

the AMERICAN ACADEMY *of* PAIN MEDICINE

ETHICS

CHARTER



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AAPM Council on Ethics

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Part I. Foundations for the Ethical Practice of Pain Medicine

PREAMBLE

The American Academy of Pain Medicine (AAPM) is a medical specialty society representing physicians practicing in the field of Pain Medicine. The management of pain is fundamental to the practice of medicine. All physicians have an obligation to address acute and persistent pain. Adequate assessment and management of many types of pain states require a multidisciplinary or interdisciplinary approach with one physician having primary responsibility for coordination and continuity of care.

AAPM endorses both the American Medical Association's (AMA) Principles of Medical Ethics, which focus on our primary obligation to our patients, and the AMA's Declaration of Professional Responsibility, which specifies the duties of physicians to humanity (see Appendixes A and B). The AAPM *Ethics Charter* is a complementary document developed to address the unique scope and breadth of the practice of Pain Medicine.

The ethical imperative to provide relief from pain requires all physicians to apply themselves toward improvement in the following areas:

- assessment of the pain sufferer as a whole person, including all relevant biological, social, psychological, and spiritual dimensions pertaining to etiology and impact of pain
- treatment of the person in pain with competence and compassion
- education of professional colleagues, patients, the public, and policy-makers on the principles and methods of Pain Medicine
- support of and/or participation in basic and clinical pain research
- advocacy to ensure access to pain care and its continuous improvement.

AAPM supports the normalization of Pain Medicine within all patient care settings so that exceptional interest, commitment, and moral courage are not required to meet the needs of patients in pain, and especially those with persistent or complex pain disorders. AAPM further recognizes and accepts a commitment to overcome professional and social obstacles to the alleviation of human pain. Specifically, this includes the commitment to

- facilitate patient access to Pain Medicine services
- encourage medical institutions to assign priority to routine pain assessment and management
- encourage a focus on the diagnosis and treatment of underlying conditions that contribute to pain
- avoid acting on unwarranted patient claims of disability
- encourage professional education on adequate and thorough assessment of pain in all patients
- provide education about adequate assessment of disability arising from persistent pain problems

- familiarize members and colleagues with new evidence-based findings and concepts about pain, its assessment, and its treatment
- provide education in pain treatment–related substance misuse, abuse, addiction, and diversion, including risk assessment and management
- assist in resolving concerns about iatrogenic addiction and its detection, prevention, and management
- participate in Pain Medicine–related advocacy and policy development.

PROFESSIONAL RELATIONSHIPS AND THE PHYSICIAN’S DUTY TO THE PATIENT

The assessment and management of complex or persistent pain conditions often require interdisciplinary evaluation and treatment of patients, requiring collaboration among healthcare professionals.^{1,2,3} Pain specialists need to recognize, understand, and respect the ethical bounds of their collaborative relationships in the context of their primary ethical obligations to the patient. Commonly encountered interprofessional domains that pose potential ethical challenges for pain specialists are elaborated below.

EXPERTISE

Patients in pain commonly seek complementary or alternative medicine methods.^{4,5} Because many patients do not tell their healthcare professionals about their use of these treatments, the potential for significant harm exists, especially from adverse interactions with other pharmacologic agents the patient is using. Pain specialists need to be educated about and aware of these methods, particularly about herbal medicine, and they need to ask their patients about their use of complementary methods at the initial evaluation. Pain specialists have a duty to inform patients of potentially harmful effects of these modalities. The Current Opinions in the AMA’s *Code of Medical Ethics* caution that “it is unethical to engage in or to aid and abet in treatment which has no scientific basis and is dangerous, is calculated to deceive the patient by giving false hope, or which may cause the patient to delay in seeking proper care.”⁶

Many chronic pain patients will see multiple healthcare professionals in an effort to get pain relief. In the course of taking the patient’s history and reviewing the records, pain specialists may come across treatment and care that seem to be significantly below the standard of care or that may appear to be incompetently administered or even to be harmful to the patient. The AMA’s *Code of Medical Ethics* unequivocally states, “A physician should expose, without fear or loss of favor, incompetent or corrupt, dishonest, or unethical conduct on the part of members of the profession.”⁷ It is strongly recommended that incompetent or unethical professionals undergo corrective action such as mandatory education and/or peer counseling. This aim is best accomplished if concerns are reported through appropriate channels, such as state medical societies, peer review organizations, or licensing boards.

Pain Medicine is a relatively new field of specialization that is evolving in tandem with pharmacologic and procedural advances that mandate continuing medical education (CME). While there may be mandatory, state-regulated CME requirements for continued licensure, “fulfillment of mandatory state CME requirements does not necessarily fulfill the physician’s ethical obligation to maintain his or her medical expertise.”⁸ Maintaining professional expertise is particularly important for pain specialists because research indicates that an alarming amount of misinformation and potentially harmful attitudes concerning pain exist among other healthcare professionals, adversely affecting patient care.⁹

TYPE OF PRACTICE

The ethical conduct of Pain Medicine practice should be uniform, regardless of the practice setting or the physician’s employment arrangement.

Private Practice. A primary challenge for private practice specialists is practicing in a setting where access to other specialists may be restricted, not easily available, or fraught with lengthy delays or long and difficult commutes for the patient. In an effort to circumvent these difficulties and help the patient expeditiously, practitioners may be tempted to perform an evaluation or treatment procedure that is outside their area of specialty or expertise. This problem is often exacerbated in private practice, where financial pressures and incentives may be very strong. It is unethical for health professionals to provide treatment that exceeds their training or scope of practice or to recommend interventions that are not purely in the best interest of the patient.

Academic Practice. Ethical dilemmas arise in settings where accommodating the training needs of medical students, residents, and fellows may conflict with maintaining adequate care for patients. The bioethical principles of nonmaleficence and beneficence demand adequate support and supervision for all trainees. Decisions about medical interventions should be made independent of trainees’ needs for experience and potential financial benefits to attending staff and the institution. Patients need to be fully informed of the training status of those involved with their care, and their autonomous right to choose whomever they want treating them must be preserved. Explaining the benefits of trainees’ participation often helps patients in their decision: “Patients should be informed of the identity and training status of individuals involved in their care. . . . Patients are free to choose from whom they receive treatment. . . . Health care professionals should relate the benefits of medical student participation.”¹⁰

REFERRALS AND CONFLICTS OF INTEREST

Pain specialists often act as consultants to other parties. Regardless of the referral source, physicians should retain their primary professional duty to the patient. This duty is compromised when the pain specialist is asked by the referral source to perform a procedure, such as a nerve block, that the pain specialist does not believe accords with the standard

of care, or when the pain specialist is asked to depart from his or her normal practice (e.g., when the referral source “forbids” a consultation or referral with a psychologist). Ethical practice requires independent judgment to determine indications for any diagnostic test or potentially therapeutic procedure. This determination can be derived only from sufficient evaluation and examination of the patient, prior to the provision of a treatment.

