No Pain, No Gain - The Agency for Health Care Policy & Research's Attempt to Change Inefficient Health Care Practice of Withholding Medication from Patients in Pain

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NO PAIN, NO GAIN? THE AGENCY FOR
HEALTH CARE POLICY & RESEARCH'S
ATTEMPT TO CHANGE INEFFICIENT HEALTH
CARE PRACTICE OF WITHHOLDING
MEDICATION FROM PATIENTS IN PAIN

Pain is perfect misery, the worst [o]f evils.¹

It is unthinkable that patients suffer needlessly when we have
the medical know-how to prevent more than half the cases of
unrelieved pain.²

The health care industry's current standard of care concerning acute
pain is to treat the pain retroactively as needed, rather than with prevent-
ative measures.³ This practice has its foundation in two long-standing
myths of western culture. The first myth is that enduring pain develops
character, making one a better, stronger, and more moral person.⁴ The
second myth is that patients will become addicted to drugs administered
for pain relief.⁵ These two social mores help form the basis of the medi-

¹. Steven Findlay, Taking Control of Your Pain, U.S. NEWS & WORLD REP., June 15,

². UCSF School of Nursing Faculty Member Helps Draft New Guideline on Pain,
New Guideline on Pain] (quoting Health and Human Services Secretary Louis W. Sullivan,
M.D.).

³. See Findlay, supra note 1, at 67 (“In ordering painkillers as needed most doctors
have simply followed the dictates of convention.”).

⁴. Id.; see also Cynthia Starr, The Politics of Pain: A New Attitude Toward Treatment,
136 DRUG TOPICS, Sept. 21, 1992, at 60, 62 (declaring false the statement that pain is neces-
sary and builds character); Pain and the Doctors, WASH. POST, Mar. 14, 1992, at A22 (“Sto-
icism is out the window.”).

⁵. See Post-Op Patients To Get More Pain Relief (National Public Radio broadcast,
Mar. 6, 1992), at 1 available in LEXIS, Nexis Library, NPR File [hereinafter NPR Broad-
cast]. “[T]here is an inherent fear among physicians of making addicts out of patients and,
as a consequence, patients are frequently underdosed.” Id. (quoting oncologist Robert
Segal). This fear is codified in the Controlled Substances Act's five categories for hazard-
ous drugs that pose varying restrictions on access to drugs depending on their “potential
for abuse.” 21 U.S.C. § 812(b)(2) (1988). However, a drug's classification becomes contro-
versial when supporters argue that the medicinal value of a drug outweighs the policy
problems surrounding the drug. See Alliance for Cannabis Therapeutics v. D.E.A., No. 92-
attempt to reschedule marijuana from Schedule I to Schedule II of the C.S.A. in order to
permit physicians to prescribe it for therapeutic purposes).
cal community's view that pain is an unavoidable and tolerable aspect of surgery, illness, injury, and dying.\(^6\)

In 1992, the United States Public Health Service's Agency for Health Care Policy and Research (AHCPR) released clinical practice guidelines concerning assessment and treatment of specific kinds of acute pain in different types of patients.\(^7\) The plan "affirms that everybody . . . is entitled to adequate pain relief."\(^8\) Announced on March 5, 1992, the guidelines mark the first time the United States government has published clinical advisory standards.\(^9\) The significance of the guidelines lies in their use as a procedural tool for the government, their recognition of patient autonomy, and their emphasis on the governmental interest in cost-effective health care.\(^10\) The guidelines are an outgrowth of the expansion of the hospice philosophy, the Patient Self-Determination Act of 1990,\(^11\) and the role of physicians as gatekeepers.\(^12\) These three developments brought the themes of adequate pain relief, patient self autonomy, and efficient resource allocation to the forefront of health care policy issues.\(^13\)

Proponents of the hospice philosophy, legislators, and bioethicists rec-

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6. See Findlay, supra note 1, at 67. "Most doctors learn to give pain drugs only as needed, even though research has shown that people do not become addicted to morphine when it is given for a short period . . . ." NPR Broadcast, supra note 5, at 1. Patients need to know that "pain is not a normal part of recovery." Id.


8. Starr, supra note 4, at 60.

9. Id. (quoting Arthur Lipman, professor of clinical pharmacy and member of the AHCPR's Acute Pain Management Guideline panel). "Nobody tells people how to practice medicine in this country." Id.

10. See id. at 60 (describing the "brand new era" for health care concerning government sponsored advice and government's "major financial stake in cost-effective health care"); see also Agency For Health Care Policy and Research, U.S. Dept. of Health & Human Services, PUB. No. 92-0032, CLINICAL PRACTICE GUIDELINE, ACUTE PAIN MANAGEMENT: OPERATIVE OR MEDICAL PROCEDURES AND TRAUMA 2 (1992) [hereinafter CLINICAL PRACTICE GUIDELINE] ("[t]he importance of effective pain management increases beyond patient satisfaction when additional benefits for the patient are realized, e.g., earlier mobilization, shortened hospital stay, and reduced costs").


12. For a thoughtful discussion on the concept of medical gatekeeping, see Edmund D. Pellegrino, M.D., Rationing Health Care: The Ethics of Medical Gatekeeping, 2 J. CONTEMP. HEALTH L. & POL’Y 23 (1986). Dr. Pellegrino defines a gatekeeper as "the designated guardian of society's resources." Id.

13. See infra notes 80-117 and accompanying text (discussing each of the three developments in health care and their important themes echoed by AHCPR's guidelines).
ognize the need to balance the cost-effective treatment of pain with patient autonomy. AHCPR is "charged with improving the quality, appropriateness, and effectiveness of healthcare services." This Comment considers whether AHCPR's practice guidelines on pain will bring about such change and strike the crucial balance between effectiveness and efficiency in pain treatment. This Comment discusses AHCPR's historical development, goals, and procedures, and summarizes the agency's eight clinical recommendations for pain management. This Comment examines the philosophical developments in hospice care, patient advance directives, and medical gatekeeping that form the backdrop for AHCPR's recommendations for pain management. Arguments supporting and criticizing the practice guidelines on pain are then addressed. This Comment concludes that AHCPR is positioned to serve as an effective catalyst for health care change because the agency strikes the crucial balances between patient and medical provider, and between cost and quality.

