Relieving Unnecessary, Treatable Pain for the Sake of Human Dignity

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Since 1995, the American Society of Law, Medicine & Ethics, with the generous and steadfast support of the Mayday Fund, has generated the research that is essential for changing public policy regarding effective pain relief. For all of us who have been involved since the beginning of these Mayday Projects at ASLME, this has been a labor of love and passion.

All creative work requires inspiration, and the inspiration for this body of work is the stories the patients tell of the burden of unrelieved pain. Who can listen to this parent and not feel moved:

[W]e had a good family, but how much can you watch? How much suffering can you watch from your child, your 7-year-old child, and still keep your mind?1

And so we have worked to improve the treatment of pain for all patients with a special focus on changing public policy, removing regulatory barriers, and relieving fear on the part of health-care professionals.

Although the focus of the projects has been on the legal and regulatory issues in pain management, those issues are invariably wrapped in medical, cultural, practical, and ethical concerns. Thus, this work has required all of the disciplines that converge in the American Society of Law, Medicine & Ethics. In particular, our passion for improving the care of patients in pain emerges from a basic ethical principle: Human dignity requires and demands that unnecessary, treatable pain be relieved. Severe or chronic pain blocks or seriously impedes the realization of almost all other human values. Relief from unrelenting pain is required to allow the human being to reflect, to enjoy human relationships, and even to think and function on a most basic level. The necessary concomitant of this starting point is that physicians, nurses, and other caregivers have a duty to provide effective pain relief where available. Although there may be serious ethical and medical concerns about particular interventions in particular situations, the ethical obligation to relieve pain is quite well accepted.

The scholars involved in the Mayday Projects since 1995 have relentlessly pursued one question: If the importance of pain relief and the ethical obligation to relieve pain are so widely recognized, why do we continue to neglect treatable pain? That single question has led us to investigate medical licensure and discipline (in the 1996 and 1998 special issues of the Journal of Law, Medicine & Ethics); interprofessional matters (in this issue); payment policies and practices (in 1996 and 1998); cultural, racial, and sex and gender differences in treatment (in 1996 and again in this issue); criminal prosecutions for the treatment of pain at the end of life (in 1998); and civil liability (in this issue). This third special issue on pain relief once again presents groundbreaking research, and we believe it will have the strong effect that the first two issues produced. The Journal of Law, Medicine & Ethics has been the major communication tool for these projects, and it has served that role well.

With the help of the Mayday Fund, we will continue to pursue this single question in all of its facets because this work is making a difference. The Pain Relief Act, proposed in the 1996 issue of the Journal, has become law in at least one state and formed a motivating force and a basis for change in rules in others. The research conducted and published as part of the Mayday Projects has formed a significant influence in the development of new guidelines recommended by the Federation of State Medical Boards for state disciplinary agencies. The Mayday Projects have produced not only a
body of important research; they have also developed a leadership group of lawyer-scholars who have devoted their considerable talent and expertise to this valuable effort. The Mayday Scholars who have been funded as part of these projects have provided consultative services to many professional associations, governmental organizations, patient advocacy groups, media, and public policy efforts.

These projects have been one of the most rewarding experiences that a scholar can have. To work on an important question with a group of talented and committed people within an organization that is committed to interdisciplinary and interprofessional collaboration and with the generous support of a foundation that believes in the importance of the effort is anyone’s dream. I and ASLME thank the Mayday Fund for making all of this possible and their executive director, Fenella Rouse, for her guidance and encouragement. We also thank the Mayday Scholars for their efforts, which have always exceeded the letter of their original commitment, and especially Diane Hoffmann, who has taken the Society’s work in this area to another level. I personally am grateful to ASLME’s executive director, Ben Moulton, who has provided the structure that has allowed me to continue with the Mayday Projects. Finally, Saint Louis University’s Center for Health Law Studies has been a central locus for this work from the beginning. The Center’s students assisted with the research; the Center’s faculty provided peer review of the papers; and the staff has provided a hospitable home for the Mayday Scholars’ Workshop each year.

We look forward to the next Mayday Project at the American Society of Law, Medicine & Ethics.

REFERENCES

The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain

Diane E. Hoffmann and Anita J. Tarzian

To the woman, God said, “I will greatly multiply your pain in child bearing; in pain you shall bring forth children, yet your desire shall be for your husband, and he shall rule over you.”

Genesis 3:16

There is now a well-established body of literature documenting the pervasive inadequate treatment of pain in this country. There have also been allegations, and some data, supporting the notion that women are more likely than men to be undertreated or inappropriately diagnosed and treated for their pain.

One particularly troublesome study indicated that women are more likely to be given sedatives for their pain and men to be given pain medication. Speculation as to why this difference might exist has included the following: Women complain more than men; women are not accurate reporters of their pain; men are more stoic so that when they do complain of pain, “it’s real”; and women are better able to tolerate pain or have better coping skills than men.

In this article, we report on the biological studies that have looked at differences in how men and women report and experience pain to determine if there is sufficient evidence to show that gender differences in pain perception have biological origins. We then explore the influence of cognition and emotions on pain perception and how socialized gender differences may influence the way men and women perceive pain. Next, we review the literature on how men and women are diagnosed and treated for their pain to determine whether differences exist here as well. Finally, we discuss some of the underlying assumptions regarding why treatment differences might exist, looking to the sociologic and feminist literature for a framework to explain these assumptions.

We conclude, from the research reviewed, that men and women appear to experience and respond to pain differently, but that determining whether this difference is due to biological versus psychosocial origins is difficult due to the complex, multicausal nature of the pain experience. Women are more likely to seek treatment for chronic pain, but are also more likely to be inadequately treated by health-care providers, who, at least initially, discount women’s verbal pain reports and attribute more import to biological pain contributors than emotional or psychological pain contributors. We suggest ways in which the health-care system and health-care providers might better respond to both women and men who experience persistent pain.

Do Men and Women Experience Pain Differently?

The question of whether men and women experience pain differently is a relatively recent one. Until about a decade ago, many clinical research studies excluded women, resulting in a lack of information about gender differences in disease prevalence, progression, and response to treatment. Research on sex-based and gender-based differences in pain response has mounted over the past several years, partially motivated by 1993 legislation mandating the inclusion of women in research sponsored by the National Institutes of Health.

Three review articles summarized the research findings on sex-based differences in pain response through the mid-1990s, with most research focusing on sensory (often laboratory-induced) pain. Unruh examined variations between men and women in clinical pain experience through an extensive review of available research. She found, in general, that
women reported more severe levels of pain, more frequent pain, and pain of longer duration than men. Women were more likely than men to report migraines and chronic tension headaches, facial pain, musculoskeletal pain, and pain from osteoarthritis, rheumatoid arthritis, and fibromyalgia. Women were also more likely than men to develop a chronic pain syndrome after experiencing trauma similar to that experienced by men.

Berkley drew similar conclusions — that for experimentally delivered somatic (skin or deep tissue) stimuli, females have lower pain thresholds, greater ability to discriminate pain, higher pain ratings, and less tolerance of noxious stimuli than males. Berkley, however, cautioned that these differences were small and affected by many variables, such as type of pain stimulus, timing of the stimulus, size or bodily locus of the stimulus, and experimental setting. For example, more reliable differences between the sexes have been found when patients are exposed to electrical and pressure stimuli as opposed to thermal stimuli, and when pain is induced in experimental settings as opposed to clinical settings.

Lastly, Fillingim and Maitlyn reviewed research on sex-based differences in response to noxious stimuli. The studies they reviewed also indicated that although pain responses were highly variable among individuals, females exhibited greater sensitivity to laboratory-induced pain than males. They concluded that “it seems plausible that such disparity in the experience of clinical pain [between men and women] could be explained, at least in part, by enhanced pain sensitivity among females.”

While approximately half of all existing studies prior to 1997 found no difference between men and women in their response to experimental pain, of those studies that did, all were in the same direction: “lower pain threshold, higher pain ratings, and lower pain tolerance for women.”

More recent studies have contributed further empirical evidence of a difference between men and women in pain response. Much of this research has focused on a search for biological differences. Although these early findings do suggest biologically based differences, there remain many research questions yet to be answered.

**Biological differences**

A number of scientists have hypothesized about potential biological explanations for gender pain differences. Berkley described three aspects of male and female biology that plainly differ: the pelvic reproductive organs, types of circulating hormones, and cyclical changes in hormone levels. Other biological explanations for the differences in pain response include mechanisms of analgesia having to do with opioid receptors in the body, mechanisms of nerve growth factor, and sex-based differences in sympathetic nervous system function (e.g., sex-based differences in areas of the brain associated with reproduction). Berkley stated that these differences could result in men and women experiencing different emotional responses to pain (e.g., anxiety, fear, depression, or hostility).

**Reproductive hormones**

A number of studies have added to the body of literature on the influence of reproductive hormones on biological pain differences. Berkley concluded that the reproductive hormones appear to influence sex-based pain differences through the action of a number of neuroactive agents, such as dopamine and serotonin.

Giamberardino and colleagues found that a woman’s pain sensitivity increases and decreases throughout her menstrual cycle, with skin, subcutaneous tissue, and muscles being affected differently by female hormonal fluctuations. They also found that sex-based differences in pain response may depend on the proximity of the stimulus to external reproductive organs. Fillingim and colleagues found that the menstrual cycle produced greater effects on ischemic (i.e., lack of blood flow and oxygen), compared with thermal, pain sensitivity. The authors suggest that opioid receptors could be desensitized by reproductive hormones during certain phases of a woman’s menstrual cycle, thus increasing pain sensitivity (particularly ischemic pain sensitivity) at those times.

Glaros, Baharloo, and Glass found that lower levels of circulating estrogens may be associated with higher levels of temporomandibular disorder (TMD) pain and other joint pain in women. Dao, Knight, and Ton-That studied the influence of reproductive hormones on TMD. They hypothesized that there is a link between reproductive hormones and inflammation and pain — that the hormones may “act directly in the muscles to modulate the release of nitric oxide,” which causes vasodilation (blood vessel dilation), inflammation, and pain. In addition, estrogen may interact with various mediators of inflammation (i.e., swelling) and increase pain sensation.

**Stress-induced analgesia responses**

Differences have been found between male and female rats for “stress-induced analgesia” responses. Stress-induced analgesia involves activation of an intrinsic pain inhibitory system by a noxious stressor, such as exercise-induced stress or predator-evoked stress.

Mogil and colleagues report on a sex-specific stress-induced analgesia mechanism in female mice that is known to be estrogen-dependent and to vary with reproductive status, but for which the neurochemical identity has remained obscure. The authors performed genetic mapping experiments to identify the gene underlying stress-induced analgesia in both sexes and found a specific genetic component in female mice but not in male mice.
Brain and central nervous system

Some research has shown differences in the brain and central nervous system of men and women that may contribute to differences in pain response. For example, Fillingim and Maixner describe neural mechanisms that contribute to sex-based differences in the perceptual, emotional, and behavioral responses to noxious stimuli. These include peripheral afferents (impulses sent to the brain), brain and central nervous system networks, and peripheral efferents (commands sent from the brain to the muscles). The authors note differences in female tissue thickness and sensory receptor density as one example of structural differences in females that may contribute to enhanced perception of sensation to the skin.

Animal studies provide some evidence that sex-based differences in pain response have biological and genetic origins. Aloisi, Zimmermann, and Herdegen found differences in immune chemicals in the hippocampus and septum of male and female rats that were subjected to a persistent painful stimulus and restraint stress. The authors hypothesized that hormonal and behavioral differences between the sexes are accompanied by genetic differences in the limbic system — an area of the brain that, in humans, is involved in cognition and emotion.

Other researchers have probed the human brain for sex-based differences that influence pain responses. Mayer and colleagues found that, compared to male patients with irritable bowel syndrome, female patients with the same syndrome showed specific perceptual alterations in response to rectosigmoid (intestinal) balloon distension and differences in regional brain activation measured by positron emission tomography (PET). Findings suggest that physiological sex-related differences in the experience of pain exist in irritable bowel syndrome patients and can be detected using specific stimulation models and brain imaging techniques.

Paulson and colleagues studied cerebral blood flow through PET imaging in normal right-handed male and female subjects as the subjects discriminated differences in the intensity of painless and painful heat stimuli applied to the left forearm. Females had significantly greater activation of the contralateral prefrontal cortex, the contralateral insula, and the thalamus when compared to the males. The authors surmised that the differences between men and women in their response to pain were (1) a direct result of physiological differences between men's and women's brains; (2) mediated by emotional or cognitive responses that are different between men and women and are responsible for brain activation differences between men and women; or (3) a result of both (1) and (2).

Biology as explaining too much, too little

Given the physiological sex differences reviewed thus far, one might expect the gap in pain responses between men and women to be greater than the research evidence indicates. This paradox in the research has led Unruh — commenting on Berkley's conclusion that differences between men and women in pain perception and response exist but are small and highly variable — to argue for a "conceptual shift" in "our efforts to understand the relationships between sex and pain experience".

The question changes from "Why do women and men differ in their experiences of pain?" to "How do women dampen the effect of powerful sex differences in physiological pain mechanisms to achieve only small sex difference in their actual pain experience?"

Consequently, researchers must look not only at why women may experience more pain than men, but also at why the difference in experience is not greater than recent findings regarding physiological pain-related differences would indicate. One answer to this paradox may be that some physiological differences between men and women actually make their pain responses similar. For example, DeVries and Boyle concluded that despite major differences in physiological and hormonal conditions, differences between the sexes in the brain create a mediating effect on pain, perhaps resulting in men and women displaying remarkably similar behaviors.

Another explanation is that more than physiological differences are at work.

What is clear is that the research to date provides ample evidence that differences between men and women in pain response exist. What is unclear is whether the reasons for these findings are grounded in differences in biology or differences in coping and expression, or both.

The mind-body connection

Although modern scientists have attempted to identify and localize specific pathophysiological mechanisms that produce and influence pain sensations, progress on this front is advancing slowly. Most experimental pain research has focused on laboratory-induced noxious sensory stimuli, such as heat, cold, pressure, and shock. Subjects report the level at which they detect pain ("threshold") and the level at which they can no longer tolerate pain ("tolerance"). Bendelow writes: "The experimental nature of these studies does not allow the social context to be taken into account and the psychological research on pain perception is weighted heavily towards sensory cues, with little emphasis on the subjectivity, or indeed any recognition of models of perception that emphasize interaction between sensory cues and expectations or prior experience."

The focus on a physiological basis for pain has ignored the findings that one's response to pain is influenced by a multitude of factors, which may include the biological, psychological, and cultural differences between men and women.
External stimuli may set off a biological cascade that contributes to the sensation of pain, but cognition and emotion also contribute to the experience of pain. Cognitive awareness of and emotional response to pain (which are affected by psychosocial and cultural influences) in turn influence the brain’s and body’s subsequent physiological responses. Unlike the “Cartesian” approach that views pain as a product of either biology (body) or psychology (mind), a more informed approach is to acknowledge the interdependence of the two, in addition to cultural influences.33

Psychological and cultural gender differences
Psychological factors influencing the pain response include cognitive appraisal of pain (i.e., meaning-making), behavioral coping mechanisms, and cultural influences. According to Unruh, “[u]nderlying biological differences in pain mechanisms may predispose women to have more pain and may affect recovery from pain but sociological [i.e., cultural] and psychological factors also influence pain perception and behavior.”34

Cognitive appraisal and meaning-making
Cognitive appraisal refers to the process of attributing meaning to an event, which then influences one’s behavioral response to that event.35 For various reasons, men and women may attribute different meanings to their pain experiences.

For one, the types of pain that men and women experience tend to be different. Women more often experience pain that is part of their normal biological processes (e.g., menstruation and childbirth), in addition to pain that may be a sign of injury or disease. Women may thus learn to attend to mild or moderate pain in order to sort normal biological pain out from potentially pathological pain, whereas men do not need to go through this sorting process.36

In addition, men’s and women’s different gender role expectations may influence how they attribute meaning to their pain. Women have been found, for example, to describe their pain by giving more contextual information, such as impact on personal relationships and child-care duties. M en, on the other hand, are more likely to wait to attend to pain until it threatens to interfere with their work duties. Their pain reports are more likely to be an objective reporting of physical symptoms or functional limitations, and to lack reference to contextual factors such as impact on personal relationships.37

According to one study, factors that influenced women’s likelihood of seeking health care for their pain included a predisposition to “resilience or positive regard for their ability to handle the problem.” M en, in contrast, were influenced to seek health care by “a negative attitude about the condition in terms of its harmfulness, loss or threat.”38 Thus, gender differences in cognitive appraisal and meaning-making of pain may explain some of the differences between men and women in pain response.

Behavioral coping
Prompted by one’s cognitive appraisal of a stressor like pain, individuals respond using various coping mechanisms. Researchers have found that men and women differ in their mechanisms of coping with stress—particularly, coping with pain. Unruh, citing other studies, reported that women more frequently use coping strategies that include “active behavioral and cognitive coping, avoidance, emotion-focused coping, seeking social support, relaxation, and distraction, whereas men rely on direct action, problem-focused coping, talking problems down, denial, looking at the bright side of life and tension-reducing activities such as alcohol consumption, smoking and drug abuse.”39 Thoits found that women’s ways of coping involved more expression of feelings and seeking social support, whereas men’s ways of coping were more rational and stoic (e.g., accepting the situation, engaging in exercise).”40 Unruh, Ritchie, and M erskey found that in response to pain, women reported significantly more problem-solving, social support, positive self-statements, and palliative behaviors than men.41 Jensen and colleagues found that among individuals with long-term intractable pain in the neck, shoulder, or back, women increased their behavioral activity (e.g., household chores and social activities) as a coping strategy more often than men.42 Other studies suggest that coping strategies are influenced more by the type and duration of pain than by whether the person is a man or a woman.43

Research has also shown that women, as compared to men, respond more aggressively to pain through health-related activities (e.g., taking medications or consulting a health-care provider).44 This is consistent with studies that have shown that women tend to report more health-care utilization for treatment of pain than do men.45

Culture, gender, and pain
The interplay between behavior and the value systems of a culture is complex and may influence pain perception in many ways. Children are socialized from a very young age to think about pain and to react to painful events in certain ways. In many societies, boys are actively discouraged from expressing emotions.46 Pollack reports that in the United States, “[r]esearchers have found that at birth, and for several months afterward, male infants are actually more emotionally expressive than female babies. But by the time boys reach elementary school much of their emotional expressiveness has been lost or has gone underground. Boys at five or six become less likely than girls to express hurt or distress, either to their teachers or to their own parents.”47
this change to attitudes toward boys that are “deeply ingrained in the codes of our society” and as a result of which “boys are made to feel ashamed of their feelings, guilty especially about feelings of weakness, vulnerability, fear, and despair.” Male pain research participants have reported that they “felt an obligation to display stoicism in response to pain.” Other investigators found that whether the researcher was a man or a woman influenced male pain response in a laboratory setting, with males reporting less pain in front of a female researcher than a male researcher, whereas the researcher’s sex did not affect the responses of female subjects.49

Culture and socialization may also account for the differences in pain reporting between men and women. Women have been found to adopt a more “relational, community-based perception of the world” that allows them to form more extended social support networks and to express their emotions more than men.50 Because of these different socialization experiences, women’s and men’s styles of communication differ,51 which most likely influence how they report their pain to each other and to health-care providers. Miaskowski noted that “women are better able to fully describe their pain sensations than men, or are more willing to describe them, especially to female nurses.”52 In addition, as already mentioned, women tend to describe their pain to a health-care provider by including contextual information, like the pain’s effect on their personal relationships.53

Differences in treatment

The literature suggests not only that men and women communicate differently to health-care providers about their pain, but that health-care providers may respond differently to them. Miaskowski reported on several studies that identified such differences in response and treatment.54 Faherty and Grier studied the administration of pain medication after abdominal surgery and found that, controlling for patient weight, physicians prescribed less pain medication for women aged 55 or older than for men in the same age group, and that nurses gave less pain medication to women aged 25 to 54.55

Calderone found that male patients undergoing a coronary artery bypass graft received narcotics more often than female patients, although the female patients received sedative agents more often, suggesting that female patients were more often perceived as anxious rather than in pain.56 Another study, examining post-operative pain in children, found that significantly more codeine was given to boys than girls and that girls were more likely to be given acetaminophen.57

Miaskowski further reported on two more recent studies. In a 1994 study of 1,308 outpatients with metastatic cancer, Cleeland and colleagues found that of the 42 percent who were not adequately treated for their pain, women were significantly more likely than men to be undertreated (an odds ratio of 1:5).58 In another study of 366 AIDS patients, Breitbar and colleagues found that women were significantly more likely than men to receive inadequate analgesic therapy.59

The assessment of undertreatment in both studies was based on guidelines developed by the World Health Organization for prescribing analgesics.

Other studies also indicate differences in how men and women are treated by health-care providers for their pain. In a retrospective chart review of male and female post-operative appendectomy patients without complications, McDonald found that in the immediate post-operative period, males received significantly more narcotic analgesics than females.60 However, differences were not significant when taking into account the whole post-operative period. McDonald suggested that these differences might be due to gender-stereotyping during the initial post-operative period when the patient is still drowsy from anesthesia and not always able to make his or her pain needs known. The nurse may respond differently to male and female patients during this time, as compared to later in the post-surgical recovery period when patients are more fully awake and able to report their pain.61

A recent prospective study of patients with chest pain found that women were less likely than men to be admitted to the hospital. Of those hospitalized, women were just as likely to receive a stress test as men, but of those not hospitalized, women were less likely to have received a stress test at a one month follow-up appointment.62 The authors attributed the differences in treatment to the “Yentl Syndrome,” i.e., women are more likely to be treated less aggressively in their initial encounters with the health-care system until they “prove that they are as sick as male patients.” Once they are perceived to be as ill as similarly situated males, they are likely to be treated similarly.63

The “Yentl Syndrome” hypothesis fits well with the results of a study by Weir and colleagues, which found that of chronic pain patients who were referred to a specialty pain clinic, men were more likely to have been referred by a general practitioner, and women, by a specialist.64 The results suggest that women experience disbelief or other obstacles at their initial encounters with health-care providers. An older study (1982) also found that of 188 patients treated at a pain clinic, the women were older and had experienced pain for a longer duration prior to being referred to the clinic than the men. In addition, the researchers found that women were given “more minor tranquilizers, antidepressants, and non-opioid analgesics than men. Men received more opioids than did women.”65 These findings are consistent with those reported by Elderkin-Thompson and Waisken, who reviewed evidence from the American Medical Association’s Task Force on Gender Disparities in Clinical Decision-Making. Physicians were found to consistently view women’s (but not men’s) symptom reports as caused by emotional factors, even in the presence of positive clinical tests.66

In addition to actual differences in treatment, studies have also shown differences in health-care providers’ per-
exceptions of men’s and women’s experiences of pain. McCaffery and Ferrell, using a questionnaire administered to more than 300 nurses, found that nurses perceived differences between men and women in sensitivity to pain, pain tolerance, pain distress, willingness to report pain, exaggeration of pain, and nonverbal pain expressions. M ore respondents felt that women, as compared to men, were less sensitive to pain, more tolerant of pain, less distressed as a result of pain, and more likely to report pain and express pain through nonverbal gestures. In another study, nurses were given vignettes describing a particular patient and situation, and were asked to estimate the minutes needed for specific nursing interventions for each patient. In their estimations, the nurses planned significantly more analgesic administration time (as well as ambulation and emotional support time) for male patients than for female patients.

In addition to whether the patient is a man or a woman, physical attractiveness and nonverbal expressions of pain have been found to influence a health-care provider’s response to the patient’s pain. Hadjistavropoulos and colleagues found that physically unattractive patients were more likely to be perceived as experiencing greater pain than more attractive patients and that the more attractive patients were more likely to be viewed as able to cope with their pain. These differences in perception were more likely to be true for female patients than male patients — that is, the effect of the patient’s attractiveness (or lack thereof) on a health-care provider’s perception of the patient’s pain sensitivity was not significant for male patients but it was for female patients. Attractive female patients were thought to be experiencing less pain than unattractive female patients. The authors concluded that a “strong ‘beautiful is healthy’ stereotype” was used by health-care providers in assessing patient pain and that attractive persons were perceived to be experiencing less pain intensity and unpleasantness, less anxiety and less disability than physically unattractive persons. The authors further concluded that such stereotypes have a negative effect for both attractive and unattractive individuals.

**What Accounts for Differences in Treatment?**

The available literature indicates that women receive less treatment for their pain than men. These findings raise the question of whether such a difference in treatment is justified or whether the differences are the result of unproven assumptions and biases about men and women and their sensitivity toward pain or their credibility in reporting pain.

**Rationales supported by the data**

Treating men and women differently for their pain might be justified if they experience pain differently or respond differently to pain treatment modalities. As for the latter argument, previous research has shown that men and women metabolize medication differently. In response to pain medications specifically, Gear and colleagues showed that women experience significantly greater analgesia from kappa-opioids like pentazocine than males. Others have predicted that genetic research will lead to identifying drugs for pain that are specific to men’s and women’s biological needs.

In addition, evidence indicates that men and women do experience pain differently. There is no consensus, however, whether this difference in experience is because women are biologically more sensitive to pain than men, although recent studies provide evidence to support this explanation. What is clear is that women in clinical studies often report greater sensitivity than men in response to the same noxious stimuli. This could mean that, in fact, there is a biological difference between men and women that results in women experiencing greater pain than men when exposed to the same stimulus. Or, it could mean that women do not tolerate pain as well as men, or that women are more likely to report pain than men are.

The data support the assertion that women are more likely to report pain than are men in response to the same stimuli. Apart from differences in pain sensitivity, this could be attributed to differences in coping. The literature on coping appears to indicate that women tend to cope in more constructive ways, such as seeking a health-care provider, reaching out to others, and/or praying, whereas men tend to accept the pain, ignore it, or resort to drugs or alcohol rather than consult with a health-care provider. These strategies are consistent with cultural mores that discourage men from expressing weakness or vulnerability.

An alternative hypothesis that may explain why men’s pain complaints evoke more medical and nursing interventions is that men wait longer than women to seek medical assistance for their pain and thus are at a stage where their pain characteristics are more extreme and in need of more immediate care. But while there is some evidence that men are less likely to seek medical care for their pain at early
stages (or until it interferes with their ability to work), there is no evidence that they are in need of more aggressive care than women when they enter the health-care system for pain relief. Rather, study findings suggest that women report more severe pain symptoms than men because they suffer from more severe pain-related diseases. For example, in a telephone survey of those with rheumatoid arthritis, researchers found that women reported more severe symptoms than men and that this difference was due to "more severe disease rather than a tendency by women to over-report symptoms or over-rate symptom severity."80

The perception of women by health-care providers

Given that women experience pain more frequently, are more sensitive to pain, or are more likely to report pain, it seems appropriate that they be treated at least as thoroughly as men and that their reports of pain be taken seriously. The data do not indicate that this is the case. Women who seek help are less likely than men to be taken seriously when they report pain and are less likely to have their pain adequately treated.81 This conclusion raises the question of what accounts for this difference in treatment. In light of the apparent lack of objective data supporting lesser treatment of women for pain, a likely explanation is the health-care provider's attitudes regarding male and female sensitivity to or tolerance of pain and the validity of their self-reports. There are, in fact, data to support the hypothesis of this attitude or bias by health-care providers. The study by McCaffery and Ferrell of 362 nurses and their views about patients' experiences of pain found that while most of the nurses (63 percent) agreed that men and women have the same perception of pain, 27 percent thought that men felt greater pain than women. Only 10 percent thought that women experienced greater pain than men in response to comparable stimuli.82 This result has no justification in the literature (and, as discussed above, is actually contradicted by it). The authors do not speculate as to what might contribute to this difference in attitude.

The same study also found that almost half of the respondents (47 percent) thought that women were able to tolerate more pain than men as compared to 15 percent who felt that men were able to tolerate more pain than women. This result, although consistent with other studies,83 seems at odds with our societal notions that men are stronger and tougher than women and better able to withstand physical discomfort. McCaffery and Ferrell explained this seeming contradiction by speculating that while society attributes strength and bravery to men, these characteristics are displayed by an unwillingness to complain or express discomfort rather than by an actual tolerance of discomfort.

Other researchers offer alternative explanations for this perceived difference in tolerance. Some have asserted that as a result of women's biological role in childbirth, women are capable of withstanding significantly more pain than men.84 Fillingim and Maixner postulate that the sum of men's and women's differences in pain response exist as a consequence of evolutionary pressures that increase reproductive potential and species survival.85 In her study of the interplay of pain, gender, and culture, Bendelow found that women were frequently thought to be equipped with a "natural capacity to endure pain," in part linked to their reproductive functioning.86 This attitude does appear to be somewhat common among certain groups, as conveyed by offhand remarks such as, "if men had to bear children, there wouldn't be any."87 Bendelow found that "the perceived superiority of capacities of endurance is double-edged for women — the assumption that they may be able to 'cope' better may lead to the expectation that they can put up with more pain, that their pain does not need to be taken so seriously."88 Crook and Tunks point to the influence of the psychoprophylaxis movement in the United States with its implicit assumption that it is good to experience childbirth without the aid of analgesia. As a result, some women who have "gone through psychoprophylaxis classes, feel guilty if they relent at the last minute and ask for an epidural"; according to the authors, "these attitudes imply that we have a value system endorsed by some parts of our population that suggest women should be encouraged to keep a stiff upper lip."89

Another possible explanation of why health-care providers view women as better able to tolerate pain and thus in need of less treatment is that women have better coping mechanisms than men for dealing with pain. The literature confirms that women in fact have a greater repertoire of coping skills to deal with their pain. These include a greater ability to verbally acknowledge and describe their pain, to seek health-care intervention, and to gain emotional support. Men, in contrast, are likely to ignore the pain or delay seeking treatment.90 Yet this reluctance on the part of men does not lead to the conclusion that women, as not reluctant, must therefore be less in need of adequate treatment. Rather, a request for medical care would seem to imply that the person perceives her pain as real and enough of a threat to her lifestyle to seek outside assistance.

What men's reluctance says — if anything at all — is that they are perhaps, as a whole, more undertreated than we think. While their complaints of pain appear to be taken more seriously than women's pain complaints when they initially enter the health-care system, many may not seek medical assistance for their pain and, as a result, may be disadvantaged in getting relief from their painful symptoms.