Furthermore, because the onset of pain may result from accidental injury or other causes of trauma,¹¹ referrals to pain specialists may come from third-party sources such as attorneys or workers’ compensation boards. In such instances, the pain specialist must exercise his or her best judgment and not accede to any unreasonable demands or pressures from third parties that might abridge standard practices or work against the patient’s best interests.

Economic pressures and incentives, and the desire to maintain good relationships with referral sources, should not compromise the pain specialist’s primary responsibilities to the patient.

Pain specialists need to disclose any financial interest they have in their referrals to other facilities (e.g., a rehabilitation facility, gym, pharmacy, imaging facility, or surgicenter). The AMA’s Current Opinions in its *Code of Medical Ethics* notes that “in general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or services when they have an investment interest in that facility. . . . The physician needs to have personal involvement with the provision of care on site.”¹² An exception to the requirement of “personal involvement” is made “if there is a demonstrated need in the community for the facility and alternative financing is not available.”¹³ But even in these exceptional cases, full disclosure of an investment interest to the patient as well as provision of alternative facilities and assurances that the patient will not be treated differently if he or she chooses a different facility is recommended.¹³

Referral within an interdisciplinary practice, which is the standard of care in Pain Medicine, also poses potential conflicts: “When services are provided by more than one physician, each physician should submit his or her own bill to the patient and be compensated separately, if possible.”¹⁴ Financial arrangements, including those that pose potential conflicts of interest, should be clearly described and transparent to all parties.

RELATIONSHIPS WITH PHARMACISTS

Pharmacotherapy is the mainstay of long-term Pain Medicine for many patients with disabling pain. A Pain Medicine physician may obtain information from a pharmacist regarding prescriptions and refill patterns when it is in the best interest of the patient. A Pain Medicine physician may communicate to a pharmacist concerns regarding a patient’s drug therapy, particularly any unusual occurrences. In order to protect

confidentiality, only relevant information should be disclosed.

By virtue of their unique role, pharmacists can find themselves at the center of conflicts that may emerge around the prescribing and dispensing of Pain Medicine, involving both physicians and patients. Although the pharmacist's questioning of prescription validity may seem to challenge the physician's judgment or the patient's "legitimacy," the pharmacist's responsibility to verify prescriptions for their medical legitimacy should be respected. Inquiries from a pharmacist to validate the accuracy, legality, or medical necessity of a prescription should be responded to quickly and respectfully. Reports to law enforcement of attempts to acquire pain medications illegally need to be based on confirmed firsthand information.

In keeping with the bioethical principle of justice, all essential and commonly used drugs for Pain Medicine should be available to all patients at all pharmacies regardless of geographic location. Pain Medicine physicians should work to reduce disparities in prescription practices or stocking that are based on unfounded racial, ethnic, or socioeconomic demographics. We recognize that patients "have the right to have a prescription filled wherever they wish."¹⁵ When necessary to promote safe and effective patient care, a Pain Medicine physician may insist that a patient use only one pharmacy, as long as the patient is free to choose the pharmacy, in order to ensure compliance and safety in treatment.

SOCIETAL RESPONSIBILITIES

Physicians have long recognized their responsibilities to individual patients. The importance of this ethical commitment was first expressed in the Hippocratic Oath, written more than 2,500 years ago: "Whatever houses I may visit, I will come for the benefit of the sick."¹⁶ It is also expressed in the World Medical Association's *Declaration of Geneva*, adopted in 1948 after offensive lapses in medical ethics during World War II: "I will practice my profession with conscience and dignity; the health of my patient will be my first consideration."¹⁷ Although medical ethics does not require limitless sacrifice from physicians, some physicians have shown exemplary virtue in caring for their patients, even when doing so has exposed them to personal risk and required personal sacrifice. Exemplary physicians are often the physicians who exceed their duties to patients, treating patients humanely and serving as advocates of their needs and interests.

Human health does not depend only on treatment by physicians. Social and political circumstances profoundly influence the health and well-being of all people. It is not enough to care for individual patients if the causes of their ill health are rooted in harmful social practices and unjust political arrangements.¹⁸ Access and equity in social and political matters directly affect human health. For example, health is directly affected by access to adequate food, clean water, and safe housing. It is also directly affected by

protection from chemical toxins and political disturbances. The adequacy of social responses to natural disasters also affects human health. Medical ethics has come to acknowledge the direct link between human health and the social environment. For that reason, medical ethics now acknowledges a responsibility on the part of physicians to protect health through social interventions.

In the United States, the AMA recognizes social responsibility for human health in this way: "A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health."¹⁹ Because physicians have different skills and expertise, they can meet this responsibility in a variety of ways, ranging from provision of direct care to the indigent to political advocacy. This social responsibility of physicians has been recognized as a core element of the AMA's "Declaration of Professional Responsibility: Medicine's Social Contract with Humanity," adopted in 2001 (see Appendix B). Among other things, the declaration commits physicians to work toward the development of advances in medicine and public health. Specifically, the declaration commits physicians to educate people about threats to the health of humanity and to advocate for the social, economic, educational, and political changes necessary to relieve suffering and to advance human well-being.

A number of social and political obstacles to improving the theory and practice of Pain Medicine currently exist. These include inadequate training and education in the management of pain, real and perceived barriers to the use of pain medications, and inadequate research in pain control. These obstacles directly affect the ability to treat patient suffering. Consequently, Pain Medicine physicians have a responsibility to educate the public about advances in Pain Medicine and to work toward better medical education and training in Pain Medicine. Pain management physicians also have a responsibility to promote research in Pain Medicine and to help eliminate social prejudices and legal obstacles that interfere with the medical management of pain.

These responsibilities may be carried out in a variety of ways. Acting on their own, individual Pain Medicine physicians can educate the public about advances in Pain Medicine through teaching, writing, and lecturing on the subject. Success in overcoming regulatory and legal obstacles to effective Pain Medicine, however, will require concerted and organized efforts on the part of the profession as a whole. Real, meaningful reform will require members of the profession to participate in reform of regulatory policy and practice and to ensure that safe practice guidelines for pain treatment are taken into account when legislators draft regulations and laws that apply to pain. To encourage collective action, professional organizations representing Pain Medicine physicians have a responsibility to regularly review the status of Pain Medicine and to advocate publicly for the changes in regulations and laws that compromise the ethical practice of Pain Medicine.

