prompt, thorough, consistent, and competent pain assessment and management, individuals with attitudes and practices that are inconsistent with that objective will be forced to change or leave.

I have noted in this article the serious, adverse sequelae of vigorously waging a "War on Drugs" in the absence of so much as even a declaration of a "War on Pain": physicians and the medical boards that license them become conscripts; pain patients become noncombatant casualties; and a core value of medicine — the duty to relieve pain — suffers grave collateral damage. This state of affairs epitomizes the complete absence of "balance" in national pain policy.

The missing factor that explains why professional education plus attitude adjustment equals changes (improvements) in the clinical management of pain is accountability. IPTAs, for example, in no way
seek to require physicians to provide appropriate pain relief. Similarly, medical board policies and guidelines that merely encourage physicians to assess and manage their patients’ pain, but threaten no disciplinary action when they do not, amount to little more than policy window dressing – mere rhetoric rather than genuine reform. Only disciplinary actions such as those in Oregon of Dr. Bilder and California of Dr. Whitney, or judgments such as those in James and Bergman, introduce genuine accountability into the equation. Going forward, public policy on pain should strongly reinforce the proposition that competent pain management is an essential element of minimally acceptable patient care.169

169 See, e.g., Kathryn Tucker, A Piece of the Puzzle: Bringing Accountability to the Failure to Treat Pain Adequately, 6 J. PALLIATIVE MED. 615 (2003).