A third possible explanation of why health-care providers might view men as less tolerant of pain than women may be a projection that men need more assistance with their pain because they are the household breadwinners. In their study, McCaffery and Ferrell found that nurses tended to equate "day-to-day physical functioning with pain tolerance" and that nurses believed men were more likely to stop functioning when they were in pain whereas women would continue
their role as homemaker in addition to working outside the home. Another study similarly found that men were “more likely to be referred earlier for active treatment with a combination of therapies because of the demands of their breadwinner roles.”103 Again, such reasoning is unfounded. Unruh argued that women may, in fact, more readily attend to pain and more aggressively manage it because they assume more role responsibilities than men.93 As a result, they “may have more complex concerns about managing the interference of pain in the activities and responsibilities of daily life.” Given this possibility, it would again make more sense for health-care providers to at least be as aggressive in treating women for pain as they are in treating men.

Another factor that may play a key role in explaining the different treatment of men and women for pain and the tendency to treat women less aggressively is the subjective nature of pain and the credibility given to women's self-reports of pain. These two factors perhaps exacerbate the likely undertreatment of women for pain.

**Western medicine discounts female pain expression**

In Western medicine, health-care providers are trained to rely predominantly on objective evidence of disease and injury. This is not only true of physicians but also nurses. One study of nurses found that they incorrectly expect patients who report moderate to severe pain to have elevated vital signs or behavioral expressions of pain.93 The medical model overemphasizes objective, biological indicators of pain and underacknowledges women’s subjective, experiential reports. Johansson and colleagues state, “medical models often end up in reductionism and medico-centrism, since they look for expert explanations in biological facts.”94 They cite a study by Baszanger which revealed that physicians attempting to make a diagnosis after consulting with a patient considered “cellular pathology as ‘something,' whereas illness-provoking, psycho-social circumstances were ‘nothing.’”95

The subjective nature of pain requires health-care providers to view the patient as a credible reporter, and stereotypes or assumptions about behavior in such circumstances (oversensitivity, complaining, stoicism) add to the likelihood of undertreatment of some groups and overtreatment of others.96 The feminist literature is rife with examples and criticism of women’s voices not being heard or considered credible in the male-dominated health-care system. Sherwin describes physicians as frequently “patronizing, detached, disrespectful, ... and unwilling to trust the reports of their women patients.”97 Dresser, in characterizing the literature on women’s health care, finds that women’s “[s]ubjective experiences of illness and treatment are frequently ignored.”98

A deeper examination of why women are treated this way is explored by several feminist authors. They attribute it to a long history within our culture of regarding women’s reasoning capacity as limited99 and of viewing women’s opinions as “unreflective, emotional, or immature.”100 In particular, in relation to medical decision-making, women’s moral identity is “often not recognized.”101 In a recent article, Parks argued that women’s requests for physician assisted suicide (PAS) are likely to be ignored. Parks reasoned that while a man’s request for help in ending his life is likely to be considered a “reasonable self-evaluation” if marked by “intolerable pain, personal suffering or terminal illness, ... women’s similar experiences are much more likely to be rejected, discounted, or unheeded because their capacity for such determinations of personal suffering are questioned.”102

Evidence of health-care providers’ doubting the pain experience of women with chronic pain is provided by Grace. She found that women with pelvic pain expressed difficulty communicating with their general practitioner about their pain, and some difficulty communicating with their gynecologist.102 A significant number of the women “did not think the doctor (GP) really understood what they said and left the doctor’s office feeling that there were things about their pelvic pain that they hadn’t talked about.”104 These women had received seventy-three different diagnoses to explain the cause of their pain, and reported that their physician implied “nothing was wrong” if no physical cause of pain could be identified.103 More than half of the women said that on occasion they felt that the doctor was not taking their pain seriously or that the doctor expected them to put up with their pain.

Women are also portrayed as hysterical or emotional in much of the medical and other literature. While men may be seen as forceful or aggressive, women are perceived as hysterical for the same behavior.106 Physicians have found women to have more “psychosomatic illnesses, more emotional liability and more complaints due to emotional factors” than men.107 In a frequently cited paper by Engel, “the majority of the case histories presented to illustrate ‘psychogenic pain and the pain prone patient’ are histories of females.”108 Fishbain and colleagues found that female chronic pain patients were more likely to be diagnosed with histrionic disorder (excessive emotionality and attention-seeking behavior) compared to male chronic pain patients.

Some researchers have argued that a “bias toward psychogenic causation for disorders in women has occurred even in well defined painful biological processes. ‘Despite the well documented presence of organic etiologic factors, the therapeutic literature is characterized by an unscientific recourse to psychogenesis and a correspondingly inadequate, even derisive approach to their management.’”109 These findings are consistent with studies reporting that female pain patients are less likely than their male counterparts to be taken seriously or are more likely to receive sedatives than opioids for the treatment of their pain.

The health-care provider’s bias toward psychogenic causes of women’s pain is problematic on two levels. First, women are more likely than men to have their pain attributed to psychogenesis whether or not that is in fact a cause of their
pain. Second, for those women whose pain is exacerbated by emotional disorders, the health-care provider’s bias against psychological contributors to pain may lead them to undertreat the pain. Some claim that health-care providers’ predisposition toward attributing women’s pain to emotional causes is related to the higher prevalence of emotional problems (e.g., depression and anxiety) among women.116 However, it is possible that a gender bias exists in the processes by which women are evaluated for and diagnosed with these psychological disorders. What is clear is that women are more likely than men to express their feelings and more likely than men to have their symptoms (including pain) attributed to emotional factors. What is unknown is the degree to which emotional factors actually contribute to women’s and men’s pain experiences.

The tendency of health-care providers to discredit women’s pain reports may, in part, be rooted in communication differences between men and women. Vallerand argues that “[b]ecause pain is a subjective phenomenon that can be assessed most reliably from the patient’s self-report, the ability to communicate the discomfort of pain to a HCP [health-care provider] should be an advantage.” In contrast, it appears that “women’s ability to verbalize their emotions causes their responses to be viewed with suspicion [e.g., considered psychologically based] and treated less aggressively.” Alternatively, women’s style of communication may simply not fit neatly into the traditional medical interview model adopted by most physicians. In this model, Smith writes:

[the] physician controls the entry and exit of topics and controls the time devoted to a certain topic. By interrogative speech acts, ... the physician also controls the introduction and timing of topics. Through interruptions, the physician allows or cuts off patient lines of questioning. Several studies have shown that the physician-led medical interview is confined mainly to the question-and-answer mode of speech and that patient-initiated questions are often “dispreferred” in medical interviews.112

In general, women in Western societies are socialized to take turns in conversation, to downplay their own status, and to demonstrate behaviors that communicate more accessibility and friendliness.113 While both men and women might benefit from a more humanistic approach to physician-patient communication,114 it is likely that women are more likely to be disadvantaged by the traditional medical interview model. Women with chronic pain may be particularly vulnerable in this traditional communication style and rebuffed by physicians in their attempts to express the multiple ways in which their pain affects the quality of their lives and their ability to function.115

Lastly, patient characteristics and behaviors may also play a role in how female pain patients are perceived and, thus, how they are treated by their physicians. To the extent that women are culturally influenced to try to look good, even on visits to their physician, they may be viewed by their physician as attractive and thus not really in pain.116 Alternatively, if female patients present with hostility, they may not receive appropriate treatment. Patient hostility has been reported as an obstacle to establishing a rapport with a health-care provider. A few studies have indicated a correlation between female pain patients and high levels of hostility.117 Such hostility, however, may be the result of frustration with the medical system and difficulty finding a sympathetic health-care provider. There is evidence that chronic pain patients must see dozens of physicians before finding one that is willing and/or able to treat their pain.118

**Summary, Implications, and Recommendations**

The research findings point to several troubling inconsistencies or paradoxes regarding the differences between men and women in pain response and treatment:

- While women have a higher prevalence of chronic pain syndromes and diseases associated with chronic pain than men, and women are biologically more sensitive to pain than men and respond differently to certain analgesics, women’s pain reports are taken less seriously than men’s, and women receive less aggressive treatment than men for their pain.
- Although women have more coping mechanisms to deal with pain, this may contribute to a general perception that they can put up with more pain and that their pain does not need to be taken as seriously.
- Although women more frequently report pain to a health-care provider, they are more likely to have their pain reports discounted as “emotional” or “psychogenic” and, therefore, “not real.”
- Women, being socialized to attend more to their physical appearance, are more likely than men to have health-care providers assume they are not in pain if they look more physically attractive.
- Men with chronic pain are more likely to delay seeking treatment, but generally receive a more aggressive response by health-care providers once they enter the health-care system.
- Both men and women are more likely to have the emotional or psychological component of their pain experience suppressed due to Western medicine’s tendency to separate mind and body and to view objective, biological “facts” as more credible than subjective feelings.

If one examines these findings from different ethical perspectives, they are deeply problematic. From a justice
perspective, for example, there exists a strong argument that individuals should be treated equally effectively according to their needs. Thus, a just approach to providing sex-specific, gender-sensitive pain management treatments acknowledges that men and women in pain may have different needs. The current situation, in which women are more likely than men to be undertreated for their pain, is ethically unjustifiable.

From a utilitarian perspective, undertreating women who have persistent pain is likely to have negative outcomes not only for productivity in the workforce but also for families and children. While undertreating men for pain has implications for their role as monetary providers, the implications of undertreating women are perhaps more far-reaching. In many families, the woman is now the breadwinner or one of the breadwinners. In addition, the woman typically takes on the primary role of family caretaker, making sure the household runs well, there is food on the table, and the children are cared for. If women are unable to function because of their pain, the possibility of extensive harm to families and children is very real.

The consequences for our health-care system are also potentially negative. A health-care system that continues to discriminate in its treatment of women is also likely to lose the confidence of its female patrons. There is, in fact, evidence that more women than men use alternative therapies for health-care treatment. While the loss of confidence in the conventional health-care system is a threat to its continued well-being, the elevated interest in complementary and holistic therapies may be a positive side effect of female patients' dissatisfaction with the traditional medical system. The question of whether such therapies will be alternative or complementary to conventional medical therapies will be influenced by how conventional health-care providers respond to the demand for a more holistic approach to pain management.

From a perspective of narrative or care ethics, the fact that pain defies mind-body dichotomization and that women, in general, tend to adopt a more holistic approach to health and illness might provide justification for a female-specific approach to pain treatment — one that explores etiologies of pain without bias for or against biology, psychology, or other affective contributors, and one that acknowledges context and lived experiences.

Although the growth of holistic medicine may be one silver lining of conventional medicine's gender-biased approach to pain treatment, this does not change the ethical imperative to rectify our mainstream health-care system's unjust treatment of women with pain. It is necessary to begin educating health-care providers and those who train them to expose biases that lead to the undertreatment of women. Some research has shown that efforts at educating and enlightening health-care providers regarding women's health needs has positive effects. Moreover, the bias against psychological or emotional pain contributors adversely affects both women and men. Women's pain tends to be viewed as more emotionally based and thus less credible — or, likewise, less credible if indeed it is emotionally based. Men's pain is more likely to be acknowledged strictly as a physical symptom, thus reinforcing the societal expectation that men suppress their emotions, even if it impedes their pain treatment and recovery. Medical schools must endorse, and teach students, an approach that best elicits the concerns of any patient in pain — an approach that does not discount the patient's subjective reports of pain. This will require attentiveness to the emotional aspects of a patient's reports of pain. As Johansson and colleagues state:

A purely diagnosis-oriented approach is not enough, and an attitude of healing through adaptation must be completed with a gender perspective on women's actual circumstances. The medical encounter ought to provide possibilities for the patient to express psychosocial problems. Physicians must have a chance to listen, voice concern, discuss solutions and offer remedies such as counseling as well as medication to empower the patient.

In addition to more attention to this issue in the medical school curriculum by modeling effective physician-patient communication with respect to pain management, there needs to be scrutiny on the part of quality care evaluators such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), as well as ethical awareness-raising by institutional ethics committees about the current bias in the pain treatment of women. Without this pressure, change is unlikely. The fact that JCAHO has established new pain management standards for the institutions that they accredit is a step in the right direction. Perhaps inclusion of evaluative mechanisms to ensure that vulnerable populations are not undertreated for pain due to a health-care provider's gender, ethnic, age, or racial biases will contribute to a more just approach to pain management. In addition to JCAHO's regulatory approach, institutional ethics committees have a role in educating and enlightening health-care providers regarding unjust pain treatment. Indeed, future JCAHO standards that address organizational ethics may dovetail into the same arena.

**Conclusion**

Research indicates that differences between men and women exist in the experience of pain, with women experiencing and reporting both more frequent and greater pain. Yet rather than receiving greater or at least as effective treatment for their pain as men, women are more likely to be less well treated than men for their painful symptoms. There are numerous factors that contribute to this undertreatment, but the literature supports the conclusion that there are gender-
based biases regarding women’s pain experiences. These biases have led health-care providers to discount women’s self-reports of pain at least until there is objective evidence for the pain’s cause. Medicine’s focus on objective factors and its cultural stereotypes of women combine insidiously, leaving women at greater risk for inadequate pain relief and continued suffering. Greater awareness among health-care providers of this injustice, a readjustment of medicine’s preoccupation with objective factors through education about alternative approaches, and scrutiny by quality and ethical reviewers within health-care institutions are necessary to change health-care providers’ behavior and ensure that women’s voices regarding treatment of their pain are heard.

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3. See P.L. Land and D.W. Cook, “Brief Communication: Gender and Sex: Vive la Difference,” American Journal of Physical Anthropology, 106, no. 2 (1998): 255–59, who underscore maintaining the distinction between “sex” (the anatomical or chromosomal categories of male and female) and “gender” (socially constructed roles that are related to sex distinctions). It should be noted that while isolating the influence of sex and gender on pain response and treatment is the focus of this article, we do not mean to discount the powerful influence of class, race, culture, education, and other such variables that likely affect pain response and treatment.
9. Id. at 209.
12. See Berkley, supra note 7.
13. Id.
14. Id.
19. Id. at 667.
20. Id.
23. Fillingim and Mäixner, supra note 8, at 214.
31. One difficulty in interpreting evidence from research studies is the individual variability of the pain response. Greater variability makes research on pain responses more difficult, as it decreases power and thus increases the likelihood of having insignificant results due to an insufficient number of subjects studied. This has been recently corroborated in a meta-analysis by Riley and colleagues, who determined that only seven of thirty-four studies reviewed on gender differences in pain response had adequate sample sizes. This implies that gender differences have been underestimated rather than overestimated in pain research. See J. L. Riley III et al., “Sex Differences in the Perception of Noxious Experimental Stimuli: A Meta-Analysis,” Pain, 74 (1998): 101–87.


33. Duncan describes how Cartesian (i.e., Descartes’) mind-body dualism is inaccurate equated with medical reductionism, the latter of which tends to dismiss mind (psychology) and favor body (physiology) in the diagnostic encounter. See G. Duncan, “Mind-Body Dualism and the Biopsychosocial Model of Pain: What Did Descartes Really Say?,” Journal of Medicine and Philosophy, 25, no. 4 (2000): 485–513. A more holistic approach is supported somewhat by M. elzack and Wall’s gate-control theory of pain, in which a neural mechanism in the spinal cord is thought to function like a gate to control the flow of nerve impulses into the central nervous system. Whether sensory transmission is increased or decreased (causing, respectively, a greater or lesser pain intensity perception) is influenced by cognitive and emotional input such as anxiety, mood state, attention, and past experiences. Bendelow and Williams state that the gate-control theory “signals the end of the mind/body split with regard to pain.” However, these authors acknowledge that currently “the biological remains dominant over the social.” Indeed, Duncan points out that the contemporary biopsychosocial model of pain does not entirely escape mind-body dualism. See also R. S. Lazarus and S. Folkman, Stress, Appraisal, and Coping (New York: Springer, 1984), as cited in A. O’Leary and D. C. Turk, eds., Painful Conditions, 17, no. 2 (1995): 139–65, at 143.

34. Unruh, supra note 6, at 157.


36. Id. at 158.


44. Miaskowski reports that women report more visits to health-care providers on retrospective assessment, but on prospective studies, men and women seek health care at the same rate. Researchers have attributed this difference to the possibility that men are more reluctant than women to admit visiting health-care providers or less likely to remember such visits. See C. Miaskowski, “The Role of Sex and Gender in Pain Perception and Responses to Treatment,” in R. J. Gatchel and D. C. Turk, eds., Psychosocial Factors in Pain: Critical Perspectives (New York: The Guildford Press, 1999): 401–11, at 406. In one prospective study, E. Berkanovic, C. Telesky, and S. Reeder found that perceived efficacy of health care, perceived seriousness of one’s symptom, and reported disability from that symptom were more highly correlated with health-care utilization than was gender, although older women were found to have accessed a physician more than men. “Structural and Social Psychological Factors in the Decision to Seek Medical Care for Symptoms,” Medical Care, XIX, no. 7 (1981): 693–709.


47. Pollack, supra note 46, at 11.
differences in attitudes or emotional responses, and that endogenous pain inhibition may be affected by hormonal variation."

76. Although episodes of acute, severe pain will often be associated with an increase in heart rate or blood pressure, and increased heart rate is used in some studies (e.g., with infants) as a proxy measure of pain, others discourage clinicians from relying on these physiological measures as evidence of a patient’s pain. See M. M. Caffery and B. R. Ferrell, “How Vital Are Vital Signs?,” Nursing, 22, no. 1 (1992): at 45 (“No firm clinical evidence exists to support the assumption that moderate to severe pain is always accompanied by a change in vital signs.”).

77. Unruh, supra note 39.

78. O’Leary and H egelson, supra note 35; Unruh, supra note 6; Weir et al., supra note 38.


80. Id. at 441.

81. C. Laskowski, supra note 45, at 406.

82. M. M. Caffery and Ferrell, supra note 67.

83. Bendelow, supra note 32, at 130. See also N. Urofen, Pain Relief Study (London: Kings Fund, 1989), as cited in Bendelow, supra note 32, at 36.


85. Fillingim and M. Aixon, supra note 8.


88. Id. at 115–16.

89. Crook and Tunks, supra note 66, at 38.

90. Unruh, supra note 39.

91. See L.M. Verbrugge, “Females and Illness: Recent Trends in Sex Differences in the United States,” Journal of Health and Social Behavior, 17 (1976): 387–403, as cited in Weir et al., supra note 38, at 288. Bendelow also describes how women’s more predominant involvement in the domestic sphere has associated them more with the “natural” world in the form of bodily functions, whereas men have been more involved in the “public” world of work and therefore more dominant, emotional rather than rational, biased rather than authoritative, and complaining rather than assertive.”


93. M. M. Caffery and Ferrell, supra note 76.

94. Johansson et al., supra note 84, at 1792.


96. Studies have found that the most significant predictor of inadequate pain relief is a discrepancy between the patient and physician regarding the severity of the patient’s pain. See Cleeand et al., supra note 58.


98. Id. at 147.


101. Id.


104. Id. at 525.

105. Id.

106. See Sherwin, supra note 97, at 48. See also J.F. Smith, “Communicative Ethics in Medicine: The Physician-Patient Relationship,” in S.M. Wolf, ed., Feminism & Bioethics (New York: Oxford University Press, 1996): 184–215, at 194 (“Women who do speak assertively are often taken to be domineering rather than dominant, emotional rather than rational, biased rather than authoritative, and complaining rather than assertive.”). Kate Nicholson, a disability lawyer who is writing a book about her experiences living with chronic neuropathic pain, and who commented on an earlier version of this manuscript, expressed concern that acknowledging gender differences in pain response might lead to gender stereotyping. She made a point of trying to report her pain to health-care providers factually and emotionally, and recalled one female pain specialist’s comment to her, “You are not crazy; you’re not like my other patients.” Additionally, she recalled a male acquaintance’s adamant demand from emergency room staff to give him something for his acute pain (“You SOB’s, you are giving me something for pain and you’re giving it to me right now!”). He got the pain medication. Yet Nicholson was aware that if she had done something similar, “I’d have been perceived extremely differently, in all likelihood.”

107. See Unruh, supra note 6, at 158, summarizing the literature on this point.


110. Women are four times as likely to be diagnosed with a major depression, and twice as likely as men to be diagnosed with a general depression, although rates vary with ethnicity and culture. Possible reasons for this may include that women are more willing to seek help and thus may be diagnosed more frequently; there may be biological differences that predispose women to developing depression (e.g., effects of reproductive hormones); or women may be more likely to suffer from depression due to external stressors (e.g., the effects of sexism, domestic violence, lower pay, and relationship stressors). See F.M. Culbertson, “Depression and Gender,” American Psychologist, 52, no. 1 (1997), 25–31. See also O’Leary and Hegelson, supra note 35. Also, female chronic pain patients are more likely than male chronic pain patients to be diagnosed with and treated for depression. See W.E. Haley, J.A. Turner, and J.M. Romano, “Dep-
112. Smith, supra note 106, at 190.
114. Smith, supra note 106.
115. Female physicians, however, have been found to spend more time with patients, engage in more positive talk, ask more questions, and elicit more responses from patients. See Roter and Hall, supra note 113. See also J. Bensing, A. Van den Brink-Muinen, and D. de Bakker, “Differences Between Male and Female General Practitioners in the Care of Psychosocial Problems,” Medical Care, 31 (1993): 219–29.
118. In a Connecticut focus-group study with chronic pain patients, participants reported visiting multiple physicians (quoting “60 to 100”) in order to find a diagnosis and a practitioner with whom they felt comfortable. See S. Grantham and M. Robbins, The Connecticut Pain Management Initiative Focus Group Report (Boston: John Snow, Inc., February 11, 2000).
121. Controversy over use of the term “alternative” rather than “complementary” medicine demonstrates the point being made here. The former describes therapies that are not sanctioned by conventional medicine and which patients choose instead of conventional medical therapy. The latter views such therapies as complementing conventional medical therapies. The goal would be for women (as well as men) to have access to both traditional and non-traditional therapies for pain management, with a focus on a holistic approach that provides optimal pain relief. This holistic approach is the accepted standard for many pain clinics and inpatient pain teams, but adequate access to such care is limited for many individuals — either because the pain teams and clinics are not available in their area or they do not get the referral they need.
122. Davidson and Freudenberg conclude that women in general, as a result of their socialization, are not as likely to develop a distinction between themselves as individuals and the world around them, whereas men are socialized to objectify and control their environment and to define themselves as separate from the world around them. Men would thus be more apt to try to separate biological and psychosocial pain etiologies, whereas women would tend to view them more holistically. See D.J. Davidson and W.R. Freudenberg, “Gender and Environmental Risk Concerns: A Review and Analysis of Available Research,” Environment and Behavior, 28, no. 3 (1996): 302–39. This theory is affirmed by Bendelow’s findings that women spoke of pain experiences more holistically as compared to men and that “men were significantly less inclined to think that the emotional component of pain perception had any importance.” See Bendelow, supra note 32, at 90.
124. That is, women may: (1) have their pain complaints erroneously dismissed as being emotionally-based and therefore “not real” when there is no significant psychological component to the pain; (2) have the likely psychological components that accompany chronic pain be misidentified by health-care providers as the cause, rather than the result of their unrelieved pain, leading to a discounting of the pain; or (3) have the psychological problem that is the source of their pain be discounted and not adequately addressed. All three are inappropriate and reveal a disdain for psychosocial contributors to pain over evidence of organic causation. See Duncan, supra note 33.
125. Bendelow found that men who were given an opportunity to discuss the emotional aspects of their pain experiences did so and were grateful for the opportunity, even though they did not initially acknowledge emotions as contributing to their pain. See Bendelow, supra note 32, at 90–94.
126. Johansson et al., supra note 84, at 1800.
Pain Management and Provider Liability: No More Excuses

Barry R. Furrow

Pain is undertreated in the American health-care system at all levels: physician offices, hospitals, long-term care facilities. The result is needless suffering for patients, complications that cause further injury or death, and added costs in treatment overall. The health-care system's failure to respond to patient pain needs corrective action. Excuses for such shortcomings are simply not acceptable any longer.

Physicians have long been accused of poor pain management for their patients. The term "opiophobia" has been coined to describe this remarkable clinical aversion to the proper use of opioids to control pain. If the professional mandate of the health-care professional is to relieve suffering, then physicians are falling far short of their obligations by accepting myths about the use of opioids in the face of evidence to the contrary.

The possible reasons for health-care providers' failures to properly manage pain are many. First, physicians are poorly educated in medical school about narcotics and proper pain management, and they remain ignorant in practice about appropriate treatment choices for pain management, often rapidly absorbing professional norms that simply reflect a culture hostile to drug use. Second, threats of legal action loom large in providers' vision: criminal prosecution for use of controlled substances; sanctions involving the loss of hospital staff privileges for use of opiates; medical licensing board disciplinary action; and so on. Uncertainty about legitimate opioid use, coupled with a regulatory system that threatens sanctions, intimidates physicians. Third, patients, worried about tolerance and addiction to the opioids, receive little adequate information or education by providers. Patients suffer unnecessary pain as a result. Fourth, lack of insurance coverage may deny patients access to costly long-term pain management with its multiple modalities of treatment.

Scholars have examined many of these barriers — restrictions on insurance reimbursement; Medicare and Medicaid limits; and criminal prosecutions — and their effect on the use of effective tools for pain control. It is clear that the legal and regulatory environment is a complicated one, with cross-currents that make it difficult for physicians to offer optimal care. What is missing is an external source of norms that articulate the values of pain relief and impose a penalty on providers for their shortcomings. Such a source of pressure can counteract the fears of criminal prosecution and the pressures of both inertia and restrictions on reimbursement that push physicians, hospitals, managed care organizations, and nursing homes to undertreat pain. Tort liability is a powerful external threat, and it can work in tandem with other constructive pressures in the environment to improve provider management of patient pain.

The threat of a malpractice suit for undertreatment of pain is presently quite low. Few judicial decisions discuss pain management and undertreatment. Pain as a component of a tort suit shows up primarily in pain and suffering awards for a physician's negligent treatment or diagnosis of a patient that leads to physical harm and accompanying pain; workers compensation claims for pain treatments; or a component of emotional distress claims. If, however, a physician's treatment of the patient's illness meets the medical standard of care, then the pain attendant on the normal course of illness has typically not been the object of tort damages. What is needed is recognition that the standard of care in treating patients includes pain management as much as it does treatment of the disease.

Treatment and management of pain by both physicians and institutional providers can be improved by the threat of tort litigation, which would spotlight providers' failures to
comply with an emergent standard of proper pain management. This threat of litigation can be a powerful incentive to change medical practices. This article will analyze existing and emerging liability theories and doctrines that should have an impact on the attitudes of physicians and institutional providers toward pain management.

I. THE NATURE OF PAIN: TOUGHING IT OUT

Pain is often viewed as an inevitable part of illness, as a necessary adjunct to disease and its treatment. Too often physicians simply force patients to tough it out, to cope with pain that is unnecessary and debilitating. Patients may also share an attitude that pain is normal and should simply be endured, although this is in contrast to patients with advanced diseases, who welcome pain management for their symptoms. Most pain can be treated and relieved, even though sadly it is too often untreated or poorly managed.

A. Categories of pain

Pain is traditionally divided into acute and chronic pain. Acute pain may be the result of surgery, dental work, burns, or other somatic damage that results in pain of limited duration. Chronic pain may be divided into cancer pain and nonmalignant pain. For nonmalignant pain, palliative medicine is the therapeutic response, defined as “the study and management of patients with active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life.” Such pain is also often termed “intractable,” to mean any condition or situation that is unmanageable or untreatable. While the disease or condition may be untreatable, the pain and symptoms most often can be treated. Chronic pain is usually viewed as appropriately treatable by opioid analgesics on a long-term basis.

Cancer pain is one of the largest categories of pain. Millions of cancer patients suffer pain that could be relieved and managed by proper treatment. One estimate is that more than 90 percent of cancer pain can be controlled with available treatment options. Analgesic drugs, in particular, are an effective approach to managing cancer pain; these include aspirin, codeine, morphine, and their substitutes. The elderly, particularly in nursing homes, suffer high levels of pain — chronic and nonmalignant in many cases — that is poorly managed up to 70 percent of the time. According to clinical practice guidelines on the management of chronic pain in older persons, “For some conditions, chronic pain is defined as pain that exists beyond an expected time frame for healing. For other conditions, it is well recognized that healing may never occur. In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. Because there are many differences in what may be regarded as chronic pain, the definition remains flexible and related to specific diagnoses or cases.”

The standard of practice for pain management is well articulated for cancer pain, for surgical pain, and for nonmalignant chronic pain. But medical practice has been slow to adopt this standard due to fear of addiction and a multiplicity of other factors.

B. Proper pain management

Pain management is defined in the most recent Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines as “a comprehensive approach to the needs of patients, residents, clients, or other individuals served who experience problems associated with acute or chronic pain.” Proper assessment of pain, based on patient self-reporting, is at the heart of any organizational approach to pain management. Pain comes in many forms, but treatment of so-called “intractable” pain follows a generally agreed-upon pyramid of treatment, in which the non-steroidal anti-inflammatory drugs (NSAIDs) and other drugs in combination with patient training come first, and opioids are the final and effective treatment for all forms of pain that fail to respond to milder drugs. Joranson and colleagues state, “the use of opioids in the class of morphine is the cornerstone of pain management.” Yet patients and clinicians continue to be unduly concerned about addiction. Joranson and colleagues comment that “[h]ealth care professionals may be reluctant to prescribe, administer, dispense, or stock controlled substances for fear of causing addiction or contributing to the drug abuse problem.” Addiction is viewed as an evil to be avoided even when its likelihood is low, leaving patients to a stoic absorption of pain that most cannot achieve. Recent studies confirm that abuse of opioid analgesics has remained low in spite of increases in their medical use. Failure to properly manage pain — to assess, treat, and manage it — is professional negligence.