Part II. Ethical Opinions

CLINICAL CONCERNS

PROBLEMS OF DECISION-MAKING CAPACITY IN PATIENTS WITH PAIN

Physicians who treat patients in pain must be aware of their patients' decision-making capacity. In a medical setting, pain itself can alter decision-making capacity, and iatrogenic causes, including pharmacologic and psychological influences, may exacerbate a patient's vulnerability to undue influences. In recognition of the patient's right to self-determination, physicians who treat such patients are ethically and legally obligated to assess and evaluate their patient's decision-making capacity. Autonomous informed consent requires

1. understanding of information and consequences
2. demonstration of insight
3. reason and judgment
4. the ability to evince a decision or articulate a preference
5. voluntariness.²⁰

The patient's decision to proceed with any course of therapy should be voluntary and should express the patient's authentic desires and wishes. Patients' decision making should meet all five criteria. The physician whose patient does not adequately meet these criteria needs to determine whether the patient has identified a surrogate decision maker or, in instances in which withholding or discontinuing life-prolonging treatment is being considered, whether an advance directive exists. "In some instances, a patient with diminished or impaired decision-making capacity can participate in various aspects of health care decision making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities."²¹

In all instances, the physician must secure informed consent to treatment from a legally valid source, whether it be the competent patient or the incompetent patient's surrogate. Nevertheless, certain patients with diminished capacity may be able to participate in some or even all decisions pertaining to their care. Ethical dilemmas may arise when the physician believes that the surrogate's decision may be contrary to the patient's best interest. The physician's ethical and legal obligations are to advance the patient's welfare. The attending physician may wish to consult with an ethics committee or ethics consultant in such cases. "When a physician believes that a decision is clearly not what the patient would have decided or could not be reasonably judged to be within the patient's best interests, the dispute should be referred to an ethics committee before resorting to the courts."²¹

PSYCHOSOCIAL AND SYSTEMS BARRIERS TO SHARED DECISION MAKING IN THE TREATMENT OF PAIN

In addition to assessing the patient's decision-making capacity, the physician should strive to enable the patient to participate in the decision-making process. "Physicians should encourage their patients to document their treatment preferences."²¹ The physician should be cognizant of the psychosocial barriers to shared decision making in the treatment of pain.²² Adversarial processes, such as workers' compensation claims or litigation, are common external influences in Pain Medicine settings. Other sources or causes of influence on patient decision making include ethnocultural beliefs or traditions, family, work, and financial pressures, literacy and language comprehension, and the stigma of opioid use.

Systems barriers that compromise shared decision making in pain treatment often include the influence of third-party payers, historical racial or ethnic biases with resultant absence of trust, poor communication and discontinuity of care, delayed or denied care, and insufficient resources (e.g., time pressures, poor access to consultants).

Physicians have an obligation to consider the implications of cost or the availability of therapeutics in the development of a plan of care. Physicians should educate themselves about resources that may be available to ensure or facilitate their patients' ability to comply financially and socially with a plan of care.

CONFIDENTIALITY AND ITS LIMITS IN THE CONTEXT OF PAIN MEDICINE

Physicians are legally and ethically required to protect patient confidentiality and the privacy of patients' medical information. "The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree."²³ Physicians should share information with third parties only with the consent of the patient on the basis of the third parties' right and need to know, and even in those instances physicians should share only relevant information. Exceptions to ensuring patient confidentiality can be made in certain circumstances, such as when the threat of bodily harm to others or to the patient is present. In such circumstances, notification of law enforcement authorities is required.

It should be recognized that because of the multidisciplinary practice of Pain Medicine today, relationships with other pain specialists, as well as with third-party payers, attorneys, and other agencies, place demands related to the sharing of patient information. The free exchange of information between professionals is thought to improve patient care. Psychologists' reports, which often contain sensitive information, may present particular ethical conflicts of confidentiality. Patients need to be fully informed about the limits of confidentiality between team members and other interested parties.²⁴

MISMANAGEMENT OF PAIN

Mismanagement of pain includes actions on the part of a physician that constitute the insufficient or inadequate assessment of pain or the poor, inadequate, or otherwise ineffective treatment of pain.²⁵ Mismanagement of pain during all phases of life is a breach of the physician's duty of beneficence.

State laws and regulatory practices may lead physicians into patterns of mismanagement. Nonetheless, physicians have an obligation to be knowledgeable about prescribing laws in their state, and when these laws contradict patients' best interests, physicians have a duty to advocate for change in these laws.

PAIN AND ADDICTION

Patients with pain disorders who are addicted to drugs and/or alcohol deserve the same competent pain assessment and management that all other patients deserve. However, managing the pain of these patients may pose special challenges to physicians.

Physicians have an obligation to educate themselves about standards of care in addictive disease and substance abuse disorders and should make use of resources to comanage these patients, when indicated.^{26,27}

Physicians have an obligation to be knowledgeable about prescribing and practice laws in their state, especially in regard to controlled substances.^{26,28} When laws contradict patients' best interests, physicians have a duty to advocate for change in these laws. Physicians have an obligation to evaluate and distinguish among the psychophysiologic-pharmacologic phenomena of tolerance, physical dependence, chemical coping, substance abuse or misuse, addiction, and pseudoaddiction.

The principle of balance recognizes that opioids are indispensable for the relief of pain and suffering, that they also may be abused, and that efforts to address abuse should not interfere with legitimate medical practice and patient care. The principle creates an ethical framework for the use of controlled substances in all patients with pain, where opioids are efficacious, while preventing abuse or diversion.^{26,29}

PAIN MEDICINE AT THE END OF LIFE

RELIEF FROM PAIN

The management of pain at the end of life is often recognized as posing special difficulties for physicians.^{29,30,31} Physicians caring for patients with terminal illness are ethically required to manage pain, according to currently available clinical science. Satisfactory compliance with this requirement may necessitate consultation with colleagues who have special skill and expertise in managing pain at the end of life.

Physicians should discuss with the patient his or her wishes regarding the treatment of pain at the end of life. Physicians who are treating patients

with disease processes that may be life-limiting should diligently assist their patients in developing goal-directed advance directives, and they should be faithful in implementing these choices.

COMFORTABLE DYING AND PATIENT SELF-DETERMINATION

The end outcome measures of “safe and comfortable dying” and “self-determined life closure,” elaborated by the National Hospice and Palliative Care Organization, pertain to the management of refractory pain experienced by patients with certain end-stage pain-producing illnesses. When pain motivates a patient’s intention to end his or her life, all reasonable means to relieve pain should be sought.