I. HISTORY AND GOALS OF THE AHCPR

On December 19, 1989, Congress passed the Omnibus Budget Reconciliation Act of 1989, which established the Agency for Health Care Pol-

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14. See, e.g., NPR Broadcast, supra note 5, at 1. Anesthesiologist Daniel Carr asserts that contemporary treatment results in unnecessary pain because health care providers only prescribe painkillers when patients request them:

   By the time the patient . . . pushes the nurse call button, they're already in pain. The nurse either has to go to the patient's room or ask over the intercom what the problem is, come in, assess it, then go look at the medication book and see what are her options for responding to that need. Then she has to find the key to the controlled substances closet, if the medicine is, let's say, eight milligrams of morphine. Morphine comes in 10-milligram tubes. [He or she] has to find another nurse to witness . . . discarding two milligrams, then they both have to sign on a document that this was done. Then she goes back to the patient, gives a shot into the patient's muscle and, after a number of minutes, let's say 15 or 20 minutes, that's absorbed into the patient's blood.

Id.

15. Starr, supra note 4, at 60; see Warren E. Leary, More Advice for Doctors: U.S. Guides on Treatments, N.Y. TIMES, Apr. 15, 1992, at C14. Dr. J. Jarrett Clinton, director of AHCPR, states: "We serve as a catalyst . . . We have gotten groups that normally don't talk to each other to join around our table and determine what is best for patient care." Id. Furthermore, the guidelines are supposed to "lay out options for care rather than picking certain practices as standards from which health workers should not deviate." Id.; see also Clark W. Bell, Embrace Practice Guidelines, MODERN HEALTHCARE, Apr. 13, 1992, at 44 ("It's time to get serious about assessing the value of practice guidelines as a method of containing costs and improving quality of hospital care.").
icy and Research. 16 AHCPR replaced the National Center for Health Services Research and Health Care Technology Assessment, a subsidiary of the United States Public Health Service (PHS). 17 The enabling statute directs AHCPR to lead research projects in two distinct areas. 18 First, to achieve the goal of improving "the quality, appropriateness, and effectiveness of health care services," 19 AHCPR is authorized to continue traditional research focusing on "health care services and procedures. " 20 Second, Congress authorized AHCPR to carry out new research to evaluate different treatments to determine which are most effective, and to publish the results as clinical practice guidelines. 21 This new area of research balances the effectiveness of a health care service against the cost


18. Raskin & Maklan, supra note 17, at 162.


The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

Id.; see also Agency for Health Care Policy and Research, Fact Sheet, AHCPR-Commissioned Clinical Practice Guidelines, Jan. 1992, at 1 (emphasizing that improving effectiveness is the primary responsibility of the agency) [hereinafter Fact Sheet].

20. 42 U.S.C. § 299(a)(2) (Supp. III 1991); see also Raskin & Maklan, supra note 17, at 162 (stating AHCPR will continue the work of the National Center for Health Services Research & Health Care Technology Assessment).


AHCPR was created because we believe that the Federal government has a responsibility to provide leadership in the conduct of health services research - research that is essential to the formation of sound public health policies. Without better information and analysis about health care quality, access, costs, and outcomes, we cannot expect to manage our health care system effectively.

Two conceptual premises underlie Congress' determination that clinical practice guidelines are necessary and effective to bring about needed change in the health care system. First, there is a correlation between variations in health care practices and differences in patient outcomes. Second, health care practices will change if scientific evidence showing their inappropriateness is provided to patients and care providers. The syllogism is simple: studying inconsistent treatments will provide scientific proof that certain practices are inappropriate. Dissemination of the studies' results in the form of practice guidelines serves as a catalyst to needed change.

The practice guidelines are developed and overseen by AHCPR's Office of the Forum for Quality and Effectiveness in Health Care (Forum). First, the Forum selects guideline topics. A number of factors are weighed to determine which health conditions to research. Once a topic is selected, the Forum convenes a panel of experts representing a wide variety of health care providers and consumer representatives. After the AHCPR administrator selects the chair(s) and appoints the nominees, the panel organizes a methodology for developing the guide-

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22. Raskin & Maklan, supra note 17, at 185 n.2 (the agency's publication advocates evaluating whether the health benefit exceeds the risk or negative consequences by a healthy margin); see 42 U.S.C. § 299a(a)(5) (Supp. III 1991) (stating that guidelines should be developed with respect to "health care costs, productivity, and market forces"); see also 42 U.S.C. § 299(b) (Supp. III 1991) (using the term "appropriateness" to prescribe a balancing test).

23. H.R. REP. No. 247, supra note 17, at 2102. "Research on primary care, particularly research based in clinical practice, is another area of health care that has not received adequate attention." Id.

24. Raskin & Maklan, supra note 17, at 164.


27. See 42 U.S.C. § 299a-2(b)(2) (Supp. III 1991). The Administrator must consider "safety, efficacy, and effectiveness, and as appropriate, the cost-effectiveness, legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographical factors." Id.; see also Fact Sheet, supra note 19, at 2 (commenting that these factors include: adequacy of scientific evidence about the condition, amount of people affected by a condition, probability of being able to reduce variations in treatment associated with it, Medicare and Medicaid need, and cost of the condition to all payers).

28. See 42 U.S.C. § 299b-2(c) (Supp. III 1991). Panelists may include physicians, specialists, nurses, or other health care experts. Fact Sheet, supra note 19, at 2. Nominations for panelists are received after an announcement in the Federal Register. Id.

