

## Pain Management: A Fundamental Human Right

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This article surveys worldwide medical, ethical, and legal trends and initiatives related to the concept of pain management as a human right. This concept recently gained momentum with the 2004 European Federation of International Association for the Study of Pain (IASP) Chapters-, International Association for the Study of Pain- and World Health Organization-sponsored "Global Day Against Pain," where it was adopted as a central theme. We survey the scope of the problem of unrelieved pain in three areas, acute pain, chronic noncancer pain, and cancer pain, and outline the adverse physical and psychological effects and social and economic costs of untreated pain. Reasons for deficiencies in pain management include cultural, societal, religious, and political attitudes, including acceptance of torture. The biomedical model of disease, focused on pathophysiology rather than quality of life, reinforces entrenched attitudes that marginalize pain management as a priority. Strategies currently applied for improvement include framing pain management as an ethical issue; promoting pain management as a legal right, providing constitutional guarantees and statutory regulations that span negligence law, criminal law, and elder abuse; defining pain management as a fundamental human right, categorizing failure to provide pain management as professional misconduct, and issuing guidelines and standards of practice by professional bodies. The role of the World Health Organization is discussed, particularly with respect to opioid availability for pain management. We conclude that, because pain management is the subject of many initiatives within the disciplines of medicine, ethics and law, we are at an "inflection point" in which unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right.

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**O**n October 16, 1846, at the Massachusetts General Hospital in Boston, the anesthetic effect of ether was first demonstrated to a public audience. Upon hearing the news, Oliver Wendell Holmes, the celebrated writer and physician, triumphantly stated "... the deepest furrow in the knotted brow of agony has been smoothed forever." Yet 60 yr later, exactly a century ago, in his preface to *The Doctor's Dilemma*, Shaw wrote: "When doctors write or speak to the public

about operations, they imply that chloroform has made surgery painless. People who have been operated upon know better" (1).

Today at the dawn of the 21st century, the best available evidence indicates a major gap between an increasingly sophisticated understanding of the pathophysiology of pain and widespread inadequacy of its treatment. In the poorest and most socially dysfunctional developing nations, this gap is for the most part ignored despite pandemic suffering from Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS), poverty, oppression and violence, and war and its aftermath (e.g., land mines). In the developed world, this gap has prompted a series of declarations and actions by national and international bodies advocating better pain control. Every clinician (including pain specialists) recognizes that, even with limitless resources, not every patient's pain can be eliminated. Yet the growing number of statements and initiatives on the necessity for pain management issuing from inside and outside the medical community amount to a "call to arms" based upon three propositions. First, pain, whether acute or chronic, is inadequately addressed for

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a variety of cultural, attitudinal, educational, political, religious, and logistical reasons. Second, inadequately treated pain has major physiological, psychological, economic, and social ramifications for patients, their families, and society. Third, it is within the capacity of all developed and many developing countries to significantly improve the treatment of pain. This review surveys current strategies and initiatives that address the under-treatment of pain from the disciplines of medicine, law, and ethics. We present evidence that medicine is at an inflection point, at which a coherent international consensus is emerging: the unreasonable failure to treat pain is poor medicine, unethical practice, and is an abrogation of a fundamental human right.

## CONSEQUENCES OF INADEQUATELY TREATED PAIN

### Physiological and Psychological

Under-treatment of pain is poor medical practice that results in many adverse effects. Unrelieved pain after surgery increases heart rate, systemic vascular resistance, and circulating catecholamines, placing patients at risk of myocardial ischemia, stroke, bleeding, and other complications (2,3). Unrelieved acute pain commonly elicits pathophysiologic neural alterations, including peripheral and central neuronal sensitization, that evolve into chronic pain syndromes. Chronic pain is linked with a constellation of maladaptive physical, psychologic, family, and social consequences, and can be regarded as a disease entity *per se* (4,5). Physically, these responses include reduced mobility and consequent loss of strength, disturbed sleep, immune impairment and increased susceptibility to disease, dependence on medication, and codependence with solicitous family members and other caregivers (4,5). The psychologic ramifications of chronic pain are profound. A World Health Organization (WHO) study revealed that individuals who live with chronic pain are four times more likely than those without pain to suffer from depression or anxiety (6), consistent with other statistics on chronic pain as a risk factor for both conditions (7,8). Persistent pain in patients with cancer interferes with the ability to sleep (9,10), eat (11), concentrate, and interact with others (12).

### Social and Economic

In addition to physical and psychologic burdens on the individual, chronic pain incurs massive social and economic costs to society. Persons with chronic pain are more than twice as likely to have difficulty working (6,13). A systematic review of chronic pain prevalence studies found it to be clearly associated with low socioeconomic status as well as reduced participation in the labor force (14). A prevalence study in Australia revealed a strong association between chronic pain and being unemployed for health reasons and receiving disability benefits (15). Separate American (16) and Australian (17) studies estimated separately for each

country a multibillion dollar cost of “presenteeism” in chronic pain, i.e., the substandard productivity of chronic pain sufferers who come to work rather than staying at home. The latter study revealed that lost workdays and “reduced-effectiveness” workdays combined to produce a total of 36.5 million “total lost workdays” at an annual cost of \$5.1 billion (Australian). Extrapolated to the population of the United States, this would equate to US\$50–70 billion per annum, a figure similar to the former study’s estimate.

Contemporary rehabilitation medicine seeks restoration of as normal level of function as possible, whether or not pain can be eliminated. Chronic pain contributes significantly to the overall costs of rehabilitation. To these direct costs are added the indirect, frequently hidden costs and burdens of caregiving by family and friends, the costs of health care services and medication (18), the loss of wages, non-productivity in the home, the costs of worker compensation and disability payments (19). These costs are compounded by expenses related to litigation (20).

The US Food and Drug Administration and the WHO emphasize patient-reported outcomes in evaluating many therapies or health-related interventions. Pain, especially chronic pain, is a key patient-reported outcome whose poor control undermines quality of life (21) and whose physical, psychologic, social, and economic ramifications evolve, overlap, and compound one another. Conversely, effective treatment of chronic pain improves the overall quality of life, including maintenance of function and interaction with family and friends (22,23). Such principles have already been well accepted by and indeed form the foundation of palliative care, in which they extend to the treatment of all symptoms.

## THE SCOPE OF THE PROBLEM WORLDWIDE

### Acute Pain in Medical Settings

Acute pain is a worldwide phenomenon. Emergency and elective surgery, severe medical illness, trauma, childbirth, burns, natural calamities, war, and torture all contribute to its burden. In many countries political conflict, social dislocation, and inadequate availability of analgesia conspire to make the relief of acute pain sporadic at best. In addition, despite the advent in developed countries of acute pain teams, the relief of acute pain in medical settings remains more rhetoric than reality (24–26). The 1995 SUPPORT study found that half of patients with life-limiting diseases had moderate to severe pain during their last days of life (27). Subsequent studies continue to indicate that even with therapeutic intervention, 40% of postoperative patients report inadequate pain relief, or pain of moderate or greater intensity (25,26,28).