The problem from a malpractice perspective is one of establishing a standard of care based on a clear practice in favor of sophisticated pain management. The current versions of the ethical principles governing clinical practice — the Hippocratic Oath and the Code of Ethics of the American Medical Association (AMA) — and the statements of medical leaders do articulate the duty to relieve suffering. For example, the AMA’s Code of Medical Ethics states in pertinent part, “[p]hysicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care. This includes providing effective palliative treatment even though it may foreseeably hasten death.” Nurses likewise are admonished to “use full and effective doses of pain medication for the proper management of pain in the dying patient. The increasing titration of medication to achieve adequate symptom control, even at the expense of life, thus hastening death secondarily, is ethically justified.” But medical practice at all levels lags behind these ethical expressions of the duty to treat pain.
II. **Physician Failures to Treat Pain: Tort as a Beacon**

A. Functions of tort liability

The rules developed by courts in malpractice suits serve a range of functions in altering medical practice. First, tort rules reinforce good medical practice. Case law is the voice of common law judges stating minimum principles of generally accepted medical practice. The cases typically defer to the medical consensus on a standard of practice without much judicial scrutiny of the standard. But case law is still an influencing force on medical practice nonetheless, as it imposes financial burdens on providers and their malpractice insurers for medical errors, ignorance of good practice, and tolerance of sloppy practice. A lawsuit inflicts a price on providers in insurance costs and defense costs. Providers, as consumers of lawyers and insurance, are at least somewhat sensitive to increases in price, heightening their sensitivity to bright-line rules of practice.

Second, tort rules give voice to patients who have been patronized, ignored, actively manipulated, or cruelly treated by physicians. Informed-consent doctrine has forced medical recognition of patients’ informational needs; EM TALA has forced stabilizing treatment by hospitals inclined to simply push patients out the door; disclosure obligations have built on the physician’s fiduciary duty toward patients.

Third, malpractice litigation drives institutional practices toward convergence on validated standards of practice. Lawyers can introduce evidence of emerging clinical practice guidelines as a way of arguing for a standard of care that the defendant failed to satisfy. Proof of malpractice thus slowly moves from elastic expert opinion toward more empirically validated clinical practices. This means that the defense has less wiggle room in the average malpractice case and, as a result, the law indirectly forces physicians toward heightened awareness of standards.

Fourth, tort law often articulates new duties of care for providers. Physicians not only must pay attention to emerging practices, but must also disclose risks to third parties created by a patient, candidly make a referral to a more skilled specialist, be honest with the patient, and watch out for the patient’s interests over those of the provider. These new duties force providers to focus on the patient as primary.

These tort functions have implications for improving pain management. We have come to expect providers to master these new roles: provider of full information to patients as consumers of health care; protector of public health, through obligations to warn family members and third parties; stabilizer of patients even without a contractual relationship; and comforter and counselor of families. But current incentives in the health-care system push powerfully toward physicians’ undertreating pain. As Ann Martin writes: [S]trong rewards, both internal and external to the practice of chronic pain management, reinforce the principle in the ethic of under-prescribing to say no. A practitioner who accepts that addiction is harmful and that assisting or hastening death is a wrong has a duty to prescribe drugs in a manner that will not result in either. Federal and state prescribing laws, societal norms about the dangers of drugs, and board rules and regulations reward practitioners who under prescribe by making saying yes a risky proposition — to practitioners’ livelihood, reputation, and status in the practice community and under the law.

The threat of malpractice litigation may offset these powerful forces, making anxious providers either overestimate the risk of suit or at least adjust their practice to a new assessment of the risk of suit. Surprisingly, most patients do not file a malpractice claim because of uncertainty as to the cause of their injury. This is true even though studies of medical error have concluded that “the burden of iatrogenic injury is large enduring, and an innate feature of hospital care in the United States.” Even for patients with major permanent injuries, it appears that only about one in six file suit. However, the threat of tort litigation has a substantial psychological impact on physicians in excess of the diluted financial incentives created. Physicians overestimate the risk of being sued and the size of feared judgments. The sheer unpleasantness of being sued also deter, although it has been argued that the lack of clarity as to the locus of negligence in most cases does not provide useful feedback to providers.

Physicians clearly perceive a threat from the system, judging their risk of being sued as much higher than it actually is. The Harvard New York Study, surveying New York physicians, found that physicians who had been sued were more likely to explain risks to patients; to restrict their scope of practice, and to order more tests and procedures. M alpractice insurers, particularly the physician-owned companies in many states, now engage in aggressive review of claims. These companies insure about 40 percent of physicians in active practice, and to order more tests and procedures. If a physician loses his malpractice insurance, he may quit, switch jobs, or go without insurance. He may also go to a surplus-lines insurance company that charges much higher premiums for coverage. Claims exposure can thus lead to a direct financial impact on the physician who is forced to carry such expensive insurance.

The litigation process is neither as arbitrary nor as unfair as critics suggest. The jury turns out to be a surprisingly reliable decision-making institution. Lawyers are good
screens for frivolous cases. A physician named as a defendant may, as a consequence, spend more time on exams or patient histories, invest in further training, increase support staff, or develop a more systematic approach to pain management. The few available studies have found that physicians who have been malpractice defendants often alter their practice as a result, even if they win the litigation. Perceived risk is thus important to physician conduct. Hospitals have instituted risk management offices and quality assurance programs; informed-consent forms have become ubiquitous; medical record-keeping with an eye toward establishing proof of care at trial has become the rule. There is little doubt that the threat of malpractice litigation has had some effect on provider practices, and that increases in litigation over inadequate pain management would likely spur improvements at the individual provider and institutional levels.

B. The general malpractice rule

1. National standards of care

A liability analysis of pain management starts with the physician, since it is the physician who fails to prescribe proper medication or to assess and manage patient pain. The liability of physicians is governed by general medical malpractice principles. Malpractice is usually defined as unskillful practice resulting in injury to the patient, which constitutes a failure to exercise the “required degree of care, skill and diligence” under the circumstances. A physician is not a guarantor of good results, nor is he or she required to exercise the highest degree of care possible. As one court said, “The physician will not be held to a standard of perfection nor evaluated with benefit of hindsight.”

The standard of care by which most state courts measure the conduct of both general practitioners and specialists is a national standard. A good statement of this standard is found in Hall v. Hilbun:

The duty of care ... takes two forms: (a) a duty to render a quality of care consonant with the level of medical and practical knowledge the physician may reasonably be expected to possess and the medical judgment he may be expected to exercise, and (b) a duty based upon the adept use of such medical facilities, services, equipment and options as are reasonably available.

Most jurisdictions impose a national standard of care on physicians because of concerns about a “conspiracy of silence,” unfair limitations on the use of experts, and a recognition of the national character of medical education and practice. Nonetheless, many jurisdictions allow evidence describing the practice limitations under which the defendant labors. Some jurisdictions explicitly allow the trier of fact to consider the facilities, staff, and other equipment available to the practitioner in the institution where he or she is affiliated. This follows the general rule that courts should take into account the locality, proximity of specialists, and special facilities for diagnosis and treatment. The standard of care governs a physician’s conduct during the period when the patient was under his or her care; this includes follow-up care to ensure that a patient obtains medical records and information as requested.

Proving negligent pain management is difficult for the plaintiff in light of contemporary failures by the medical profession to practice pain management practices. Traditionally, tort law has allowed the medical profession to set the standards of practice, with the courts enforcing these standards in tort suits. Defendants trying to prove a standard of care normally present expert testimony describing the actual pattern of medical practice, historically without any reference to the effectiveness of that practice. Most jurisdictions give professional medical standards conclusive weight, so that the trier of fact is not allowed to reject the practice as improper. On rare occasions, the courts have allowed the case to proceed in spite of agreement that the defendant satisfied the customary practice of his or her specialty because evidence was presented that the defendant was aware of the dangers in the standard practice. Other more recent decisions have found that proof of “ordinary care” can prevail over a defense of compliance with custom.

The standard of care is not usually a bright-line rule. The standard in Hall for judging the defendant’s conduct was “minimally competent physicians in the same specialty.” This minimal competence test seems less demanding than standard jury instructions in other states that require comparison to “the average practitioner in the class to which he or she belongs.” “Average” suggests a midpoint in the range of practitioners, while “minimal” places the defendant’s conduct distinctly lower on a scale of practice. The standard of care must be at least in compliance with available technology at the time the diagnosis or treatment was offered to the patient, without the benefit of hindsight. So the issue of what is known by a “minimally competent” practitioner, held to a national standard and assuming up-to-date education, is a classic jury question, leaving the trier of fact to resolve the dispute among sparring experts from either side.

a. Clinical practice guidelines

What a minimally competent practitioner must know has not traditionally been derived from an external authority, such as a government standard, but rather from medical standards developed through the interaction of leaders in the profession, professional journals and meetings, and networks of colleagues. Most clinical policies develop from an ongoing exchange in the literature, at meetings, and in peer dis-
discussions. Over a period of time, a clinical policy takes shape from this series of interactions. If it becomes generally accepted, it becomes "standard practice."60

The development and proliferation of clinical practice guidelines has speeded the process by which good evidence-based medical practice becomes recognized and disseminated as such. In response to the rapid growth in medical research and published findings, these guidelines have become one of the transforming forces in current medical practice.61

Medical knowledge about evidence-based medicine has accumulated at a staggering rate. Between 1966 and 1995, the number of clinical research articles based on randomized clinical trials jumped from about 100 to 10,000 per year.62 American physicians and specialty groups have expended substantial effort on standard-setting in recent years, specifying treatments for particular diseases. Clinical practice protocols (also referred to as practice parameters or guidelines)63 have been developed by specialty societies such as the American Academy of Pediatrics, by the government, through the National Institutes of Health; and by individual hospitals in the clinical setting.

The development of practice standards and guidelines by national medical organizations has accelerated the process of moving all medical practice toward national standards.64 Such guidelines provide a particularized source of standards against which to judge the conduct of the defendant physician, and the fact that they are produced by national medical specialty societies and the government means that they will be influential.65

Such guidelines are sets of suggestions, described in decision rules, based on current medical consensus about how to treat a certain illness or condition. The Institute of Medicine has defined clinical guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." They are standardized specifications for using a procedure or managing a particular clinical problem. Such guidelines may be quality-oriented, reducing variations in practice while improving patient care; they may also be cost-reducing, promoting a lower cost approach to care.

A clinical standard may be presumptive evidence of due care if expert testimony introduces the standard and establishes its sources and its relevancy.66 The guidelines can also be used to impeach the opinion of a medical expert.67 Clinical guidelines potentially offer an authoritative and settled statement of what the standard of care should be for a given treatment or illness. A court has several choices when such guidelines are offered into evidence. A guideline might be evidence of the customary practice in the medical profession. A doctor practicing in conformity with a guideline would be shielded from liability to the same extent as one who can establish that she or he followed professional custom. A guideline could also serve as a defense to a claim that the defendant deviated from customary practice, insofar as it represents the practice of at least a "respectable" minority of the relevant profession.68 The guideline acts like an authoritative expert witness or a well-accepted review article. Using guidelines as evidence of professional custom, however, is problematic if they are ahead of prevailing medical practice.

Guidelines have already had an effect on settlement patterns, according to surveys of malpractice lawyers.70 Plaintiffs have used such guidelines to their advantage in malpractice cases, particularly the guidelines of the American College of Obstetricians and Gynecologists.71 Such guidelines provide a particularized source of standards against which to judge the conduct of the defendant physician. A widely accepted clinical standard may be presumptive evidence of due care, but expert testimony would still be required to introduce the standard and establish its source and relevancy. A guideline could thus be treated as negligence per se or at least a rebuttable presumption, which could then be countered with evidence.

Standards of care for pain management are increasingly well-established. Organizations such as the Agency for Health Care Policy and Research, the Agency for Healthcare Research and Quality, the American Pain Society, the American Academy of Pain Medicine, the American Geriatric Society, and the American Society of Anesthesiologists have promulgated pain control standards.72 The Joint Commission on Accreditation of Healthcare Organizations and the National Committee on Quality Assurance have also been paying more attention to an institution's standards for pain management during the accreditation process.73

The use of such guidelines in pain management litigation is therefore likely. Consider the Practice Guidelines of the American Society of Anesthesiologists.74 These guidelines develop an interrelated set of approaches to proper pain management, with several levels: a comprehensive evaluation and treatment plan; a diagnostic evaluation; counseling and coordination of care; periodic monitoring and measurement of clinical outcomes; and multidisciplinary, multimodal pain management. Multimodal therapy is "concomitant use of separate therapeutic interventions under the direction of a single practitioner to obtain additive beneficial effects or reduction of adverse effects." These interventions might include neural blockade with medications, rehabilitative therapies with neural blockade, and medications of varying strengths.

Pain management guidelines demand at least an initial diagnostic assessment of pain as a clear starting point and then attention to following the patient and using pain management strategies in a well-established hierarchical fashion. For physicians who work in hospital settings or depend on managed care organizations for the bulk of their patients, knowledge of and compliance with guidelines will become a
necessity. The guidelines provide the beginning of a bright-line test for measuring provider shortcomings in managing patient pain.

b. Web-based databases

The second force that reinforces the power of clinical practice guidelines is their easy availability on a range of Web sites. Web sites have proliferated to help physicians gain efficient and user-friendly access to this even-greater proliferation of guidelines and other medical information.

The National Guideline Clearinghouse77 is the best example of this; it offers free access to physicians and others to the current clinical practice guidelines, with instantaneous searches of the database. A search produces all guidelines on a given subject, along with an “appropriateness” analysis for each guideline.78 The Clearinghouse also provides a standardized abstract of each guideline, and grades the scientific basis of its recommendations and the development process for each. Full text or links to sites with the guidelines are provided. Readers are given synopses to produce a side-by-side comparison of guidelines, outlining where the different sources of guidelines agree and disagree. Physicians can access electronic mail groups to discuss development and implementation.

To be included on the Web site, these guidelines must pass certain entry criteria: They must be current; contain systematically developed statements to guide physician decisions; have been produced by a medical or other professional group, government agency, health-care organization, or other private or public organization; and show that they were developed through a systematic search of peer-reviewed scientific evidence. The benefits of such a database are apparent. It has search features, comprehensiveness, and easy access through its Internet location, making it the most powerful tool for using guidelines to date.79

Clinical practice guidelines have the power to influence the finding of a standard of care in a malpractice case, but are often ignored by busy physicians.80 Physician adherence to guidelines appears to be hindered by inertia, lack of awareness, and external barriers, such as lack of time or difficulty of use.81 As Stephen Lande writes: “The reality of the system ... is that physicians will resist attempts to change treatment practices and will ultimately revert to their own way of thinking except when they are explicitly pressured.”82 Physicians who work within managed care systems, as most do today, need to have reminder and feedback systems in place to reinforce their attention to guidelines.

Resistance to pain management practices combines these forces of inertia with the provider’s additional fears about the extensive regulation of powerful opioids. However, Internet access to such guidelines in a quick and user-friendly way may hurry along the process of awareness and adoption of such guidelines and increase physicians’ comfort level with better pain management practices. The location of current information on the Internet facilitates access for anyone with a computer, and the fact that the guidelines are linked to other commercial sites makes them easy to find, no matter what portal a physician uses to access medical information databases on the Web.83

With the rapid clinical deployment of personal digital assistants (PDAs), which can download material from the Internet and store volumes of clinical reference information, physicians will be expected to be familiar with the appropriate clinical guidelines for the patients they treat. One company, docuCare, now offers a handheld device to document patient care at the bedside — to record vital signs, medications, the physician’s pain assessment, and the patient’s responses to a pain satisfaction survey.84 The fact that a pain assessment survey is included with the device should emphasize to physicians the standard nature of taking such a survey.

A provider’s failure to access medical databases like the National Guideline Clearinghouse is likely to become an important piece of evidence in a malpractice suit, since it is evidence that a physician failed to stay current in his or her field of practice. A physician who displays ignorance of current treatment guidelines may be attacked by the plaintiff using the results of a computer search to display these guidelines and their relative ease of access.85 Refusal to listen to a patient’s description of pain or to move to more effective drugs as needed, following the World Health Organization treatment pyramid or the pain management guidelines of various specialty organizations, will not be excused because of a claim that customary practice does not require it.

2. Other reasons to conform to the standard of care

A spectrum of liability doctrines are potentially available in situations where pain management is not given or is substandard.86 The theoretical underpinning of all such theories is the same: failure to be aware of the standard of care for proper pain management or failure to conform to it.

The heart of any malpractice case is proof by the plaintiff that the defendant failed to meet the standard of care. If the physician provides pain management for a patient, it must be done properly. A claim for a failure to treat for pain is dependent on evidence that the standard of care requires proper pain management in the situation experienced by the plaintiff. A patient can expect proper treatment, defined by the emerging standards of care as encompassing a right to relief from pain.87

Can a physician argue defensively that he or she was not trained in medical school as to proper pain management and that the customary practice among physicians is to undertreat pain? If a customary practice is a nonreflective and uninformed practice, it may be attacked by the plaintiff’s experts. A growing body of testimony by physicians who have
studied pain reflects a growing consensus on the proper treatment of pain — and you can bet that a plaintiff’s pain is something about which every jury can understand and empathize. 

The issue is whether the customary practice is a reflective one or the result of ignorance and inertia. Modern case law has at times instructed the trier of fact that customary practice need not always be an absolute defense — that evidence of good practice may be introduced. Judicial deference to customary practice is, in fact, weakening. The Wisconsin Supreme Court observed in Nowatske v. Oserhoh: 

should customary medical practice fail to keep pace with developments and advances in medical science, adherence to custom might constitute a failure to exercise ordinary care…. [W]hile evidence of the usual and customary conduct of others under similar circumstances is ordinarily relevant and admissible as an indication of what is reasonably prudent, customary conduct is not dispositive and cannot overcome the requirement that physicians exercise ordinary care.

The respectable minority defense allows a physician who wants to follow pain management guidelines to defend his or her practice in the face of a different customary practice. Pain management guidelines are already generally accepted and used as a reference in workers compensation cases in many states, since workers often claim both job-related disability and the pain that results from that disability. The workers compensation judge often has to make findings as to whether a particular medical treatment is necessary. Statutes clearly allow compensation not only for curative treatment but also for palliative treatment, including aggressive pain management using opioids long term.

In City of Jennings Police Department v. Dorr, for example, the claimant suffered from chronic pain and depression due to a severe back injury. She had tried a variety of drugs, and her physician finally prescribed morphine sulphate for pain relief — specifically, 180 milligrams every eight hours, a dose usually reserved for chronically or terminally ill cancer patients. The court noted that the medical literature supported long-term treatment in certain cases with high dosages, although there was a split of opinion in the medical community. The court found that the level of drugs prescribed was not excessive and upheld the treatment plan of the physician as appropriate.

Courts in a variety of cases — malpractice, workers compensation, and medical discipline, for example — apply a standard increasingly calibrated to proper pain management practices. As long as the physician can present evidence of a thoughtful program of pain management for a particular patient, the courts are willing to respect aggressive opioid use.

C. Other tort norms forcing pain management

1. Referrals to pain specialists

Multidisciplinary pain programs are acknowledged to provide cost-effective approaches to pain. The ideal program includes specialists who can provide a range of services, including an anesthesiologist, a behavioral medicine specialist, a physical therapist, rehabilitative medicine specialist, and case managers to oversee and coordinate care. Consequently, it is necessary for the primary care physician and other specialists to be familiar with the existence and expertise of a pain specialist. This is more than a statement of medical necessity for the patient; established tort principles require a physician to make a referral to the appropriate specialist when the physician lacks the knowledge or experience to properly treat the patient.

In Freeman v. Cleveland Clinic Foundation, the plaintiffs’ son committed suicide. They argued that the surgeon who was treating the young man for his knee injury negligently failed to refer him to a pain management clinic after he concluded that the patient would not benefit from further physical treatment of knee problems. The court held that failure to refer did not proximately cause the young man’s death, a common judicial way of avoiding the imposition of liability for suicide. The court did not, however, reject the possibility of such a duty to refer. In a more typical malpractice case, where a patient is experiencing acute or chronic pain and the treating physician fails to treat it because of a lack of pain management knowledge, it is more likely that a duty to refer will be found. For instance, in Johnson v. Kokemoor, a Wisconsin informed consent case, the court held that the physician’s inexperience with a surgical procedure should have led him to offer the patient the choice of a referral to a nearby experienced surgeon.

The common law tort duty to refer is a well-established one. As the specialties of pain management mature, physicians who do not want to manage their patients’ pain have a duty to refer. Patients with complicated pain imbedded in their disease process, like many cancer patients, require pain management as an integral part of their treatment. A pain management specialist must therefore be a part of the treatment team at a minimum. A physician who refuses either to treat the pain in conformity with current guidelines or to refer the patient is acting unethically. One could even argue that refusal to treat a pain patient is analogous to refusing to treat HIV-positive patients. The duty to refer must be carefully developed in light of the problem of pain, typically imbedded in the disease process for many patients. It can be argued that a primary care physician in particular must become familiar with pain management treatments, since referral may not always be possible — either because of insurser limitations or physical proximity. In such cases, the
duty of continued treatment binds the physician to learn about pain and its control, or risk an action for abandonment of the patient.

2. Negligent or intentional infliction of mental distress

Can a patient or the family as bystanders sue for infliction of emotional distress because of the patient's suffering unrelieved by proper pain management? The family members of a post-operative patient, or a terminally ill patient, are vulnerable, worried, and anxious. Visible suffering, unrelieved by the tools of pain management, can predictably create emotional distress in family members. Witnessing a family member in a hospital or nursing home suffer from unrelieved pain is itself painful.

No case law exists to support such a duty toward family members, but it can be movingly and persuasively argued. Courts have allowed plaintiffs to sue health-care providers for the negligent infliction of emotional distress under particularly egregious circumstances. One example is Oswald v. Legrand. The plaintiffs, a married couple, sued for mental injury as the result of a series of obstetric events. The wife was pregnant and began to have difficulties prior to her five-month check-up. She was admitted to the hospital, where she was treated rudely by physicians and staff and finally gave birth to a child who was presumed to be stillborn but turned out to be alive. The sequence of events was outrageous. The Oswalds claimed, among other things, severe emotional distress and mental anguish caused by witnessing the negligent treatment of their newborn infant. The court observed that tort law allows recovery for emotional distress when it is connected to physical injury or "where the nature of the relationship between the parties is such that there arises a duty to exercise ordinary care to avoid causing emotional harm.... [W]e think liability for emotional injury should attach to the delivery of medical services" (emphasis added).

Oswald focused on the vulnerability of the plaintiffs, coupled with the "cruel insensitivity" of the medical staff. A similar case is Wargel v. Sisters of Mercy Health Corporation, where a series of obstetric disasters befell the plaintiffs. The obstetrician made only two visits during labor, even though a Cesarean section was indicated due to the plaintiff's lopsided uterus and the fact that the fetal monitor indicated distress. The staff failed to react, and an intern subsequently delivered the plaintiff's child, not breathing and blue in color, and placed it on the mother's stomach as if it were a healthy child. Realizing the child's condition, the obstetrician then grabbed the child and began to pound on her chest and administer electric shocks to revive it. A call for a pediatrician to help went unanswered, and after fifteen minutes, the rescue attempt was abandoned. The Michigan court applied the bystander rule, which permits a family member witnessing an injury to a third person to recover if the family member is present or suffers shock "fairly contemporaneously" with the accident. The court held that "the cumulative effect of all the events surrounding the stillbirth of the child, if proven to be negligent at trial, are sufficient to cause a parent to suffer emotional and mental distress."

In these cases, the courts have required observation of the disturbing events. "Observation" has been liberally construed by some state courts to include a discussion with a physician about a loved one's deteriorating condition. Most courts, however, require some direct observation of the events causing the bad outcome, not just observation of the bad outcome itself.

Some jurisdictions are reluctant to allow observational distress, fearing a litigation explosion and difficulties of proof in such cases. In Gray v. INOVA Health Services, a mother sued a hospital for negligent infliction of emotional distress after seeing her young daughter's physical reactions to an overdose of drugs during a medical test. The plaintiff alleged that she contemporaneously experienced extreme shock, blacked out, fell to the floor, vomited, and still suffers from mental anguish. The court affirmed a demurrer for the defendant on the grounds that the hospital owed no duty to the mother, only to the child who was the patient. However, Gray is distinguishable from the Oswald case, where active labor and its stresses involved both parents intimately in the birth process and where the staff's behavior was reprehensible. In Gray, the fault lay in a negligent dosage of drugs, not a cascade of rude and insensitive behaviors directed at vulnerable parties.

The doctrine of negligent infliction of emotional distress, therefore, has the potential to offer a remedy to vulnerable family members as they watch a loved one suffer needlessly in pain. The analogy to the labor and delivery cases is clear in the hospital or nursing home setting where the patient is obviously suffering. The doctrine is arguably applicable to any instances of intractable pain and its poor management in extreme cases.

3. The doctrine of informed consent

Can a plaintiff argue that informed-consent doctrine requires that pain management be disclosed as an alternative treatment to doing nothing for intractable pain, even if the physician does not want to use opiates or otherwise manage the pain? Such an obligation is connected to the duty to refer discussed above.

Physicians are required to discuss alternative methods of treatment — along with their risks and consequences, and their probability of success — if these methods of treatment are generally acknowledged within the medical community as feasible. Physicians are obligated to discuss with patients the side-effects of drug treatments where
driving or other life activities might be impaired. Some courts have held that alternatives should be disclosed even if the alternative is more hazardous or the physician is not capable of performing the procedure or evaluating its risk. The threshold is only that the alternative treatment be considered within the standard of care. Such alternatives might include access to pain control programs or other specialty services. Aggressive pain management through opioid prescription is, at present, at least a minority practice within the medical professions using comprehensive pain management strategies.

The definition of “treatment” for purposes of when “informed consent” is needed has been construed broadly to include diagnostic options and choices of hospitals for performing a procedure. Physicians must disclose diagnostic procedures that might assist patients in making an informed decision about treatment. In Martin v. Richards, the physicians failed to inform the parents of a minor patient of the availability of a CAT scan to detect intracranial bleeding and the unavailability of a neurosurgeon at the hospital to operate on the child. The court held that it was for the jury to decide whether these things caused the patient’s brain damage.

In Vachon v. Broadlawns Medical Foundation, the plaintiff suffered severe multiple trauma injuries. The issue was whether the plaintiff’s transfer to a university hospital two hours away instead of to closer trauma hospitals was reasonable. The court held that the decision to transfer was part of the patient’s treatment and raised an issue of reasonable care. In Johnson v. Kokemoor, the court included within the surgeon’s duty of disclosure an obligation to inform the patient of the proximity of experienced providers in a nearby clinical setting who would have been able to perform the operation at a lower risk.

The corresponding pain management issue is whether a physician should be sufficiently aware of choices — hospices for cancer patients, pain management programs for nonmalignant pain sufferers, or other physicians trained in modern pain management techniques — to be able to inform a patient of his or her options in treatment. It does not seem a stretch to require a duty to inform patients in such circumstances that a full range of pain therapies is available. Failure to discuss pain management options and the possibility of referral or transfer might well appear as a count in the patient’s malpractice complaint for pain mismanagement.

D. Proving pain as damages

Present and future pain and suffering is a legitimate component of a damages claim by a malpractice plaintiff. As Dobbs says, “[t]he pain for which recovery is allowed includes virtually any form of conscious suffering, both emotional and physical.” This can even include the pain of recalling past pain. Pain experts can testify about such pain, as can the plaintiff; inferences about the degree of pain can also be drawn from the nature of the plaintiff’s condition and the kind of medical treatment needed. Pain includes the sensation of physical pain.

In the normal tort case, pain is the result of a bodily injury caused by the defendant. The court is willing to instruct juries on pain and suffering when the plaintiff has suffered tangible injury due to the defendant. In the medical setting, pain from a missed diagnosis and lost opportunity to treat can be part of damages. The pain management failures are more complicated: The physician or provider is responsible not for the patient’s condition, but for the mismanagement of pain, which is a by-product and symptom of an underlying disease. Pain, therefore, becomes the only component of damages, by analogy to the mental distress torts. The loss of enjoyment of life, as a corollary of the pain, may be allowed as a separate component of damages. The plaintiff’s reactions to the pain and his or her sense of loss as a result may also be compensable.

III. Institutional Failures to Manage Pain: Thoughtless Systems

Pain is ignored in the institutional setting as well as the physician’s office. The consequence of unrelieved pain, particularly cancer pain, is not only patient suffering and decreased quality of life. It has been estimated that “[b]etween 30 and 50 percent of cancer patients in active treatment and 70 to 90 percent of those with advanced disease experience moderate to severe pain...” In surveys of surgical patients, it has been found that approximately half of all hospitalized post-operative patients failed to receive adequate pain relief. Patients reporting moderate to high levels of pain received less than half of the pain medication that was ordered.

The result of this undertreatment is decreased quality of life, functionality, activity, appetite, and productivity. The patient, having experienced such severe pain, can also become unwilling to continue treatment and become suicidal. At the M D Anderson Cancer Center in Texas, the annual hospital costs for pain admissions are estimated at $4.7 million annually. Most of this pain can be managed by proper assessment of causes and treatment with opioid analgesics. And most of this pain is found in patients in institutional clinical settings — general medical, surgical, and oncology wards; burn units; emergency departments; and pediatric wards.

Failures of pain management can have catastrophic consequences for patients and for health-care institutions. Undertreatment may also lead to patient suffering, surgical complications, and other negative treatment results. Pain is not just a background noise produced by a disease like AIDS or cancer, to be stoically ignored or endured; it is the cause of somatic failures and expensive hospitalization and of patient resistance to treatment. Lower back pain, as one ex-
ample, costs millions of dollars a year in loss work time. Pain, in other words, operates as an independent medical condition, and its continuation when modalities of treatment are available is iatrogenic — that is, injury that is provider-induced.120

Malpractice tends to isolate the individual physician as the cause of patient injury and suffering. The evidence as to undertreatment suggests that while physicians may often be at fault, it is primarily the system of care that has failed to reorganize its resources to address the problem. Since educational approaches lack efficacy, the better approach is to affect the systems that influence physician behavior.

Treatment and management of pain by institutional providers can be fostered by the possibility of liability for failure to satisfy a standard of care for effective pain relief. These threats of litigation can be powerful incentives to counteract physician resistance to the adoption of sound pain management practices.