The project's scope and goals must be defined according to what scientific evidence needs to be examined. Using the scope and goals as a "road map," the panel assesses the clinical benefits and harms indicated from the scientific evidence. Next, a public forum, announced in the Federal Register, provides the opportunity for open discussions about the health care policy issues raised by the project. The final guidelines are prepared following public participation. Finally, the guidelines are widely disseminated to inform patients, physicians, and health care providers of the appropriateness of treatment options.

The clinical practice guidelines are not intended to serve as "cookbook medicine" mandating specific treatments and interfering with the relationship between doctor and patient. Instead, the guidelines are intended to be a useful tool "to enhance the critical decisions of the provider and patient in each health care encounter." The purpose of the guidelines is not to force doctors to practice according to a set formula, but to empower patients to make informed decisions about treatment.

II. A "NEW" APPROACH TO RELIEF FROM PAIN

One of the first practice guidelines issued by AHCPR concerned post-operative and injury-related pain control. In reaching a "new" approach to relief from pain, an eighteen member panel co-chaired by

32. Fact Sheet, supra note 19, at 2.
33. Id.
34. Id.
35. See 42 U.S.C. § 299b-3(c) (Supp. III 1991); 42 U.S.C. §§ 299a-1(a)(1)-(2) (Supp. III 1991); Raskin & Maklan, supra note 17, at 174 (describing the process of dissemination as strategic use of scientific methods to inform physicians, patients and health care providers about study findings).
36. Leary, supra note 15, at C14. The guidelines lay out options for care rather than choosing certain practices as standards from which health workers should not deviate. Id.
37. Raskin & Maklan, supra note 17, at 185.
38. Barry Meier, Rx for a System in Crisis, N.Y. TIMES, Oct. 6, 1991 (Magazine), at 18 (noting that providing outcome research will "empower patients to make informed choices about their treatment options").
39. Aggressive Pain Management, supra note 7, at A-16; see, e.g., Milt Freudenheim, Business and Health; Combating Waste in Medical Care, N.Y. TIMES, Sept. 3, 1991, at D2 (naming the acute pain management guideline AHCPR's first).
40. The approach is not "new" to the extent that for a few decades United States hospices advocated the preventative treatment of pain over "as needed" treatment. Starr, supra note 4, at 61.
Daniel B. Carr\(^{41}\) and Ada K. Jacox\(^{42}\) as well as sixteen other representatives from the private sector studied the variations in clinical treatment of pain, technical articles on pain relief, and also considered the personal experiences of the panelists.\(^{43}\) The panel determined what was the most effective treatments and released a unique practice guideline\(^{44}\) outlining eight suggestions to improve the quality and efficiency of pain control.\(^{45}\) These eight recommendations attempt to strike the crucial balance between health care provider control and patient autonomy.\(^{46}\)

A. **Summary of AHCPR's Practice Guideline for Treatment of Pain**

Recognizing that "[i]t is unthinkable that patients suffer needlessly when we have the medical know-how to prevent more than half the cases of unrelieved pain,"\(^{47}\) the Secretary of Human Health Services, Louis W. Sullivan, issued eight recommendations for more aggressive pain control in one of AHCPR's first clinical practice guidelines.\(^{48}\) First, physicians should communicate the importance of effective pain relief to their patients and provide them with an opportunity to make informed decisions.

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41. Dr. Daniel B. Carr is the director of the Division of Pain Management, Department of Anesthesia, at Massachusetts General Hospital. **Clinical Practice Guideline**, *supra* note 10, at v.

42. Ada K. Jacox, RN, FAAN, is the Independence Foundation Chair in Health Policy at The Johns Hopkins University School of Nursing. *Id.*


44. *Id.* One writer describes the AHCPR guideline as unique: While over 10,000 guidelines have been developed in the history of medical practice, AHCPR's pain management guideline is considered unique because it was developed by an [eighteen]-member panel of pain management experts, including a surgeon, a primary care physician, nurses, an anesthesiologist, a medical ethicist, and a consumer/patient. *Id.*

45. **New Guideline on Pain**, *supra* note 2, at 2; *see infra* Part II. A. and accompanying notes (discussing the eight suggestions).

46. *See supra* notes 36-38 and accompanying text (describing the balancing test); *see also* Wendy M. Margolis, Comment, *The Doctor Knows Best? Patient Capacity for Health Care Decision Making*, 71 Or. L. Rev. 909, 910-913 (1992) (describing the evolution of the doctor-patient relationship as one from paternalism to self-determination); Clark C. Havig-hurst, Practice Guidelines for Medical Care: The Policy Rationale, 34 St. Louis U. L.J. 777, 801 (1990) (asserting that the expectation that consumers will be able to make choices within the various guidelines is unrealistic).


free of the myths concerning pain. Second, physicians should chart a patient's pain intensity and level of pain relief, keeping it close at hand for reference by doctor and patient. Suggested methods of pain intensity measurement include a descriptive words scale, a numeric ratings scale, and a poker chip assessment method for use with pediatric patients. Third, hospitals should establish a threshold pain intensity level that triggers an institutional review to determine how well the patient's

49. Clinical Practice Guideline, supra note 10, at 75. The first recommendation states that:

[patients should be informed before surgery, verbally and in printed format, that effective pain relief is an important part of their treatment, that talking about unrelieved pain is essential, and that health professionals will respond quickly to their reports of pain. It should be made clear to patients and families, however, that the total absence of any postoperative discomfort is normally not a realistic or even a desirable goal.]

Id.

50. Id. The second recommendation states that:

[a] simple assessment of pain intensity and pain relief should be recorded on the bedside vital sign chart or a similar record that encourages easy, regular review by members of the health care team and is incorporated in the patient's permanent record. The intensity of pain should be assessed and documented at regular intervals . . . . The degree of pain relief should be determined after each pain management intervention . . . .