In 2006, two major studies on pain management in neonatal units in Australia and New Zealand revealed that most units do not regularly undertake pain assessments and do not have an explicit policy for

procedure-related pain control. Only a third of such units routinely used any analgesic method for neonates undergoing procedures such as heel prick or venopuncture (29,30). Mather and Mackie found that most children experience postoperative pain unnecessarily, with 15% experiencing severe pain (31).

### Chronic And Cancer Pain

Persuasive epidemiologic evidence, mainly drawn from developed nations, has proven that chronic pain is a widespread public health issue. Despite the heterogeneity of study methods, community-based surveys find that 15%–25% of adults suffer from chronic pain at any given time, a figure that increases to 50% in those older than 65 yr (14,15,32–34). Compounding this prevalence is fatalism. In one of the largest survey studies of pain, 18% of American respondents who rated their pain as severe or unbearable had not visited any health care professional because they did not think that anyone could relieve their suffering (35). A more recent US telephone survey supports this gloomy view (36). In their study of persistent pain in nursing home residents, Teno et al. found that 14.2% of residents were in persistent pain across two assessments and that 41.2% of residents in pain at the first assessment were in severe pain 60–180 days later (37).

Throughout the world, 10 million new cases of cancer are diagnosed annually. By 2020, that figure will double, with approximately 70% occurring in developing countries (38). For patients with cancer, up to 70% suffer from pain caused by their disease or its treatment (39,40). In patients with advanced cancer, pain is described as moderate to severe in approximately 40%–50% and as very severe in 25%–30% (41–43). Equally, for the millions suffering HIV/AIDS, 60%–100% will experience pain at some stage in their illness (44–46). Studies of cancer patients' pain control consistently reveal that up to half of patients receive inadequate analgesia and 30% do not receive appropriate drugs for their pain (40). In separate large studies of cancer patients in France (47), the United States (43,48), and China (49), the percentages of patients receiving inadequate analgesia were 51%, 42%, and 59%, respectively. Eighty percent of children dying of cancer in two Boston teaching hospitals experienced pain in the last month of life, according to parental report (50). Less than a third of the parents reported that treatment of their child's pain was successful, and half the parents described their children as having "a great deal" or "a lot" of suffering as the direct result of poorly controlled pain (50).

The above figures, drawn from the acute, chronic, cancer and noncancer contexts, are from neither the historic past nor the third world. All emanate from contemporary work in developed countries. They indicate a global failure to adequately respond to the challenge.

## BASES FOR DEFICIENT PAIN MANAGEMENT

It is universally acknowledged that pain, on a global scale, remains inadequately treated because of cultural, attitudinal, educational, legal, and system-related reasons.

### Cultural and Societal Attitudes

The history of pain treatment is extensive (51–55), and amply documents a pervasive influence of pain on every facet of life since the earliest human experience (56–57). Prehistoric humans had sufficient intrusions on life due to pain as to have developed acupuncture, as documented by recent computed tomographic studies of a Bronze Age cadaver, the "Iceman," tattooed in the distribution of sciatic pain likely due to lumbar facet arthritis (58). Experiments with natural analgesics, including opium, belladonna, and mandragora, are recorded in very ancient times. Nearly every religion has dealt with the problem of pain. Indeed, religion, philosophy, and folklore have "saturated pain with meaning" (59). More broadly, culture influences the individual and collective response to all aspects of human activity, including health and disease. All cultures have clear attitudes to pain and the treatment of pain (59).

Societal attitudes toward pain relief during surgery and childbirth illustrate the complex interactions between cultural concepts of pain, pain relief, and social behavior. Knowledge of medicinals with analgesic properties expanded greatly during the Renaissance. There was no concerted effort, however, to develop anesthesia for surgery or childbirth, as analgesic interventions were unreliable, often leading to death. An emphasis on individual perceptions and well-being emerged during the Romantic era in the late 18th and early 19th centuries, as visual artists, essayists, poets, and philosophers drew attention to the individual and introduced a more personal focus into these fields (60). In his postretirement doctoral thesis, after a distinguished career as a pioneer in academic anesthesiology, Professor Emmanuel Papper argued that the articulation of individual rights in revolutionary France and the United States, and the rise of democratic states, created an environment in which individual pursuit of better health care, including pain relief, became explicit goals (60).

This growing focus upon the individual set the scene for the introduction of surgical anesthesia with ether in 1846, and analgesia for childbirth with chloroform in 1847. However, both events were initially attended by skepticism, ridicule, and opposition from powerful contemporaries. In the case of surgical anesthesia, such opposition was famously deflated when the powerful Boston surgeon, Dr. Warren, said of ether: "Gentlemen, this is no humbug!" In the case of analgesia for childbirth, there was bitter resistance on religious grounds. Fundamentalists cited the Bible as ordaining that childbirth was a necessarily painful process. Opposing both the church and powerful obstetricians, Queen Victoria requested that James



Simpson administer chloroform analgesia for the delivery of her son, thus overcoming powerful negative attitudes that discouraged relief of the pain associated with childbirth.

One might have expected that the relief of pain in other settings would have swiftly followed these watershed events. However, the shift in societal attitudes toward acute, chronic, and cancer pain to echo the humanitarian triumph of pain relief during surgery and childbirth has been much slower. As described in other sections of this article, the shift has come only recently. WHO initiatives in cancer pain have been developed over the past two decades. The United States has introduced federal clinical practice guidelines on treatment of acute (3) and cancer-related (61) pain and, subsequently, standards for pain assessment and treatment by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). Indeed, the US Congress declared 2001 through 2010 as the "Decade of Pain Control and Research." The United States is not alone in developing government-endorsed national guidelines on pain management (62). The European Federation of International Association for the Study of Pain (IASP) Chapters (EFIC) declared a "European Week Against Pain," within which the WHO, IASP, and EFIC cosponsored a "Global Day Against Pain." In addition, there has been a recent promulgation of statements on patients' rights to pain management by professional bodies, and publication of books and articles in the lay press based on eloquent descriptions of the harmful effects of severe unrelieved pain (4,5) and strongly advocating the right of patients to having their pain addressed. This growing activism has been motivated, in part, by the studies described above that have rigorously documented the enormous financial and social costs of persistent pain.

Despite the growing number of initiatives by prestigious organizations and thought leaders to improve pain management, powerful myths (and their proponents) are well entrenched and continue to spread with the ease of an epidemic, independent of any need for logic or rationale (62). The belief that pain is an inevitable part of the human condition is widespread (63). The word "patient" itself is derived from the latin *patiens*, meaning "one who suffers." Examples of pain myths shared by health professionals and patients alike (2) include the notions that pain is necessary, natural and hence beneficial, that pain is essential for diagnosis, that "good patients" do not complain and never challenge health professionals, that undertreated pain has negligible economic consequences, that severe pain after surgery or in association with cancer is unavoidable and that many patients with chronic noncancer pain are malingerers or have purely psychological problems. These myths are further con-founded with specific concerns about opioid analgesia (see below).