A. Hospitals: the mandate of pain management
In the hospital setting, unnecessary patient pain frequently imposes higher costs as the result of lost wages and higher health-care utilization, such as emergency room visits and unnecessary hospitalizations.121 The hospital system has not been designed to recognize pain as a valid indicator of suffering and track and treat it with the intensity with which a fever is treated in a hospital. “[R]eports of unrelieved pain do not invariably result in corrective measures; pain may not be visible at the coordinating centers of the ward, and physicians and nurses have not traditionally been held accountable for providing titrated analgesia.”122

1. The general duty to manage complex systems
Hospitals have been slow to adopt pain management practices. Hospital staffs have not made pain relief a priority, and hospital organizational structures have failed to incorporate pain management support.123 For instance, the SUPPORT Study in 1995 found that hospital treatment for dying patients involved poor communication between physicians and patients, overly aggressive treatments, and inattention to patient pain and suffering. It provided a discouraging indictment of the hospital system — namely, that it failed to treat patients with pain at the end of life. Critically ill patients were and continue to be bombarded with the newest medical technologies to extend their lives, even in the face of their stated wishes for a prompt relief of pain and suffering. A recent study of hospital palliative care concluded that lack of financial reimbursement is one of the reasons that end-of-life care is not a priority for hospitals.124

Guidelines from the Agency for Healthcare Policy and Research (AHCPR) provide for the minimization of the incidence and severity of acute pain.125 These guidelines were published in 1992, but “evidence suggests that suitable pain management programs have yet to be developed.”126 This is despite the fact that the technologies are available, including intraspinal opioid administration, opioid infusion, and inhalational analgesia,127 and that the organizational structures are well-defined.128

Hospital-based clinical management has neglected post-operative pain. In the words of Blau and colleagues, “[r]ecent data suggest that many patients continue to fear severe pain after surgery, and many post-operative patients continue to have significant pain. Further improvements in the quality of pain control will not occur unless it is recognized as a priority by health care providers, and an institutional approach is taken to assure that high quality analgesic care is consistently provided.”129 In spite of sound guidelines, “many health care institutions continue to lack any organized institutional approach for the management of acute pain.”130

Yet the benefits of pain management are apparent. Surgical outcomes are improved by effective post-operative pain management, which may also reduce patient time in an intensive care unit, accelerate discharge readiness, and reduce the overall cost of hospitalization. These outcome benefits are based on inhibition of the metabolic stress response after surgery. Evidence shows that inadequate control of pain can also interfere more directly with recovery by impairing pulmonary function and movement and delaying the recovery of gastric and bowel function.131

Many medical disciplines are responsible for pain management. Pain management needs to be an institutional priority, supported with resources and leadership.132 A health-care institution, whether a hospital, nursing home, or clinic, is liable to its patients for negligence in maintaining its facilities, providing and maintaining medical equipment, hiring, supervising and retaining nurses and other employees, and failing to have procedures in place to protect patients.

Basic negligence principles govern hospital liability for injuries caused by something other than the negligent acts of the medical staff.133 Hospitals are generally held to a national standard of care for hospitals of their size and treatment category. Where, however, a new technology of proven efficacy has been adopted by some hospitals, the standard may be used to measure the practice in all hospitals.134

The professional duty of a hospital is to provide a safe environment for patient diagnosis, treatment, and recovery. If an unsafe condition on the hospital’s premises causes injury to a patient as a result of the hospital’s negligence, the hospital has breached its duty qua hospital.135 The test is “whether the negligent act occurred in the rendering of services for which the health care provider is licensed.”136 Hospitals must have minimum facilities and support systems to treat the range of problems and side effects that accompany the procedures they offer. Equip-
Pain management requires a systematic team approach. Much of the case law that has articulated hospital responsibility has come to focus on the administrative and treatment systems in place. For example, short staffing has been rejected as a defense where the available staff could have been juggled to achieve closer supervision of a problem patient. Failure to provide an adequate twenty-four hour anesthesia service also may create liability. A hospital and its contracting physicians may be liable for damages caused by inadequate or defective systems they develop and implement, particularly where emergency care is involved. Poorly designed systems can create harm just as readily as an incompetent staff member. Hospital on-call systems must work properly, and systems for storing and supplying medications must function effectively. Another example of such an administrative failure is when a hospital fails to properly schedule a specialist consultation once it has been requested by a staff physician.

Hospitals will be liable for injuries caused by inadequacies in the internal programs that are mandated by statutes. Once a hospital assumes a new responsibility, it need not be state of the art.

Courts have expanded the doctrine of corporate negligence. The few cases that reject a hospital’s duty to monitor are increasingly outside mainstream jurisprudence on hospitals. Most jurisdictions have held hospitals to a duty to take reasonable steps to ensure the competence of its medical staff. The monitoring and retention of hospital staff have led to expanded duties to detect incompetence. A properly designed utilization review process within an institution will produce data as to unnecessary procedures, high error rates, and other early warnings of problems with a staff physician. The existence of such a process will give a hospital actual notice of possible incompetence, exposing it to liability if it fails to act to deal with the problem.

In addition to determining which staff physicians are incompetent to handle certain procedures, the hospital must detect any concealment by its staff of medical errors. While some courts have limited this duty to only those situations where a hospital has learned of physician insufficiencies, others have talked of “negligent supervision” in terms of an affirmative duty to detect problems. The few cases that reject a hospital’s duty to monitor are increasingly outside mainstream jurisprudence on hospital responsibility.

Pain management obligations should be shouldered by physicians, with continuous feedback and attention to the level and quality of such management by the hospital. A failure to provide training and feedback and to detect physician reluctance to use proper techniques provides an argument of corporate negligence.
b. Duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care

The broad statement of this fourth duty of hospitals, as articulated in Thompson v. Nason, properly defines the role of corporate negligence in addressing institutional management of all dimensions of patient care. The regular charting of pain should be treated as a “fifth vital sign” along with the other vital signs of temperature, pulse, respiration, and blood pressure. Pain management is now a dimension of hospital administration in light of the new JCAHO standards. The duty to monitor patient care to ensure that staff physicians are properly treating patients must now include proper pain management.

i. JCAHO standards and pain management as a priority

Hospitals are regulated by their states, and state regulation typically defers to the standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The standard of care applied by courts in malpractice actions also reflects a baseline mandated by JCAHO standards, including its peer reviews through internal committee structures. Courts have consistently allowed evidence of JCAHO standards, state hospital licensure laws, and the hospital’s own by-laws, which the trier of fact is entitled to accept or reject, as creating a permissive inference of negligence or a rebuttable presumption.

Failure to follow new JCAHO standards for pain management can thus lead to liability, with such standards being admissible as evidence of the standard of care once they are implemented for the hospital’s accreditation. The standards force integration of pain management into a hospital’s overall care of a patient. A team approach to medical practice, incorporating pharmacists and other providers, is likely to further reduce risks. The standards developed by JCAHO and the National Committee on Quality Assurance need to rapidly incorporate the current findings of the Institute of Medicine report, To Err Is Human: Building a Safer Health System, and increase the pressure on individual and institutional health-care providers to redesign their systems to reduce risk.

Only within the last few years have JCAHO standards finally addressed pain management in hospitals and the need for proper organizational structures to promote such management. In 1991, JCAHO mandated that pain be routinely assessed and outcomes of care be routinely documented for terminally ill patients, but not for other patient populations experiencing acute or chronic pain. By 1995, JCAHO had written pain management into its guidelines. Finally, with the 2000 and 2001 editions of the JCAHO accreditation manuals, JCAHO now requires surveyors inspecting hospitals to include in their surveys a systematic look at pain assessment and management; the surveyors must determine whether the hospital has integrated compliance with the pain management standards with the overall care of patients.

If proper pain management is now part of the hospital accreditation process, then corporate negligence suits will use such accreditation guidelines, along with common law decisions that generally impose a duty of institutional responsibility for patient care, to establish the hospital’s standard of care.

ii. Emergency Medical Treatment and Labor Act (EMTALA)

The Emergency Medical Treatment and Labor Act, or EMTALA, provides another source of liability that particularizes the standard of care expected of hospitals that participate in the federal Medicare program and have emergency departments. The Act requires covered hospitals to provide a medical screening examination to any patient coming into the emergency department of the hospital.

The question from the perspective of pain management is twofold: Is pain an emergency medical condition that requires stabilization before transfer is possible, and is avoidable or treatable pain a material deterioration of the patient’s condition? The control of avoidable physical pain is a significant obligation of medical treatment. Severe physical pain that could have been avoided with appropriate medical care is arguably a material deterioration of the patient’s condition.

If an emergency medical condition is present, the hospital must provide treatment to stabilize the patient’s medical condition unless the patient requests the transfer in writing, or a physician certifies that the benefit of the transfer to the patient outweighs the risk. If the hospital transfers the patient, the transport support provided must meet the statutory standards for adequacy of equipment and personnel, the receiving facility must agree to accept the transfer, and the transferring hospital must provide all medical records to the receiving facility. Patients may refuse treatment, may refuse to consent to the transfer, and may request transfer.

EMTALA provides for a private cause of action for violation of the statute. Any individual suffering harm as a “direct result” of a hospital’s violation of the statute has a cause of action against the hospital. The statute also provides for civil monetary penalties against the hospital and against the “responsible” physician for violations of the Act. The statute provides that civil damages for a hospital’s violation of the Act shall be “those damages available for personal injury under the law of the State in which the hospital is located.” Although claims under EMTALA are not claims for medical malpractice, plaintiffs usually claim both a violation of EMTALA and medical malpractice.

The Act provides that “if any individual ... comes to the emergency department,” it is the hospital’s duty to assess whether the patient has an emergency medical condition.
The claim of failure to provide an appropriate medical examination requires that the patient be physically present in the emergency department, but some courts have held that a claim of transfer in an unstable condition does not require that the patient enter the hospital through the emergency room.179

Courts interpreting EMTALA’s medical screening requirement have generally adopted a standard of differential treatment and not professional standards. Plaintiffs must prove that the hospital’s policy is to conform with professional standards. To the extent that the hospital has established written guidelines or has followed consistent practices in emergency medical examinations, it is, of course, essential for plaintiffs to prove their content.180 The patient’s examination may be so cursory or inadequate as to amount to no examination at all, resulting in a finding that EMTALA was violated.181

A hospital violates the Act if it fails to provide an “appropriate medical screening examination” to the patient arriving in the emergency room. If the hospital provides an appropriate examination that detects an emergency condition or if the patient’s emergency condition is otherwise known to the hospital, the hospital is liable under the Act if it transfers or discharges the patient in an unstable medical condition. Courts have required the plaintiff to prove that the hospital actually knew of the plaintiff’s emergency condition in order to trigger the duty to stabilize prior to transfer or discharge.182 Where the hospital lacks actual knowledge of the patient’s emergency condition as a result of a statutorily inadequate medical screening examination, the hospital would be liable at least for violating the examination requirement of the Act.183

Courts look at several factors in deciding whether a patient was stable before transfer or discharge. If the hospital actually admitted and treated the patient for a significant amount of time, this is some evidence of stability.184 Patient stabilization must be judged from the perspective of professional standards rather than standards established by each hospital.185 The Act explicitly defines “stabilized” as a condition in which “no material deterioration of the condition likely, within reasonable medical probability, to result from or occur during the transfer.”186

The EMTALA action is a small piece of the liability package for pain mismanagement. No case law has yet developed such a theory with regard to pain. But recognition of the importance of pain management in the new JCAHO pain management guidelines means that hospitals that seek JCAHO accreditation will need to develop policies for assessing and treating patient pain, including emergency admissions. This then sets a standard that must be followed in screening patients and stabilizing them. EMTALA then offers a statutory basis for suit in emergency admissions when patients are not properly screened or stabilized for pain.

B. Managed care organizations: paying for pain relief

Managed care organizations undertake to “manage” the care of subscribers. For outpatient conditions, such as lower back pain or other kinds of disability that can result in chronic intractable pain, it is arguable that a managed care organization should be responsible for designing and paying for institutional approaches to proper pain management. If clinical guidelines describe an ideal approach to pain, then the individual or institutional health-care provider is responsible for implementing such a strategy. Cost-sensitive managed care organizations, however, may resist.

For example, emergency room treatment for pain is likely to be resisted by utilization reviewers, arguing that it is too subjective and will impose excessive costs on the plan. Likewise, hospice care for cancer or other patients at the end of life is not provided consistently by all managed care organizations.187 Nonmalignant chronic pain, such as that experienced by nursing home residents or those with other disabilities, can be expensive to treat with some of the new treatment approaches and is often neglected because of difficulty in defining it.188 The complex sources of chronic nonmalignant pain make diagnosis and management difficult. As a result, patients with such pain may need extensive diagnostic tests and referral to specialists or multidisciplinary centers.189

Managed care plans are worried about the costs of proper pain management, and with some justification. Susan Wolf notes:

Just as research on pain is in its infancy, research on how well or poorly MCOs [managed care organizations] do in treating pain similarly seems to be at an early point. It is clear that “MCOs’ outpatient prescription drug benefits are subject to restrictions... such as generic substitution, therapeutic substitution, and limited formularies.” Moreover, these benefits may be available in some MCOs only by subscriber purchase of an extra “rider” to the coverage contract, and coverage affects access to pain-relieving drugs. MACH remains to be determined about the effectiveness of MCOs in addressing pain, however, especially for patients at the end of life.190

Managed care organizations and insurers are reluctant, in large part, because they feel that many of the pain management guidelines are not based on extensive clinical studies.191

Until recently, courts have held that ERISA (the Employee Retirement Income Security Act) preempted most litigation against managed care organizations for medical errors. But this position has been deteriorating in the face of
quality-of-care abuses by managed care organizations. At bottom, managed care organizations are businesses. They market their care to potential employers and subscribers in a competitive marketplace for health care. They recruit and organize their physicians through their networks. They design a corporate system in which health care is delivered. And they must administer this system in a safe fashion that avoids injury to subscribers caused by the negligence of plan physicians and other providers. Malpractice claims based on vicarious liability, corporate negligence, negligence per se, and intentional infliction of mental distress may be allowed to proceed against managed care organizations under the current law as quality-of-care issues outside the scope of an ERISA claim for benefits (i.e., quantity-of-care, or coverage, issues).192

1. Agency doctrine

Under theories of agency, managed care organizations may be on the hook for the liability of the physicians and other providers who work for them. Such vicarious liability has been upheld by the majority of courts, having considered the question of liability not to be preempted by ERISA.193 The reason is that the managed care organization’s plan is irrelevant to the claim, since the claim of agency does not rise and fall with the plan.194 Rather the claim is established by reference to the parties' reliance and representations, a question of fact not involving the interpretation of an ERISA plan.195 If, however, the underlying claim against the treating physician is a failure to treat — a denial of benefits — then it relates to the benefits plan, and the claim could not be resolved without reference to a determination on benefits. In such a situation, one circuit court has held that ERISA completely preempts the agency claim.196

2. Substandard plan design and administration

Claims of negligent design and administration of the delivery of health-care services have been allowed in recent cases.197 A negligence claim against a plan for providing contractual benefits in “such a dilatory fashion that the patient was injured are intertwined with the provision of safe care.”198 In Pappas v. U.S. Healthcare, the issue was a delay in transporting the plaintiff to a specialty trauma unit for care. The delay arguably was caused by the utilization review process of the managed care organization, which did not allow transport to the best hospital unit in the area for spinal injuries. The case appears to involve both a system-induced delay and a benefits question as to which hospitals were available to the plaintiff. The case was remanded by the U.S. Supreme Court for reconsideration in light of its decision in Pegram v. Herdrich. Absent ERISA preemption as a defense, the doctrine of corporate negligence could be held to apply.199

A claim that a ERISA managed care plan is “substandard” and has led to patient injury as a result has been allowed to avoid ERISA preemption. In Moreno v. Health Partners Health Plan,200 the District Court held that there was “no relation between an action for medical malpractice and the recovery of benefits or the clarification of rights to future benefits under an ERISA plan.”201 An action for negligent supervision of plan physicians has been allowed by courts to proceed as a quality issue and has not been deemed preempted by ERISA.202 Likewise, a plan decision to discharge a patient from the hospital to her home rather than a skilled nursing facility has been considered a “quality” issue, not suitable for preemption.203

Where a plan is responsible for the continuum of care and it proves to be inadequate — even if that means it refuses to cover a benefit at a rehabilitation hospital or other facility — courts have found this to be a complaint of substandard care and thus not preempted by ERISA.204 If a plan is negligent in failing to provide appropriate screening tests and studies, this, too, could be viewed as a negligent provision of benefits and not a denial of benefits, thus subject to ERISA.205 The U.S. Supreme Court’s recent decision in Pegram v. Herdrich206 further opens the door to state tort litigation against managed care organizations on all the theories that hospitals are subject to, by refusing to interpret ERISA as imposing a fiduciary duty on physicians making “mixed eligibility decisions.”

The problem with managed care organization liability is that pain management is still in its infancy. The field lacks clinical practice guidelines that are well-grounded in clinical studies. The practitioners of pain management are credentialed by different organizations and the lack of a consensus as to the gold standard for accreditation means that managed care medical directors are properly uncertain about to whom patients should be referred. Evidence of fraud in hospice billing in some cases has exacerbated managed care organization reluctance. As Diane Hoffmann writes:

additional resources and attention need to be devoted to developing guidelines for treatment of various types of pain and... more research needs to be conducted on the effectiveness and cost effectiveness of various pain treatment modalities and palliative care.... Additionally, there needs to be broader recognition of what constitutes a pain specialist and when a referral to a pain specialist is appropriate.... [U]ntil more widespread consensus develops on what constitutes effective treatment of pain, especially chronic pain, or agreement on credentials for certification of pain providers, we can expect insurers and M COs to be reluctant to approve coverage of some forms of pain treatment and continuing variation across plans in the way they deal with this issue.207
Managed care plans should be expected to be a market for effective pain management practices, since the use of the “substandard” test by the federal courts suggests not only an ERISA preemption defense for plaintiffs, but the emergence of a corporate negligence test that applies directly to managed care organizations.

A set of standards by accrediting bodies such as the Joint Commission on Accreditation of Healthcare Organizations and the National Committee on Quality Assurance will push managed care organizations in the direction of better pain management, both through market pressure and through the provision of a standard of care in tort actions. The law, after all, usually reflects the maturing and solidification of medical practice, demanding of practitioners and institutions that they measure up to standards set by their own institutions. NCQA has not yet provided specific standards for pain management, while JCAHO’s new guidelines indicate that the field is maturing. NCQA should be urged to develop a standard that reinforces JCAHO’s guidelines, thereby acknowledging the central importance of pain management in the care of patients.

C. Long-term care facilities: pain and quality of life

Nursing homes are increasingly the final stop before death. It has been estimated that half of the Americans who live to the age of 65 will live in a nursing home before they die. In 1996, there were over 1.56 million nursing home residents in the United States.

The elderly in nursing homes are often undertreated for pain. Improper pain management in nursing homes can lead to high levels of chronic pain. Most nursing home residents are chronically, rather than acutely, ill. The average length of stay for nursing home patients is much longer than the average length for patients in acute-care hospitals. More than 84 percent of nursing home residents receive help with three or more activities of daily living, including eating, dressing, bathing, toileting, and transferring from one location to another. Pain is often the companion for these residents.

The elderly, the primary residents of such long-term care facilities, are poorly treated. The elderly also have lacked effective tort remedies: Causation may be hard to establish, given multiple diseases, and damages are hard to prove, with the exception of pain and suffering. The primary case to date that has imposed a duty to treat for pain is Estate of Henry James v. Hillhaven Corp.

In this case, James was admitted to a nursing home with prostate cancer that had metastasized to his left femur and spine. Upon admission, it was estimated that he had about six months more to live. His personal physician prescribed 7.5 cc’s of oral morphine elixir every three hours, as needed for pain. A nurse at the nursing home countermanded this order, after assessing James as addicted. She implemented a pain management plan using a mild tranquilizer and delaying or withholding analgesics.

The court found that James experienced physical pain and suffering and mental anguish, described as “inhuman treatment” inflicted “without regard to the consequences and without care as to whether or not the patient received analgesic relief and without care that the result and procedures were torture of the human flesh.” During the trial, medical and nursing experts testified about the standard of care for opioid analgesics and morphine for intractable pain. A nurse also testified that proper quality assurance in nursing homes requires proper pain management. Thus, the issue again becomes the role of well-established clinical practice guidelines, JCAHO accreditation standards, and other sources to which a court can turn for a standard in evaluating the failures of a physician or nurse in a long-term care setting or the failure of the facility to detect and correct negligent treatment.

1. Damages and causal problems with nursing home litigation

The nursing home population, in contrast to the typical hospital patient, will have more difficulty in succeeding in private litigation to remedy harms suffered as a result of breaches of established standards of care. Physical injuries such as broken bones and bruises in very frail elderly persons may be caused either by ordinary touching or by poor care or abuse. Causation, therefore, is difficult to prove. The mental impairment of many nursing home patients makes them poor witnesses, since they are unable to testify as to their experiences of pain. Their limited lifespan and their disabilities minimize legally recognizable damages for injury or death. They do not suffer lost wages. Their access to private attorneys has been limited because small damage awards discourage contingent fee arrangements and because of the isolation of institutionalization. Because of these limitations, several states have enacted statutes providing for private rights of action for nursing home residents. These statutes generally provide a cause of action for breach of statutory standards and may provide for enhanced damages and attorney’s fees.

2. False Claims actions under O B R A

The newest approach to poor quality of care in nursing homes is the False Claims Act under the Omnibus Reconciliation Act of 1987 (O B R A ’87). O B R A deals with (1) service requirements for those facilities in the Medicare and Medicaid programs; (2) a survey and certification process; and (3) enforcement and sanctions. O B R A requires a thorough assessment of each resident’s functional capacity, to be used in developing a written care plan; specialized rehabilitation; a requirement that homes use less restrictive measures before turning to physical restraints; a prohibition of “unnecessary”
drugs; and an explicit statutory basis for residents’ rights. The goal of OBRA is to address a nursing home resident’s condition so that he or she can achieve and maintain the “highest practicable physical, mental, and psychosocial well-being.”

The False Claims Act provides a statutory source, either used by the government or in a Qui Tam action by a private party, for using OBRA as setting the minimum standard for quality of life in a nursing home. A prima facie case must be made to prove that: (1) the defendants presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; (3) the defendants knew the claim was false or fraudulent; and (4) the United States suffered damages as a result of the false or fraudulent claim.

The False Claims Act was initially used for overbilling or billing for unnecessary services. Its use by U.S. Attorneys against nursing homes has been based on allegations of billing for unrendered, yet necessary services, leading to a poor quality of care for residents. Providers claiming reimbursement under the federal Medicare and/or Medicaid programs implicitly certify compliance with all applicable federal regulations pertaining to program eligibility. When providers, either knowingly or recklessly, fail to render the appropriate level of care, they may be susceptible to liability under the False Claims Act, having falsely certified compliance.

The False Claims Act has potential for extreme violations and obvious misconduct in nursing homes, such as bedsores and major sanitary problems with frail elderly patients. Undertreatment of pain, absent an extreme case such as the facts in Henry James and absent an aggressive and protective family, will continue to be difficult to prove, even with this new weapon. But the specter of a large judgment against any patient, pain based on a patient’s pain is one additional source of pressure on nursing home operators to incorporate effective pain management into their care of residents.

**Conclusion**

Pain management is evolving as critics clamor for improvement in patient care. Progress, however, has been surprisingly slow — the result of continued uncertainty by providers as to appropriate opioid use, lack of institutional attention to pain management, and inattention by medical schools.

A convergence of forces is now building pressure on health-care providers to incorporate pain management into their practices. First, JCAH O’s new statement of Pain Assessment and Management establishes a new standard of pain as the “fifth vital sign,” which must be monitored and treated by hospitals for continued accreditation. Second, pain management clinical practice guidelines are now readily found through the Internet for easy access by health-care providers.

One can only hope that medical school education will also incorporate a contemporary version of pain management into its curriculum.

Tort liability can now build on this convergence in pain management standards. It can reflect this convergence in medical practice and amplify the message so that providers hear it and change their practices accordingly. Patients suffer from too much pain — it is time for our hospitals, nursing homes, and doctor’s offices to reduce this suffering.

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**References**

1. Pain is defined as “an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage. Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life. It is unquestionably a sensation in a part or parts of the body but it is also always unpleasant and therefore an emotional experience.” International Association for the Study of Pain, “Pain Terms: A List with Definitions and Notes on Usage,” Pain, 6 (1979): 249.

2. The classic article calling attention to undertreatment is that of R.M. Marks and E.J. Sachar, “Undertreatment of Medical Inpatients with Narcotic Analgesics,” Annals of Internal Medicine, 78 (1973): 173.


6. For example, it is not true that sustained use of opioids inevitably addicts a patient; that a maximum dose for opioid use exists; or that a large dose of opioids invariably depresses respiration. See generally C.S. Hill, Jr., “When Will Adequate Pain Treatment Be the Norm?,” JAMA, 274 (1995): 1881.

7. A.H. Lebovits, I. Florence, R. Bathina et al., “Pain Knowledge and Attitudes of Healthcare Providers: Practice Characteristic Differences,” Clinical Journal of Pain, 13 (1997): 237–243 ("The overall concordant score of 56% reflects significant knowledge deficiencies regarding currently accepted principles of pain management practice, as well as beliefs that could interfere with optimal care. Perhaps even more compelling is that significant and consistent differences in knowledge and attitude exist by profession and clinical practice area." The authors found that professionals mistakenly thought that addiction to narcotics is far more prevalent in pain patients than is actually the case.) The Institute of Medicine, in a 1997 report, found that “[d]eficiencies in undergraduate, graduate, and continuing education for end-of-life care reflect a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning.” See Approaching Death, supra note 3, at 207.


13. Id.


22. AGS Panel on Chronic Pain in Older Persons, “The Management of Chronic Pain in Older Persons,” Journal of the American Geriatrics Society, 46 (1998): 635–51, at 635. “The guidelines describe four types of pain: (1) Nociceptive pain, ... often derived from stimulation of pain receptors. Nociceptive pain may arise from tissue inflammation, mechanical deformation, ongoing injury, or destruction. Examples include inflammatory or traumatic arthritis, myofascial pain syndromes, and ischemic disorders. Nociceptive mechanisms usually respond well to traditional approaches to pain management, including common analgesic medications and nonpharmacologic strategies. (2) Neuropathic pain results from a pathophysologic process that involves the peripheral or central nervous system. Examples include trigeminal neuralgia, post-herpetic neuralgia, poststroke central or thalamic pain, and postamputation phantom limb pain. These pain syndromes do not respond as predictably as nociceptive pain problems to conventional analgesic therapy.... (3) Mixed or unspecified pain is often regarded as having mixed or unknown mechanisms. Examples include recurrent headaches and some vasculitic pain syndromes. Treatment of these syndromes is more unpredictable and may require various trials of different or combined approaches.... (4) Psychogenic pain results when psychological factors are judged to have a major role in the onset, severity, exacerbation, or persistence of pain.... Examples may include conversion reactions and somatoform disorders. Patients with these disorders may benefit from specific psychiatric treatments, but traditional medical interventions for analgesia are not indicated,” Id. at 635–36.

23. Pseudoaddiction is one phenomenon that occurs throughout the population of pain patients, but is especially common among the victims of chronic nonmalignant pain. See M. Pappagallo and L.J. Heinberg, “Ethical Issues in the Management of Chronic Nonmalignant Pain,” Seminars in Neurology, 17 (1997): 203, at 205. Pseudoaddiction is a range or cluster of behaviors that are suggestive of addiction, but are the iatrogenic effect of ineffective pain management.


26. Id. at 1712–13 (“Opioid analgesics, including the five study drugs, are a relatively small part of drug abuse as measured by the DAWN system ... the abuse levels have remained low and relatively stable for the past seven years despite substantial increases in the medical use of opioids.... Conventional wisdom suggests that the abuse potential of Opioid analgesics is such that increases in medical use of these drugs will lead inevitably to increases in their abuse. The data from this study with respect to the opioids in the class of morphine provide no support for this hypothesis. The present trend of increasing medical use of Opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of Opioid analgesic abuse.”).


39. Other studies have provided recent useful data on this issue. See, e.g., F.A. Sloan et al., “Medical Malpractice Experience of Physicians: Predictable or Haphazard?,” JAMA, 262 (1989): 3291.


41. See Bell, supra note 35, at 973–90.


44. E.g., Bahn v. Harp, 478 P2d 480, 484 (Cal. 1970).


46. 466 So. 2d 856, 872–73 (Miss. 1985). Hall was followed in Turner v. Temple, 602 So. 2d 817 (Miss. 1992).


50. Vergara v. Doan, M.D., 593 N.E.2d 185, 187 (Ind. 1992) ("availability of facilities may be considered").

51. See Blair v. Eblen, 461 S.W.2d 370 (Ky. 1970); Restatement (Second) of Torts, § 293A cmt. g (1977) ("allowance must be made also for the type of community in which the actor carries on his practice. A country doctor cannot be expected to have the equipment, facilities, experience, knowledge or opportunity to obtain it, afforded him by a large city.").


55. See Nowatske v. Osterloh, 543 N.W.2d 265 (Wis. 1996).
where the court noted that “customary conduct is not dispositive and cannot overcome the requirement that physicians exercise ordinary care... We recognize that in most situations there will be no significant difference between customary and reasonable practices. In most situations physicians, like other professionals, will revise their customary practices so that the care they offer reflects a due regard for advances in the profession. An emphasis on reasonable rather than customary practices, however, insures that custom will not shelter physicians who fail to adopt advances in their respective fields and who consequently fail to conform to the standard of care which both the profession and its patients have a right to expect.”