A physician’s inability to relieve pain does not justify intentional hastening or causing the death of his or her patient.^{32,33} *Euthanasia*, defined as the intentional administration of a lethal substance in order to cause death as a means of relieving suffering, is illegal throughout the United States.³⁴

Physicians caring for patients suffering with a terminal illness or an advanced disease frequently worry about “hastening death” through the use of opioids. This worry has been determined to be scientifically and medically unfounded. There is no evidence to demonstrate that titrating opioids to achieve relief of pain causes a “foreseeable risk” of causing death. In any case, medical ethics has long accepted pain control as an ethically defensible practice, even if it has unintended consequences in affecting the duration of a patient’s life.^{35,36}

PALLIATIVE SEDATION FOR INTRACTABLE SYMPTOMS

The duty of beneficence and the principle of proportionality require physicians to consult with those who have ample expertise in palliative care if they are unable to meet the patient’s needs prior to resorting to palliative sedation.^{37,38,39} Palliative sedation is a medically humane, ethical, and legal alternative to the intentional hastening of death. This practice involves the physician’s inducing and maintaining deep sleep to relieve pain that is refractory to standard palliative care.^{40,41} Palliative sedation should be reserved as an intervention of last resort for the management of pain. Patients experiencing profound existential or psychological suffering should receive psychological and/or spiritual interventions from a specialist trained to relieve end-of-life suffering.³⁷ Palliative sedation should be implemented and maintained by those with sufficient experience and expertise in end-of-life care, and in this procedure in particular.^{42,43}

THIRD PARTIES AND THE PATIENT-PHYSICIAN RELATIONSHIP

Physicians caring for persons in pain should understand that the practice of pain and palliative medicine is a rapidly evolving field. As in all advanced fields of medicine, other parties have a necessary vested interest in that field’s developments as they affect the cost and effectiveness

of care. These third parties have social, economic, and political agendas that can positively influence both the profession and the public. The process of informing third parties about Pain Medicine's positions on therapeutic modalities, as well as on those treatments that should not be applied to those suffering with pain, and persuading them to adhere to these positions, requires a combination of communication, collaboration, sensitivity, and advocacy.

In their relationships with managed care and other third-party agencies and regulators, physicians caring for persons in pain should specifically

- engage managed care agencies in an active manner that ensures that competent pain care is provided
- turn to others in the community, both on a case-by-case basis and in more general policy initiatives, for support in influencing the approaches taken by managed-care and third-party regulators. It may be of particular benefit to enlist other pain care physicians in the community or region, as well as voluntary agencies committed to the support of those in pain
- engage in advocacy for those in pain through the education of managed-care and third-party regulators
- promote policies and procedures that recognize the importance of pain and symptom management in patient care.^{44,45,46}

Physicians caring for persons in pain should recognize the unique role that pharmaceutical companies play in pain-related clinical research and education, and in some circumstances, patient assistance programs to provide needed drugs. Pain specialists and their organizations are cautioned to avoid conflicts of interest that may arise from consultation agreements and educational programs. Compensation that bears no relationship to the time and effort expended by the physician in educational or research activities should be eschewed. All physicians should recognize the need for lifelong learning, and all physicians should recognize that the receipt of substantial gifts, consulting fees, or honoraria should be commensurate with the nature and extent of educational or research contributions. Gifts of substantial value or remuneration out of proportion to educational or research activities are inappropriate and unethical.^{47,48}

Physicians with particular knowledge and expertise in pain and symptom management have a singular responsibility to assume educational and advocacy roles for competent and compassionate pain relief as an essential feature of sound patient care. Fulfillment of these important roles may include offering testimony within the judicial system or providing expert opinions to oversight and policy-making agencies. In the context of these interactions, it is necessary for physicians to

- keep complete, accurate, and clear records of pain care, including the use of valid instruments to measure pain, suffering, and physical and mental impairment, as well as improvements in level of function and quality of life

- be prepared to explain the content of their medical and surgical records related to pain care fully and objectively
- support the judicial system by providing competent, credible evidence concerning patients' physical and psychological pain and pain-related disorders. In this process, the educational role of the medical professional is paramount, and physicians caring for people in pain should provide only testimony and opinions that can be asserted with a reasonable degree of medical certainty and that are based upon the physician's knowledge of the particular patient's diagnosis, prognosis, and both current and anticipated levels of impairment
- provide testimony that is balanced, objective, and consistent with the best current standards of the medical profession regardless of whether the physician is testifying as a factual or expert witness for the plaintiff or defendant.^{49,50,51,52}

RESEARCH CONCERNS

ETHICAL USE OF DRUGS AND TECHNOLOGIES FOR NONAPPROVED INDICATIONS

The field of Pain Medicine is relatively new and has a nascent evidence base. Innovations in therapy that serve the best interest of patients are to be encouraged, within the accepted constructs of ethically and methodologically sound research practices.

In the face of severe pain, patients may become desperate and be willing to try anything that the physician suggests. Care must be taken to avoid active or passive, intentional or unintentional (inadvertent) coercion. The physician must inform the patient of any recommended therapies that have not been validated by peer-reviewed evidence and fully inform patients of the potential risks.

Although Food and Drug Administration guidelines and labeling approvals for drug use are important, these do not override physicians' primary responsibility to adequately treat the pain and suffering of their patients. Use of medication outside of FDA approval should be for individual patient benefit and justified by sufficient need and the exercise of sound clinical judgment. These thought processes (the rationale for "off-label" use of a drug) should be documented in the medical record, and any adverse drug reaction should be reported immediately to the proper regulatory agency.

Pain Medicine physicians should also subject novel clinical innovations to formal scientific trials as soon as practical, a practice recommended by the 1978 Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

INFORMED CONSENT

Because of the unique nature of pain and suffering and because patients with pain have particular vulnerabilities concerning dependency and psychological needs, extra care must be taken to ensure voluntary

informed consent and adequate participation in decision making. Pain Medicine physicians should actively participate in institutional review boards in order to share their expertise in providing informed review of evaluation of risks and benefits of proposed studies as well as their procedures for ensuring voluntary participation and informed consent.

USE OF PLACEBOS

A placebo is an inert substance that is used with some subjects in clinical trials to provide a basis for comparison with other subjects who actually receive the drug under study. The use of placebos is well established in randomized clinical trials and is ethical as long as certain conditions are met. A placebo-controlled study design is generally accepted when harm to patients from not using other known effective treatment is minimal, when the tested treatment is unproven, and when reasonable evidence exists of more benefits for future patients. It is unethical to deny patients enrolled in controlled trials the benefit of treatment already proven effective. The use of a placebo control must be explicitly explained to patients who are being asked to serve as research subjects. In placebo-controlled trials on patients with pain, rescue medications must be available.⁵³

Placebo use for the treatment of pain in other than research settings is usually considered unjustifiable, both for ethical and clinical reasons.

EMPATHY IN THE PRACTICE OF PAIN MEDICINE

Adopted December 2007.

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Empathy is the engagement of one person in the emotional or intellectual experiences of another. Unlike sympathy, which involves identifying with the experiences of another, empathy requires reflective and imaginative effort on the part of the empathizer.^{54,55} Importantly, however, this effort is not one-sided. The empathic encounter is dynamic and interpersonal. This means that while the empathizer must “cultivate the capacity for imagining the perspectives to which she lacks immediate access”⁵⁴, the person for whom empathy is shown must also cultivate the capacity for honesty in self-expression.