Combating such myths has been made easier by the availability of government-endorsed clinical practice guidelines and other national initiatives on behalf of pain treatment (62). However, the impact of such initiatives does not spread with the ease of myths. Indeed, the contrast between the almost universal instinct of healthy members of society to come to the aid of an injured person, and the tendency to under-treat or shy away from those with pain, especially chronic pain, is striking. Equally, if not more, powerful than guidelines and standards have been the efforts of champions. The foremost of these in the last century was John J. Bonica, who founded the IASP and led in many other clinical, research, educational, societal, and political initiatives aimed at improving pain management. The effectiveness of influential proponents is also evident in the success of the JCAHO initiative and the US Congress's declaration of the Decade of Pain Research and Treatment. These two initiatives resulted from concerted efforts of a small number of pain physicians. The development of a new teaching program on pain for US medical schools, called Topics on Pain Medicine (TOP MED), is now in progress. This educational initiative has been supported by such prominent figures as former US Secretary of Health and Human Services, Dr. Louis Sullivan and former US Surgeon General, Dr. David Satcher (64). In Europe, IASP, EFIC (65), and the European Society of Regional Anesthesia and Pain Therapy have taken a similar leadership role in pain education.

### Political and Legal Barriers

In addition to cultural, medical and religious impediments, entrenched political and legal barriers discourage adequate pain management. Opioids remain the drugs of choice for the treatment of moderate to severe pain, regardless of etiology. Fears of opioid diversion, abuse, and addiction, however, continue to shape policies on opioid importation, manufacture, distribution, and prescription (66). Nevertheless, in a sea of myth there are several incontrovertible facts. Morphine consumption is especially low in most developing countries. In 2004 data published by the International Narcotics Control Board (INCB), 6 nations accounted for 79% of medical morphine consumption and 120 consumed little or none (67). Two principal impediments to opioid availability are restriction and cost. As narcotics, opioids are subject to international, national, and local (e.g., US state-level Drug Enforcement Administration [DEA] and medical board) control. Although the mere availability of opioids is insufficient to force prioritization of pain management or palliative care as public health issues, overly stringent regulations discourage the medical use of controlled drugs. Many countries have inefficient procurement, manufacture, and distribution of opioids (68) or impose limits on their prescription. In

some countries, opioids cannot be prescribed for cancer pain yet are available for postoperative pain. In other countries, they cannot be prescribed for children yet are available to adults. In some countries, only immediate-release preparations of morphine tablets are available (69).

More subtle political influences may also be at play. One critic contends that in the United States, physicians have been conscripted into the government's war on drugs and that they assume the role of assisting regulators in preventing drug diversion and excessive prescribing of analgesics (70). Whether or not there is merit in this hypothesis, the present structures of US state medical licensing boards and federal regulations on opioid analgesics remain restrictive, although both levels of regulation are currently in a state of flux. For example, faced with evidence of inconsistencies and restrictions in state pain policies, the Federation of State Medical Boards of the United States adopted model guidelines for the use of controlled substances for the treatment of pain (71) and then updated these "to assure adequate attention to the undertreatment of pain" (72).

Another political contribution to the global burden of pain and the inadequacy of its treatment is torture (73). The Amnesty International Report of 2006, an annual survey of human rights around the world, contains reports of torture or ill-treatment by state agents in 104 countries. Any discussion of pain relief as an international problem must include this political reality, particularly in light of continuing investigations of deliberate physical and psychologic abuse of currently held prisoners of war (74) and the well-described chronic pain syndromes that arise as sequelae of torture (73). Equally, it would be incomplete for any domestic pain program not to prohibit, at least as part of its mandate, state-sanctioned torture.

### **Medical and Lay Opiophobia and Opioignorance**

Principal among the attitudinal barriers of health care professionals to pain relief are misconceptions about medications, especially opioids, which emerged in the late 19th century both in China and in the West (75). First, there is considerable concern about opioid addiction, tolerance and hyperalgesia (76), including dose escalation and dependence. Opioids are also associated with side effects such as constipation (77). Many physicians and patients harbor unrealistic anxieties about precipitating adverse side effects, believing that opioids should be reserved for the "end" in cancer pain. There is also an unfounded assumption among physicians and patients that chronic opioid treatment necessarily impairs quality of life. Patients may believe that opioids can only be given parenterally. Physicians may believe that opioid analgesia may delay accurate initial diagnosis of a change inpatient condition. Lastly, there is widespread belief that at least some pain is inevitable, and that opioid doses should be

related to the severity of the disease rather than the intensity of the pain. These attitudes recur in surveys of clinicians and patients about analgesia (78,79).

Opiophobia among health care providers is compounded by opioignorance. Repeatedly, survey respondents acknowledge that they have received insufficient training in, or exposure to, pain management (43,80,81). At heart, therefore, these attitudes toward analgesia spring from inadequate education. Among patients and families, higher levels of concern about opioids are associated with advancing age, lower levels of education, and lower incomes (82). Such concerns appear to be cross-cultural: studies in Puerto Rico (83), Taiwan (84), and the United States (82) found similar concerns about the use of opioid medication.

### **Prosecution of Physicians for Opioid Prescribing**

Early in the present decade, two important developments occurred in the United States. First, concern about diversion and illicit use of prescription opioids increased as instances of OxyContin misuse and abuse (some fatal) became more common. Second, a consensus emerged between pain clinicians and opioid regulators that the twin public policies of adequate pain management and restriction of illicit opioid use should be pursued concurrently and with mutual respect. This "doctrine of balance" reached its high water mark in August, 2004, when the DEA posted a series of frequently-asked questions (FAQs) and answers about the use of medications, particularly opioids, in pain management, on its website. These FAQs were prepared by a blue-ribbon panel of clinicians and regulators. Three months later, concurrent with its prosecution of a physician for inappropriate opioid prescription, the DEA abruptly withdrew its support for this consensus statement and removed the FAQs from its website. To pain clinicians a major inconsistency had emerged between best clinical practice and the potential for regulatory scrutiny and prosecution for opioid prescription. After years of reassurance by the DEA that legitimate, appropriate opioid prescription would not attract liability, its 2004 actions had a chilling effect. In late 2006 the DEA made a concession to clinicians' anxieties (and fears by their patients of decreased access to medications) by proposing to amend its regulations to allow physicians to provide patients with multiple prescriptions of the same schedule II (controlled) substance to be filled sequentially to provide up to a 90-day supply. As of early 2007, the FAQs have not been re-posted and the physician in question remains imprisoned. This and other, less well-known prosecutions of physicians who prescribed unusually large quantities of opioids suggest inconsistencies between the educational efforts of some government agencies to encourage the appropriate prescribing of pain medications, and prosecution by other agencies of physicians who do so (85).