57. Hall, 466 So. 2d at 871.
59. See Klisch v. MericCareMedical Group, Inc., 134 F.3d 1356 (8th Cir. 1998), where the patient sued for negligent performance of surgery. The Court of Appeals held that (1) a jury instruction in which the jury was asked to consider the state of medical technology at time of the allegedly negligent surgery was appropriate; and (2) under Minnesota law, the jury in a medical malpractice action should weigh information available to physicians at the time of treatment and without benefit of hindsight.
63. See, e.g., Rosoff, supra note 61, at 369.
64. The Agency for Health Care Policy and Research (AHCPR) within the Health Care Financing Administration, for example, has the responsibility of developing guidelines for clinical practice through the administration's Medical Treatment Effectiveness Program. This program supports research, data development, and other activities to develop and review clinically relevant guidelines, standards of quality, performance measures, and medical review criteria in order to improve the quality and effectiveness of health-care services. See Pub. L. No. 101-239 (1990).
69. See generally A.L. Hyams, D.W. Shapiro, and T.A. Brennan, “Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective,” Journal of Health Politics, Policy & Law, 21 (1996): 289. The respectable minority defense allows a defendant physician to defend by arguing that her practice is followed by at least a respectable minority of other physicians in that practice area or specialty.
70. Id.
74. These guidelines can be found online at <http://www.asahq.org/practice/chronic_pain/chronic_pain.html>.
75. J.P. Kassirer, “Patients, Physicians, and the Internet,” Health Affairs, 19 (2000): 115 (noting that physicians access medical information on-line, even though older physicians are slower to adopt more wide-ranging uses for the medium).
77. The National Guideline Clearinghouse can be accessed online at <http://www.guideline.gov>.
78. The Clearinghouse was created to deal with the criticism that guidelines published in peer-reviewed medical literature do not adhere to established methodological standards. See T.M. Shaneffelt, M.F. M.ayo-Smith, and J. Rothwangl, “Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature,” JAMA, 281 (1999): 1900.
79. See P.G. Shékelle and D.L. Schriger, “Evaluating the Use

80. "Passive dissemination of guidelines (such as via publication or the World Wide Web) is a weak way of modifying physician behavior." D.L. Schriger et al., "Implementation of Clinical Guidelines Using a Computer Charting System: Effect on the Initial Care of Health Care Workers Exposed to Body Fluids," JAMA, 278 (1997): 1585, at 1589. The studies conclude that some form of active implementation of guidelines at the local level is needed in order to involve physicians. In one study, in a hospital emergency department in a university hospital, patients were health-care workers exposed to blood. A computer charting system provided real-time information regarding history and recommendations for laboratory testing, treatment, and disposition based on rules derived from clinical guidelines. The study found that documentation and compliance improved. Compliance with testing guidelines increased from 63 percent to 83 percent during the intervention phase and decreased to 52 percent when the computer system was removed. Real-time application of a computer-based system that provides practice guidelines literally "at the physician's fingertips" may be an effective method to improve the quality of patient care. "The fusion of electronic charting, computer databases, and clinical guidelines may offer the best hope for efficiently guiding, monitoring and improving the quality of ambulatory medicine." Id. at 1590. See also I. Ray-Coquard et al., "Impact of a Clinical Guidelines Program for Breast and Colon Cancer in a French Cancer Center," JAMA, 278 (1997): 1591; K. Elam et al., "Impact of a Worker's Compensation Practice Guideline on Lumbar Spine Fusion in Washington State," Medicare Care, 35 (1997): 417 (through use of guidelines for elective lumbar fusion as part of inpatient utilization review program, tied to reimbursement limitations, lumbar fusion rate declined 26 percent compared with a 3 percent decline for all lumbar operations over five years).


83. Internet-based physician-oriented Web sites are available on a commercial basis. One example is MDConsult, a commercial database available by subscription that provides easy access to hundreds of medical textbooks and treatises, as well as clinical practice guidelines. Another example is Medscape, which provides a full range of on-line resources.

84. See <http://www.docucare.net/>.

85. See Warrick v. Giron, 290 N.W.2d 166 (M inn. 1980).


87. State v. McAfee, 385 S.E.2d 651 (Ga. 1989), where a quadriplegic incapable of spontaneous respiration sought court approval for discontinuation of his respirator. The Georgia Supreme Court affirmed his right to refuse medical treatment and to receive proper sedation as well: "M r. M cAfee's right to be free from pain at the time the ventilator is disconnected is inseparable from his right to refuse medical treatment. The record shows that M r. M cAfe has attempted to disconnect his ventilator in the past, but has been unable to do so due to the severe pain he suffers when deprived of oxygen. His right to have a sedative (a medication that in no way causes or accelerates death) adminis-


89. 543 N.W.2d 265, 272 (Wis. 1996).

90. Shapiro, supra note 86.

91. 736 So. 2d 366 (C.A. La. 1999).

92. Most of the legal discussion of substandard practice is not found in malpractice cases, but in medical discipline actions. For example, in Holladay v. Louisiana State Board of Medical Examiners, the Louisiana State Board of Medical Examiners imposed sanctions on a physician for prescribing controlled substances in a substandard way. He had prescribed controlled drugs in the absence of any treatment plan and medical examinations for up to eight months. He had also failed to check on the substance abuse record of his patients. According to the testimony of experienced physicians, the physician had breached the standard of care for proper pain management given these omissions.


94. Shapiro, supra note 86, at 361.


97. 546 N.W. 495 (Wis. 1996).

98. 453 N.W.2d 634 (Iowa 1990).


100. Johnson v. Ruark O bstetrics and Gynecology Associates, PA., 395 S.E.2d 85 (N.C. 1990) (expectant parents of a stillborn fetus sued the physicians for the negligent infliction of mental distress, alleging that they had observed events surrounding the death of the fetus; the North Carolina Supreme Court allowed negligent infliction of emotional distress based on a test of reasonably foreseeable consequences).

101. See, for example, Frame v. Kothari, 515 A.2d 810 (N.J. Super. Ct. App. Div. 1985) (defendant physician's misdiagnosis of a cerebellum hemorrhage and acute hydrocephalus due to blunt trauma to the skull was held to be an event perceived by the parents; first, the parents' discussion with the defendant about their son's deteriorating condition was an "observation"; and second, their distress was foreseeable after the doctor was informed of the condition and failed to properly treat it). See also Ochoa v. Superior Court of Santa Clara County, 216 Cal. Rptr. 661, 703 P.2d 1 (Cal. 1985) (mother suffered distress after visiting her son who was receiving "woefully inadequate" medical care in a juvenile detention home).

102. See, for example, Smelko v. Brinton, 740 P.2d 591 (Kan. 1987) (parents waiting outside the operating room for their baby to undergo surgery; baby is negligently burned during the surgery and they discover the burn when he is brought out; court held that merely seeing the bad result is not sufficient for recovery). But see Martinez v. Long Island Jewish Hillside Medical Center, 518 N.Y.S.2d 955, 512 N.E.2d 538 (N.Y. 1987) (physician negligently diagnosed a pregnant woman's condition as requiring an abortion; the woman aborts the fetus and then discovers the abortion was not needed; recovery allowed).
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103. 514 S.E.2d 355 (Va. 1999).
105. Case law requires physicians to warn third parties about, or take steps to protect them from, patients who are taking medication. These steps might include warning the patient about the effects of medication, or even refusing to prescribe the medication if the patient might still drive. See Weke v. Kuzilla, 375 N.W.2d 403 (Mich. Ct. App. 1985); Myers v. Quesenberry, 193 Cal. Rptr. 733 (Cal. Ct. App. 1983) (physician failed to warn his patient, a diabetic, of the dangers of driving); Calwell v. Hassan, 908 P.2d 184 (Kan. Ct. App. 1995) (physician treated patient for sleep disorder, failed to warn him not to drive).
108. See Morris v. Ferriss, 669 So. 2d 1316 (La. Ct. App. 4th 1996) (physician did not have to advise patient that psychiatric treatment was an alternative treatment for epileptic partial complex seizures since it was not accepted as feasible); Lienhard v. State, 431 N.W.2d 861 (Minn. 1988) (managing pregnancy at home rather than in hospital not a choice between alternative methods of treatment; therefore, disclosure was not required).
109. Martin v. Richards, 531 N.W.2d 70 (Wis. 1995) (failure to inform parents of patient that a CT scanner was available to diagnose head injuries and that facility lacked neurosurgeon to treat intracranial bleeding).
111. 490 N.W.2d 820 (Iowa 1992).
112. 545 N.W.2d 495 (Wis. 1996).
114. Id.
116. Id.
117. Id. at 224.
118. Id. at 225-226 (“most cancer pain can be managed by the appropriate assessment of the causes of pain and treatment with non-invasive opioid analgesics. However, despite recent progress in the management of cancer pain, many patients experience severe pain due to inadequate analgesia.”).
120. The most important work to date addressing the broad issue of medical error is the Institute of Medicine report, To Err Is Human: Building a Safer Health System. The report is groundbreaking in its emphatic recognition, finally, that health care is a complex technological system prone to error. The report calls for “a comprehensive approach to improving patient safety,” noting that “[m]ost errors and safety issues go undetected and unreported both externally and within health care organizations.” With the exception of anesthesia, where the recognition that systems factors cause errors has led to a fail-safe system and better training to reduce such errors, health care has yet to implement any larger mechanism to detect errors based on system deficiencies and individual errors.
122. Id. at 1875.
123. For an early acknowledgment of this problem, see generally S.Y. Fagerhaug and A.L. Straus, Politics of Pain Management: Staff-Patient Interaction (Reading, Massachusetts: Addison-Wesley, 1977). A more recent review of the literature is found at Organ, supra note 4.
129. Blau, Dalton, and Lindley, supra note 73.
130. Id.
131. Id. at 467.
134. Washington v. Washington Hospital Center, 579 A.2d 177 (D.C. Cir. 1990) (defendant had not yet placed end-tidal carbon dioxide monitors, which allow for early detection of insufficient oxygen in time to prevent brain injury, in their operating rooms; plaintiff’s injuries would have been prevented by the early detection that such monitors make possible).
136. Id. at 57.
142. See Habuda v. Trustees of Rex Hospital, 164 S.E.2d 17 (N.C. Ct. App. 1968) (hospital liable for inadequate rules for handling, storing, and administering medications); Herring v. Hilder, 883 F.2d 411 (5th Cir. 1989) (failure to provide for adequate twenty-four hour anesthesia service).

143. Decker v. St. Mary’s Hospital, 619 N.E.2d 537 (Ill. App. Ct. 1993). Such a duty was rejected by the M aine Supreme Judicial Court in Gafner v. Down East Community Hospital, 1999 WL 605619 (M e. 1999) (refusing to recognize corporate liability action against hospitals for failing to have explicit policies in place to control the actions of independent physicians).


145. See, e.g., Johnson v. University of Chicago Hospital, 982 F.2d 230 (7th Cir. 1992), on remand, 1994 WL 118192 (N.D. Ill. 1994) (holding that hospital that provided telemetry communications to ambulance paramedics, directing them to the proper hospital in the system, could be liable for negligent operation of the system).


147. The case most identified with corporate negligence is Darling v. Charleston Community Memorial Hospital, 211 N.E.2d 253 (Ill. 1965). The Illinois Supreme Court relied upon several sources of standards to establish the standard of care for the hospital, including standards by the Joint Commission on Accreditation of Healthcare Organizations for hospital accreditation, the state licensing regulations, and the defendant’s bylaws. All of these sources mandated that a hospital assume certain responsibilities for the care of the patient. The court allowed the jury to use these standards to evaluate the failure of both the nursing staff and administrators to blow the whistle on the defendant’s handling of the case.


149. See, e.g., Strubhart v. Perry Memorial Hospital Trust Authority, 903 P.2d 263 (Okla. 1995) (adopts doctrine of independent corporate responsibility, requiring hospitals to ensure that only competent physicians have staff privileges; also requires hospitals to take reasonable steps to ensure patient safety when it knows or should know that physicians have displayed incompetence); NKC Hospitals, Inc. v. Anthony, 849 S.W.2d 564 (Ky. Ct. App. 1993).


151. Such a duty was rejected by the M aine Supreme Court in Gafner v. Down East Community Hospital, 1999 WL 605619 (M e. 1999).


155. Strubhart v. Perry Memorial Hospital Trust, 903 P.2d 263 (Okla. 1995) (noting that twenty-two states have adopted some form of the corporate negligence doctrine); Albain v. Flower Hospital, 553 N.E.2d 1038 (Ohio 1990).


157. See St. Luke’s Episcopal Hospital v. Agbor, 952 S.W.2d 503 (Tex. 1997) (holding that hospitals were immune from liability under the Texas Medical Practice Act for negligent credentialing absent a showing of malice); H ill v. North Valley Hospital, 498 P.2d 136 (M ont. 1972).


160. The new JCAHO Pain Management standards must be satisfied by hospitals, home care agencies, nursing homes, behavioral health facilities, outpatient clinics, and health plans. These standards include:

1. the right of patients to appropriate assessment and management of pain;
2. assessing the nature and intensity of pain in all patients;
3. recording the results in a way that allows regular reassessment and follow up;
4. determining and assuring staff competency in pain assessment and management, including in the orientation of all new staff;
5. establishing policies and procedures to support appropriate prescription or ordering of effective pain medications;
6. educating patients and families about effective pain management; and
7. addressing patient needs for symptom management in the discharge planning process.

These new standards will be scored for compliance in 2001. They explicitly note that pain is a co-existing condition with a number of diseases and injuries, and it requires explicit attention. For example, a patient with breast cancer should be treated effectively not only for the actual illness, but also for any associated pain.


162. This Act is also often referred to as “COBRA” for the budget reconciliation act of which it was a part, or as the “Anti-Dumping Act.”


164. The statute requires that the hospital “provide for an appropriate medical screening examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition … exists.” 42 U.S.C.A. § 1395dd(a).

165. 42 U.S.C.A. § 1395dd(a).


167. The statute defines this term as “a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part.” 42 U.S.C.A. § 1395dd(e)(1). This section also defines the term for women in labor.

168. The statute defines the terms “to stabilize” and “stabilized” with reference to the potential for material deterioration in the patient’s condition, i.e., “no material deterioration of the condition is likely, within reasonable medical probability” resulting from or occurring during the transfer. 42 U.S.C.A. § 1395dd(e)(3)(A) and (B).

169. 42 U.S.C.A. § 1395dd(c)(1).

170. The statute includes discharge of the patient within the definition of “transfer.” 42 U.S.C.A. § 1395dd(e)(4).
171. 42 U.S.C.A. § 1395dd(c)(2).
172. 42 U.S.C.A. § 1395dd(b)(2) and (3) and (c)(1)(A)(i).
174. 42 U.S.C.A. § 1395dd(d)(1)(A) and (B).
175. The statute also provides that a plaintiff in a civil action under the Act may receive "such equitable relief as is appropriate." Few reported cases thus far have issued equitable relief, but see Owens v. Nacogdoches County Hospital District, 741 F. Supp. 1269 (E.D. Tex. 1990). 176. 42 U.S.C.A. § 1395dd(d)(2)(A).
177. The statutory language requires that the patient request examination or treatment, but the request for treatment in the emergency room has generally not been the subject of dispute. However, see Steverson v. Enid Health Systems, 920 F.2d 710 (10th Cir. 1990).
180. But see Collins v. DePaul Hospital, 963 F.2d 303 (10th Cir. 1992), in which the court "accept[ed] as true counsel's assertion that ordinarily" such a patient would have had a certain diagnostic procedure and that the hospital staff had thought the procedure had been done even though in fact it had not. The court upheld summary judgment for the defendant because the statute did not "require a hospital to determine ... all of the emergency medical conditions from which a particular individual may be suffering." The applicability of this statement should be limited to the facts of Collins: the patient was transported to the emergency room with multiple injuries, including a fractured skull, and he stayed at the hospital for nearly a month recovering from his injuries. A fractured hip was not detected. 181. See, e.g., Baber v. Hospital Corporation of America, 977 F.2d 872 (4th Cir. 1992); Cleland v. Bronson Health Care Group, 917 F.2d 266 (6th Cir. 1990).
183. See Abercrombie v. Osteopathic Hospital Founders Association, 950 F.2d 676 (10th Cir. 1991), for jury instructions on liability for violation of each of the requirements of the Act.
184. See, e.g., Collins v. DePaul Hospital, 963 F.2d 303 (10th Cir. 1992); Thornton v. Southwest Detroit Hospital, 895 F.2d 1131 (6th Cir. 1990).
185. See, e.g., Burditt v. United States, 934 F.2d 1362 (5th Cir. 1991); Deane v. Cade, 986 F.2d 387 (10th Cir. 1993); Green v. Touro Infirmary, 992 F.2d 537 (5th Cir. 1993).
187. See generally Hoffmann, supra note 12.
188. According to clinical practice guidelines on the management of chronic pain in older persons, "[f]or some conditions, chronic pain is defined as pain that exists beyond an expected time frame for healing. For other conditions, it is well recognized that healing may never occur. In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. Because there are many differences in what may be regarded as chronic pain, the definition remains flexible and related to specific diagnoses or causes." AGS Panel on Chronic Pain in Older Persons, supra note 22 and accompanying text on the four types of pain, at 635–36.
1992, at A-1 (noting that patient’s family was awarded $15 million from the nursing home).

215. In Bergman v. Chin, the family of an elderly hospital patient filed suit after the state medical board failed to act against the treating physician. The daughter said: “We found that the care was grossly inadequate to my father, that they did not provide adequate pain medication or relief to him while he was in the hospital or when he was discharged to our home to have hospice care.” California’s Elder Abuse Act has no cap like that for medical malpractice claims. Punitive damages and attorneys fees are recovered, and pain and suffering survives death and can accrue to the estate. “The goal of the family in this case and of Compassion in Dying is that this kind of accountability will motivate physicians and other providers to be more attentive and aggressive in caring for pain.” V. Foubister, “Doctor Faces Charges for Allegedly Undertreating Pain,” AMA News (March 20, 2000).


217. See, e.g., Stiffelman v. Abrams, 655 S.W.2d 522 (Mo. 1983) and Harris v. Manor Healthcare Corp., 489 N.E.2d 1374 (Ill. 1986), both interpreting state statutes creating private rights of action. See also Stewart v. Bernstein, 769 F.2d 1088 (5th Cir. 1985); Chalfin v. Beverly Enterprises, 741 F. Supp. 1162 (E.D. Pa. 1989), holding no private right of action under “pre-OBRA 1987” federal statutes. But see Roberson v. Wood, 464 F. Supp. 983 (E.D. Ill. 1979), holding that a private right of action existed. Despite these earlier cases, one could argue that there is an implied private right of action under the current federal statute. The Medicare and Medicaid statutes provide that the statutory remedies “are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law.” 42 U.S.C.A. § 1395i-3(h)(5); 42 U.S.C.A. § 1396(h)(8).

218. OBRA ’87, 42 U.S.C. § 1396r (involving the enhancement of quality of life and the psychosocial needs of residents).


Race, Ethnicity, and Pain Treatment: Striving to Understand the Causes and Solutions to the Disparities in Pain Treatment

Vence L. Bonham

I would like for them to know that I am in pain or this part of my body hurts or the other part hurts — that I am not lying about it. To examine me and to cut down on the pain.... And help me out.1

Patient with Sickle Cell Disease, Focus Group Participant

Pain in the United States is widely recognized to be undertreated; however, the capacity to treat pain has never been greater.2 The causes of this undertreatment are varied. As we focus on pain and why it is too often ineffectively treated, we also discover that this undertreatment afflicts some more than others. What divides the some from the others isn't limited to one factor, but one particularly disturbing factor is race and ethnicity. Racial and ethnic minority populations are at higher risk for oligoanalgesia, or the ineffective treatment of pain. Only through further study of the differences in pain treatment based on race and ethnicity can we develop strategies to reduce the disparities in care.

Racial and ethnic disparities in health care in the United States have received greater focus in the last ten years than any time in our history. Numerous studies have revealed that racial and ethnic minority groups often receive different and less optimal management of their health care than white Americans. Research studies have identified inequalities in the treatment of black Americans for early stage lung cancer,3 ischemic heart disease,4 and access to invasive cardiac procedures5 as well as cadaveric renal transplantations.6 Studies have shown that a patient's race has a substantial effect on the treatment provided and the mortality rates among Medicare beneficiaries7 and veterans.8

Scholars have concluded that persistent racial disparities in access to health care and treatment result from unequal health care that is the legacy of a racially divided health system.9 In October 1999, the Henry J. Kaiser Family Foundation published a comprehensive review of the literature on racial and ethnic differences in access to health services from 1985 to 1999.10 This major study did not, however, include a review of racial and ethnic differences related to pain treatment. It is time that this occurred.

This paper has three aims. It will (1) review the published literature on disparities in the treatment of pain based on race and ethnicity; (2) outline what may be some of the causes for disparities in pain treatment; and (3) provide suggestions for future health-services research regarding the causes and solutions to pain treatment disparities.

Biological and cultural disparities in pain?

People interpret and react to health symptoms, including pain, based on their life experiences and their cultural norms.11 Numerous anthropological studies have been conducted on differences in the perception of pain based on culture, race, and ethnicity.12

The 1969 seminal study by Mark Zborowski, People in Pain,13 is a comparative study of the role of cultural patterns in attitudes toward and reaction to pain. Other anthropologists and sociologists have expanded on Zborowski's work. Subsequent studies have included various racial and ethnic groups;14 the studies, however, are not without limitations.15 Some of the studies demonstrated significant racial and ethnic variation in baseline pain threshold and/or tolerance.

A second body of literature involves experimental studies in which subjects are exposed to pain stimuli and the pain responses of the different racial, ethnic, and cultural...
groups are studied.\textsuperscript{16} These studies have not found differences in the ability to discriminate painful stimuli of a neurosensory basis based on race and ethnicity.\textsuperscript{17} Researchers will continue to look for biological and cultural differences in the perception of pain, but we must also study actual clinical treatment and investigate the differences that have been documented there.

A Summary of the Literature

The studies chosen for this review were published in peer-reviewed journals indexed in the bibliographic databases, MEDLINE\textsuperscript{18} and HealthSTAR.\textsuperscript{19} The databases were searched for articles published in the United States between July 1, 1990 and June 30, 2000 using the following search words: analgesic, pain, ethnicity, race, and treatment.

A total of 472 articles were identified. Reviewing the references cited in the selected articles provided additional articles. Eight published studies that had a primary objective to investigate differences in pain treatment were then selected for this literature review. Table 1 provides a summary of each study, including author and publication source, study population and location, research question, methodology, results, and limitations. In the discussion below, the studies have been divided by type of health-care setting (emergency department, inpatient post-operative care, and nursing home) and by type of pain (long bone fracture pain, cancer pain, and other types of pain).\textsuperscript{20}

Pain Treatment in the Emergency Department

The emergency room used to be the worst part of my going to the hospital; the nurses didn’t understand, the doctors didn’t understand, they do all this questioning. They wanted to know why the medication was not working? Why you are still in pain? If you are crying, why you are crying; if you are not crying, how can you be in pain? If you are laughing or talking, it is mental. Really you are not only experiencing your pain — the crises you are going through — but you are experiencing other peoples’ opinions and feelings; that makes it worse.

Dealing with your crisis and dealing with someone else who comes into your room to tell you that you can do this or, if you are doing that, something else is wrong. It’s better for them to keep their opinions to themselves and just treat you.\textsuperscript{21}

Patient with Sickle Cell Disease, Focus Group Participant

The lack of an established patient-physician relationship in an emergency department may increase the influence of physicians’ stereotypes of patients and, consequently, the failure to properly treat pain. Four studies were reviewed in which the clinical setting was the emergency department.

Long bone fracture pain

Todd, Samaroo, and Hoffman

Todd, Samaroo, and H Hoffman published, “Ethnicity as a Risk Factor for Inadequate Emergency Department Analgesia,” in the Journal of the American Medical Association in 1993. The objective of the study was to determine whether Hispanic patients with isolated long bone fractures are less likely to receive emergency department analgesics than similar non-Hispanic white patients.\textsuperscript{22} This retrospective cohort study is important because it is the first article published in the Journal of the American Medical Association to analyze disparities in pain treatment due to one’s ethnicity. The study has stimulated other researchers to conduct similar studies (with a similar study design) with different populations.

The study found that Hispanic patients with isolated long bone fractures were twice as likely as similar non-Hispanic white patients to receive no pain medication in the emergency department. Fifty-five percent of Hispanic patients received no analgesic, as compared with 26 percent of the non-Hispanic white patients.\textsuperscript{23} The relative risk of receiving no analgesic was more than twice as great for Hispanics compared with non-Hispanic whites. Controlling for specific covariates, such as patient characteristics (sex, language, and insurance status), degree of injury severity (admission, open fracture, and reduction), and factors associated with potential presentation (concurrent ethanol intoxication, time of presentation, and occupational injury), did not substantially change the relative risk.

Todd and colleagues concluded that one possible explanation for the differential analgesic use relates to a failure on the part of physicians, and perhaps other staff members, to recognize the presence of pain in patients who are culturally different from themselves. They also concluded that it was unlikely that the underuse of analgesics in Hispanic patients occurred because these patients felt less pain than did the non-Hispanic white patients.\textsuperscript{24} The study is limited by its sample size of 139 patients — specifically, 31 Hispanics and 108 non-Hispanic whites — who were diagnosed with isolated long bone fractures and treated at the UCLA Emergency Department between January 1, 1990 and December 31, 1991.\textsuperscript{25} Nonetheless, the study begins to unravel the causes of the disparities in pain treatment based on race and ethnicity. What is the role of language and physician-patient communication in the differences in pain treatment based on ethnicity? Is the issue of disparity also a function of education, income, and status?
Todd, Lee, and Hoffmann

A 1994 published study by Todd, Lee, and Hoffmann analyzed whether physicians’ estimates of pain severity were influenced by a patient’s ethnicity. This companion study to Todd’s 1993 study was a prospective analysis of the doctors’ medical judgment of pain severity at the time the patients were seen in the emergency department for medical care and pain treatment. The study did not investigate the actual treatment of pain. They found that there was no difference between physicians’ assessment of pain for white and Hispanic patients.

In the context of the body of research of treatment differences in pain based on perception, communication, and culture, this study is important for its finding of no difference in how physicians assessed pain based on ethnicity. Todd and colleagues commented: “Thus the unequal use of analgesics we observed in our original study is not explained by physicians’ inability to assess the pain experience of Hispanic patients, assuming that physicians in this study do not behave in a fundamentally different way from the very similar group of physicians whose behavior was the subject of the previous study. Another possible explanation of the discrepancy in treatment pattern is straightforward bias by physicians who are equally aware of pain in both ethnic groups, but less interested in treating it when patients are Hispanic.”

Is physician behavior based on stereotypes and discrimination the cause of the disparity? What Todd and colleagues in the 1994 companion study did was to confront the question of physician bias in pain treatment. They presented data in support of the position that physician bias and discrimination are factors in the disparity of pain treatment based on ethnicity.

Karpman, Del Mar, and Bay

In 1996, Karpman, Del Mar, and Bay conducted a study to replicate the study by Todd and colleagues in 1993. The study, titled “Analgesia for Emergency Centers’ Orthopaedic Patients: Does and Ethnic Bias Exist?,” was published in Clinical Orthopaedics and Related Research in 1997. The objective of the study was to determine if a correlation existed between the race and ethnicity of the patient and the amount of analgesia administered to reduce pain related to a long bone fracture. The study was conducted in a community hospital in Phoenix, Arizona. The community surrounding the facility had been historically diverse both ethnically and racially, with a majority of the residents Hispanic. The study included both an adult and pediatric cohort of patients. The adult cohort consisted of 84 patients (29 Hispanics and 55 whites) seen between January 1, 1992 and December 31, 1992 for isolated long bone fractures requiring a closed reduction.

Karpman and colleagues found that 44.8 percent of the Hispanic patients and 43 percent of the white patients received no analgesia. The relative risk of Hispanic patients not receiving analgesia was not significant. Their findings indicated that 55.2 percent of Hispanic patients and 56.4 percent of white patients received analgesia. Analysis of high versus low dose for those who received analgesia also indicated no statistically significant differences (50 percent of Hispanic patients and 32.3 percent of white patients received the high dosage). The study did not confirm the findings of the 1993 study by Todd and colleagues, but found that Hispanics were not likely to be undermedicated for fracture reduction at that facility.

Karpman recognized that the study’s small sample size of 84 adults was a limitation of their study, which was smaller than the sample size in Todd’s 1993 study. Karpman and colleagues concluded that the health-care facility’s diversity might account for the differences found between this study and Todd’s.

This study directly raises the question of whether the type of facility and the patient populations there influence the treatment of pain. Does it make a difference where the facility is located and the demographics of the patients who are typically treated there? Does it matter if the facility is a large urban academic health center, a community hospital in an ethnically and financially diverse neighborhood, or a community hospital in an upper socioeconomic neighborhood with limited ethnic and racial diversity? This study identifies the type of health-care facility and its geographic location as important variables in investigating the disparities in the treatment of pain based on race and ethnicity.

Todd, Deaton, D’Adamo, and Goe

The most recent study published as of June 30, 2000 on race and ethnicity as variables in pain treatment is a January 2000 study published by Todd, Deaton, D’Adamo, and Goe, titled “Ethnicity and Analgesic Practice,” in the Annals of Emergency Medicine.

The objective of this study was to determine whether black patients with extremity fractures were less likely to receive emergency department analgesics than similarly injured white patients. The study builds on Todd’s 1993 study of Hispanics at the Southern California Academic Center in the city of Los Angeles.

The study was a retrospective cohort study at an urban emergency department in Atlanta, Georgia. Emergency department records were reviewed for a forty-month period (September 1, 1992 through December 31, 1995) to identify all black and white patients discharged from the emergency department with a diagnosis of isolated long bone fracture. The study consisted of 217 patients, of whom 127 were black and 90 were white. The study found that the white patients were significantly more likely than black patients to receive analgesics (74 percent versus 57 percent, p = 0.01) despite similar records of pain complaints in the medical record.
The risk of receiving no analgesic while in the emergency department was 66 percent greater for black patients than for white patients. The researchers stated:

We have previously examined health professionals’ ability to assess pain in different ethnic groups, by testing physicians’ skill in estimating pain severity among Hispanic and white patients with extremity trauma. Although disparities between patient and physician pain scores were noted, they were identical for the two ethnic groups. This implies that any ethnic disparity in analgesic prescribing could not be attributed to differences in pain assessment. We are left then, with the final step, the physician’s decision to administer analgesics. Our findings suggest that patient ethnicity affects decision-making independent of objective clinical criteria. Beyond this, we have no specific data to shed light on the reasons physicians order analgesics less frequently for minority patients than for white patients.

This study replicates Todd and colleagues’ original work with a different population. The findings conclude that disparity in the treatment of pain for long bone fracture in an emergency room is different based not only on the ethnicity of the patient, but also on the race of the patient. Being black is just as significant a factor as being Hispanic in receiving different pain treatment from white patients. The study also shows that disparity of pain treatment based on race and ethnicity occurs in different geographic areas of the country. Seven years after his first study, Todd and colleagues require us to confront empirical evidence of continued disparities in pain treatment in the emergency department based on race.