Empathic engagement plays an important role in the healing relationship.^{55,56,57} Clinicians who empathize with their patients are able to discern aspects of their patients’ experiences that might otherwise go unrecognized.⁵⁸ The insight gained from empathic engagement better enables clinicians to diagnose and achieve therapeutic ends. This apparent link between empathy and optimal therapeutic outcome has encouraged the view that empathy is not just a form of emotional or intellectual engagement, but a form of moral engagement as well.⁵⁶

Despite its importance, the empathetic encounter between clinician and patient is often difficult to realize. In the context of pain management, pain

specialists face special challenges in cultivating empathetic engagement with their patients. The kind of effort required to sustain an empathic encounter with a patient is often at odds with background psychosocial and physiological responses to pain.⁵⁹ Patients experiencing chronic pain, for example, often develop coping mechanisms (physiologic and emotional) that hinder honest self-expression or accurate interpretation of their pain. Similarly, difficulties in managing chronic pain can lead pain specialists to experience feelings of anger or professional inadequacy. Displacement of these feelings onto the patient hinders the development of empathy.^{59,60} Finally, even when pain specialists successfully initiate empathic engagement with their patients, these background psychosocial and physiological responses to pain can distort the empathetic encounter. They can cause the pain specialist to inaccurately perceive the patient's pain or distress. This "empathetic inaccuracy" can result in the undertreatment or overtreatment of pain.⁵⁹

The American Academy of Pain Medicine (AAPM) recognizes the therapeutic role that empathy plays in the effective treatment of pain. However, AAPM also recognizes that empathic engagement in the context of pain management can be uniquely challenging. To facilitate the development of empathic accuracy in the context of pain management, AAPM encourages pain specialists to do the following:

1. Acquire an understanding of the specific ways in which the patient's personal experience of pain can undermine the development of a therapeutic empathic relationship.
2. Acquire an understanding of the specific ways in which their own self-protective responses to the patient may undermine the development of an empathic relationship.
3. Define specific steps to identify and correct empathic inaccuracies that may hinder the appropriate treatment of pain.
4. Realize that, although the experience of pain is personal, the development of a therapeutic empathic response to pain depends on interpersonal involvement between the clinical team and the patient.⁵⁹ Reliance on the interdisciplinary model can provide a good structure to cultivate empathic engagement as well as to identify and respond to the kinds of problems raised above.⁶⁰

DISPARITIES IN PAIN MEDICINE

Adopted December 2007.

Michael Francis, MD; Carmen Green, MD; Allen H. Lebovits, PhD; Knox H. Todd, MD

The American Academy of Pain Medicine (AAPM) endorses the World Health Organization (WHO) declaration that pain relief is a human right. The Academy advocates strongly for access to high-quality pain care for all persons, seeking to overcome any and all inequities that exist. AAPM embraces the American Medical Association's statement on disparities, affirming that

*“disparities in medical care based on immutable characteristics such as race must be avoided. Whether such disparities in health care are caused by treatment decisions, differences in income and education, sociocultural factors, or failures by the medical profession, they are unjustifiable and must be eliminated. Physicians should examine their own practices to ensure that racial prejudice does not affect clinical judgment in medical care.”*⁶¹ While federal agencies have paid increasing attention to healthcare disparities in recent years,⁶² the impact of pain on individual patient’s lives, their families, and society are notably absent in most federal research agency’s strategic plans and position statements. The reality today is that there has been little impetus or effort among agencies of influence to promote, no less uphold, an acceptable standard of pain care among all groups of patients.

There continues to be major disparities based upon patient sociodemographic factors (e.g., race, ethnicity, socioeconomic status, age, gender) for all types of pain (e.g., nociceptive, neuropathic) and across all settings (e.g., inpatient, outpatient).⁶³ Overall, minorities report significantly more psychological and physical morbidity, including Posttraumatic Stress Disorder and disability, than non-Hispanic whites across the age continuum.^{64,65} Respondents of an American Pain Society (APS) and AAPM survey on ethical concerns in pain care identified pain management at the end of life and the general undertreatment of pain (particularly in the elderly and children) as the major ethical dilemmas confronting the practice of pain.⁶⁶ Neither racial nor ethnic disparities in pain care were identified as a concern. Although lack of patient access to pain services was identified as the sixth most significant ethical dilemma in pain, the qualitative comments referred to the lack of 24-hour coverage and lack of certified practitioners rather than insufficient access due to race and ethnicity or socioeconomic status (SES).

Several ethical and healthcare policy considerations must be addressed to optimize pain assessment and treatment for those at particular risk for substandard pain care.⁶⁷ There are many predictors of pain care disparities: SES, race and ethnicity, language, geography, extremes of age, gender differences, health literacy, specific types of pain-related conditions (e.g., HIV/AIDS), specific comorbidities (e.g., substance use disorders), and others. AAPM’s *Ethics Charter* identifies many of these but will focus on those that affect people most commonly: SES, race and ethnicity, and geographic location.

SOCIOECONOMIC DISPARITIES

Access to healthcare is strongly influenced by financial status.⁶⁷ Research suggests that Pain Medicine physicians give preferential treatment to more profitable patients.⁶⁷ The principle of distributive justice would dictate that all patients under similar clinical circumstances would receive equal access to all necessary and indicated treatment modalities. Prevailing economic forces coupled with insensible and even discriminatory policies

within our healthcare system proscribe against fair treatment for many patients in pain. Low SES is broadly associated with poor access to care, fewer community healthcare resources, and higher overall morbidity and mortality rates.^{68,69,70} Overall, minority persons are much more likely to be poor than non-Hispanic whites. Health insurance has allowed improved access and health, but 15% of non-Hispanic whites in the U.S. are uninsured as compared to 18% of Asians and Pacific Islanders, 20% of African Americans, and 32% of Hispanics.⁷¹ Minority persons without insurance are half as likely to have a regular physician when compared to insured African Americans, limiting their access to specialty care such as Pain Medicine.⁷²

RECOMMENDATIONS

Because pain is a universal experience with a substantial health impact, all physicians should support efforts to ensure access to high-quality pain care for all, without regard to the patient's financial means. Advocating for reforms in public policy to remove barriers to access to care through the provision of some form of healthcare coverage (insurance or its equivalent) for all persons is an ethical imperative. Successful implementation of such policy reform will lessen health disparities in general and disparities in pain care in particular.

GEOGRAPHIC DISPARITIES

It has been well-demonstrated that a person's place of residence strongly influences his or her access to health-related services.⁷³ Overall, locations with relatively poor healthcare resources, especially for specialist-level pain care, tend to correlate with the percentage of minority inhabitants, although there is substantial variation in racial and ethnic disparities across geographic lines. Perhaps the only consistent pattern is that pain specialists tend to practice in urban areas. There is an insufficient number of pain specialists overall, requiring that primary care physicians provide care even for patients with complex pain management needs, particularly in rural settings.