## **HISTORICAL PERSPECTIVES ON THE ETHICS AND LAW OF PAIN MANAGEMENT**

Why has it taken so long to recognize the ethical and legal importance of pain relief? There are complex and overlapping reasons for this delay. For centuries, medical and surgical treatment has emphasized saving the life of the patient rather than ameliorating the patient's pain, particularly when there were few options for the latter. As described above, medical understanding of pain mechanisms and treatment has progressed slowly, with a few notable exceptions such as the introduction of general anesthesia. The rise of the modern biomedical model of disease emphasized pathophysiology rather than the patient's quality of life, and objective quantitative measurement rather than qualitative patient narrative (86). At the same time, entrenched attitudes to pain and its rationalization persist, such as that pain in childbirth is biblically preordained. Redemptive qualities continue to be ascribed to pain, such as the withholding of surgical anesthesia for the military in battle on the basis of a "masculine cult of toughness and callousness" (87). These dismissive attitudes further contributed to the myth that neonates do not feel pain. In an often hostile medical and cultural milieu in which the clear ethics of pain management have encountered multiple barriers, desensitization and "compassion fatigue" of health professionals surrounded by patients in pain have been widespread.

## **STRATEGIES FOR IMPROVEMENT—TOWARD A WORLD OF BETTER PAIN MANAGEMENT**

### **The Promotion of Pain Management as an Ethical Issue**

The "right" to pain management has a variable foundation in law. Separate from, and indeed underlying the pursuit and enforcement of this right by the law, are the ethics of pain relief. The earliest articulations of the responsibilities of doctors to their patients are not legal but ethical. The Hippocratic Oath states "I will keep them from harm . . ." and its modern equivalent, the Declaration of Geneva, states "the health of my patient will be my first consideration." The health professional associations of many countries enunciate a similar ethical basis for the relief of pain. The American Medical Association states that "physicians have an obligation to relieve pain and suffering" (88), and the American Nurses Association's position is that "nursing encompasses . . . the alleviation of suffering . . ." (89).

The importance of pain relief as the core of the medical ethic is clear. The relief of pain is a classic example of the bioethical principle of beneficence. Central to the good actions of doctors is the relief of pain and suffering. As Post et al. state, "the ethical duty of beneficence is sufficient justification for providers to relieve the pain of those in their care . . ." (90). The principle of nonmaleficence prohibits the infliction of harm. Clearly, failing to reasonably treat a patient in pain causes harm; persistent inadequately

treated pain has both physical and psychologic effects on the patient. Failing to act is a form of abandonment (62). As Somerville states "many persons would rather be dead than unloved, abandoned and, too often, left in pain" (91). Equally, for a patient's doctor to ignore the patient's complaint of pain or to refuse to accede to a reasonable request for pain relief arguably contravenes the autonomy of patients and self-determination of their medical care. Indeed, unrelieved pain *per se* may affect, or even preclude, the exercise of autonomy. Unrelieved pain may so consume the patient that it "should be considered a major impingement on a patient's ability to make choices regarding care and ethically obligates health-care workers to treat such pain on the basis of restoring autonomy . . ." (92).

The bioethical principle of justice, seeking the equitable distribution of health care, is the greatest challenge to inadequate pain management worldwide. However admirable the ideal of pain management as a universal human right, the reality is a world in which massive resource discrepancies preclude fulfillment of such a right (93). Thus, unequal access to pain relief is but one example of the broader problem of health disparities that arise due to inequities of socioeconomic status or from membership in a minority racial or ethnic group (94).

Beyond principlism, i.e., an approach founded on the strength of a broader principle, a virtue ethics approach to bioethics would also yield a clear response to patients' pain. A virtuous doctor would place the recognition, monitoring, and treatment of pain as a high priority. To this end, a virtuous doctor would inquire regularly about pain, respond appropriately, and refer wisely if unable to control it.

If there is a clear ethical duty to relieve suffering or to act virtuously by doing so, then one may argue that from that duty springs a right. The moral right to pain management emerges from, and is directly founded upon, the duty of the doctor to act ethically. Classically the holder of a right has the capacity to enforce a duty in a person or institution. That "other" has a duty to fulfill that right. Indeed, a basic tenet of the philosophy of rights is that a right can only exist if there is a preexisting obligation. If one accepts that a health professional has an obligation, where appropriate, to manage pain, then the patient has a concomitant right, where appropriate, to receive such care.

One response to the inadequacy of pain treatment is to question the ethical foundations of the modern medical profession (71). Equally, any campaign of promotion of better pain management should have, as its basis, precisely that ethic: that pain management is a moral enterprise and emanates from the heart of bioethics.

### **The Promotion of Pain Management as a Legal Right**

Frustrated by the slow pace of medical, cultural, legal, and political change, many within the community of pain clinicians have begun to promote the status of pain



management beyond that of appropriate clinical practice or even an ethic of good medicine. They advocate nothing less than a paradigm shift in the medical professions' perspective on pain management from simply good practice to an imperative founded on patient rights. The rise of the consumer movement, the advent of international human rights law, renewed concern for minority rights, and overall promotion of individualism has brought about a focus on the interrelated duties of powerful agents such as governments and physicians, and on what may be expected of them by more vulnerable agents, such as patients.

The term "right" is a convenient way to promote an ideal and enforce a duty. However, one difficulty with articulating a right is its indeterminate nature. Is the statement that patients have a right to pain management an exercise in moral persuasion or a statement of law? If it has any pretence to the latter there are clear difficulties in stating that there is a right if it has neither legal foundation nor enforceability. To Jeremy Bentham (original date of publication 1789) the argument that a right existed without legal foundation was "nonsense on stilts" (95). To Bentham rights were man-made and could not spring from mere assertions of principle. To what extent then is the assertion of a right to pain relief "nonsense on stilts?"

Besides a probable basis in international law, the provision of adequate pain relief has some foundation in domestic law. That foundation includes national constitutions, domestic legislation, and the law of negligence.

### Constitutional Guarantees

Many of the world's nations have written constitutions, some of which enumerate the right of their citizens to receive adequate health care. None expressly articulate a right to pain relief.

The US Supreme Court, in the cases *Washington v. Glucksburg* (96) and *Vacco v. Quill* (97), while rejecting a constitutional right to physician-assisted suicide, nevertheless expressed sympathy for the view that there is a constitutional right to adequate palliative care. Furthermore, it felt that individual states should not obstruct the provision of pain relief in the palliative setting. These significant judgments have three practical ramifications. First, they have placed pressure on individual US states to reform current laws and policies that restrict the availability of opioids for the management of pain. The general inhibitory effect of state drug laws is now vulnerable to challenge (98,99). Second, their judgments have provided American doctors caring for the terminally ill with counter-arguments against regulatory medical boards "ignorant or dismissive of the evidence that high-dosage prescriptions of opioids for treating pain and other distressing symptoms are safe, effective and appropriate" (98). Lastly, these decisions have compelled states to not only properly fund, but also remove impediments to appropriate end-of-life care. Justice Souter wrote that if states refused to address

these issues they may be guilty of "legislative foot-dragging" (*WA v. Glucksburg* at p. 2293) (96) and Justice Breyer stated that such states would "infringe directly upon . . . the core of the interest in dying with dignity," which involves "medical assistance, and the avoidance of unnecessary and severe physical suffering." (*WA v. Glucksburg* at p. 2311-2312) (96).

Whether the US Supreme Court may, in the future, stipulate a constitutional right to pain relief in other contexts, including chronic noncancer pain, is a matter of conjecture. Interestingly, the EFIC submitted a declaration to the European Parliament proposing that chronic noncancer pain is a "disease in its own right" that warrants increased attention.