PAIN TREATMENT OUTSIDE THE EMERGENCY DEPARTMENT

Cancer pain

In 1994, Cleeland, Gonin, Hatfield, and additional colleagues published a multicenter study in the New England Journal of Medicine that found that outpatients with cancer who went to clinics that served ethnic and racial minority patients were three times more likely to be undertreated with analgesics than were patients in other settings. The percentage of patients indicating inadequate analgesia was significantly higher in community clinical oncology programs that treated predominantly black and Hispanic patients than in university cancer centers and community-based hospitals and practices. Also, black and Hispanic patients were more likely than non-minority patients to have inadequate analgesia no matter what the setting.

Cleeland, Gonin, Baez et al.

Cleeland, Gonin, Baez, and additional colleagues published a follow-up study in the Annals of Internal Medicine, “Pain and Treatment of Pain in Minority Patients with Cancer,” in 1997. The objective of the second study was to analyze specifically the severity of cancer-related pain and the adequacy of prescribed analgesics in black and Hispanic patients by treatment site, determine which factors might predict inadequate pain management for minorities, and whether pain treatment differed among ethnic minority groups. The study involved patients from academic health centers, community hospitals and practices, and centers that primarily treat minority patients. The racial and ethnic demographics of the patients were described as 106 blacks, 94 Hispanic, and 16 persons of other racial and ethnic minority groups. Their pain severity was measured using the Brief Pain Inventory. The researchers estimated the adequacy of analgesic prescription by using the Pain Management Index.

The researchers concluded: “Patients who were treated at centers that primarily saw black persons, Hispanic persons, or both and patients who were treated at university centers were more likely to receive inadequate analgesia than were those who received treatment in non-minority community treatment settings.” To reach this conclusion, Cleeland and colleagues compared data from their previous study and found that 65 percent of minority patients with pain received inadequate analgesic prescription, compared with 50 percent of patients from non-minority settings. Minority patients were more likely to have had the severity of their pain underestimated by their physicians and to have reported that they needed stronger pain medication.

Cleeland and colleagues discussed what might be some of the causes for the disparity in pain treatment:

Inadequate prescribing of analgesics for minority patients may result from many factors, including concern about potential drug abuse in minority patients, fewer resources with which to pay for analgesics, greater difficulty in assessing care and in filling analgesic prescriptions, and greater difficulty for the physicians in assessing pain in minority patients because of differences in language and cultural background. Inadequate treatment may also result from the patient’s fear of aggressive treatment, the patient’s lack of assertiveness seeking care, or lack of expertise at the sites that treat patients belonging to ethnic minority groups.

The Cleeland studies highlight the importance of considering the type of health-care facility when analyzing the data for disparities in pain treatment based on race and ethnicity. More research should be conducted to better understand the influence of health-care facilities’ financial pressures, staffing inadequacies, and the predominant socioeco-
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| Todd, Deaton, D’Adamo, and Goe | Sample consisted of 217 patients who were discharged from emergency department with isolated long-bone fracture diagnosis. | Whether black patients with extremity fractures are less likely to receive emergency department analgesics than white patients with similar fractures. | Retrospective cohort study of medical records for a forty-month period. | Some Key Findings: | • Small number of subjects.  
• Limited number of minority physicians to test association between physician and patient race and ethnicity and analgesic-prescribing patterns. |
| | Ethnicity:  
black (n = 127)  
white (n = 90)  
Mean Age:  
black: 33 (24–42 range)  
white: 35 (25–47 range)  
Sex:  
black: 59% male  
white: 58% male | | | | |
| Todd, Samaroo, Hoffman | Sample consisted of 139 patients who were discharged from emergency department with diagnosis of isolated long-bone fractures. | Whether Hispanic patients with isolated long-bone fractures are less likely to receive emergency department analgesics than similar non-Hispanic white patients. | Retrospective cohort study of emergency department medical records for a two-year period. | Some Key Findings: | • Hispanics were twice as likely as non-Hispanic whites to not receive analgesics in the emergency department (55% of Hispanics received no analgesic vs. 26% of non-Hispanic whites).  
• Ethnicity was the strongest predictor of no analgesic administration in the emergency department after controlling for covariates.  
• Patient’s primary language reached borderline significance (p = 0.052) as an independent predictor of the absence of any analgesic administration. | • Ethnicity was not self-reported. Classification of Hispanic ethnicity was based on clerical emergency department personnel’s perception of patient’s ethnicity.  
• The extent to which patient advocates, such as family members or friends, might have influenced physicians’ pain management decisions was not measured.  
• The presence and use of translators in this study wasn’t measured. Availability of translators might have influenced physicians’ management decisions. |
| | Ethnicity:  
Hispanic (n = 31)  
non-Hispanic white (n = 108)  
Mean Age:  
Hispanic: 32.8 (10.4 SD)  
non-Hispanic: 31.3 (9.6 SD)  
Sex:  
Hispanic: 71.0% male  
non-Hispanic: 58.3% male  
Primary Language English:  
Hispanic: 58.1%  
non-Hispanic: 97.2% | | | | |
| Todd, Lee, and Hoffman | Sample consisted of 207 patients. | Whether a patient’s ethnicity influences a physician’s estimate of the severity of pain. | Prospective cohort study. | Some Key Findings: | • Mean patient pain assessment, mean physician pain assessment, and mean disparity in patient and physician pain assessment were not significant between white and Hispanic patients (0.86, 0.23, and 0.38 respectively).  
• Patient pain assessment was higher than physician pain assessment for both Hispanics (p = 0.003) and whites (p = 0.005).  
• Patient ethnicity was not predictive of disparity in patient vs. physician pain assessment. | • Evidence of the clinical significance of differences in pain assessment on a visual analog scale was not established.  
• Convenience sample of patients presenting during dates and times when research assistants were available was used for this study. |
| | Ethnicity:  
Hispanic (n = 69)  
non-Hispanic white (n = 138)  
Mean Age:  
Hispanic: 33.8 (12.6 SD)  
non-Hispanic: 34.9 (15.1 SD)  
Sex:  
Hispanic: 68.1% male  
non-Hispanic: 58.7% male  
Primary Language English:  
Hispanic: 27.6%  
non-Hispanic: 89.1% | Patients enrolled for study during a seven-month period (July 1992 through January 1993). | | | |
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<td>Ng, Dimsdale, Rollnik, and Shapiro</td>
<td>Sample consisted of 454 consecutive patients who were treated with patient-controlled analgesia (PCA) for pain in the immediate inpatient post-operative period (the first eight to twelve hours after surgery).</td>
<td>Whether ethnicity influences PCA for treatment of post-operative pain.</td>
<td>Retrospective medical record abstraction for patients seen between January and June 1993.</td>
<td><strong>Some Key Findings:</strong> Subjective pain scores reported by patients of different ethnic groups did not differ statistically from one another.</td>
<td>• Sample sizes for blacks and Asians were relatively small. • Patients’ body sizes were not measured in relation to both the amount of analgesics they were prescribed and the amount they self-administered. • Patients’ primary language was not measured, especially in relation to patients’ completing the visual analog scale. Patients’ primary language can influence physicians’ pain management decisions based on patients’ ability (or inability) to communicate subjective pain experience.</td>
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<td>Bartfield, Salluzzo, Raccio-Robak et al.</td>
<td>Convenience sample of 91 adult emergency department patients treated and released with non-traumatic lower back pain.</td>
<td>Whether physician impression of the degree of a patient’s pain and patient demographics influence the prescription of analgesics.</td>
<td>Physician pain score measured on same scale as patient pain score; both patient and physician were blind to each others’ scales.</td>
<td><strong>Some Key Findings:</strong> • 38% received analgesics (n = 35). • Of these, 28% were Caucasian (n = 9) and 44% non-Caucasian (n = 26). • Patient ethnicity was determined not to be significant.</td>
<td>• Small sample size (type II error). • Race and ethnicity were not defined beyond Caucasian vs. non-Caucasian. • Hawthorne effect (even though physicians didn’t know their decision to administer analgesics was being examined, their decisions might have been influenced by their completing the visual analog pain scale for their patients).</td>
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<td>Ng, Dimsdale, Shragg, and Deutsch</td>
<td>Ethnicity: Hispanic (n = 100) black (n = 36) white (n = 114) Insurance: • Hispanics = 100% Medicaid or other publicly funded program • blacks = 89% public, 11% private • whites = 91% Medicaid or other publicly funded program; 10% private insurance</td>
<td>Whether patient ethnicity influences the receipt of post-operative analgesia.</td>
<td>Of 250 consecutive patients who were hospitalized for open reduction and internal fixation of a limb fracture, the following data were collected:</td>
<td><strong>Some Key Findings:</strong> Significant number of diagnoses (p = 0.001): whites had larger number. No differences in receipt of acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) across ethnic groups. Significant differences among blacks, Hispanics, and whites (p &lt; 0.002) in analgesic consumption (narcotics): whites = 22 mg/day blacks = 16 mg/day Hispanics = 13 mg/day (approx. 60% less than whites)</td>
<td>• Low proportion of blacks compared to rest of sample. Authors considered insurance status (in this case, the majority didn’t have any) as a possible proxy for social class. A more precise measure of social class is needed.</td>
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| Bernabei, Gambassi, Lapane et al. | Sample consisted of 13,625 cancer patients who were 65 or older and discharged from a hospital to one of 1,492 Medicare-certified and/or Medicaid-certified nursing homes in five states participating in the Health Care Financing Administration's demonstration project. | Whether pain management in elderly and minority cancer patients admitted to U.S. nursing homes is adequate. | 350-item minimum data set completed by multidisciplinary team of various researchers (SAGE database) | Some Key Findings:  
- Minority patients were less likely to have pain recorded relative to whites (even after language differences were taken into account). Statistical significance only for blacks, but trend was there for Hispanics, Asians, and American Indians.  
- Minority patients were more likely to receive no analgesics compared to whites (univariate analysis).  
- Blacks were less likely to receive analgesics (relative risk = 1.63; CI 1.18 to 2.26) — specifically a 63% increased probability of being untreated relative to whites. | Small number of persons per racial group.  
- Limitations in accuracy of assessment of pain: Data set was not focused specifically on pain; observational evaluation of patient's pain by staff may be underestimation of pain; site of pain was not located with certainty. |
| Karpman, Del Mar, and Bay | Sample consisted of 84 adult patients older than 16 years of age who were discharged from the emergency department of a level-I trauma center community hospital with a diagnosis of isolated long-bone fractures requiring a closed reduction. | Whether Hispanic patients with isolated long-bone fractures are less likely to receive emergency department analgesics than similar non-Hispanic white patients seen at Maricopa Medical Center. | Retrospective cohort study of emergency department medical records for a one-year period.  
- Medical record abstraction procedure:  
  - demographic and analgesic information collected,  
  - record reviewed if an analgesia was recorded in the physician's progress note and medication records,  
  - linear regression was used to assess the relationship between ethnicity and the equivalent dose of analgesia, and  
  - patients not receiving analgesia were excluded. | Some Key Findings:  
- 44.8% of Hispanic patients and 43.6% of white non-Hispanic patients received no analgesia. The relative risk for Hispanic patients not receiving analgesia was 1.03 that of white patients, so the probabilities of receiving analgesia for the two groups were not significant.  
- Analysis of high versus low dose for those who received analgesia also indicated no difference: 50% of Hispanic patients and 32.3% of white patients received the high dosage. | Small sample size in the current study.  
- Incomplete information from medical abstraction on payer source.  
- No evidence of a blinded review. |
| Cleeiland, Gonin, Baez et al. | Sample consisted of 281 minority (Hispanic and non-white) outpatients with cancer who were receiving care at university cancer centers, community hospitals and cancer centers, and centers that treat predominantly minority patients. Of the sample population, 216 patients (77%) reported that in the 7 days before the study, they had pain or had taken analgesics on a daily basis. | Whether pain treatment differed among ethnic minority groups and whether pain treatment in minority patients varied by treatment site. | Prospective cohort study of minority patients treated for cancer-related pain at nine university cancer centers (26%), seventeen community hospitals and cancer centers (26%), seventeen community hospitals and practices (41%), and four centers that primarily treat minority patients (33%). Ethnicity was reported by the institution. | Some Key Findings:  
- For 90% of the patients, the pain was attributed by their physician to the disease process of cancer.  
- In comparison to the previous study, minority patients were more likely to be undereducated (65% and 50%; p < 0.001).  
- Minority patients had the severity of their pain underestimated by their physicians (p < 0.04), reported that they needed stronger pain medication (p < 0.001), and felt that they needed to take more analgesics than their physicians had prescribed (p < 0.001). | Data were collected immediately after data collected on the non-minority comparison group, which may have biased the results.  
- Study did not consider reluctance to report pain by patients.  
- Data on patients’ race and ethnicity were not available for comparison group. |
nomic status of the facilities’ patients on the treatment of pain. As a subset of this, more studies are needed to analyze the relationship between physicians’ attitudes toward (and stereotypes of) their patients and physicians’ treatment of their patients’ pain. For instance, are physicians more likely to believe that their black and Hispanic patients, rather than their white patients, are drug abusers?

Bernabei, Gambassi, Lapane et al.
A 1998 study by Bernabei, Gambassi, Lapane, and additional colleagues of the management of pain in elderly patients with cancer included an analysis of pain treatment for elderly minority patients. The study, titled “Management of Pain in Elderly Patients with Cancer,” was published in the Journal of the American Medical Association. The study characterizes the treatment of pain for 13,625 individuals receiving Medicare. The data for the study was from the Systematic Assessment of Geriatric Drug Use via Epidemiology (SAGE) database.

The study found that black and Hispanic patients were less likely to have pain recorded relative to non-Hispanic whites. The study found that minority patients with cancer in nursing homes were more likely not to have received any analgesia. Black Americans appeared to have a 63 percent increased probability of having their pain untreated relative to whites. Similar results were observed for patients belonging to other racial and ethnic groups, although the confidence intervals were wide because of the small number of patients in these groups in the study.

Pain was assessed based on observational evaluation by the nursing home staff, which has the potential for underestimation. All of the patients were in a Medicare-certified and/or Medicaid-certified nursing home. All patients were age 65 or older and thus eligible for and receiving Medicare. Sadly, in addition to this study, other studies have found that Medicare patients who are black or poor receive a lower quality of care. The passage of the Civil Rights Act of 1964 should have provided the legal remedy for addressing racial disparities in such government-sponsored health care. Title VI of the Act prohibits institutions that receive federal assistance from discriminating. Specifically, the law provides:

No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

Medicare and Medicaid funding are within the definition of federal assistance pursuant to Title VI. The purpose of Title VI is to prohibit discrimination that is either intentional or based on policies that appear facially neutral, but have a disproportionate or adverse negative impact. Title VI, however, has failed to be an effective law to end discrimination in our country’s health-care delivery systems. Health law scholars have specifically commented about the ineffectiveness of Title VI in redressing the disparities in health-care treatment.

In 1999, the Office for Civil Rights (an office within the Department of Health and Human Services) established a Racial Disparities Task Force to further the U.S. Department of Health and Human Services Initiative to eliminate racial and ethnic disparities. The Office of Civil Rights reported in its fall 1999 newsletter: “OCR’s enforcement experience, coupled with compelling research documenting the prevalence of racial bias in physician decision-making, demonstrates that eliminating racial disparities in the provision of health care services is both a public health and civil rights challenge. Aggressive enforcement of civil rights laws must be an important component of our overall strategy to eliminate the racial disparities in health.”

Our country’s elderly have a right to equal pain treatment in a government-sponsored health-care program; hopefully, the Office of Civil Rights will take its enforcement responsibility seriously.

Post-operative pain and low back pain

Ng, Dimsdale, Shragg, and Deutsch
A study published in 1996 by Ng, Dimsdale, Shragg, and Deutsch studied the influence of a patient’s ethnicity and race on treatment of post-operative pain. The retrospective medical record study included 250 consecutive patients hospitalized for open reduction and internal fixation of a limb fracture. The objective of the study was to examine whether the findings from Todd’s 1993 study could be generalized to post-operative pain in inpatient settings and with other racial and ethnic groups.

The study found that “whites (n = 114) consistently received higher doses of analgesics than blacks (n = 36) or Hispanics (n = 100). Despite the fact that the groups differed in some demographic and clinical variables, the difference in analgesic consumption was highly significant (based upon race and ethnicity) and persisted even after controlling for these variables (age, sex, insurance status, number of diagnoses).” The authors commented: “What is it about ethnicity that influences so profoundly pain behavior? The receipt of analgesic medication requires a transaction between patient and staff. Our study cannot disentangle whether the differences in analgesic used reflect patient behavior/attitudes, staff behavior/attitudes, or both.”

Ng, Dimsdale, Rollnik, and Shapiro
A follow-up study, titled “The Effect of Ethnicity on Prescriptions for Patient-Controlled Analgesia for Post-Opera-
predictor of the amount of narcotic prescribed. However, ethnicity continued to be a significant independent variable on the initial patient-controlled analgesia prescription. When the study statistically controlled for these variables, the treatment plan of pre-operative narcotic use influenced the physician’s decision on the initial patient-controlled analgesia in the immediate post-operative period. The ethnic and racial sample included Asians (n = 37), blacks (n = 30), Hispanics (n = 73), and whites (n = 314).

The study found that the amount of narcotic prescribed was greater for whites than for Hispanics, and greater for blacks than for Hispanics and Asians. The study indicated that variables such as age, sex, site of the surgery, and history of pre-operative narcotic use influenced the physician’s decision on the initial patient-controlled analgesia prescription. When the study statistically controlled for these variables, however, ethnicity continued to be a significant independent predictor of the amount of narcotic prescribed.

The authors commented that this study suggests that ethnicity exerts a prominent effect on physicians’ behavior, even when patients’ behavior is relatively constant across ethnic groups. Although other issues—like the effectiveness of communication between the physician and patient before surgery, the physician’s ethnicity, and the physician’s prior experience in treating pain—still have to be considered, it seems clear that ethnicity has a profound influence on the physician’s treatment plan.

In making the Presidential Address to the American Psychosomatic Society in 1999, Dimsdale described the conclusion of the original and follow-up studies in bleak terms:

The doctor apparently arrives at the patient’s bedside with preconceived notions about the patient’s needs for pain medication that are tied to ethnicity and not to the illness per se. What is worse is that there are no data to suggest that such perceptions are accurate, nor are physicians even aware of their behavior.

Bartfield, Salluzzo, Raccio-Roback et al.

Contrary findings were found in a 1997 study conducted by Bartfield, Salluzzo, Raccio-Roback, and additional colleagues. The study, titled “Physician and Patient Factors Influencing the Treatment of Low Back Pain” and published in Pain, was designed as a prospective study of adult patients treated for non-traumatic low back pain. Bartfield and colleagues investigated the influence of the physician’s impression of the patient’s pain, race, and ethnicity on the prescribing of analgesics. They concluded that the physician’s impression of the patient’s pain, rather than the patient’s ethnicity and race, influenced analgesic use.

In a 1997 study, Ng et al. found that ethnicity was a significant predictor of the amount of analgesics prescribed. The study was conducted on a sample of 454 patients who were prescribed patient-controlled analgesia for pain following a surgical procedure. Patients were excluded from the sample if they did not have a surgical procedure prior to the use of the patient-controlled analgesia or did not use the patient-controlled analgesia in the immediate post-operative period. The ethnic and racial sample included Asians (n = 37), blacks (n = 30), Hispanics (n = 73), and whites (n = 314).

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Understanding the Lessons of the Studies

The studies as a body of research paint the clear picture that one’s race and ethnicity matter in the treatment of pain. The common thread is that there are empirical data indicating differences in pain treatment based on the patient’s racial and ethnic background. The studies’ most poignant findings are related to the disparity in treatment of blacks and Hispanics in comparison to the treatment of whites. The studies, when reviewed as a group, find that disparities cross different types of health-care facilities and treatment settings, from the emergency room to the community hospital to the nursing home.

Not all studies found disparities that could be attributed to the patient’s race or ethnicity. Two of the eight studies reviewed did not find a difference in treatment based on race. These studies concluded that the type of health-care facility and the physician’s impression of the patient’s pain were more determinative factors than race and ethnicity in the extent to which pain was treated (or not treated) prop-
perly. What the studies do as a body of research is make a very strong argument that this is an important area for further research, physician education, and health advocacy to improve the treatment of pain for all people in our society. The larger dialogue on improving pain relief should not be permitted to marginalize the evidence of disparities in pain treatment for people of color.

**General Limitations of the Studies**

The studies presented have provided a foundation for other researchers to further study the treatment of pain based on the race and ethnicity of the patient. Much can be learned from this work including the limitations of the studies. General limitations of the studies include:

1. **Sample Size.** The limited number of subjects in the studies diminishes their ability to be generalized. The sample size is a major limitation of most of the studies.

2. **Unreliability of Recorded Information.** A limitation of retrospective medical record reviews is the accuracy of the information collected, which may include misclassifications of predictor or outcome variables. Recognizing this limitation is important in describing and analyzing pain treatment.

3. **Race and Ethnicity Identification.** How information about race and ethnicity is collected is an important component of study design. Studies must clearly state how the information is collected and how race and ethnicity are defined. Race and ethnicity misclassification must be recognized as a potential limitation of health-services research that collects data from medical records and by hospital staff judgment. The validity of health-services research data is based on the assumption that the categories of race and ethnicity are consistently defined and collected. As a result, how race and ethnicity are classified and collected should be a part of any discussion of racial and ethnic disparities in health care.

**Causes of the Disparities in Pain Treatment**

**Perceptions of race and ethnicity**

“When people look at me, they tend to fill in the blank with what they’re comfortable with and often assume I’m Asian. So I hear things that maybe I wasn’t supposed to see or hear. I know what it feels like to be black in America and I know what it feels like to be Asian.”

The classification of individuals’ racial and ethnic identity is fraught with researchers’ biases. Race is not defined in a singular way. Race is an ambiguous concept that has played a prominent role in health-services research. Demographic data, including race and ethnicity, are commonly collected by admitting clerks at hospitals at the time of admission. Many institutions do not have any formal rules for assigning race to a patient. The “gold standard” for the classification of race and ethnicity is self-identification. However, there is a competing theory that physicians’ perceptions of a patient’s race would be more appropriate. In the 1993 Todd study, the researchers wrote:

Hispanic ethnic classification is recorded by clerical personnel in our ED [emergency department] on the basis of Hispanic surnames and use of Spanish as the primary language in the home. It is possible that such classification was imprecise and even erroneous, but it seems unlikely that “perception” of ethnicity by treating medical personnel would have been significantly different than that of the registration clerks.

Too often, a physician’s perception of a patient’s race and ethnicity, which is not based on any communication with the patient, is being recorded and used by the healthcare team to make clinical decisions and medical and social judgments about the patient. This practice perpetuates physician paternalism and racism.

Today in our nation, we are facing the political and social issue of defining people by race and ethnicity in a new way. Race is a social construct that continues to influence how people are treated. In future research, we must further investigate how physicians’ preconceptions about race and ethnicity are biasing not only the way they treat patients for pain, but also how information about race and ethnicity is collected.

**Language barriers**

The health-care provider’s level of fluency in patients’ primary language is an important factor in effective physician-patient communication. Physician-patient communication is essential to properly assessing a patient’s pain. It should be noted that in the 1993 Todd study, the effect of ethnicity on pain treatment persisted after controlling for primary language use.

One area that the Office for Civil Rights has targeted for enforcement is ensuring access to health-care services for Limited-English Proficient (LEP) patients. The Office of Civil Rights has issued a Guidance Memorandum on national origin non-discrimination and Limited-English Proficiency to its staff to ensure consistent application of Title VI of the Civil Rights Act of 1964 to health and social services programs funded by the department. The focus of the Office of Civil Rights is on the ability of
patients with limited English proficiency to obtain access to health care.89

In April 2000, the Commonwealth of Massachusetts passed the “Emergency Room Interpreter Bill,” effective July 1, 2001. This law requires all hospitals that provide acute care in emergency rooms or acute psychiatric services to use competent interpreter services when treating non-English speakers.90 The law recognizes that effective pain assessment requires the ability to communicate with the patient.

**Patient-physician communication**

Once you go through registration and you go in the back, it is like your little prison; you are sitting there, you listen to everybody’s crying, and in pain, and you are in pain, so you try to hold back. You are wondering if he (Doctor) is coming or not coming. They make you feel like you are in a prison, a ward, and you are stuck there until it gets better and it never gets better. I hate it. I really, really hate it. Then there has been some wonderful times, I went in and got treated.91

*Patient with Sickle Cell Disease, Focus Group Participant*

Studies have shown that race and ethnicity are important cultural barriers in patient-physician communication. A study92 by Cooper-Patrick and colleagues found that African American patients had significantly less participatory visits with their physicians than white patients. The objective of the study was to determine how the race, ethnicity, and sex of patients and physicians were associated with physicians’ participatory decision-making styles.93 Physicians who involved their patients in treatment decisions were defined as having a “shared” or “participatory” decision-making style.94

Understanding the influence of race, ethnicity, and sex in the clinical decision-making process is important in understanding their effect on the communication between patients and physicians. Cooper-Patrick indicated that ethnic differences between physicians and patients are often barriers to partnership and effective communication. She theorized that a number of physician and patient factors might account for these problems, including that physicians may unintentionally incorporate racial biases, such as stereotypes, into their interpretation of patients’ symptoms, predictions of patients’ behaviors, and medical decision-making.95 Physicians may not understand a patient’s expression of his or her symptoms. Patients might contribute less to participatory medical visits because of factors such as language barriers, low health literacy, little education, as well as the inability or failure to advocate for one’s health.96

**Socioeconomic status**

Race, ethnicity, and socioeconomic status are intertwined in the United States. It is difficult to isolate racial and ethnic disparities from socioeconomic disparities.97 Socioeconomic status is commonly used to discuss disparities in health-care status and treatment; however, the way it is defined is not always clear. Socioeconomic status includes both resource-based and prestige-based measures. Resource-based measures refer to income, wealth, and educational credentials. Prestige-based measures refer to an individual’s status in a social hierarchy, typically evaluated by reference to people’s access to and consumption of goods, services, and knowledge, as linked to the prestige of their occupation, income, and education level.98

The influence that a patient’s socioeconomic status has on the treatment of pain should be further studied and separated from the race and ethnicity of the patient to better understand the causes of disparities in pain treatment. The type of facility where patients receive their health care is associated with socioeconomic status and should be considered in understanding disparities in pain treatment. The Cleeland studies found that the percentage of patients with inadequate pain treatment was significantly higher in community clinical oncology programs that treated predominantly black and Hispanic patients than in the other settings.99 This may be caused by many factors, including resources available at the facility and the health-care providers’ perceptions of their patients.

Sidney Watson, commenting on disparities in care in the inner city, stated: “Most doctors and hospitals who serve only the poor do, in fact, provide unequal care. In some cases the differences may be only cosmetic.... In others, the differences mean less than optimal service — fewer prescription drugs, fewer staff, less care. Under our present system, inequality results from inadequate financing. Even with financing reforms, however, the poor do not have the political clout to demand better services. Programs designed specifically for their needs may slip inexorably into providing substandard care.”100 Studies of pain treatment and racial and ethnic disparities in treatment must include, as a variable and a major focus, analysis of the type of facility in which the patient received care.

**Clinical assessment of pain**

We need to get physicians and nurses, health-care providers in general, to understand we deserve to be triaged better than we are.... They always triage us badly. I think as a sickle cell person I need to be moved up in the triage process. Don’t take my complaints quite so lightly. We are always the last people to be seen. Our pain is as real as that
Assessment of pain is the first step in its treatment. Thus, understanding the potential for bias in the assessment of pain based on differences of race, ethnicity, and socioeconomic status is necessary if we are to reduce barriers to equal pain treatment. Knox Todd commented that a possible cause of the disparity in treatment is not racial and ethnic bias, but a failure to properly assess the patients’ pain. “It is possible that, unless prompted, physicians are less likely to perform an adequate or conscious pain assessment for Hispanic or other minority patients, which could then explain the disparity in [the] ordering of analgesics. If this were true, the chance of changing physician behavior would appear to be much greater than if conscious racial bias were the root cause.” The 1994 study by Todd and colleagues raised many questions to support the need for further research of differences in the assessment of pain.

“Pain is a complex, subjective response with several quantifiable features, including intensity, time course, quality, impact, and personal meaning. The reporting of pain is a social transaction between caregiver and patient.” Because pain and the reporting of pain are so subjective, standardized pain assessment is a critical process in ensuring complete patient-physician communication regarding pain. The debate continues regarding the best approach to assess pain and the use of various pain scales. Too often, however, nothing is used and pain is not discussed and assessed in any type of routine clinical manner. See Figure 1 for the Agency for Healthcare Research and Quality’s clinical guidelines for acute pain assessment.

The Need for More Research

Further study is needed to look at differences of treatment based on patient-physician racial and ethnic concordance. This is important to further understand the differences in pain treatment and to decrease disparities based on non-clinical factors.

The first major study on differences in pain treatment based on race and ethnicity was published in 1993. We are only beginning to unravel the causes of this disparity, and we must continue this work. Additional study of the influence of English language proficiency on pain treatment should be pursued to understand how patient-physician communication influences the assessment of pain. The role of acculturation in how pain is communicated and assessed by physicians should also be further studied.

How pain is assessed, the influence of trust between a health-care provider and patient, physicians’ perception of patients, and patients’ perception of physicians must, too, be studied as part of the investigation of the differences in treatment based on race and ethnicity.

The influence of socioeconomic status on pain treatment must be further studied. Intra-race and Intra-ethnicity studies can provide valuable data in distinguishing differences based on socioeconomic factors from differences based on race and ethnicity. Further studies to understand the role of the health-care institution on the treatment of pain will help health-care providers understand why some institutions have significantly different treatments based on race and ethnicity and others do not. The National Institutes of Health, the Agency for Healthcare Research and Quality, and private foundations should fund projects with sufficiently large stratified study populations to be generalizable to the national population and sub-populations by race and ethnicity, geographic location, sex, and insurance and income status.

Standard data collection is needed to provide researchers accessible and accurate data on pain treatment by race, ethnicity, sex, and age. Empirical data and effective laws can work together to assist in reducing barriers in treatment based on race and ethnicity.

Conclusion

Because racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race, physicians should examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussion about the issue. Such discussions should take place as part of the medical school curriculum, medical journals, at professional conferences, and as a part of professional peer review activities.