Although pain complaints are one of the most common reasons that people seek medical care, studies consistently report that physicians receive very little education specifically directed at managing pain. Patients requiring specialized pain care may need to travel long distances for evaluation and treatment. In addition, the availability of essential medications required for the treatment of pain varies geographically, even within metropolitan areas and across a state.^{74,75} Pharmacies located in minority and low-income neighborhoods are less likely to carry opioid analgesics than those in nonminority neighborhoods. The reluctance to prescribe and the decreased ability to obtain pain medications both complicate appropriate pain management for racial and ethnic minority persons and impair their overall health and well-being.

RECOMMENDATIONS

1. Pain Medicine physicians, in concert with pain management advocacy groups, should identify regional variations in the quality and availability of pain care and promote the development of training programs and public policy initiatives to fill the need of underserved areas.
2. Pain Medicine physicians must work in concert with pain management advocacy groups and regulatory agencies to eliminate barriers both to prescribing and obtaining indicated analgesics.
3. Pain Medicine physicians must advocate for and help organize improved pain management education to primary care physicians and other health-care professionals practicing in areas with limited access to specialized pain care.

RACIAL AND ETHNIC DISPARITIES

The bioethical principle of justice is severely strained when there are racial and ethnic disparities in treating individuals with pain. A recent Institute of Medicine (IOM) report identified consistent and overwhelming racial and ethnic disparities in health and health care for a wide variety of illness and healthcare services but only briefly addressed pain care.⁷⁶ IOM clearly documented the disparities in providing pain care for acute pain problems in the emergency room and for cancer pain. More recent reviews further document racial and ethnic differences in a variety of settings (e.g., emergency departments, inpatient, nursing homes) and conditions (e.g., nociceptive, neuropathic, and experimental pain).^{64,65}

These reports conclude that racial and ethnic minorities are at risk for poor pain assessment when compared to non-Hispanic whites. The pain complaints of racial and ethnic minorities, the elderly, and women are often handled less aggressively by physicians than those of non-Hispanic white men. Minority persons often report increased pain and pain-related sequelae while being at increased risk for undertreatment. These differences in pain assessment and treatment by physicians are based upon patients' demographic characteristics regardless of type or cause of pain.

Studies in the emergency department found a two-fold increase in the amount of analgesics administered to white patients with acute pain from long-bone fractures compared with comparably injured racial minorities. Differences were not accounted for by other patient sociodemographic factors, substance use, or medical characteristics.⁶³ In another study using black and white actors presenting with acute chest pain, women and minorities received inferior pain care. A survey of 13,625 elderly nursing-home residents with cancer pain showed that blacks were less likely to have their pain assessed and were 63% more likely than whites to not receive any pain medications.⁷⁷ Additionally, minorities carry a higher disease burden than non-Hispanic whites, adding to the diminished

physical, social, and emotional health imposed by persistent pain.

Recent work reveals that there are generational differences in pain reports and pain-related sequelae among blacks, with younger patients reporting more distress than their older counterparts. The cultural reasons for this are not completely clear; but, over time, this has significant implications for an increasingly aging society.

In addition, minority patients are prescribed less potent analgesics and are significantly undertreated using the WHO's pain management guidelines. African Americans were significantly less likely to receive a prescription for a COX-2 inhibitor than Caucasians.⁷⁸ Emanuel has noted that even in end-of-life care, services such as hospice care are more available for the "well-heeled white sectors of society than others."⁷⁹ The workers' compensation literature provides additional evidence for disparate pain care with racial and ethnic minorities receiving less treatment and lower disability ratings while being twice as likely to be disabled 6 months following occupational back injuries.

RECOMMENDATIONS

Ongoing research and monitoring of disparities related to ethnic or racial background are required in order to inform public policies that can remediate inequities in pain care. Pain Medicine physicians have an ethical obligation to advocate for research funding and policy changes to eliminate disparities and optimize pain care among all patients.

ACCESS TO PAIN CARE

Racial and ethnic minorities have less access to primary care, resulting in fewer referrals to pain management specialists, and they are at an increased risk of having their pain complaints discounted and undertreated. Many minority patients with pain complaints believed that they should have been referred to specialty pain care sooner, felt that ethnicity influenced pain care, and reported that persistent pain is a major financial burden more so than whites.

Racial and ethnic disparities in pain care may result from patient and clinician-level factors. Minority patients are more likely to refuse recommended therapies, adhere poorly to treatment regimens, and delay seeking medical care.^{80,81} These behaviors are the consequence of patients' mistrust in physicians (lack of identification with and empathy from mostly white practitioners), past negative experiences with the health-care system, and limited health literacy.⁸² Physician sources of racial and ethnic disparities may result from bias or prejudice, stereotyping, poor cross-cultural communication skills (i.e., cultural competency), and greater clinical uncertainty when treating minority patients.^{83,84} Physician-patient congruence has been shown to improve compliance. However, physicians from racially and ethnically diverse backgrounds are underrepresented in medicine.

RECOMMENDATIONS

1. Pain Medicine physicians should provide culturally competent care to reduce the potential for miscommunication, stigma, and stereotyping. This can be accomplished through a commitment to ongoing continuing education programs that focus on cross-cultural competence.
2. Pain Medicine physicians should advocate for cultural competence education and training programs at their professional conferences.
3. Pain Medicine physicians should become involved in undergraduate and postgraduate education opportunities to engage and inspire minority students to pursue careers in Pain Medicine.

LEGAL TESTIMONY

Adopted December 2007.

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“As professionals with specialized knowledge and experience, Pain Medicine physicians have an obligation to assist in the administration of justice.”⁸⁵ The courts frequently call on Pain Medicine physicians to participate in a variety of legal proceedings to establish and interpret medical diagnoses, prognoses, and treatments. Pain Medicine physicians who participate in legal proceedings should do so only within the boundaries of their training, expertise, and professional experience. They should also avoid any real and perceived conflicts of interest that could undermine their ability to testify in a prepared and truthful manner. Pain Medicine physicians should decline compensation in an amount or of a type (e.g., contingency) that may influence the objectivity of their testimony.

SPECIFIC OPINIONS

- *Competence*

Pain Medicine physicians vary widely in regard to their background, training, and practice. Pain Medicine physicians who commit themselves to participate in legal proceedings should have a good faith basis to believe that they possess the knowledge, skills, and experience required to assess the case under review and render an informed and credible opinion on the matter or matters at issue.

- *Preparation*

Expert witnesses should thoroughly review all pertinent aspects of, and documents pertaining to, the case and the relevant science that informs the opinions offered.

- *Objectivity*

An expert witness may not become an advocate or partisan for either side in the legal proceedings. Testimony must be impartial and unbiased.