### Statutory Regimens

If the ultimate objective of patient advocates is to establish a right to pain management that is both unambiguous and legally enforceable, the best framework for such a right is the statutory one. There are several models for such a framework. The first is an explicit statutory statement of the right to pain relief. An example is from the Australian Capital Territory, where the *Medical Treatment Act* of 1994 states "... a patient under the care of a health professional has a right to receive relief from pain and suffering to the maximum extent that is reasonable in the circumstances" and, further, "in providing relief from pain and suffering to a patient, a health professional shall pay due regard to the patient's account of his or her level of pain and suffering" (100).

The second model is a statutory protection for doctors. An example is contained in the South Australian *Consent to Medical Treatment and Palliative Care Act* of 1995 which protects medical practitioners, in their care of terminally ill patients, from any criminal or civil liability if they administer treatment with the intention of relieving pain, providing such treatment is given with consent, in good faith, without negligence, and in accordance with "proper professional standards of palliative care" (101). Several US states offer similar protection from disciplinary action by their respective state medical boards when controlled substances are given in the course of treatment of a person for "intractable pain" (102).

The third model is a wider package of statutory requirements for pain management and education. An example is a California statute (103) that imposed three obligations. The first is a duty for doctors who refuse to prescribe opioids to a patient with severe, chronic intractable pain to inform the patient that there are physicians who specialize in the treatment of such pain. The second is a duty of all doctors to complete mandatory continuing education in pain management and the treatment of the terminally ill. The third is the requirement of the California Medical Board to develop a protocol for investigation of complaints concerning the under-treatment of pain and to include in its annual report to the state legislature a

description of actions relating to that practice. Dr. Russell Portenoy, past president of the American Pain Society described the law as “a very extraordinary step . . . to address what is clearly an enormous problem” (104). In March 2004 a New York State legislative statute was introduced that included mandatory medical school training and continuing medical education in pain, statutory protection of clinicians providing pain treatment consistent with authoritative clinical guidelines, and explicit recognition that failure to manage pain adequately is a basis for medical board discipline (105).

These recently enacted statutes in Australia and California are models for any future legislative activity. Indeed, they offer professional or lay groups a powerful agenda to lobby legislators to reform local statutes. The strongest possible statutory foundation to support best practice in pain relief would involve core aspects of the above legislation. The essential components of such legislation are:

1. Reasonable pain management is a right.
2. Doctors have a duty to listen to and reasonably respond to a patient’s report of pain.
3. Provision of necessary pain relief is immune from potential legal liability.
4. Doctors who are neither able nor willing to ensure adequate analgesia must refer to a colleague who has this expertise.
5. Pain management must be a compulsory component of continuing medical education.

A remarkable legislative reform came in Uganda in 2004. The national government, confronted with the pandemic of HIV/AIDS, recognized a simple fact. Like so many countries, especially those with limited resources and scarce medical personnel, palliative care patients often had great difficulty in accessing opioid analgesics. A regulation was made by the Minister of Health authorizing nurses with palliative care certificates to prescribe narcotic analgesics “as part of the palliative care of patients” (106). The practical impact of this legislation has not yet been evaluated.

### Negligence

Margaret Somerville, Professor of Law and Medicine at McGill University, has long argued that the unreasonable failure to provide adequate pain relief constitutes negligence. There is a solid foundation for this assertion. The emphasis in law regarding medical negligence is the taking of reasonable care in all aspects of patient management. There are several aspects of pain relief where doctors may potentially breach their standard of care: an unreasonable failure to take an adequate history of pain from the patient; an unreasonable failure to adequately treat pain (107); and, in the context of uncontrolled pain, an unreasonable failure to consult an expert in pain management. The latter is based on a general principle of referral as

held by courts in British Columbia (108) and New South Wales (109).

The United States case of *Estate of Henry James v. Hillhaven Corporation* (1991) (110) is illustrative. James, a 75-yr-old man with metastatic adenocarcinoma of the prostate, was admitted to a nursing home. His pain had been well controlled by regularly administered opioids. A nurse documented both her impression that the patient was addicted to morphine and her intention to wean the analgesic regimen and substitute a mild tranquilizer. While unilaterally deciding to wean the patient from opioids, the nursing staff did not consult the doctor. In his summary statement approving a final settlement in favor of the plaintiff, the judge emphasized the potentially serious legal consequences faced by health care providers when they negligently fail to provide patients with adequate analgesia. With time, as more cases are decided, the boundaries of reasonable action by doctors and nurses in pain management will be more clearly defined. Given the litigious climate in so many societies, such cases are inevitable.

Somerville also points to what she refers to as “systems negligence” when health care institutions fail to take reasonable steps to establish systems that offer patients ready access to pain management (111).

### Elder Abuse

Another area of jurisprudence that may expand is the law’s examination of pain management in the geriatric setting. The question of when inadequate pain management of an elderly person constitutes elder abuse (*Bergman v Chin* 1999) (112) was argued with reference to California’s Elder Abuse and Dependent Adult Civil Protection Act (113). Mr. Bergman was an 85-yr-old man who was admitted to the hospital with lower back pain. Within days he was diagnosed with metastatic lung cancer and multiple bone metastases. Throughout his 6-day admission the patient consistently rated his pain intensity in the 7–10 range (on a scale of 0–10), and on the day he was discharged the level was 10. He died at home 4 days later. Although the doctor testified that he followed established protocols in prescribing pain medications, the court ruled that the treatment fell within the statutory definition of elder abuse.

### Public Interest Litigation

An example of litigation based on the public interest in better pain management occurred in India in 1998. On behalf of the nation’s cancer patients and Drs. SR and RB Ghooi, the All India Lawyers Forum for Civil Liberties filed a public interest suit in the Delhi High Court. They requested a court order to state governments to simplify the procedures for the supply of morphine for cancer patients. The applicants were successful. The Court ordered that every application for licenses or supplies of morphine must be attended to expeditiously. State governments were



asked to allot morphine without delay and aggrieved persons were granted the freedom to approach the Court if dissatisfied. Again, a rights-based discourse entered the final judgment: "It is a right of patients to receive any medication they need, particularly morphine. Any official standing in the way will be viewed very seriously by the court." (In the High Court of Delhi, 1998).

### **Criminal Law**

Criminal law is relevant to a discussion of pain relief: is it possible for a health professional to be criminally culpable in giving analgesia? For that liability to be found, the court would need to find beyond reasonable doubt that the health professional intended to shorten the life of the patient. While several jurisdictions allow euthanasia in some circumstances, the vast majority of pain and palliative medicine is based on a measured, proportionate response to pain in which the intention is to relieve pain and not to accelerate death. Traditionally, the doctrine of double-effect has been applied here: the criminal law concentrates on intention, so that if the intention of the doctor is to relieve pain and not to shorten the life of the patient then the act of prescribing and dispensing analgesia is not a criminal act (114).

Several jurisdictions, including three in Europe (the Netherlands, Belgium and Switzerland) and one in the United States (OR) have legalized euthanasia and/or physician-assisted suicide. Clearly the interface of pain management and the criminal law in those jurisdictions will reflect the precise wording of the relevant legislation and criminal code.