The majority of the studies conducted to date have found a disparity in pain treatment. The studies have found that blacks and Hispanics are more likely to be undertreated for pain than whites. “Any attempt to remedy disparities in the delivery of health care services must confront the possibility of racism as a motivating factor in treatment decisions.”

Why are so many people of color (racial and ethnic minorities) not surprised by these findings? Vanessa Northington-Gamble comments: “They [African Americans] perceive, at times correctly, that they are treated differently in the health care system solely because of their race, and such perceptions fuel mistrust of the medical profession. For
**PRINCIPLES**

- Patients who may have difficulty communicating their pain require particular attention. This includes patients who do not speak English and patients whose level of education or cultural background differs significantly from that of their health care team.
- Family members should be involved when appropriate.

**PAIN ASSESSMENT TOOLS**

- The single most reliable indicator of the existence and intensity of pain—and any resultant distress—is the patient’s self-report.
- Self-report measurement scales include numerical or adjective ratings and visual analog scales. Tools should be reliable, valid, and easy for the patient and the nurse or doctor to use. These tools may be used by showing a diagram to the patient and asking the patient to indicate the appropriate rating.
- The tools may also be used by simply asking the patient for a verbal response (e.g., “On a scale of 0 to 10 with 0 as no pain and 10 as the worst pain possible, how would you rate your pain?”).
- Tools must be appropriate for the patient’s developmental, physical, emotional, and cognitive status.

**PREOPERATIVE PREPARATION**

- Discuss the patient’s previous experiences with pain and beliefs about and preferences for pain assessment and management.
- Give the patient information about pain management therapies that are available and the rationale underlying their use.
- Develop with the patient a plan for pain assessment and management. Select a pain assessment tool, and teach the patient to use it. Determine the level of pain above which adjustment of analgesia or other interventions will be considered.
- Provide the patient with education and information about pain control, including training in nonpharmacologic options such as relaxation.
- Inform patients that it is easier to prevent pain than to chase and reduce it once it has become established and that communication of unrelieved pain is essential to its relief.
- Emphasize the importance of a factual report of pain, avoiding stoicism or exaggeration.

**POSTOPERATIVE ASSESSMENT**

- Assess the patient’s perceptions, along with behavioral and physiologic responses. Remember that observations of behavior and vital signs should not be used instead of a self-report unless the patient is unable to communicate.
- Assess and reassess pain frequently during the immediate postoperative period. Determine the frequency of assessment based on the operation performed and the severity of the pain. For example, pain should be assessed every 2 hours during the first postoperative day after major surgery.
- Increase the frequency of assessment and reassessment if the pain is poorly controlled or if interventions are changing.
- Record the pain intensity and response to intervention in an easily visible and accessible place, such as a bedside flow sheet.
- Revise the management plan if the pain is poorly controlled.
- Review with the patient before discharge the interventions used and their efficacy and provide specific discharge instructions regarding pain and its management.

example, a national telephone survey conducted in 1986 revealed that African Americans were more likely than whites to report that their physicians did not inquire sufficiently about their pain, did not tell them how long it would take for prescribed medicine to work, did not explain the seriousness of their illness or injury, and did not discuss test and examination findings.\textsuperscript{107}

The experience of racism in the every day lives of people is pervasive.\textsuperscript{108} It is a part of our unconscious and conscious lives to treat people who look or speak differently as in fact different from those who look or speak like ourselves. The majority of the time, the disparity in how we treat people is only a demonstration of our ignorance. However, health care is an area where this ignorance can cause potentially life-threatening outcomes. If we are to solve these disparities in treatment, we must study them and determine their causes. We must have a serious dialogue about the many factors that cause racial and ethnic disparities in health-care treatment. Health inequities should be an important bioethics concern.\textsuperscript{109}

Race matters in the delivery of health care services. While the causes of health-care disparities are more complicated than race, we must continue to study race as a factor.\textsuperscript{110}

The Council on Ethical and Judicial Affairs for the American Medical Association stated in its 1990 report, “Black-White Disparities in Health Care,” that one response to the disparities is greater awareness.\textsuperscript{111} Greater awareness is particularly important for the study of the treatment of pain. Greater awareness by the legal, medical, and ethics communities of the studies that have investigated race, ethnicity, and pain treatment, as well as these communities’ promotion of further research, is a step in eliminating the disparities. It is my hope that by reviewing the research conducted on pain treatment based on patients’ race and ethnicity and presenting the voices of people who experience pain, I will encourage others to pursue research in this field. Only then will we fully understand the causes of disparities and identify solutions to eliminate them.

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References

1. The following statement is from a member of a focus group of adults, aged 19 through 54, with sickle cell disease. The focus group was conducted as part of the Race and Pain Treatment Project, which includes a qualitative study of the pain treatment experiences of adults with sickle cell disease. Sickle cell disease is an inherited blood disorder and is characterized by excruciating musculoskeletal pain that punctuates the lives of patients with the disease. Often referred to as “crises,” these episodes of pain are the principal causes of morbidity among patients with the disease. See O.S. Platt et al., “Pain in Sickle Cell Disease,” N. Engl. J. Med., 325 (1991): 11-16. The voices of individuals whose lives are intertwined with pain episodes provide an important personal context to the data of race and pain treatment studies. They also should also serve as a plea — a demand — for further study of the inequities resulting from the differences in pain treatment based on race and ethnicity.


15. The research of differences in cultural presentation of pain supported by this literature has many limitations. Language and communication barriers and researcher bias are significant limitations to much of this work. Howard Greenwald’s commentary about Zborowski’s and other studies observing differences in pain associated with race and ethnicity concluded that: “These and related studies leave much uncertainty about the relation between ethnicity and pain today. The variety of methods used to assess expression of pain makes comparison of research findings difficult. Most studies do not control for social background variables other than ethnicity that may affect perceptions or interpretation of pain.” See Greenwald, supra note 12, at 157.
18. MEDLINE is the National Library of Medicine’s premier bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the health-care system, and the pre-clinical sciences. The MEDLINE file contains bibliographic citations and author abstracts from approximately 3,900 current biomedical journals published in the United States.
19. HealthSTAR contains citations to journal articles, monographs, technical reports, meeting abstracts and papers, book chapters, government documents, and newspaper articles from 1975 to the present. HealthSTAR focuses on the non-clinical (emphasizing the evaluation of patient outcomes and the effectiveness of procedures, programs, products, services, and processes) aspects of health-care delivery.
22. Id. at 1538.
23. Id. at 1539.
24. Id. at 1537.
26. See Todd, supra note 22.
27. See Todd, supra note 26, at 926. A total of 207 patients participated in the study (138 non-Hispanic white and 69 Hispanic non-white). Sixty-five different physicians evaluated the patients. There was no difference between white and Hispanic patients with regard to patient pain assessment, which was higher than the physicians’ pain assessment for both groups.
29. Id. at 926.
30. Id. at 927.
31. Id. at 927–28.
32. See Todd, supra note 21.
34. Id. at 275.
35. Id. at 274.
36. See Todd, supra note 22.
37. See Karpman, supra note 33.
38. Id. at 275.
39. See Todd, supra note 22.
40. See Karpman, supra note 35.
42. See Todd, supra note 22.
43. See Todd, supra note 41.
44. Id. at 11.
45. Id. at 14–15.
47. Id. at 59.
49. Id. at 813.
50. Id. at 814 (“The Pain Management Index is based on guidelines form the World Health Organization and the Agency for Healthcare and Quality.”).
51. Id. at 814.
52. See Cleeland et al., supra note 46.
53. See Cleeland et al., supra note 48, at 815.
54. Id. at 815.
56. Id. at 1878. “SAGE” is a population-based multilinked database that includes computerized data collected as part of the Health Care Financing Administration’s Multistate Nursing Home Case-Mix and Quality Demonstration Project.
57. Id. at 1879.
58. Id. at 1880.
59. Id. at 1881.
62. United States v. Baylor University Medical Center, 736 F.2d 1039, 1500 (5th Cir. 1984).
63. S.D. Watson, “Minority Access and Health Reform: A Civil Rights to Health Care," Journal of Law, Medicine & Ethics, 22 (1994): 127–37, at 130 (“Enactment of Title VI ended the most blatant forms of healthcare discrimination. But Title VI has proved ineffective in ending the less obvious inequities caused by policies and practices that disproportionately adversely impact on racial minorities. Title VI’s deficiencies are inherent in the structure of the statute: it relies on administrative enforcement; it fails to define statutorily prohibited discrimination and the evidentiary burdens in a case alleging discrimination because of disparate racial impact; it relies on voluntary receipt of federal funds; and it lacks monetary remedies in a private enforcement action.”). See also S.D. Watson, “Reinvigorating Title VI: Defending Health Care Discrimination — It Shouldn’t Be So Easy,"
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64. Office for Civil Rights, U.S. Department of Health and Human Services, OCR Update (Fall 1999): 1–12.

65. Id. at 3.


67. See Todd, supra note 22.

68. See Ng et al., supra note 66.

69. Id. at 127.

70. Id. at 128.


72. Id. at 11.

73. Id. at 12.


76. Id. at 211.


84. See Bluestein, supra note 81.

85. See Todd, supra note 22.

86. On October 20, 1997, the Office of Management and Budget (OMB) published Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. See 62 Fed. Reg. at 58,781–58,790. The standards changed the data collection policies for all federal agencies. Under the new policy, federal agencies are required to offer respondents the option of selecting one or more of the following racial categories: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. These categories are the minimum set for data on race for federal statistics, administrative reporting, and civil rights compliance reporting. For ethnicity, the standards require the collection of data on whether or not a person is of “Hispanic or Latino” culture or origin. See Tabulation Working Group of the Interagency Committee for the Review of Standards for Data on Race and Ethnicity, Provisional Guidance on the Implementation of 1997 Standards for Federal Data on Race and Ethnicity (December 15, 2000), available on-line at <http://whitehouse.gov/omb/inforeg/r6_e_guidance2000update.pdf>.


88. See Todd, supra note 22.

89. “The key to ensuring equal access to benefits and services for LEP persons, is to ensure the service provider and the LEP client can communicate effectively, i.e., the LEP client should be given information about, and be able to understand, the services that can be provided by the recipient to address his/her situation and must be able to communicate his/her situation to the recipient service provider. Recipients are more likely to utilize effective communication if they approach this responsibility in a structured rather than on an ad hoc basis.” See Office for Civil Rights, Guidance Memorandum, Title VI Prohibition Against National Origin Discrimination — Persons with Limited-English Proficiency (January 29, 1998).


91. See Adult Sickle Cell Disease Focus Group Voices, supra note 1.


93. Id. at 583.


96. See Cooper-Patrick, supra at note 92.


99. See Cleeland et al., supra notes 46 and 48.


101. See Adult Sickle Cell Disease Focus Group Voices, supra note 1.


104. See Todd, supra note 26, at 927–28.


111. See Council on Ethical and Judicial Affairs, supra note 105.
From Confrontation to Collaboration: Collegial Accountability and the Expanding Role of Pharmacists in the Management of Chronic Pain

David B. Brushwood

Federal and state laws create a tightly controlled system for distribution of those drugs that have recognized value in therapy, but also have the potential for abuse. The challenges pharmacists face in keeping controlled substances within the closed system are many and complex. Drug abusers and drug dealers have at times seen pharmacists as easy marks for access to abusable drugs. Unfortunately, pharmacists often find themselves in a game with criminals, who use both sophisticated and dangerous methods of inducing pharmacists to divert controlled substances. The effects of this problem on the health-care system have been judicially noted:

The frequency of these crimes has terrorized the community of dispensing pharmacists. Some pharmacists have ceased to carry drugs that are highly desired on the black market, although this interferes with their patients’ ability to obtain necessary medicine. This has a serious potential to impede the delivery of health care in many communities around the nation.1

Pharmacists are mindful of their gatekeeper position at the end of a long chain of drug distribution and of their responsibility to not provide drug diverters with easy access to this closed system. Pharmacists are equally mindful of their responsibility to care for patients and to provide drug therapy that is medically indicated, despite concerns of potential diversion. Pharmacists strive to always fill valid prescriptions and to always refuse purported prescriptions, but divining between valid and false prescriptions is not an easy task and some error is inevitable. Conscientious pharmacists try to strike a balance between being too trusting (and thus sometimes filling false prescriptions) and suspecting wrongdoing with every irregularity (and thus at times refusing to fill valid prescriptions).

In light of the complex decision-making that is demanded of it, the pharmacy profession is reinventing itself. Traditionally viewed as sentries standing guard over the nation’s medicinal drug supply, confronting any patient or physician whose activities threatened to compromise the integrity of the drug distribution system, modern pharmacists have begun to assume new responsibilities that extend beyond assuring accuracy and appropriateness in the processing of pharmaceutical orders — namely, to assume the promotion of good therapeutic outcomes for patients. This expansion of pharmacy practice is not occurring at the expense of medical practitioners, but in collaboration with them. Pharmacists and physicians are creating drug therapy management teams that benefit from the strengths of each team member. This new approach to practice is specifically authorized by the practice acts or administrative rules in twenty-seven states; in most of the other states, proposals are pending to recognize the authority of pharmacists and physicians to collaborate in the management of drug therapy.2 Empirical evidence supports this type of collaboration as an effective means to improve therapeutic outcomes, reduce health-care costs, and relieve human suffering.3

The types of disease that are most frequently managed by pharmacists in collaboration with physicians are diabetes, asthma, hyperlipidemia, and anticoagulation therapy.4 Most expanded pharmacy practices are situated in the institutional setting, but they are increasingly being developed for the local drug store. Although there are reports of collaborative practices in which pharmacists manage chronic pain therapies, such collaborations are not widespread. The low frequency of collaborative pain management practice
stands in contrast with the high level of responsibility that has traditionally been accepted by pharmacists in the control of opioid analgesics and the high level of regulatory control over pharmacists’ dispensing of these drugs. For example, pharmaceuticals that have the highest potential for abuse generally must be prescribed in writing and their prescriptions cannot be refilled. Those drugs that are subject to a lower potential for abuse may be prescribed verbally, but their refilling is limited in time and quantity and the record-keeping requirements are stringent. It is the pharmacist’s legal responsibility to insist on clarification by the prescriber if the formal requisites of a controlled-substance prescription have not been met. Thus, the nature of the physician-pharmacist interaction with regard to opioid analgesics has traditionally been one of confrontation rather than collaboration.

**Requiring confrontation**

The stringent regulatory controls over controlled-substance prescribing and dispensing — and the confrontational practices they produce — have historically been a significant barrier to effective therapeutic use of controlled substances. Pharmacists have at times overemphasized the regulatory imperative to not fill purported prescriptions at the expense of the therapeutic imperative to fill valid prescriptions. As recently as 1980, instructions to pharmacists in The Pharmacist’s Manual, an official publication of the federal Drug Enforcement Administration (DEA), stated, “A pharmacist who has any doubts, whatever, concerning the legitimacy of a prescription order presented to him should not dispense it.”

A pharmacist who heeds this advice may well be able to adopt practice strategies that reduce the number of purported prescriptions filled, but such strategies necessarily will also result in the refusal to fill valid prescriptions. The pharmacist’s rapport with physicians and with patients will suffer. The trusting relationship that is essential to effective patient care will not develop.

Fortunately, over the past decade, public policy toward pain management has shifted in the direction of tolerance toward — and enthusiastic support of — practices that may occasionally result in the dispensing of controlled substances pursuant to purported prescriptions. The therapeutic imperative to assure that patients who need pain medications get them has led to a more tolerant view of the occasional error by a pharmacist who has acted in good faith but who has nonetheless been duped into filling a purported prescription.

The language cited above from The Pharmacist’s Manual no longer appears in that publication. Nevertheless, there is empirical evidence to suggest that, just as physicians continue their reluctance to prescribe adequate medications for chronic pain, pharmacists continue to be similarly reluctant to dispense high doses of opioid analgesics.

**Policy-on-paper versus policy-in-practice**

Reacting to widely publicized examples of overzealous prosecution or disciplinary action of health-care providers for “overuse of narcotics,” state legislatures have enacted provisions that establish a policy of tolerance, even encouragement, of high-dose opioid use for severe pain. These new policies-on-paper are understandably rewarding for pain advocates who regularly review state statutes, administrative regulations, and published standards of practice. Continuing education programs have been mandated to “get the word out” about the newly published pain management policies because the point of them is not to make pain advocates feel better, but to make patients feel better. The problem is that changes in policy-on-paper have not necessarily led to changes in policy-in-practice. Even when physicians and pharmacists have been informed that the policy-on-paper has changed — through continuing education programs or the like — a history of threatened regulatory enforcement may be causing them to believe that if the new policy seems too good to be true, then it probably is.

Although changes in policy-on-paper are necessary to relieve the problem of undertreated chronic pain, a sufficient solution to the problem will be found only through changes in policy-in-practice. Changing behaviors is more than a function of changing laws or mission statements; there must be a concerted effort to change attitudes. Pharmacists and physicians have a tendency to simplify difficult decisions by adopting their own policy-in-practice shortcuts, e.g., “My policy is to not prescribe Schedule II narcotics over the telephone,” or “We don’t carry Schedule II narcotics.” Although neither of these informal policies-in-practice is supported by official policy-on-paper, they (and others like them) persist as barriers to effective pain management.

**A solution to changing policy-in-practice**

This article suggests a solution to effecting a change in policy-in-practice. Through collaborative drug therapy management, pharmacists and physicians can work together — not only to assure that patients are appropriately treated, but to assure that a solid objective foundation exists to withstand an accusation of inappropriate medication use. Collaborative practice is an avenue through which physicians and pharmacists can manage the risk that regulatory authorities will misapply the policy-on-paper and criticize the prescribing of high doses of opioid analgesics as inappropriate and/or illegal. The interprofessional collaborative agreement, with the checks and balances that come from a care plan based on recognized clinical practice guidelines, can provide a safe harbor for physicians who aggressively treat chronic pain. In turn, pharmacists will feel more comfortable dispensing high doses of opioid analgesics to patients whose drug therapy they understand and for whom they share responsibility. Suffering is
relieved and the responsible health-care providers can present a unified, evidence-based explanation of high dose opioid use if confronted by regulatory authorities.

This article begins with a description of the pharmacist’s traditional dilemma as a health-care provider who has been unwillingly conscripted into the nation’s “war on drugs.” As “drug police,” pharmacists have been required to challenge prescribers who order large doses of opioid analgesics, and they have been administratively disciplined for activities that may result in the diversion of controlled substances from medical to nonmedical purposes.

The article then turns to a description of the pharmacist’s role in the monitoring of drug therapy. Administrative rules — primarily those promulgated under the authority of the Omnibus Budget Reconciliation Act of 1990 (OBRA) — and emerging standards of practice recognized in civil malpractice litigation have begun to require that pharmacists assure that prescribed medications are appropriate for the patient. No longer is it acceptable for a pharmacist to merely follow a prescriber’s orders if those orders place the patient at an unreasonable risk of harm.

Finally, this article describes the philosophy of practice known as “pharmaceutical care,” in which pharmacists work with patients as well as with physicians and other health-care providers, to promote drug therapy for the purpose of achieving definite outcomes that are intended to improve a patient’s quality of life. The article reviews the movement toward incorporation of pharmaceutical care into a pharmacist’s practice through authorization of physician-pharmacist collaboration. Pain management is described as an area of therapy that is particularly appropriate for collaborative practice.

**The Pharmacist and Diversion Prevention**

The overall pattern of controlled substance regulation reflects the reality that some drugs of abuse are medically useful. Even the DEA admits that to overregulate these drugs would interfere with effective therapy and do more harm than good.  

Controlled substances are placed in one of five “schedules”: Schedule I for those abusable drugs that have no currently accepted medical use and Schedules II through V for those abusable drugs that do have a currently accepted medical use.

The regulatory goal is to construct a closed system of distribution for controlled substances in Schedules II through V. The system requires registration of those who may legally possess controlled substances, and it imposes stringent record-keeping requirements so that auditors have the ability to track any drug within the system from manufacture to ingestion. A controlled substance that is diverted outside the system is in violation of the law, and the diverter is subject to civil and/or criminal penalties.

**The “corresponding responsibility” rule**

DEA regulations instruct pharmacists on the judgment they should be exercising in screening suspicious prescriptions and preventing their diversion outside this closed system. The relevant DEA regulation states:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription. ... and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

This regulation, dubbed the “corresponding responsibility” rule, sets out the basic process to be followed by pharmacists in interpreting the legitimacy of controlled-substance prescriptions. Due to the use of the word “knowingly,” pharmacists are not subject to strict liability under this regulation. However, pharmacists cannot turn their backs on obvious indicia of invalidity and later claim ignorance that a purported prescription lacked validity.

The leading case interpreting the corresponding responsibility rule is United States v. Hayes, from the Fifth Circuit Court of Appeals. The defendant in this case had filled huge quantities of purported prescriptions for a small number of persons. All of the controlled substance prescriptions had been written by a single physician, who was moving from one motel to another, and was known by the pharmacist to be under investigation for controlled-substance diversion. The pharmacist had always telephoned the physician and received assurance that the prescriptions were valid.

The pharmacist claimed that this telephone verification was the limit of his legal responsibility, despite the existence of additional compelling evidence that the prescriptions were not valid. He further argued that a pharmacist cannot possibly have a corresponding responsibility to that of a physician because the pharmacist cannot examine a patient as the physician can. Thirdly, the pharmacist argued that because it is impossible to determine what is really meant by the phrase “corresponding responsibility,” the regulation is ineffectual and unconstitutionally vague.

The court admitted that the phrase “corresponding responsibility,” standing alone, is not crystal clear. But when...
read in context, the regulation gives adequate notice of proscribed conduct in order to pass constitutional muster. In affirming the pharmacist's conviction, the court emphasized that the pharmacist is not required to have a corresponding responsibility to practice medicine. What is required is the responsibility not to fill an order that purports to be a prescription — but is in fact not a prescription — when the pharmacist knows the practitioner "has issued the prescription outside the scope of medical practice."

The court observed that the regulation requiring pharmacists to fill only prescriptions issued for a "legitimate medical purpose" is in reality a requirement that they fill only prescriptions issued in the "scope of medical practice." This observation is an important one because it simplifies the otherwise challenging concept of "legitimate medical purpose." Without this clarification, one might take this three-word phrase to mean that pharmacists have a responsibility under the DEA regulation to discern not just the difference between medical and nonmedical, but also the difference between legitimate medicine and non- legitimate medicine.

In other words, pharmacists are not required to refuse to dispense unless they make two separate decisions — first, that a prescription is medical, and second, that it is legitimate. If the regulation were interpreted this way, then it might, for example, cause a pharmacist to refuse to dispense a medication for an opioid analgesic that specifies an unusually large dose (perhaps incorrectly seen as not legitimate), despite assurances that the medication is intended for a patient with chronic pain (unquestionably a medical purpose). In reducing the three-word phrase to just two words, "medical practice," the court made it clear that pharmacists are not required by this DEA regulation to make judgments about the quality of medicine. They are required only to distinguish medical from nonmedical.

And this is a more realistic expectation of pharmacists. Interpreted this way, the DEA regulation does not support a pharmacist’s refusal to dispense a controlled-substance medication if he or she believes the therapy is inappropriate as long as there is a medical purpose (even a questionable one). A pharmacist who uses the corresponding responsibility rule to justify challenging the dose, or route of administration, or length of therapy, for an obviously legitimate patient, has misunderstood the narrow scope of the rule.

**Overly aggressive pharmacy practice**

Despite the relative safety of the "knowingly" phrase with the corresponding responsibility rule, some pharmacists have taken it upon themselves to be overly vigilant in their review of controlled-substance prescriptions. Pharmacists may challenge physicians, or confront patients, in an accusatory way that some find offensive. When taken to task for such behavior, pharmacists will often rely on the corresponding responsibility rule as a justification for their actions.

The leading case on aggressive diversion prevention is Ryan v. Dan’s Food Stores, Inc.,18 from the Supreme Court of Utah. The plaintiff in this case was a pharmacist who had been terminated from his employment with the defendant pharmacy based on numerous complaints by patients. The pharmacist had apparently confronted, in an accusatory way, many patients who presented controlled-substance prescriptions, suggesting that the prescriptions may be invalid. Offsetting the complaints by patients were letters from law enforcement authorities, complimenting the pharmacist on his thoroughness in detecting fraudulent prescriptions. As an employee at will, the pharmacist had only one solid argument on which to base his wrongful discharge claim — that his actions were in compliance with the law and that his discharge as a result of this compliance was contrary to public policy. The pharmacist pointed to the corresponding responsibility rule to support his position.

The court agreed that the corresponding responsibility rule does contain a clear and substantial public policy, but that this policy is a narrow one. The rule only prohibits pharmacists from knowingly filling purported prescriptions. It does not mandate or even authorize a pharmacist to question every prescription or to conduct an investigation to determine whether a facially valid prescription has been issued other than in the usual course of the prescriber’s practice. A prescription that is irregular in some way requires further inquiry by the pharmacist, but after inquiring and obtaining the verifying information, a pharmacist cannot use the rule as a basis for refusing to fill the prescription. The court affirmed the lower court’s order of summary judgment dismissing the pharmacist’s wrongful discharge lawsuit.

**Diversification in everyday practice**

Most pharmacists try to cooperate with law enforcement authorities as well as meet their patients’ needs. When suspicions are aroused regarding the validity of a prescription, pharmacists generally seek clarification from the prescriber. Administrative actions against pharmacists for failure to make an appropriate inquiry of a physician usually involve egregious circumstances that should have put any pharmacist on notice as to the suspicious nature of the prescriptions. For example, in one case, a pharmacist was disciplined for filling prescriptions that were made out for “Steve Allen,” “Jerry Lewis,” “Terry Tune,” “Pearl Harbor,” “Wells Fargo,” “Pop Warner,” and other equally fanciful patients.19 Claims by pharmacists that they simply could not have recognized the invalidity of such orders fall on deaf ears when the surrounding circumstances are examined.

But the question of validity or invalidity is not always clear cut. Modern pharmacies are busy places to work, with constant distractions and frequent problems to solve. Pharmacists take no risks with ambiguous prescriptions that may...
result in an overdose or an incorrect drug for a patient. Pharmacists are similarly serious in their efforts to accurately distinguish valid prescriptions from purported ones. But grayer areas do not elicit the same zealousness, and mistakes sometimes occur.

The law recognizes this likelihood and provides pharmacists with room for good-faith error in their interpretation of the legitimacy of a prescription. This “room for error” applies not only to filling invalid prescriptions (under the right circumstances), but also to refusing to fill valid ones. For instance, it has been held that the refusal by a pharmacist to fill a prescription based on the mistaken belief that the prescription is forged does not support a Civil Rights Act of 1964 claim against the pharmacist. It has also generally been held that a pharmacist who, in good faith, but erroneously, reports a forgery to law enforcement authorities, will not be held civilly liable for malicious prosecution, false imprisonment, or any similar tort.

This room for error — and fear of disciplinary action — has, unfortunately, created too much confusion about what the law really requires. Empirical evidence suggests that the pharmacy profession is conflicted over the appropriate way to comply with the legal requirements of controlled substances on a day-to-day basis.

For example, data reported in 1999 by Gilson and colleagues indicate that slightly less than half of pharmacists strongly agree with the statement that they would be willing to dispense a Schedule II opioid analgesic on the basis of a telephone order in an emergency. Ten percent of pharmacists strongly disagreed with a willingness to dispense under such circumstances, despite there being absolutely no regulatory basis for refusing to fill such an order. Nonetheless, 80 percent of the respondents agreed with the statement that pharmacists’ knowledge of controlled-substance regulations is generally adequate.

Furthermore, over two-thirds of the pharmacists in this study indicated that they were aware of situations in which patients with inadequately treated pain had been suspected of being “drug seekers,” due to their requests for additional pain medications. It is clear that pharmacists are confusing relief-seeking behavior with drug-seeking behavior. Other studies have confirmed that some pharmacists are unnecessarily suspicious of prescriptions for opioid analgesics written for cancer patients. The results of these studies suggest that policy-in-practice still may not accurately reflect the trend of policy-on-paper.

One recommendation for assisting patients in their relief of pain while this gap exists involves hospital-based clinical pharmacist pain management specialists. Not only do these specialists have an important role in their collaboration with physicians and other health-care professionals within the institution where they practice, but they also can serve as an interface with community pharmacy practitioners. When a patient is discharged from the hospital with a prescription for suspiciously large quantities of an opioid analgesic, a hospital pharmacist can notify the community pharmacist that the patient is on the way and that the prescription is legitimate. Intraprofessional communications of this type can improve general understanding of pain management principles among pharmacists, and they can reduce the incidence of interprofessional conflict over refused prescriptions.

The Pharmacist and Patient Safety

The possibility of conflict between pharmacists and physicians over controlled-substance prescriptions is not limited to pharmacists questioning physicians regarding the threshold issue of prescription legality. Pharmacists are also charged with a legal responsibility to verify the therapeutic appropriateness of medications legitimately prescribed for patients, and this responsibility may lead to antagonism within the physician-pharmacist relationship. When a potential problem is evident to the pharmacist once he or she sees the prescription, the pharmacist must balance the need to meet responsibilities to the patient with the need to avoid offending the physician. No matter how friendly an inquiry from a pharmacist may be, questions concerning the appropriateness of drugs that a physician has prescribed necessarily appear evaluative and critical. But a pharmacist must make the inquiry nonetheless. Standards of practice require that pharmacists clarify potential therapeutic problems prior to dispensing a medication. This responsibility has evolved through case law over the past decade, despite concerns that it could increase confrontation between pharmacists and physicians to the detriment of patient care.

The newly recognized patient safety responsibility of pharmacists is the result of several correlated factors, all of which have occurred (at least in part) due to the increasing complexity of pharmacotherapy. Pharmacists are better educated now than they have been in the past, due to the uniform adoption of the clinically oriented Doctor of Pharmacy (Pharm.D.) degree. The need for patient-safety oversight by pharmacists is evident from recent data that show significant problems with drug therapy and the positive effect of pharmacist participation in the resolution of these problems. Finally, the economic costs of drug-related morbidity are thought to be so great that there may actually be more money spent in the American health-care system treating the adverse effects of drugs, than there is spent on the drugs themselves. For these and other reasons, patient safety is now recognized as a standard of pharmacy practice under common law in many states, and it is mandated under Medicaid conditions of participation.