- *Integrity*

An expert witness will testify honestly and truthfully and ensure that his or her testimony is consistent with the facts of the case.

- *Fair compensation*

It is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.

- *Availability for peer review*

An expert witness will make his or her testimony available for peer review when requested.

- *Standard of care*

An expert witness's testimony "should reflect current scientific thought and standards of care that have gained acceptance among peers in the relevant field."⁸⁵ If a medical witness knowingly provides testimony based on a theory not widely accepted in the profession, the witness should characterize the theory as such. Also, testimony pertinent to a standard of care must consider standards that prevailed at the time the event under review occurred. Finally, the expert witness must articulate the national standard of care and clearly identify any personal differences of opinion concerning it.

- *As witness for one's own patients*

When Pain Medicine physicians are called on to testify in matters that could adversely affect their patient's medical interest, they should decline to testify, unless the patient provides a fully informed and voluntary consent or the provision of the opinion is required by law. If, as a result of legal proceedings, the patient and the physician are placed in adversarial positions, it may be appropriate for the treating physician to transfer the care of the patient to another physician.⁸⁵ In any case, the Pain Medicine physician must hold the patient's medical interest paramount, including the confidentiality of the patient's health information, unless the Pain Medicine physician is authorized or legally compelled to disclose the information.⁸⁵

- *Conflict of interest*

An expert witness should recuse himself or herself if there is an actual or apparent conflict of interest (e.g., financial, promotional, emotional), or should take appropriate measures to resolve such a conflict.

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Appendix A. American Medical Association Principles of Medical Ethics

PREAMBLE

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

Adopted June 1957; revised June 1980; revised June 2001.

Appendix B. American Medical Association Declaration of Professional Responsibility

PREAMBLE

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly, and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

DECLARATION

We, the members of the world community of physicians, solemnly commit ourselves to:

1. Respect human life and the dignity of every individual.
2. Refrain from supporting or committing crimes against humanity and condemn all such acts.
3. Treat the sick and injured with competence and compassion and without prejudice.
4. Apply our knowledge and skills when needed, though doing so may put us at risk.
5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
7. Educate the public and polity about present and future threats to the health of humanity.
8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
9. Teach and mentor those who follow us, for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Addendum. Statement on Conflicts of Interest: Interaction Between Physicians and Industry in Pain Medicine

American Academy of Pain Medicine Ethics Council

The relationship between physicians and industry-supported continuing medical education (CME), research, and innovation are critical to the advancement of medical knowledge in Pain Medicine. However, physicians and industry have fundamentally different goals. To ensure that these relationships are principled and ethical, all parties must be aware of the conflicts of interest they present and strive to manage them ethically and with transparency.

DEFINITION OF CONFLICT OF INTEREST IN MEDICINE

A *conflict of interest* is a situation in which someone in a position of trust, such as a *physician* or *medical research scientist*, has competing professional or personal interests that have the potential to influence patient care or other professional primary obligations such as research and education.

A conflict of interest exists if a reasonable observer finds it plausible that the average person could be, but not necessarily would be, swayed by secondary interests. Secondary interests can be broadly divided into personal, professional, or financial. Conflicts of interest are common throughout medicine. Perhaps the most important is the convergence of professional responsibilities and economic self-interests.

BIAS: A POTENTIAL CONSEQUENCE OF CONFLICT OF INTEREST

A conflict of interest can create bias. It cannot be overemphasized that this type of bias is a neuro-psycho-social process that is subconscious and not purposeful. Bias has the potential to influence and change behavior and clinical decisions about patient care, education, and research. It may influence the way researchers interpret their results and the results of others, and it may influence the emphasis and recommendations of medical educators. Bias also affects the way an audience evaluates and interprets publications and lectures, and what conclusions are accepted and retained.

Most physicians believe they can resist bias and its consequences by virtue of their integrity, education, intellect, and scientific training, but evidence from sound social science research contradicts this belief. Paradoxically, although physicians often believe they can resist the bias and behavioral changes inherent in conflicts of interest, they are likely to believe their peers cannot.

Physicians generally practice ethically, but their judgments may be influenced by economic self-interests. Research shows that when faced with equal choices, people tend to default to their self-serving interests.

Gifting and payment for educational and research services are forms of influence that stimulate the process and engender the need for reciprocity. A German proverb states, "Whose bread I eat, his song I sing." Research also suggests that physicians who may benefit personally from recommending or prescribing a certain treatment will subconsciously find a way to justify that decision as being the best for the patient.

DISCLOSURE

Disclosure has become the mainstay for mitigating conflicts of interest. Most medical organizations, CME providers, and journal editors require speakers, authors, consultants, and others to disclose all potential conflicts. Traditionally, disclosing potential conflicts has been seen as an appropriate way to manage them, but recent evidence suggests disclosure might do little to mitigate the potential conflict. Rather, disclosure unfairly places the burden of managing the conflict on those to whom the disclosure is made, charging them with determining how skeptical to be about the objectivity of the individual with the potential conflict (American Medical Association Council on Ethical and Judicial Affairs, unpublished data, 2008).

Recent research suggests that in some circumstances disclosure can actually be counter-productive. In order for disclosure to be at least somewhat effective, the discloser and audience must understand and accept the subconscious nature of bias and its effects. In addition, the audience must be aware of the magnitude of the effects of the influence, which is difficult to estimate. It has been established that advisors give more biased advice after disclosing that they have a conflict of interest.

There are many reasons that disclosure may be ineffective or counter-productive. Physicians differ in what they consider a conflict of interest, and therefore disclosure may be incomplete. Furthermore, it is rarely verified. In addition, when advisors instinctively feel their recommendations might be discounted because of their disclosure, they may subconsciously counter this by further skewing the way they present the information so as to justify their actions. In some instances, dollar amounts of remuneration are not specified but instead are lumped into broad categories that are difficult to pin down. For disclosure to be most meaningful, exact dollar amounts and value of materials should be disclosed.

There may also be an unexpected and paradoxical effect on a patient who is told about a physician's, educator's, researcher's, or author's conflict of interest. The disclosure might engender unwarranted trust that would reduce the patient's scrutiny. In addition, transference is a powerful emotional force between patient and physician. In order to act as a "good" patient and avoid the appearance of distrust, the patient may be less, rather than more, inclined to choose another option or seek a second opinion.

In theory, divestiture is the preferred way to manage conflicts. Nevertheless, at this time, despite its limitations, disclosure is attractive as a practical way to manage conflict. However, disclosure needs to be more specific, more rigid, and strictly enforced.

RECUSAL

Conflicted individuals are expected to recuse themselves (i.e., abstain from decisions) when a conflict exists. The imperative for recusal varies depending on how the circumstances of the case might implicate common-sense ethics, codified ethics, or state statute.