### **Pain Relief as an International Human Right**

One response to the under-treatment of pain has been to promote the concept that pain relief is a public health issue of such critical importance as to constitute an international imperative and fundamental human right (69,91,115–119). There is some legal foundation for this concept. International human rights are articulated in the foundation Covenants of the United Nations (UN). The International Covenant on Economic, Social and Cultural Rights (ICESCR) articulates the right "of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Article 12). The Covenant obliges state parties to deliver on the rights it guarantees to the maximum of their available resources (Article 2). Although there is no mention of an express right to pain management, there is a strong argument that a right to pain management may be implied from the express right to health. The Constitution of the WHO defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Adequate provision of pain management falls comfortably within this definition.

Assuming that pain management can be implied from the fundamental right "to the highest attainable

standards of health," two questions remain. First, could an individual or group, citing the Covenant, complain that this right to pain management was not honored? Second, as a corollary, can the UN exert pressure to induce countries to provide adequate pain relief as part of their health services? Unfortunately there is no direct complaint mechanism for rights enunciated in the Covenant. The international community assesses compliance with the Covenant through reports submitted by all nations to the International Committee on Economic, Social, and Cultural Rights, describing their efforts to implement these rights.

Although valid questions have been raised about the effectiveness of reporting as the principal means of overseeing compliance with international norms, such reports when properly compiled serve a useful role to encourage implementation of the obligations of the ICESCR. As Alston points out, reporting states are encouraged to identify the problems they encounter in realizing the Covenant rights, including "negative developments, frustrated aspirations and other difficulties" (120). Also stressed is the need for appropriate statistical documentation. For example, if the Committee sought to review the level of compliance with the Covenant as it applied to pain relief, it would be interested in information on the epidemiology of acute and chronic pain, the provision of pain services to rural and remote communities, and the obstacles, legal or otherwise, to the availability of opioids. As described earlier much credible information is now available on the epidemiology and financial costs of chronic pain (34).

While an individual or a nongovernmental organization cannot make a direct complaint that there are inadequate pain services in a country, they may submit information to the Committee outlining the specific deficits. However, as described above, the obligation on each member state is to fulfill its inhabitants' rights to health "to the maximum of its available resources." The concept of the progressive realization of rights such as health includes an obligation of states to take steps to provide the minimum essential levels of each right. Inadequate resources and inadequate pain management are clearly linked in many countries (94). In many countries, even the most basic pain relief needs are not met. Thus, "for so long as availability of resources is a relevant consideration even to meet minimum levels, some ambiguity is apparent in the expression and fulfillment of even the minimum obligations" (121).

In 2000 the Committee overseeing the Covenant issued a General Comment on the right to health, stating what it saw as the "core obligations" of all signatory nations, regardless of resources (122). These include obligations to ensure access to health facilities, goods, and services on a nondiscriminatory basis, to provide essential drugs as defined by the WHO, and to adopt and implement a national public health strategy. Interpreting this Comment in the context of

pain management would oblige nations to ensure universal access to pain management services, and provide basic medications for pain management, including analgesics, and the adoption and implementation of national pain policies.

A further possible source of an international right to pain relief is contained in Article 5 of the Universal Declaration of Human Rights, which states that “No one shall be subject . . . to inhuman or degrading treatment . . .” (123). Although primarily aimed at the treatment of prisoners, this text broadly serves to underpin patients’ rights to effective pain management. Indeed, in 2002 the UN Commission of Human Rights established a new position of Special Rapporteur on the international right to health. This Special Rapporteur has a broad mandate that includes a capacity to receive complaints alleging violations of this right and correspond with the relevant governments to clarify, invite comment and, where appropriate, remind governments of their obligations under international law. The Special Rapporteur has been very active, receiving complaints about lack of compliance by countries with the health right and regularly reporting to the UN.

There are several possible strategies based on a human rights argument. One is to promote an amendment to the UN Covenants expressly stating a fundamental right to pain relief. This action is unlikely, given that the foundation documents that make up the International Bill of Rights have never been amended. Another strategy is to organize international associations for pain relief and palliative care to make submissions to the Committee and the Special Rapporteur on the Right to Health that highlight the central role of pain management in the attainment of universal health. The latter strategy enables the Committee to exert moral pressure on countries to fulfill the basic pain management needs of their populations.

### Professional Misconduct

Professional misconduct is another framing of pain management as a fundamental right that lies at the boundary of law and ethics. This aspect of a right to pain management is linked to another right that patients possess: the right of complaint to a disciplinary authority. Disciplinary matters that fall within the definition of professional misconduct vary widely among jurisdictions. Some define these in detail, while in others they are subject to judicial interpretation. Professional misconduct includes conduct that “offends against the traditions of the profession” (124), that is “shameful” (125) or “infamous” (126), but that is more than “mere negligence” (127).

For pain mismanagement to constitute professional misconduct it would need to fit the statutory definition of that jurisdiction or the judicial interpretation of the term as stated above. Negligent mismanagement of pain alone is not sufficient. The medical board, tribunal, or court would also need to consider the

drastic nature of the punishment in the light of the protective function of the legislation. More likely, poor pain management may fall under “unprofessional conduct.” This has occurred twice in the United States. State medical boards of Oregon (in 1999) and California (in 2003) have disciplined individual doctors for unprofessional conduct related to inadequate pain management.

The most recent update of the US Federation of State Medical Boards’ *Model Policy for the Use of Controlled Substances for the Treatment of Pain* addresses the balance between patient rights and patient responsibilities with respect to pain management, principally opioid therapy (72). The language of this document, based upon similar language in treatment agreements promulgated by professional organizations such as the American Academy of Pain Medicine (128), describes “the use of a written agreement between physician and patient, outlining patient responsibilities including urine/serum medication screening levels when requested; number and frequency of all prescription refills, and reasons for which drug therapy may be discontinued (e.g., violation of agreement).” This document further states that “objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient’s response to treatment. If the patient’s response is unsatisfactory, the physician should assess the appropriateness of the current treatment plan.” Thus, while access to appropriate opioid therapy is a widely and appropriately applied index of the adequacy of pain management, it would be naïve to conclude that appropriate pain management involves nothing other than opioid therapy.

### Statements by Professional Bodies: Guidelines and Standards of Practice

Many professional bodies, overseeing tens of thousands of clinicians, have issued statements, guidelines, position papers, or recommendations on pain management (62). Major pain and anesthesia organizations in North America, Europe, and Australasia have published statements on pain. These groups include the American Society of Anesthesiologists, the American Academy of Pain Medicine, the American Society of Regional Anesthesia and Pain Medicine, the American Pain Society, the American Geriatrics Society, the Canadian Pain Society, EFIC, and the Australian and New Zealand College of Anesthetists Faculty of Pain Medicine and its Joint Faculty of Intensive Care Medicine. Collectively, these statements represent a clarion call to all doctors to conscientiously manage pain. Common among all is a clear statement that pain management is required within the highest professional standards. Related statements, such as the 2001 JCAHO standards, formulate this statement as a patient right (129). The best formulations not only state that patients have a right to pain management, but

also provide content to that right. Such content includes the patient's right to be believed in the expression of pain, the right to appropriate assessment and management of pain, recognition that pain is subjective, the right to have the results of assessment regularly recorded, the right to be cared for by health professionals with training and experience in assessment and management of pain, and the right to appropriate pain management strategies (129).