Id. Recognition of the importance of assessing, charting, and visually displaying (or objectifying) the patient's pain is crucial, because it acknowledges the significance humans place on the ability to quantify and measure something abstract in order to understand it and make it real. Martin Heidegger writes: "That is real which can be measured." This means that the decision about what may pass in science . . . for assured knowledge rests with that measurability supplied in the objectness of nature and, in keeping with the measurability, in the possibilities inherent in the measuring procedure." Martin Heidegger, Science and Reflection, in THE QUESTION CONCERNING TECHNOLOGY AND OTHER ESSAYS 155, 169 (William Lovitt trans., 1977) (quoting Max Planck).

51. See Clinical Practice Guideline, supra note 10, at 116-117 (reproducing a number of pain intensity or pain distress scales). The descriptive words scale for pain distress gives the patient choices to describe distress ranging from none to horrible and agonizing. Id. at 117. Another scale offers choices for intensity of pain ranging from "no pain" to "worst possible pain." Id. at 116.

52. The Appendix also prints a number line option to chart pain with zero equal to "no pain" and ten as "unbearable pain." See id. at 117 (printing a number line option to chart pain distress with zero equal to "no pain" and ten equal to "unbearable pain").

53. Id. at 121.

54. Because "[c]hildren are likely to talk less about pain than adults," the guideline lists specific devices to assess the child's pain. Id. at 54. The poker chip technique instructs health care providers to use four red poker chips and tell the child that "[t]hese are pieces of hurt." Id. at 121. For example, a nurse would explain to the child that one chip is "a little bit of hurt" and all four chips are "the most hurt you could ever have." Id. Because children often do not talk about their pain, the burden is on the health care provider to use vigilant means of assessing the situation. Id. at 54.
condition is being treated. Fourth, the agency recommends management of pain measured by periodical sampling of clinical unit patients' satisfaction. Fifth, unless contraindicated, patients should be prescribed anti-inflammatory drugs in combination with opioid drugs. “Rescue” doses should be allowed if the first two drugs administered are ineffective. Sixth, patient controlled dosing of painkillers is recommended if accompanied by special policies that limit care provider liability. Seventh, alternative pain control methods should supplement drug use rather than replace it. Finally, hospitals should regularly assess the efficiency of their programs.

55. *Id.* at 75. The third recommendation states that “[e]ach institution should identify pain intensity and pain relief levels that will elicit a review of the current pain therapy, documentation of the proposed modifications in treatment, and subsequent review of its efficacy.” *Id.; see also infra notes 59, 67* (discussing a patient’s significant role in this stage).

56. **Clinical Practice Guideline, supra** note 10, at 75-76. “At regular intervals defined by the clinical unit and quality assurance committee, each clinical unit should assess a randomly selected sample of patients who have had surgery within 72 hours.” *Id.* at 75.

57. *Id.* at 76. “Unless contraindicated, every patient should receive an around-the-clock postoperative regimen of an NSAID [nonsteroidal anti-inflammatory drug].” Analgesic drug treatment should combine non-opioid “peripherally acting” analgesics on an around-the-clock basis with opioid analgesics that are individualized to the particular patient. **Clinical Practice Guideline, supra** note 10, at 76. Morphine and Demerol are two opioid drugs commonly used in the United States for acute pain relief. *Id.* at 17-18. Heroin is another effective opioid for pain relief, but due to its illegal status, it is barred from widespread use for the treatment of pain. Suzanne Marcus Stoll, Comment, *Why Not Heroin? The Controversy Surrounding the Legalization of Heroin for Therapeutic Purposes*, 1 J. Contemp. Health L. & Pol'y 173, 176 (1985).

58. **Clinical Practice Guideline, supra** note 10, at 76.

59. *Id.* The AHCPR guideline states:

[specialized analgesic technologies, including systematic or intraspinal, continuous or intermittent opioid administration or patient controlled dosing, local anesthetic infusion, and inhalational analgesia . . . should be governed by policies and standard procedures that define the acceptable level of patient monitoring and appropriate roles and limits of practice for all groups of health care providers involved. The policy should include definitions of physician and nurse accountability, physician and nurse responsibility to the patient, and the role of pharmacy.]

*Id.* Patient controlled dosing, termed Patient Controlled Analgesia (PCA), is “a technique that allows patients to self-administer strong agents such as meperidine and morphine.” Starr, *supra* note 4, at 76. PCA’s often have valves that ultimately limit the amount of anesthesia which will enter the blood stream at any given time. **NPR Broadcast, supra** note 5, at 1.

60. The panel acknowledged that alternative pain relief exercises provide the significant advantage of placing the patient in an active role with respect to his or her own pain. **Clinical Practice Guideline, supra** note 10, at 76.

61. *Id.* The guideline recognized that methods should supplement each other, not eclipse alternate recommendations.

[Cognitive and behaviorally based interventions include a number of methods to help patients understand more about their pain and to take into an active part in the treatment process. *Id.*]
cacy of the first four recommendations.62

These eight recommendations are inspired by AHCPR’s concern for improving the quality, effectiveness, appropriateness, and efficiency of health care. The AHCPR panel advocates preventative drug therapy rather than the conventional “as needed” approach, because under the former approach patients recover more quickly and with less expense.63 The panel notes: “physiological studies confirm long standing clinical impressions that established pain is more difficult to suppress.”64 Health care providers “should encourage patients to request pain medication before the pain becomes severe and difficult to control,”65 because preventative pain treatment results in “earlier mobilization, shortened hospital stay[s], and reduced costs.”66 Patient controlled dosing67 is recommended because patients prefer it to intermittent injections,68 and patient satisfaction speeds recovery time.69 Finally, AHCPR squarely ad-