SPECIFIC CONFLICTS OF INTEREST

CONSULTANTS AND ADVISORY BOARDS

Background: Consultants to industry are essential, and it is ethical for physicians to participate. Consultants can make significant contributions to medical care and innovation. However, consultants can be either true experts or “token” consultants who are selected because they are high users or potential users of a drug, product, or medical device. Consulting for multiple competing companies does not mitigate the bias.

Recommendations: Consultants should be thought leaders with expertise that is recognized by their peers. They should bring something of value to a pharmaceutical or device manufacturer by virtue of an invention, innovation, published research or reviews, or extensive clinical expertise at minimum. There should be a written contract between the consultant and the company with details of the deliverable work product and time lines clearly defined. Payment should be fair and reasonable, commensurate with the value of the work product, and represent fair market value for time and intellectual property.

CONTINUING MEDICAL EDUCATION

Background: The goal of CME is to provide objective medical information to physicians to improve patient care. Industry can and does play a large, legitimate, and significant role in CME. It is ethical, reasonable, and necessary for physicians, institutions, and organizations to rely on funding from industry for purposes of education. However, CME programs must follow strict guidelines to minimize industry influence on CME content to ensure public confidence.

Recommendations: CME programs must be conducted independently of any content input from industry. It is preferred that CME be at formal organizational meetings, not just at those that are marketing events for industry, especially if there is only one company involved or if a commercial interest pays for tuition, travel, and lodging of attendees. Speakers should be thought leaders in their field with established expertise on the specific subject based on their research, publications, and experience. Speakers must stringently adhere to the latest Accreditation Council for Continuing Medical Education

(ACCME) guidelines. Lectures should be free of specific product endorsements and brand names. They should be evidence-based and well referenced. With rare exception for specialized, technical images, audiovisuals should be created by the speaker and neither created nor edited by the corporate sponsor. Industry representatives should have no say in the lecture content.

Speakers should be funded by the CME provider organization, not directly by any company. Industry can contribute to a central fund, which acts as a firewall, to subsidize the costs of the overall meeting. Attendees at conferences should not be funded by industry. It is ethical for speakers to receive funding for travel, basic expenses, hotel, and a reasonable honorarium, but conflicts of interests are better managed when the immediate source of the funds is the conference sponsor rather than an identifiable, private source.

SPEAKERS BUREAUS

Background: Speakers are an essential part of the CME process. However, there is the danger of bias when speakers have direct industry support. Speakers should not be local physician “opinion leaders” or simply high prescribers or users of a drug or product.

Recommendations: The recommendations for speakers are those outlined above for CME.

MEETINGS WITH SALES AND MARKETING REPRESENTATIVES OF PHARMACEUTICAL COMPANIES AND DEVICE MANUFACTURERS

Background: Sales and marketing representatives of pharmaceutical companies and device manufacturers engage in marketing; the primary goal of which is to influence a physician’s prescribing practices or the use of a product. Some physicians receive a significant amount of their medical information about drugs and devices from these representatives, although it is well recognized that this information is very biased.

It is very well established that gifts, even of small items, including free lunches, have significant influence on physician prescribing. With the considerable opportunity for physicians to receive unbiased knowledge updates on-line and at formal medical meetings, the “educational” value of the pharmaceutical representative is doubtful.

The role of samples is more complex, but merits careful thought. So-called free samples are not really free. Samples create a bias to prescribe the medication to patients. Some good can come from providing indigent patients with medications they are not able to obtain through usual pharmacy sources, but it is rare that the newer medications are significantly better than the less expensive alternatives.

Recommendations: The only absolute means to prevent influence from contact with sales and marketing pharmaceutical representatives is for physicians to eliminate visits from industry representatives and not accept gifts of any sort, including meals. The role of samples is more complex and must be individualized.

FUNDING FOR RESEARCH

Background: It is ethical, reasonable, and necessary to accept funding from industry for research. Researchers must understand the complex and inherent biases involved. Industry-funded research maintains an implicit expectation of positive findings. Research design may favor the company's product. Ghost authors may be hired to write an industry-sponsored paper, but private practice physicians or academic physician researchers might be solicited to appear as the "author," (i.e., simply have their name put on the paper). In multicenter studies, data submitted to a central depository are controlled by a company and may not be available for all the researchers to review. That company, in turn, can be hired by the funding source and, thus, has conflicts of its own. There are a disproportionate percentage of positive findings in research funded by industry. Studies with negative findings are often not submitted.

Recommendations: All prospective randomized-controlled studies should be registered. They must be reviewed by an institutional review board (IRB) at which those with conflicts of interest recuse themselves.

A physician should not claim authorship unless he or she has made a significant intellectual contribution to the research and/or writing of the manuscript. The primary author must accept responsibility for the conduct of the study, have access to the data, and control the decision as to whether, when, and where to submit the manuscript. In a manuscript, full disclosure for each author must be stated. Researchers should not accept "ghost writers." Physicians should not allow industry to have the right to prevent an author from submitting a manuscript for publication. Academic researchers who are primary equity holders may need to have their involvement in the research project considerably limited or they might need to divest their holdings entirely.

INSTITUTIONAL REVIEW BOARDS (IRB)

Background: Some IRB members think relationships with industry can be beneficial when reviewing research protocols because of the knowledge obtained by the relationship with industry. More than one-third of IRB members have relationships with industry and 15% have had protocols presented to their IRBs that were sponsored by a company with which they had a relationship. Most, but not all were disclosed. More than half of IRBs have no formal disclosure system.

Recommendations: IRBs should have formal disclosure and recusal policies. If a conflict of interest exists with respect to an industry-sponsored research protocol, those with conflicts should not participate in the discussion or voting. Some IRBs might choose to exclude the member with a conflict of interest from the meeting during the discussion and voting, which would constitute the clearest and least ambiguous resolution.

PHYSICIAN-INVESTORS

Background: Physicians have the right to invest in publicly traded medical companies, especially through publicly traded equities or mutual funds, provided the investor has no private or insider knowledge beyond that which is known to the general public.

Recommendations: Physicians should not invest privately and directly in a company for which they are conducting research, unless the physician is uniquely skilled in the procedure and it is unreasonable that someone else can be trained instead. Physicians should not invest privately in companies if it is possible that they will speak or write for any of that company's products.

FURTHER RECOMMENDATIONS

The only definitive remedy for conflicts of interest is to eliminate them, but in many instances this is neither possible nor practical. Therefore, a more reasonable approach is to identify conflicts of interest and to accept the fact that conflicts exert influence, may create bias, and might influence physician behavior. It is necessary to develop responsible means to mitigate their effects. It must be accepted that although we cannot exercise unlimited control of our instinctive behaviors, we are capable of modifying them, in part by restructuring our relationships and interactions. In addition, we can commit to the principle of practicing evidence-based medicine founded on medical evidence, which is examined and promulgated by a peer-review editorial process that systematically attempts to counteract bias.

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