It is important to see both the value and the limitations of these watershed statements. Unidimensional, numerical pain intensity assessments are at present all that is feasible in high-volume medical and surgical settings, but have been criticized for their coarseness (130) and the possibility that the use of such scales for analgesic titration may promote adverse effects when opioids are relied upon as the principal or sole analgesic for opioid-naïve patients (131). Moreover, recommendations alone do not change behavior, and professional societies' guidelines have no force in law. Nevertheless, collectively they provide to their constituent members, as well as to the entire medical and legal communities, the clarity, structure, and rationale of pain management so lacking in previous decades.

### The Role of the WHO

Pain is an international problem that requires an international solution. The WHO, as the supreme health agency of the UN, holds a critical role in any solution. The WHO has been involved with pain in three overlapping areas: the promotion and dissemination of guidelines on pain management, advocacy of improved access to opioid analgesics, and national programs of palliative care and pain relief. In the past two decades, the WHO Cancer Unit has led a global initiative in pain management. The 1986 publication of its method for cancer pain relief, and its translation into many languages, has had significant clinical and educational impact throughout the world (132). The WHO "analgesic ladder" for cancer pain pharmacotherapy was a seminal contribution. These efforts were followed by an increase in global consumption of morphine for medical purposes, that had been relatively stable at low levels for many years, and subsequently increased almost 10 fold (133). The WHO has also developed general recommendations for palliative care, with pain relief as a central component. These general recommendations recognize that many countries are resource-poor and that a single model is inappropriate. Overall, countries are encouraged to ensure that minimum standards for pain management are progressively adopted. In low-resource countries, these are best met through home-based care. In countries with medium resources, these may be met by home-based care and primary health care clinics. In countries with high levels of resources, these can be met at all levels of care (134).

### Deregulation of Medical Opioid Availability

The limited availability of opioids is not only a critical political-legal impediment to better pain relief on a world scale, but has had a unique role as the focal point for much attention and debate in policy matters related to pain control. As narcotics, opioids are subject to both international and domestic control. The Single Convention on Narcotic Drugs (1961) is the international treaty that regulates the production, manufacture, import, export, and distribution of opioids for medical use. It emphasizes the importance of a balanced approach to opioid control to ensure availability for medical purposes while preventing abuse and diversion. The treaty requires that signatory nations must annually supply a realistic estimate of their opioid requirements for medical use. However, as Dahl states, "the legislative, regulatory, and administrative impediments in various countries that lead to under-utilization of opioids in turn lead to low estimates of a nation's need for pain medicines" (135). A variety of steps have been taken in recent years to improve access to opioid analgesics. The INCB, the international body that monitors compliance with the treaty, has collaborated with the Department of Essential Drugs and Medicines Policy within the WHO and the WHO Collaborating Center for Policy and Communications in Cancer Care to promote balanced regulatory approaches to avoid unnecessarily restrictive controls. This promotion has taken three forms. First, guidelines have been developed to assist countries in conducting a self-analysis of domestic regulatory schemes to identify deficiencies (136,137). Second, increasing numbers of workshops and seminars promoting balanced opioid control policies are taking place. Third, collaboration with national opinion leaders is occurring. For example, support from the WHO was given to Italian experts in their efforts to modify Italian drug control regulations in 2001 (137).

At the domestic level, many countries have restrictive regulatory policies for opioid use. That reality may be accentuated by misperception. In the United States, for example, numerous studies have shown that fear of regulatory scrutiny influences physicians' decisions about opioid use. Rare, but highly publicized, cases have created the false impression that disciplinary actions for opioid prescribing are common (138). In recent years, there have been concerted efforts for reform. Federally, the DEA has moved to actively pursue a more balanced approach to the use of controlled substances, although at times it may have given the appearance of inconsistency in its actions. In 2001, it issued a joint statement with dozens of professional organizations expressly stating that, while vigilance to prevent illicit diversion of opioids is important, it must be balanced with the reality that "effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively" (139). This effort was followed by the 2004 posting of "FAQs" on the DEA's website,



to educate front-line practitioners about the appropriate use of opioids in a medical context. However, as noted above, this section of the DEA's website was promptly and unexpectedly removed a few months later in 2004 while it was prosecuting a controversial physician, many of whose patients came from other states to secure medical therapy for pain. Despite an official DEA explanation of this sudden withdrawal (140), an outcry resulted from many US professional organizations concerned with pain. At the time of writing, those FAQs have not yet been posted again at a US governmental website, although they may still be viewed at nongovernmental sites (141). In 2006, the DEA issued an "informational outline" of the Controlled Substances Act that, while acknowledging the appropriateness of prescribing controlled substances for legitimate medical purposes, devoted far more attention to articulating an array of regulatory requirements for doing so, and penalties for noncompliance (142). Even more recently (late 2006), the DEA proposed allowing physicians to write multiple prescriptions, with directions that they be filled sequentially, for schedule II controlled substances during a single office visit, thereby allowing for up to a 90-day supply when medically appropriate (143).

At the state level in the United States, there have also been efforts to reform prescription monitoring (138), to make education in pain management mandatory, and to affirm the appropriateness of using opioids to treat "intractable pain" (138). However, such reform has been patchwork. In part, these changes in the United States reflect the efforts of the National Association of State Cancer Pain Initiatives, whose individual state chapters have worked to remove regulatory and legislative barriers, provide education, and disseminate guidelines for effective pain management (144).

### **Toward Affordable Opioids**

An important strategy in achieving universal access to analgesia is to address the cost of medications, especially morphine. In many countries with health expenditures of less than US\$10 per capita per year, 1 month's supply of drugs promoted or offered by pharmaceutical companies may cost between US\$60 and 180. Generic immediate-release morphine sulfate tablets should not cost more than 1 cent (US) per 10 mg. Therefore, a typical month's supply of morphine sulfate tablets should only cost between US\$1.80 and \$5.40. The WHO has recommended that, in establishing a domestic policy for pain relief, a resource-limited nation should specify that immediate-release generic morphine be available to treat moderate and severe pain (144). Nevertheless, we concede that, for the most resource-poor countries, even this strategy will not achieve adequate availability of opioids.

### **National Campaigns**

Throughout the world, there are outstanding examples of national public health programs for pain

management and palliative care. The best have combined clear policies and an integrated approach with a high level of commitment to education and a decentralized community-based strategy (145). Rhetoric needs to be matched with practical programs. A systematic approach is required to combat cultural, official, and medical opiophobia, provide affordable analgesics, and integrate all aspects of pain management. Toward this end, the recent official documentation of the prevalence of pain, alongside other major public health disease burdens surveyed in the annual report of the US Centers for Disease Control is a watershed event (146).