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62. Id.
63. Id. at 5. The panel cited studies concluding that pain is enhanced without treatment, and encouraging “patients to request pain medication before the pain becomes severe and difficult to control.” Id.
64. Id.
65. Id.
66. Id. An “as-needed” order for administering drugs may result in longer hospital stays because of “prolonged delays while the nurse unlocks the controlled substances cabinet and prepares the drug for administration and until the drug takes effect.” Id. at 19.
67. One patient detailed her personal experience with PCA’s:
It’s bad enough being sick in the hospital, confined to a bed with tubes running out you. But then there is the pain, which often frightens and demoralizes patients, people like Sally Allman of Alexandria, Virginia . . . Still, the pain has not been nearly as bad as Sally Allman expected, thanks to a small push-button control she holds tightly in one hand. [Allman explains] . . . [t]hat means that a certain amount of medicine—in my case morphine—has been released into the tube. And as long as you keep doing that at fairly frequent intervals, you really don’t feel very much pain. So this gives you a little bit more feeling of control that you’re able to help yourself.
68. CLINICAL PRACTICE GUIDELINE, supra note 10, at 21. One reason might be because patients felt a greater sense of self-determination and autonomy over their treatment with PCA’s than with intermittent injections. See, NPR Broadcast, supra note 5, at 1-2.
69. CLINICAL PRACTICE GUIDELINE, supra note 10, at 21 (describing patients who are able to self-medicate with PCA’s as having less pain and more satisfied with the pain relief and stating that these patients tend to be discharged earlier from the hospital compared with those given the same drug on an “as-needed” basis). One pain panel member noted:
A major advance in pain control is patient-controlled analgesia [PCA], a tech-
dresses the addiction myth, finding that addiction to morphine or Demerol is extremely rare when administered for less than ten days for post-operative and injury-related pain.\textsuperscript{70} Therefore, the AHCPR calls for a re-education of health care professionals and patients to debunk the myths and exaggerated fears regarding opioids.\textsuperscript{71} Although the side effects associated with opioids must be taken into account, technical competence and knowledge of the drugs' benefits should reduce many of the conflicts that clinicians face when deciding which treatment course to recommend for pain management.\textsuperscript{72}

B. The Harbingers of Change

Although the AHCPR’s recommendations concerning acute pain management are inconsistent with the conventional treatment of pain and contrary to cultural myths regarding pain,\textsuperscript{73} the AHCPR’s position is not novel. For example, a North Carolina court recently held for plaintiffs in an action against a long term care facility that weaned a cancer patient off a technique that allows patients to self-administer strong agents such as meperidine and morphine. Not only does PCA provide relief from pain, it also allows patients to exercise their full dignity as people . . . [I]t’s important to recognize that the patient has to be in charge of his own well-being.

Starr, supra note 4, at 72, 76 (quoting C. Richard Chapman, pain panel member).

\textsuperscript{70} Findlay, supra note 1, at 67-68 (citing scientific studies showing 1 in 3000 patients at risk of developing addiction to drugs after treatment for ten days); see also Take Away the Pain, HARTFORD COURANT, May 9, 1992, at D8 (finding that physicians’ reluctance to use morphine due to fear of addiction is unfounded).

\textsuperscript{71} See Starr, supra note 4, at 76.

\textsuperscript{72} CLINICAL PRACTICE GUIDELINE, supra note 10, at 4-5; \textit{but see} David G. Silverman, M.D., Letter to the Editor: Complete Pain Relief Isn’t Always Possible, N.Y. TIMES, Apr. 3, 1992, at A28. It is argued that the side effects of analgesics need to be taken into account:

\[a\]lthough aggressive pain management may have short term and long term benefits, potent analgesics such as morphine must be administered judiciously. Their administration is often associated with nausea and vomiting; not uncommonly, patients elect to accept some pain, rather than incur increased nausea. Furthermore, narcotics may cause dangerous respiratory depression . . . [T]o avoid undue disappointment, patients should realize that complete pain relief is not always attainable and in addition, because of the potential side effects, does not always mean the best therapy.

Id.

\textsuperscript{73} See CLINICAL PRACTICE GUIDELINE, supra note 10, at 4. “Unfortunately, clinical surveys continue to show that routine orders for intramuscular injections of opioid ‘as needed’ will leave more than half of postoperative patients with unrelieved pain due to undermedication.” \textit{Id.} (citations omitted).

\textsuperscript{74} See \textit{supra} notes 3-6 and accompanying text (discussing the cultural myths surrounding pain).
analgesics, thereby subjecting the individual to acute pain.\textsuperscript{75} Although this case did not involve post-operative or trauma-causing pain, this case illustrates changing notions regarding the use of opioid analgesics for pain relief.\textsuperscript{76} The AHCPR panel’s recommendations were also foreshadowed by other health law policies, including the hospice movement’s emphasis on preventative medication,\textsuperscript{77} the idea of patient autonomy incorporated in the Patient Self Determination Act of 1990,\textsuperscript{78} and the bioethical concept of medical gatekeeping.\textsuperscript{79}

1. Preventative Dosing and the Hospice Philosophy

The hospice movement, originally developed for terminally ill patients, is a forerunner of the AHCPR’s preemptive pain control recommendation.\textsuperscript{80} The hospice philosophy differs from traditional health care treatment in its emphasis on the role of effective pain relief.\textsuperscript{81} Pain relief is central to the hospice mode of care. The chronic, intractable pain of many terminal illnesses, particularly cancer, can leave an individual physically drained, emotionally spent.

\textsuperscript{75} Daniel Q. Haney, Control of Pain Gains Priority in Cancer Treatment Centers; Medicine: More and More Doctors are Paying Attention to Patients’ Discomfort, L.A. TIMES, Mar. 15, 1992, at A-1 (noting that the patient’s family was awarded 15 million dollars from the nursing home).

\textsuperscript{76} Id. Professor Michael Heller, University of Pittsburgh School of Medicine, describes this case as the first time that not relieving someone’s pain was considered a “suable offense”. Id.