### **Toward a Global Campaign**

In addition to its seminal work on behalf of better analgesic practices throughout the world, the WHO has collaborated with other international bodies, including the IASP and the INCB to promote both the deregulation of domestic regulatory practices that limit opioid availability for medical use, and strategies to lower the cost of opioids. The high water mark of this advocacy was the inaugural "Global Day Against Pain." Cosponsored by the IASP, EFIC and WHO, it took place in October 2004 in Geneva, Switzerland. The theme of the day was "Pain Relief Should Be a Human Right." And so, approximately 30 yr after the 1975 inaugural World Congress on Pain (1975) and the incorporation of the IASP, the preeminent bodies involved in the overseeing and promoting of pain management collaborated to place this need firmly before the international community.

### **Toward an International Year of Pain Management**

Given the tremendous amount of activity over recent years by preeminent international and national pain bodies and the raising of awareness about pain, it is now time for the UN to consider the declaration of an International Year of Pain Management. Doing so would have several advantages. It would harness the momentum of the current activity and advance the efforts made by national and international bodies. It would serve to place pressure on nations without pain policies to address this issue, and to oppose restrictive opioid regulations. It would encourage medical and nursing schools to integrate pain management within their curricula, and possibly, too, the establishment of postgraduate educational programs such as pioneered by the University of Sydney (147) and Tufts University School of Medicine (148).

### **International Pain Convention**

Pain is a universal public health issue. Several international bodies oversee various aspects of this problem. These include the WHO, the INCB, and as argued above, the Committee that presides over the ICESCR. What is lacking, however, is a single body that unifies all aspects of obligation on national governments in this area. Such a body could expressly

state the obligation on each signatory nation to reform opioid laws and regulations, improve compliance in reporting to the INCB on each nation's requirements for opioids for medical purposes, assist in the preparation and implementation of national pain policies, the provision of education in pain management for all health professionals, and the need for the international community as a whole to work toward ensuring the universal availability of affordable analgesia.

The WHO has the power to make conventions. It has exercised it once, the Framework Convention on Tobacco. For the international community to consider a Convention on Pain would require both significant advocacy and a paradigm shift in the attitudes of many nations in their public policies related to pain control. Too often, those policies continue to be dominated by a regulatory mentality that (for example) *de facto* restricts legitimate access to opioids, rather than emphasizes meeting patients' needs for pain control.

### **PAIN MANAGEMENT: THE CONVERGENCE OF MEDICINE, LAW, AND ETHICS**

Pain-related activities in medicine, law, and ethics have reached a critical mass in which a coherent whole is emerging. Pain is now appreciated to be ubiquitous yet often under-treated, complex yet manageable. The unreasonable failure to treat pain is an unethical breach of human rights. At the same time as the global "pain community" has declared pain management to be a human right, colleagues in the worldwide palliative care community have likewise referred, in international statements and declarations, to palliative care as a fundamental right (149). Further, the Montreal Statement on the Human Right to Essential Medicines in 2005 expressly linked the international right to health with a universal access to WHO essential medications (150). This statement, presented in November 2005 to a high level task force of the UN Human Rights Commission in Geneva, has a clear relevance to pain management, especially in the accessibility and affordability of opioids.

The "right" to pain management has a multidimensional foundation in law at the international (the "right to health" in international human rights law); national (a constitutional right in many countries); and personal (the law of negligence) levels. Separate from, yet in many ways underlying, that pursuit by the law are the ethics of pain management. In terms of pain management, all four main principles of bioethics (autonomy, beneficence, nonmaleficence, and virtue) have their correlates in the law. Indeed, the earliest articulations of the responsibilities of doctors to their patients are not legal, but ethical. They consist of broad statements, from the writings of Hippocrates onwards, of principles that should guide doctors, both clinically and personally.

The right to adequate pain management emerges from, and is directly founded upon, the duty of the

doctor to act ethically. In a legal sense, the strongest parallel to this ethical stance is the law of negligence. The case of *Donoghue v. Stevenson* (1932) (151) inaugurated the modern law of negligence. The seminal nature of that case was that it universalized a principle as old as the Biblical parables. It articulated the neighborhood principle that a person owes a duty of care to another if there is relationship of proximity between them such that one person's actions may reasonably foreseeably damage the other person. And so, in modern jurisprudence, the duty owed by a doctor to a patient does not require novel ethical language, but simply extends a general and universal principle that the law applies to all parties with proximity to each other. One aspect of this duty is the provision of reasonable treatment to patients. The bioethical principle of beneficence, to act for the good of the patient, and the neighborhood principle of avoiding negligence derive from the same wellspring: the doctor has a duty to the patient to act in good faith, and patients have a right to expect the doctor to act always in good faith.

Alleviating pain is not merely a matter of beneficence but also forms part of the duty to prevent harm. The principle of nonmaleficence prohibits the infliction of harm. An unreasonable failure to act is arguably negligent, a breach of human rights, and professional misconduct.

The scope of the bioethical principle of autonomy is wide. It includes the right of patients to be informed of all aspects of their disease and treatment and allows them to make informed decisions about their care. It further includes a doctor's duty to listen to a patient's complaint of pain, to make a reasonable effort to provide pain relief, and to permit autonomy of the patient to self-determination of medical care. Conversely, failing to listen to patients' complaints of pain, and to make a reasonable effort to provide pain relief, may be found by a court to constitute negligence. Thus both the law and the medical profession offer a strong ethical foundation for a coherent policy of pain management as a right of all patients. Each discipline informs the other.

### **CONCLUSION**

Pain control is arguably the past, present, and future of anesthesiology (152). Yet, for too long, pain and its management have been prisoners of myth, irrationality, ignorance, and cultural bias. The vulnerable have lacked protection. This article has surveyed the many ways in which pain management is now being addressed across the disciplines of medicine, law, and ethics. Their respective contributions are coalescing into a coherent position in which unreasonable failure to treat pain is poor medicine and unethical practice. This viewpoint is spreading at an accelerating pace and extending widely throughout society. Even as this article was being completed, Pope Benedict XVI issued a message to celebrate

the Fifteenth World Day of the Sick on February 11, 2007, in which he praised the work of palliative care workers and stated, "There is a need to promote policies which create conditions where human beings can bear even incurable illnesses and death in a dignified manner" (153). Yet, an approach based on moral persuasion, even by a major religious leader, may founder in the absence of practical steps. Deep-seated cultural and political barriers will doom policies based on regulation without education. Reform will require an integrated approach to address the problem of under-treated pain at all levels:

1. Education for health undergraduates and graduates, including adult health professionals,
2. Adoption of universal pain management standards by professional bodies,
3. Promotion of legislative reform,
4. Liberalization of national policies on opioid availability,
5. Provision of affordable opioids,
6. Promotion of pain control programs in all nations, irrespective of resources,
7. Continuing activism of the WHO in collaboration with the foremost international pain relief organizations.

Much work and continuing vigilance will be required to make the transition from asserting that pain management is a fundamental human right, to a future in which appropriate pain management is a global reality. Until then, the bold hope of Oliver Wendell Holmes will founder on the reality of care experienced personally by Shaw and Bonica, who were personally afflicted by both acute and chronic pain, and who strove throughout their lives to improve the management of patients, the "ones who suffer."

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