\textsuperscript{77} See infra notes 80-90 and accompanying text (discussing hospice’s philosophy in support of preventative medication).

\textsuperscript{78} See infra notes 91-103 and accompanying text (overview of the Patient Self Determination Act of 1990).

\textsuperscript{79} See infra notes 104-17 and accompanying text (discussing the bioethics of medical gatekeeping).

\textsuperscript{80} Starr, supra note 4, at 61.

There has been tremendous acceptance of hospice care in the United States. From the first American hospice in 1974, there are now approximately 1700 hospices serving 200,000 patients per year. There has also been a growing interest and understanding by the medical profession in pain and symptom control and appropriate palliative care.


\textsuperscript{81} Crowley, supra note 80, at 302-03. One difference between a hospice and a hospital is the focus of care provided by the two. While hospitals focus on providing curative care, hospices emphasize palliative care, care that tends to alleviate pain without actually curing it, because their patients are facing impending death. Id. at 295-96.
and thoroughly depressed. [Hospice physicians have] long advocated the vital role of pain relief in the care of the terminal patient and [are] pioneer[s] in the use of polypharmacy as part of the palliative care provided such patients. Providing drugs to patients on a regular basis has proven to be successful in preventing pain from occurring instead of relieving it once it has occurred.82

Accordingly, the hospice philosophy is a harbinger for the effective treatment of post-operative trauma pain in two important ways. First, the hospice movement advocates the use of combined medications, for example combining peripherally acting medications with opioid analgesics.83 Second, the hospice movement recommends administering drugs on a preemptive basis rather than an “as needed” basis.84 These two approaches to health care are echoed in the AHCPR’s recommendations for post-operative pain relief.85 The AHCPR’s fifth recommendation suggests combining opioids with non-opioids to maximize patient comfort.86 Likewise, the AHCPR observes that “prevention is better than treatment.”87

Beyond emphasizing the importance of preventative dosing for effective palliative care, the hospice movement advocates dispelling the myth that pain is a necessary character building aspect of life.88 A hospice expert writes: “[T]he pain that too often comes with terminal illness is an utter waste. It does not serve to warn, or to instruct. Instead, it simply blots out . . . all ability to perceive, to think sanely, or to be in any way master of the situation.”89 The AHCPR’s attempt to change the outdated social myths regarding acute pain control mirror the hospice ap-

82. Id. at 303 (footnotes omitted). Polypharmacy is the combined use of different drugs in one situation to maximize pain relief and alertness. Id. at 303 n.65.
83. Id. at 303.
84. Id. at 302-04; see generally Starr, supra note 4, at 61. “Interest in the treatment of pain began to intensify during the past two decades with . . . the growth of the American hospice movement.” Id.
85. See supra notes 49, 57 and accompanying text (discussing the first and fifth recommendations).
86. CLINICAL PRACTICE GUIDELINE, supra note 10, at 76.
87. Id. at 5; see also Crowley, supra note 80, at 303 (stating that preemptive dosing is more effective than “as needed” treatment).
89. Id. at 140.
proach to care for the dying in this respect.


The Patient Self-Determination Act of 1990 (PSDA) is a federal fore-runner to AHCPR's pain control practice guideline. In the PSDA, Congress "recognized the individual's basic right to control the course of her own medical treatment." The PSDA attempts to increase public awareness of individuals' state-law rights to play a significant role in the decision making process. It also stresses the importance of advance directives and promotes their use. Advance directives are defined as any "written instruction, such as a living will or durable power of attorney for health care . . . ." One purpose of advance directives is to return the right to refuse treatment to the patient, thereby enhancing the patient's role in the decision making process. The PSDA attempts to increase public awareness of their rights, advance directives and to promote their use. Dissemination of information by federal and state governments on advance directives is now required. States that fail to comply with the mandates of the PSDA risk losing Medicare and Medicaid funding. Enhancing the flow of information regarding living wills and proxies ben-

90. See Starr, supra note 4, at 61.
93. Margolis, supra note 46, at 915.
94. Id.
95. Refolo, supra note 92, at 457. "By disseminating information about advance directives, the PSDA attempts to take the decision-making role away from the third party and ensure that the decisions uphold the interests of the patient, the families, and the physicians in each case." Id. at 469.
96. 42 U.S.C. § 1395cc(f)(3) (1988 & Supp. II 1990). A broad definition of advance directives includes "any statement made by an individual, while competent, of the individual's preferences for any treatment decision, or for the process of decision-making, in the event the person loses the ability to make decisions." Id. (quoting AMERICAN BAR ASS'N, COMM'N ON LEGAL PROBLEMS OF THE ELDERLY, PATIENT SELF-DETERMINATION ACT STATE LAW GUIDE, 16 (1991)). This broad definition was limited by the Patient Self-Determination Act to only include written instructions recognized under applicable state law. See 42 U.S.C. § 1395cc (f)(1)(A)(i) (1988 & Supp. II 1990) (for example, a living will, proxy, or power of attorney). Informal oral instructions made by individuals to their doctors are not included within the PSDA. Refolo, supra note 92, at 455 n.2.
97. Id. at 468.
98. Refolo, supra note 92, at 457.
99. Id. at 468.
100. Id. at 457. The PSDA is uniquely able "to compel states to work for increased
benefits society. "[The PSDA] benefits the people both individually and collectively. In an individual capacity, it promotes a person's right to choose to end his life; in a collective capacity, it promotes the public's rights by decreasing wasted resources that result from unwanted and unnecessary medical treatment."101

The policy underlying the PSDA is similar to the underpinnings of the AHCPR's pain control recommendations.102 First, the AHCPR guidelines instruct health care providers to allow patients to voice preferences when the health care providers are implementing a post-operative pain plan.103 This instruction is similar to the PSDA's advocacy of advance directives. Secondly, the AHCPR guidelines and the PSDA both promote change within the health care community by recognizing the importance of patient autonomy and the patient's right to make informed decisions.

3. *The Bioethical Notion of Medical Gatekeeping*

The medical gatekeeper concept is also a precursor to the approach taken in AHCPR's recommendations on pain management. Medical gatekeeping is the role physicians perform as the guardians of society's limited health care resources.104 Bioethicists disagree over what role the physician should play in allocating health care resources.105 The debate...
centers on whether rationing society's resources to reduce costs is an ethical task for the health care provider, who also has obligations to patients, herself, and society.\textsuperscript{106}

Bioethicists differentiate between three roles physicians may assume as gatekeepers: the negative gatekeeper, the positive gatekeeper, and the \textit{de facto} gatekeeper.\textsuperscript{107} The first two roles are used to describe the negative and positive financial incentives that effect a physician's allocation decisions.\textsuperscript{108} Gatekeeping decisions based on these coercive measures may result in ethically unsound situations.\textsuperscript{109} For example, negative medical gatekeeping may result in a conflict of interest\textsuperscript{110} when a "physician is

\begin{footnotesize}
\begin{enumerate}
\item 106. See Pellegrino, \textit{supra} note 12, at 23. "To what extent can, or should, the physician serve simultaneously the needs of his patients, his own interests, and those of society?" \textit{Id}. For a discussion on the implications of rationing and the articulation of views for and against resource allocation, see Jan Blustein & Theodore R. Marmor, \textit{Cutting Waste by Making Rules: Promises, Pitfalls, and Realistic Prospects}, 140 U. Pa. L. Rev. 1543, 1569 (1992)(questioning whether rule-making will cut waste in a straight forward manner because doctors are not willing to "unilaterally" stop inefficient practices); Leonard M. Fleck, \textit{Just Health Care Rationing: A Democratic Decisionmaking Approach}, 140 U. Pa. L. Rev. 1597, 1634 (1992) (pointing out that health care rationing is a moral problem requiring public participation in reaching a democratic consensus on the issue); Edward B. Hirshfeld, \textit{Should Ethical and Legal Standards for Physicians Be Changed to Accommodate New Models for Rationing Health Care?}, 140 U. Pa. L. Rev. 1809, 1845-46 (1992) (advocating retaining the present patient-interest standard of care and questioning whether rationing is necessary); David Mechanic, \textit{Professional Judgment and the Rationing of Medical Care}, 140 U. Pa. L. Rev. 1713, 1753-54 (1992) (asserting that "more stringent rationing of medical care is inevitable").
\item 107. See SMITH, \textit{supra} note 104, at 31-32. Negative gatekeeping results from the pressure on a doctor to restrict medical services. \textit{Id}. at 32. In contrast, positive gatekeeping occurs when a doctor is constrained to increase services for profit maximization. \textit{Id}. The third category of medical gatekeepers is the \textit{de facto} type:
\item 108. See \textit{id}. at 23.
\item 109. See Pellegrino, \textit{supra} note 12, at 24 (arguing "that the line of reasoning that leads to rationing and physician gatekeeping is morally unsound and factually suspect").
\item 110. \textit{Id}. at 29.
\item Efforts at cost-containment are not, in themselves, immoral, and, as noted above, are morally mandatory when in the best interests of the patient. They violate those interests if, for whatever reason, they deny needed services or induce the patient to demand, or the physician to provide, unneeded services. The ethical dilemmas of gatekeeping therefore arise out of the way economic incentives and disincentives modify the physician’s freedom to act in the patient’s behalf.
\end{enumerate}
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placed under constraints of self-interest to restrict the use of medical services of all kinds but particularly those that are most expensive.”

Similarly, in a positive gatekeeping situation, profit motive is the most important factor between a patient and doctor, and medical ethics are displaced by business considerations. Nevertheless, bioethicists recognize that physicians have certain unavoidable gatekeeping functions. “The unavoidable fact is that the physician recommends what tests, treatments, medications, operations, consultations, periods of hospitalization, or nursing homes the patient needs.” Thus, de facto gatekeeping recognizes the doctor's role in monitoring health care expenses. The AHCPR's pain management guidelines advocate health care providers functioning as de facto gatekeepers:

Health care is both a technical and an ethical enterprise. The ethical obligation to manage pain and relieve the patient's suffering is at the core of a health care professional's commitment. While medical treatments often involve risks and burdens, anything harmful to the patient, including post-operative pain, should be minimized or prevented if possible. The ethical importance of pain management is further increased when additional benefits for the patient are realized—earlier mobilization, shortened hospital stay, and reduced costs. If inadequate pain management results from a clinician's conflict between reducing pain and avoiding potential side effects and/or legal liability, achieving greater technical competence and knowledge of risks and benefits can help reduce such conflicts.

In effect, the guidelines and accompanying recommendations place economics and ethics in congruence and avoid the ethical failures in both negative and positive gatekeeping. Thus, the guidelines on pain management strike a balance between the importance of patient autonomy and the role physicians must play as de facto gatekeepers.

111. Id. at 27 (describing the negative gatekeeper role).
112. Id. at 32-33 (describing the positive gatekeeper role).
113. Id. at 26; cf. Margolis, supra note 46, at 919 (arguing that decision-making capacity should serve as a gatekeeper balancing autonomy with beneficence).
115. Id. at 27 (describing this type of gatekeeping as a “legitimate” and “morally binding responsibility” of physicians).
116. See CLINICAL PRACTICE GUIDELINE, supra note 10, at 4-5.
117. Id.
III. WILL THE AHCPR GUIDELINES BE AN EFFECTIVE CATALYST TO CHANGE?

AHCPR’s pain guidelines are criticized for both specific weaknesses and as a whole. First, the medical community has long been suspicious of developing guidelines for medical care “because of fears that they could lead to standardized ‘cookbook medicine’ that dictate specific treatments and interfere with the doctor-patient relationship.”118 Therefore, the AHCPR guidelines are criticized by some members of the medical profession as an “unnecessary intrusion” upon health care.119 There are also pragmatic questions over how the research will be used,120 because unlike the PSDA’s threats to discontinue Medicare and Medicaid funding,121 the AHCPR has no authority to enforce the guidelines once disseminated.122 In addition, opponents are specifically concerned about the pain guidelines recommendations on the use and dangers of morphine.123 For example, benign use of morphine is criticized because of its serious side effects, including nausea and respiratory depression.124

Proponents of the AHCPR guidelines argue that these criticisms are not fatal to the guidelines’ potential for improving the efficiency and effectiveness of pain management. Doctor and health care provider organizations support AHCPR’s guidelines as an encouraging “effort to reduce wasteful defensive medicine and better use health resources.”125 Supporters also note that the guidelines are a means to make patients equal partners in the decision-making process.126 In response to the “cookbook medicine” criticism, proponents emphasize that individual patients and health care providers are not forced to follow a prescribed treatment, but instead are empowered with information to make well reasoned deci-

119. Bell, supra note 15, at 44.
121. Refolo, supra note 92, at 457.
123. See Silverman, supra note 72, at A28 (illustrating the concerns regarding opioid side effects).
124. Id.
125. See Leary, supra note 15, at C14 (quoting Dr. James S. Todd, executive vice president of the American Medical Association).
126. See Findlay, supra note 1, at 68.
"Most doctors prefer patients who are informed . . . . A guideline can help patients see what the choices are and work with their doctor to make a decision."128

In response to pragmatic questions of how the guidelines should be implemented, proponents look to hospitals to "test and use" AHCPR's recommendations.129 Hospitals are the best place for the implementation of changes in pain management.130 Each hospital is in the best position to implement the AHCPR's practice guidelines by organizing teams of surgeons, nurses, pharmacists, and anesthesiologists to consult daily with patients on treatment options.131 The American Medical Association is also releasing a guide to help hospitals implement AHCPR's guidelines.132 Once hospitals begin to implement the changes in pain management, state and federal governments, and private payers133 can monitor the results to determine if the AHCPR's guidelines are an effective and efficient catalyst to change.134

The guidelines also could play a significant role within President Clinton's proposed Health Security Act.135 The Health Security Act would establish the National Health Board (NHB), an agency charged with es-

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127. See Meier, supra note 38, at 18; see also Findlay, supra note 1, at 68 (asserting that patients should have a say in the doctor's decision regarding pain relief).
129. Hudson, supra note 120, at 38. The AHCPR guidelines are generally supported, but questions remain as to how the health care providers will be able to use them. Id. "[A]mid these implementation questions, sources at the American Hospital Association, the American Medical Association and the Health Care Financing Administration agree that hospitals are uniquely positioned to test and use the government-generated data." Id.
130. Bell, supra note 15, at 44; see also Havighurst, supra note 46, at 800-01 (insisting that the AHCPR preserve pluralism by developing competing guidelines from which hospitals may choose).
131. Bell, supra note 15, at 44; see supra notes 49-62 and accompanying text for a discussion of the steps a hospital should take when implementing the clinical guidelines.
132. Bell, supra note 15, at 44.
133. The effect the clinical practice guidelines will have on private malpractice actions is beyond the scope of this Comment. For thorough discussions of the debate see Troyen A. Brennan, Practice Guidelines and Malpractice Litigation: Collision or Cohesion?, 16 J. HEALTH POL., POL'Y & L. 67 (1991) (asserting that practice guidelines will act as useful evidence towards a standard of care); cf. Edward B. Hirshfeld, Practice Parameters and the Malpractice Liability of Physicians, 263 JAMA 1556 (1990) (arguing that practice guidelines might increase liability exposure for health care providers who do not comply with them).
134. Bell, supra note 15, at 44.
tablishing national standards and overseeing the administration of the health care system.\textsuperscript{136} The NHB would function as an independent regulatory agency, similar to the Securities and Exchange Commission (SEC).\textsuperscript{137} "Under the SEC model, the [NHB] would oversee a private marketplace to ensure that rules are obeyed and that information is available so that consumers could make informed decisions on what health care coverage they needed and what it would cost."\textsuperscript{138} For example, the NHB may require regional alliances to inform customers if insurance policies and hospitals are incorporating AHCPR clinical practice guidelines into health care coverage.\textsuperscript{139}

"This vision of how guidelines might be used opens new possibilities for competition under conditions of informed consumer choice."\textsuperscript{140} In this way, an alliances' willingness to adopt the AHCPR recommendations is a factor individual consumers will consider when choosing between competing insurers.\textsuperscript{141} As one of the AHCPR's first completed clinical practice studies the guideline on acute pain management is in a prime position to change the standard of care for pain treatment at the initial stages of health care reform in the United States.

\textbf{IV. Conclusion}

The health care industry's current standard of care regarding acute pain management should be changed because it is inefficient. The myths that persist about the pain associated with operations, injuries and other traumas result in ineffective, inappropriate and inefficient treatment. The AHCPR's guidelines provide clinical guidance options to alleviate this problem by incorporating the ideals of preemptive dosing, self-autonomy and \textit{de facto} gatekeeping. In so doing, the AHCPR practice guidelines


\textsuperscript{137} Barr, supra note 136, at A4.

\textsuperscript{138} \textit{Id}.

\textsuperscript{139} H.R. 3222, supra note 136, at 2573 (listing the duties and responsibilities of the NHB); \textit{see generally} Health Care Relief for Consumers, N.Y. TIMES, Sept. 20, 1993, at A18 (stating that under the Health Security Act people "would choose an insurance policy among those made available by a regional purchasing cooperative").

\textsuperscript{140} Havighurst, supra note 46, at 800.

\textsuperscript{141} \textit{See} Health Care Relief for Consumers, supra note 139, at A18.
are a catalyst so that health care providers may implement necessary change.

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