Expanding responsibilities under common law

In one of the earliest cases to consider the expanded responsibilities of pharmacists for drug therapy review, Jones v. K-
Mart Corporation, a federal district court judge in 1985 speculated that Illinois common law would not support a malpractice claim against a pharmacist who had accurately dispensed medications as ordered by the patient’s physician. In a conclusion that should send chills down the spine of anyone who appreciates the importance of team work in health care, the judge stated, “the court holds that a pharmacist has no duty to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions.” Apparently concerned about pharmacist-physician relations, the court justified its holding by explaining that placing these duties on a pharmacist “would only serve to compel the pharmacist to second guess every prescription a doctor orders.”

Four years later, the Supreme Court of Washington cited the Jones opinion with approval in its own opinion, McKee v. American Home Products Corporation. Concluding that a pharmacist’s responsibilities were limited, the court noted that “[r]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment.” The court further justified limiting the patient-safety role for pharmacists by reasoning that such an expanded role “would likely create antagonistic relations between pharmacists and physicians.”

The trend of judicial reasoning took a significant shift in the opposite direction in 1994, when the Supreme Court of Indiana issued its opinion in Hooks SuperX, Inc. v. McLoughlin. The plaintiff in the Hooks case was a chronic pain patient who had been prescribed an opioid analgesic. The defendants, two pharmacists and their pharmacy, were alleged to have refilled the patient’s prescriptions more frequently than was appropriate, resulting in adverse effects that led to a suicide attempt. The Indiana Court of Appeals ruled that to impose a duty on the defendants to protect the patient from this adverse outcome would be contrary to sound public policy, because it would require pharmacists to second guess physicians and would undermine the physician-patient relationship.

The Supreme Court of Indiana reversed, recognizing an expanded duty by pharmacists to promote patient safety. The court based its ruling on three factors: (1) the relationship between pharmacists and patients, (2) the foreseeability of harm to patients when an overuse of opioid analgesics occurs, and (3) public policy considerations.

While noting the ultimate responsibility of physicians to properly prescribe medications, the court reasoned that prevention of medication misuse by pharmacists is “paramount to policy concerns about interfering with the physician-patient relationship.” On this issue, the court concluded that “recognition of a legal duty will encourage pharmacists and physicians to work together in considering the best interests of their customers and patients.” Legal scholars have generally approved of this shift in thinking. With this decision, pharmacists have been recognized as a positive influence in drug therapy — protecting patients without threatening physicians.

The OBRA 1990 mandate

The trend toward expanding legal responsibilities for pharmacists was given a significant boost by a brief section of the Omnibus Budget Reconciliation Act of 1990, in which prospective drug use review was mandated as a condition of participation in the federally funded, but state administered, Medicaid program. Prospective drug use review requires that the Medicaid state plan establish a point-of-sale review of each prescription prior to its being dispensed. Potential problems, such as therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse, should be discovered through this prospective review. Most states have implemented this standard by imposing the prospective drug use review requirement on pharmacists and specifying that, once potential problems are detected, they must be resolved, perhaps by contacting the prescribing physician.

Prospective drug use review, as defined by OBRA 1990, was judicially recognized as the standard of pharmacy practice for the first time in 1999 by the Court of Appeals of Missouri in the case of Horner v. Spalitto. In Horner, the patient had been prescribed two controlled substances concurrently, one of them in an unusually high dose. The patient died, and an autopsy stated that the death was caused by “adverse effects of multiple medications.” The lawsuit filed against the pharmacist claimed that the pharmacist had negligently failed to protect the patient from an unreasonable risk of harm. Reversing summary judgment for the pharmacist, the appellate court held:

[while] the physician still is responsible for assessing what medication is appropriate for a patient’s condition, ... the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer’s questions regarding consumption of the medication.

Regarding the potential for interprofessional conflict that could arise from patient-oriented activities by pharmacists, the court plainly said:

We disagree that a pharmacist’s consulting with a physician about an unusual prescription would
result in antagonism exceeding the potential public benefit. Pharmacists are trained to recognize proper doses and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer.39

Meeting the patient-safety challenge

While pharmacist responsibilities have changed, pharmacy practice sites have remained essentially the same. With an increasing volume of prescription orders to process, pharmacists struggle to meet both their product-oriented and patient-oriented responsibilities. Empirical data indicate that the relatively new patient-safety responsibilities are not being consistently met by pharmacists.40 In the area of pain management, the study by Gilson and colleagues suggests that some pharmacists may not be fully informed of how medications are appropriately used, thus they may not consistently provide service that is in the patient’s best interest.41 For example, almost 40 percent of respondents in that study indicated that a dose of opioid analgesic that is greater than the manufacturer’s recommended dose is “probably excessive” and is “a cause for concern.” Slightly more than 10 percent of respondents indicated a reluctance to contact the prescriber with questions about an opioid analgesic regimen prescribed for a specific patient. It is not clear from the study whether this reluctance is due to a failure to recognize the value of such contact or due to a frustration with the inaccessibility of physicians.

The limitations of the traditional pharmacy practice environment, and the obvious need for new approaches to patient care by pharmacists, have led to the development of nontraditional practices that emphasize outcomes-oriented pharmacy care. These practices enable pharmacists to cooperate with physicians and to communicate with patients. Although not widespread at present, community pharmacy practices that emphasize collaborative drug therapy management are growing rapidly. They are a positive addition to the health-care system, enabling improvement in practice for both pharmacists and physicians.

Pharmacist management of anticoagulation therapy and of aminoglycoside therapy have become a standard of practice in many hospitals, where attending physicians’ orders for “anticoagulation per pharmacy” or “gentamicin per pharmacy” are commonly seen. Success in these areas of practice — and a general tendency to attempt in the community practice what has previously been done in the hospital practice — has led to the establishment of a small number of community-based collaborative drug therapy management practices. As hospital pharmacy practice continues to evolve, and as the order “pain management per pharmacy” becomes more widespread, it is not unreasonable to expect that this hospital-based standard will similarly be copied in the community pharmacy setting. There are no guarantees that a successful transition from hospital practice to community practice will occur, but the avenue for the shift exists and it has already happened (although in limited circumstances) for other therapeutic specialties.42

Regulatory Authority for Collaborative Drug Therapy Management

The parameters of pharmacy practice are defined by the laws of each state. Not surprisingly, the traditional descriptions of pharmacy practice in most state pharmacy acts have been limited to dispensing functions.43 Dispensing has changed in concept over time — from limited definitions that include only interpreting and fulfilling orders to those definitions that more broadly include patient education and therapeutic monitoring. However, most states have not, until recently, authorized pharmacists to enter into agreements with physicians for collaborative practice under which pharmacists can order and interpret laboratory tests, modify drug doses, initiate new drug therapy, or discontinue drug therapy under a protocol or care plan approved by the patient’s physician. Even in states where collaborative drug therapy management has been specifically authorized, practices that include management of chronic pain do not seem to be widespread.

The relative infrequency of physician-pharmacist collaborations in the area of pain management may be due to the perceived burdensomeness of restrictions on controlled-substance prescribing and dispensing. However, pain management is an area of specialization that is ripe for pharmacist-physician collaboration. Many physicians who specialize in pain management find that their practices emphasize invasive procedures, such as patient-controlled infusion pumps or intraspinal administration, because compensation is readily available for medical procedures. Payment for opioid management is more difficult to obtain, thus this activity is more likely to be willingly shared with a collaborating pharmacist.

To evaluate the scope and character of existing authority for collaborative drug therapy management, executive officers from the boards of pharmacy of each state and the District of Columbia were surveyed. The questions used on the survey instrument are reproduced in Appendix I. Forty-one responses were received. Of those responses, thirty-three were complete responses, five were partial responses, and three indicated that the board was unable to complete the questionnaire. An attempt was made to contact the eight nonresponding states. Of these states, five indicated lack of time and three indicated inability to speculate on hypothetical questions as the reason for not responding.

Table I summarizes the responses to the survey questions concerning collaborative practice between physicians and pharmacists. The purpose of asking Questions 5 and 6
Table 1. Regulatory Authority for Pharmacist-Physician Collaboration

<table>
<thead>
<tr>
<th></th>
<th>NOT LEGAL</th>
<th>LEGAL ONLY</th>
<th>LEGAL in ANY</th>
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<tbody>
<tr>
<td></td>
<td>in ORGANIZED</td>
<td>in HEALTH-CARE</td>
<td>IN COMMUNITY</td>
</tr>
<tr>
<td></td>
<td>PHARMACY</td>
<td></td>
<td>PHARMACY</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>20 states</td>
<td>4 states</td>
<td>13 states</td>
</tr>
<tr>
<td>Pain Management</td>
<td>22 states</td>
<td>2 states</td>
<td>13 states</td>
</tr>
</tbody>
</table>

(see Appendix I) was to measure any difference in authority to conduct anticoagulation collaborative practice (a relatively common activity) and pain management collaborative practice (a relatively less common activity). The responses failed to show any difference. Thus, one could conclude from the data that there is no regulatory impediment to pain management collaborative practice in the states that authorize collaborative practice.

Of the states that indicated no authority for physician-pharmacist collaboration, six states indicated in open comments that while statutory authority existed for this practice, administrative rules had not yet been adopted to authorize the practice. Respondents in several other states indicated that although collaborative practice was authorized in their state, the way in which the survey question was written suggested that perhaps there could be a technical violation of the statutory requirements — thus indicating that the practice was not lawful.

Statutes or regulations in twenty-five states authorizing collaborative drug therapy management were obtained and examined. Copies of “model” collaborative drug therapy management agreements were requested, and seventeen such agreements were received from five states. Four of the model agreements were directed at pain management. Analysis of the regulatory authority and model agreements for collaborative drug therapy management discloses that collaborative practice in pain management is permitted in the sense that in no state is it forbidden under the newly adopted statutes and regulations.

A review of the model agreements received is provided below. Suffice to say at this point that collaborative drug therapy management is a recognized practice in a majority of states. This practice can enable pharmacists and physicians to improve the quality of pain management through an approach in which pharmacists and physicians function as colleagues, and through which they support each other when called to account for actions taken in the provision of medications to treat chronic pain.

The survey also queried board of pharmacy executive officers regarding the potential for state disciplinary action against pharmacists for violation of laws regarding controlled-substance diversion. The executive officers were asked to speculate whether described activities would subject pharmacists to no disciplinary action, to minor disciplinary action (e.g., a letter of reprimand), or to major disciplinary action (e.g., restrictions on practice). Table 2 summarizes the responses to questions about the potential violation of technical requirements for controlled-substance dispensing (Questions 1 and 2 on the survey instrument). Almost every respondent indicated that the simple fact of having developed a reputation for dispensing large doses of methadone to pain patients would likely not subject a pharmacist to any disciplinary action. However, the dispensing of methadone pursuant to a photocopy of a purported prescription would subject the pharmacist to minor discipline in a majority of the states responding. Taken together, these responses suggest an enlightened view of the need to avoid legal impediments to appropriate pain management, along with a continued concern that pharmacists be aware of the problem of controlled-substance diversion.

Table 3 describes responses to questions directed toward meeting the needs of patients (Questions 3 and 4 on the survey instrument). The law permits emergency dispensing of Schedule II controlled substances pursuant to a verbal order, but requires that prescribers issue a written prescription to “cover” the verbal order within seven days, and requires further that pharmacists report to the DEA any prescriber who fails to provide such a written prescription. The responses to these questions indicate that few states are willing to discipline pharmacists who make a conscientious effort to obtain the written order, but nonetheless fail to contact the DEA when their efforts are unsuccessful. This is a minor violation that seems insignificant to the boards of pharmacy. Pharmacists who refuse to fill emergency Schedule II verbal prescriptions due to past experience with prescribers who fail to subsequently provide written orders as required should expect minor disciplinary action in some states. Of the twenty-five states that indicated no likelihood of disciplinary action, many respondents provided commentary criticizing the conduct of the pharmacist who refused legal emergency verbal orders, calling the conduct unethical but not illegal.

Collegial Accountability in Principle

There is strength in numbers; and two is greater than one. These two simple statements — one a basic assumption, the other an irrefutable numerical fact — form the framework for an approach to practice that can best be described as “collegial accountability.” The purpose of collegial account-
ability is to provide an evidence-based safety blanket to facilitate potentially risky prescribing choices by physicians who treat pain. The safety blanket is necessary due to a perception that adverse regulatory activity may result from aggressive prescribing of large doses of opioid analgesics. Despite changes in policy-on-paper — and comprehensive continuing education programs designed to communicate these policy changes to physicians — there is evidence that the policy-in-practice continues to be overly cautious and that pain continues to be undertreated.44 Collegial accountability is about changing old perceptions of regulation, so that contemporary views coincide with the reality of a more tolerant regulatory community.

The mechanics of collegial accountability in pain management are straightforward. Clinical pharmacists who have expertise in pain management offer their services as consultants to physicians who request that evidence-based clinical practice guidelines be applied to a specific patient-care situation. This activity is most likely to occur in the institutional setting, where the Joint Commission on Accreditation of Healthcare Organizations recently changed the conditions of participation to mandate pain management teams. However, teamwork in health care can occur outside the institutional setting when health-care providers are motivated to work together.

The pharmacist pain management consult may be ordered explicitly by an attending physician, or it may be implicit in an approved protocol or in standing orders. The consult may require a patient interview or another patient assessment activity. The pharmacist consultant then recommends a dose of a medication, in writing, documenting the guideline or other objective authority that justifies the use of medication in the recommended way. Depending on the relationship between the physician and the pharmacist, the recommendation may require prior approval by the physician before it is implemented, or it may be automatically accepted in the absence of an express objection. Changes in medication — when there is a need to add, discontinue, decrease, or increase drug use — are made in the same way. If a reviewer later raises questions regarding the appropriateness of a patient's drug therapy, the pharmacist's written consult will serve as an accounting of what occurred and why.

### Table 2. Likelihood of Discipline by State Boards of Pharmacy for Possible Technical Violations

<table>
<thead>
<tr>
<th>Violation</th>
<th>No Discipline</th>
<th>Minor Discipline</th>
<th>Major Discipline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Doses of Methadone</td>
<td>34 states</td>
<td>1 state</td>
<td>0 states</td>
</tr>
<tr>
<td>Inadvertent Filling of Photocopy Prescription</td>
<td>13 states</td>
<td>21 states</td>
<td>2 states</td>
</tr>
</tbody>
</table>

### Table 3. Likelihood of Discipline by State Boards of Pharmacy for Failure to Meet Patient Needs

<table>
<thead>
<tr>
<th>Violation</th>
<th>No Discipline</th>
<th>Minor Discipline</th>
<th>Major Discipline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete Follow Up to Emergency Dispensing</td>
<td>33 states</td>
<td>3 states</td>
<td>1 state</td>
</tr>
<tr>
<td>Refusal to Dispense Emergency Supply</td>
<td>25 states</td>
<td>11 states</td>
<td>1 state</td>
</tr>
</tbody>
</table>

**Collegial practice**

Pharmacists and physicians have worked well together for hundreds of years. The relationship between them has generally been one in which the physician decides what medication is best for the patient and the pharmacist prepares the medication for the patient.

Formalization of this prescriber-dispenser relationship occurred relatively recently. Not until 1951 did federal statutes recognize the distinction between prescription and non-prescription drugs,45 although that distinction had been made by federal regulation in 1938.46 The need to paternalistically limit drugs to prescription-only status has been questioned47 — and some drugs have been switched from prescription to non-prescription status48 — yet significant advances in drug therapy continue to be available for patients only if they have been prescribed by a physician and dispensed by a pharmacist. The traditional drug distribution system requires pharmacists and physicians to work together, although their activities differ in character and their practice sites are very separate. Pharmacists and physicians have relied on each other and usually have been respectful and friendly with each other, but they have not been professional colleagues. While pharmacists practice independently of physicians, the processing of orders is done on their behalf by meticulously following the physicians' orders. Order processing is a technically complex activity with no margin for error, but it is not intellectu-
ally challenging and it requires little judgment.

In collaborative drug therapy management, pharmacists work with physicians rather than for them. Drug therapy management by pharmacists closes the quality loop in medication use, so that outcomes of therapy are monitored and meaningful feedback is provided to physicians. Collaborative drug therapy management attempts to solve the mystery of why a patient’s drug therapy has been less than fully effective during the months between visits to the physician. It is an advance in practice over the linear process of trial-and-error prescribing. This collaboration of pharmacists and physicians is aimed at improving the patient’s quality of life. It is a practice that has been empirically validated. A collegial approach to the pharmacist-physician relationship has also been judicially endorsed. For example, in Riff v. Morgan Pharmacy, the Superior Court of Pennsylvania recognized the value of pharmacist collaboration with physicians:

Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother’s keeper.

Although the image of a viable collaborative practice amidst the hustle and bustle of a traditional retail pharmacy may seem farfetched to some, the pharmacy industry is currently experimenting with various creative approaches that would transfer lessons learned in the hospital to selected ambulatory care facilities. It is not impossible to imagine that in the future the processing of pharmaceutical orders will be assigned primarily to offsite locations that are linked via the Internet to local pharmacies. Pharmacies might then become primarily providers of services and not products. The documented problems that can occur with unsupervised medication use, and the costs known to be associated with drug-related morbidity, suggest that someone will have to provide drug therapy monitoring. Community pharmacists are well-positioned to provide this service, although it is by no means certain that they will eventually be chosen as the ones to provide it. The implementation of pharmaceutical care activities in community pharmacies could result in expanded access to health care and reduced costs. If this is the case, then there is a distinct possibility that community-based collaborative practice could succeed. It may well be that community-based collaborative drug therapy management is the best solution to the well-documented current problems with drug therapy in ambulatory care.

Accountable practice

Responsible health-care professionals must expect that they will be held accountable for their actions. Gone are the days when public trust was so complete that health-care professionals were subject only to a limited sphere of oversight, accompanied by informal and very private sanctions when things had not gone well. Today, health-care providers are counted on to provide appropriate care, and they may be called to account for undesirable outcomes. The ability to conduct surveillance of the provider-patient encounter is enhanced through modern electronic data systems, and these data facilitate activities of accountability. Evaluators from professional associations, or licensing boards, or federal regulatory agencies, may examine performance data and then request a health-care provider to give an explanation by way of accounting for the care provided to patients. If the accounting given by the responsible health-care professional is deemed unacceptable, then there may be liability for technical violations of the law or for adverse outcomes to patients.

Accountability can be both productive and unproductive. Productive accountability would compare a health-care provider’s explanation of care with an objective standard, such as consensus-developed clinical practice guidelines. It would be flexible enough to adapt to unique or unusual medical needs of individual patients. It would be value-oriented so as to permit health-care providers to practice consistently with the goals of patients and their families. The process of productive accountability would be unobtrusive and respectful of patient privacy and the provider-patient relationship. Unproductive accountability, by way of contrast, would focus on punishment rather than improvement. Lacking specificity or explicit patient-oriented standards, unproductive accountability would coerce health-care providers into attempted compliance with a moving target, resulting in risk-averse behaviors that alternately overuse or underuse available therapies, depending on the perception of what it takes to “play it safe.”

Collegial accountability is productive accountability. It is a legitimate approach to the use of interdisciplinary expertise to explain why things were done as they were when questions of impropriety have been raised.

In collaborative drug therapy management, pharmacists are called upon to take the next logical step beyond the expanded responsibility they have so eagerly sought. The prospect of having to justify actions taken may be daunting to some pharmacists who have enjoyed the comfort zone of responsibility without accountability. Yet outcomes for patients cannot improve unless both responsibility and accountability are shared by pharmacists and physicians. Sharing accountability with a physician colleague may be a cost of
professional growth for pharmacists, but the cost is more than offset by the value of improved patient care.

**COLLEGIATE ACCOUNTABILITY IN PRACTICE**

While a pharmacist is responsible to a patient for the recommendation and/or provision of appropriate care, the ultimate decision as to appropriateness of care is made by the physician. Collegial accountability does not invade the physician’s turf because it is comprised of activities that are currently not being done by physicians. It is an entirely voluntary activity that is available to those physicians who wish to use it, but it is not required of them or anyone. The practice of collegial accountability by pharmacists would be very similar to that of the consultant medical specialist, who assists an attending physician in the care of patients, but does not usurp his or her authority.

**Regulatory authority for collaboration**

The statutes and regulations that authorize collaborative drug therapy management all tend to follow a single pattern. The regulation from the Texas Board of Pharmacy is typical of these rules, and it is reproduced in Appendix II.

The formula used by the Texas Board of Pharmacy to enable physician-pharmacist collaboration focuses on the documentation that the collaboration would produce. The rule specifies the formalities of the relationship between the physician and the pharmacist, and it imposes specific requirements for patient care within that relationship. The rule also requires a report by the pharmacist to the physician concerning the results of drug therapy management. Thus, the rule includes components related to structure, process, and outcomes of care — unlike traditional pharmacy regulations that are oriented almost exclusively to matters of structure.

Physicians can be confident of the competence of the pharmacists with whom they collaborate because the rule stipulates that only pharmacists who have been specially trained, or who have documented experience, may engage in this activity. The activities that may be performed by a pharmacist in collaborative drug therapy management are broad, but they can be limited by a specific agreement. The process that must be followed by a pharmacist who manages drug therapy is complex, perhaps establishing a standard against which drug therapy management by some physicians might not compare favorably. Frequent communication between pharmacist and physician is required, and documentation created by the pharmacist is subject to strict rules of both confidentiality and privilege.

**The character of collaborative agreements**

An examination of the collaborative drug therapy management agreements provided by the board of pharmacy executive officers discloses several important elements of a sufficient pharmacist-physician arrangement to share responsibility for drug therapy. Although the depth and breadth of the relationship between a pharmacist and a physician may be difficult to capture in a relatively brief document, the framework of that relationship can be described in two or three pages.

The first element of a sufficient collaborative drug therapy management agreement is clarity. The agreement must clearly state the role of the pharmacist within the context of the health-care team, which includes the physician and other health-care personnel. The agreement must state the responsibilities of both the physician and the pharmacist so that there is little room for disagreement over each other’s roles. The agreement should also state those duties which the pharmacist will be expected to independently perform — that is, without consulting the physician — as well as those duties which the pharmacist can perform only when individually requested to do so by the physician. The agreement may stipulate that certain duties are outside the role of the pharmacist.

An appropriate collaborative drug therapy management agreement also provides consistency. The agreement should describe the role of the pharmacist in such a way as to be applicable to various circumstances and patient needs. Less formal arrangements that have developed over time between pharmacists and physicians may have worked well as long as only a particular pharmacist and a particular physician were working together. But when other individuals become involved in collaborative activities, the unique understanding of roles within specific patient-care contexts may not necessarily transfer to new and different situations. Practice guidelines, as opposed to clinical guidelines, can show how duties are met regardless of the patient-care context. Incorporation of process-oriented practice guidelines into these agreements provides a roadmap for consistent practice.

Flexibility is a third characteristic of a sufficient collaborative drug therapy management agreement. It is important for the agreement to incorporate evidence-based clinical guidelines with therapeutic information that gives an objective foundation for care provided under the agreement. However, within a sufficient agreement, guidelines should be incorporated in a way that provides several options, recognizing that individualized clinical judgment is permissible — in fact necessary — to reflect unique patient factors. Pharmacists do not mechanically follow a physician’s orders; rather, they apply what they know about patient care within the framework of the agreement they have with the particular patient’s physician, and they adapt the drug therapy to the patient’s distinctive needs.

Collaborative agreements must also be usable in the sense that they must facilitate pharmacist-physician collaboration by describing the appropriate etiquette of the arrangement.
There would be no purpose in having an excellent agreement that nobody would use due to feelings of discomfort with it and an unfamiliarity with how to use it. A usable agreement is one that not only describes the behaviors of the pharmacist and the physician, but also the relationship between them. To be usable, the agreement must state who is responsible for what and when. It must prescribe communication lines between pharmacist, physician, and patient, and provide assurance that patient care is a shared responsibility, with the physician ultimately retaining the authority for decisions about care.

Finally, a sufficient agreement must be defensible. It must be easily understood by an outside evaluator so that he or she can readily discern what expectations were established for a physician or pharmacist under the agreement and how those expectations were to be met. The agreement must facilitate peer review activities done for quality improvement, perhaps by requiring the creation of documents that show what care was provided and the outcomes that were produced by the care. The collaborative agreement is evidence of the applicable standard of care in the therapeutic area that it addresses, and to be a defensible agreement, it must be recognized as valid by an interdisciplinary consensus group.

**Collegial Accountability in Pain Management**

Although not widespread throughout the country, there are currently practices in some states within which pharmacists and physicians collaborate to manage the treatment of chronic pain. These collaborations are beneficial to patients because the physician-pharmacist relationship reduces concerns about inappropriateness of treatment. Regulators who question the propriety of controlled-substance use will certainly understand that when two professional colleagues have agreed as to the appropriateness of medication use, there is a high probability that the use is consistent with applicable standards of care. Specific regulatory authority for physician-pharmacist collaborations increases the likelihood that no foul play will be found.

Physician-pharmacist collaboration in pain management faces several procedural obstacles that are not problematic in other therapeutic areas. Most of the medications used in the management of pain are controlled substances, and many of them are highly regulated Schedule II controlled substances. Until several years ago, it would have been very difficult to create a system in which a physician could delegate any pain management authority to a pharmacist. This was due to the high level of documentation required to show direct physician participation in decisions about medication use. The rules continue to require significant physician participation, which is, of course, not a bad thing, but some record-keeping requirements have been relaxed so as to permit advanced practices that can improve outcomes for patients. For example, partial fillings of Schedule II prescriptions were at one time restricted to a seventy-two-hour period. Thus, a pharmacist could not legally accept a physician's authority to dispense a supply of Schedule II controlled substances over a period of time extending beyond seventy-two hours. The rule was recently changed for patients who are either residents of a long-term care facility or who have a medical diagnosis documenting a terminal illness. For these patients, a pharmacist may partially fill a Schedule II prescription for up to sixty days. A separate rule has also been changed recently to allow facsimile transmission of Schedule II prescriptions for opioid analgesics if the patient is a hospice patient.

Of the collaborative pain management programs currently in place, the stated purpose is generally said to be the efficient provision of quality care to chronic pain patients. The ultimate objective of the programs is to provide a safe and standardized approach to symptom management. In furtherance of that stated goal, the programs have been developed to streamline the collaborations of the pharmacist, nurse, and physician by assuring communication and facilitating decision-making. Appendix III describes the process of collaborative pain management practice at one hospital.

The process of care customarily begins with the development of a treatment algorithm and then approval of the algorithm by the medical staff of an institution or by an individual physician. A patient is enrolled in the collaborative drug therapy management program by a signed order from a physician. A nurse then assesses the patient. A plan of care is developed by an interdisciplinary team, and is then signed by the patient's physician. The plan of care may include therapies that fall outside the pain management treatment algorithm. The treatment algorithm is then instituted, and a pharmacist dispenses needed medication as per the algorithm. Appendix IV contains the treatment algorithm for a collaborative practice at one hospital.

As the provision of care progresses through the algorithm, assessments are performed periodically by a nurse and changes in drug therapy are made as necessary by a pharmacist based on the nurse's assessment. Within twenty-four hours of any change under the algorithm, the pharmacist faxes a copy of the algorithm progress notes, summarizing the assessment and the change to both the physician and the nurse. If all steps in the algorithm are completed and the symptoms are not relieved, then the attending physician is contacted by the pharmacist. Progress notes are created for patient care and quality improvement review. Appendix V contains a sample pain management collaborative practice progress note.

Authority for pharmacists to start, stop, or change drug therapy under the algorithm is granted through a signature sheet naming all pharmacists to whom drug therapy management authority is granted. The sheet is signed by all physicians granting such authority or by the medical director of a practice group in which drug therapy management authority...
is extended to pharmacists. A standard form for algorithm progress notes is generally adopted; it is typically in a form that can easily be transmitted by facsimile. Outcomes of care are usually monitored in a systematic way, and changes are made to the algorithm as needed.

CONCLUSION

Through collegial accountability, physicians and pharmacists can be brought together to meet patient needs in pain management. A history of suspicion and confrontation within the pharmacist-physician relationship, produced in part by a regulatory community that has at times placed the importance of diversion prevention above the importance of patient care, can be replaced by a contemporary practice in which the two professions protect each other from inappropriate accusations of impropriety and, in turn, protect patients from the harm of over- or undertreatment. However, collegial accountability requires adoption of new regulations for pharmacy practice, and these new rules have been adopted in only a slight majority of states. The collaborative drug therapy management practices that have been developed by regulation have generally not included the management of chronic pain. The incentive of increased protection from perceived regulatory oversight could serve as the basis for expanded collaborative pain management practices in the future.

REFERENCES

2. See L.A. Ferro et al., “Collaborative Practice Agreements Between Pharmacists and Physicians: Some forward-thinking pharmacists are taking what may be the next logical step in the evolution of pharmaceutical care,” Journal of the American Pharmaceutical Association, 38 (1998): 655–666 (noting the lack of a clear consensus on what is permitted under collaborative practice agreements, but suggesting that, as a general rule, collaborative practice agreements between pharmacists and physicians permit the pharmacist to make specific types of changes in the drug therapy of a specific patient or group of patients, following a written protocol approved by the pharmacist and the physician). Arizona and Georgia recently became the 26th and 27th states to authorize collaborative practice under protocol by pharmacists. See “More States Join Movement to Pharmacist Participation in Drug Therapy Management,” American Journal of Health-System Pharmacy, 57 (2000): 1116–1117. The states in which drug therapy management by pharmacists is currently authorized are Arkansas, California, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington.
4. See Ferro et al., supra note 2. The therapies listed as being most frequently the subject of collaborative agreements between pharmacists and physicians are those that can be monitored by a pharmacist through a test of drug efficacy (i.e., blood glucose for diabetes, peak flow meter for asthma, blood lipids for hyperlipidemia, and the INR [International Normalized Ratio] for anticoagulation therapy). The efficacy of drug treatment for pain can also be monitored by a pharmacist through patient interviews regarding the level of comfort and pain sensation. See A.E. Bonomi, R. Shikiar, and M.W. Legro, “Quality-of-Life Assessment in Acute, Chronic, and Cancer Pain: A Pharmacist’s Guide,” Journal of the American Pharmaceutical Association, 40 (2000): 402–415 (describing the instruments currently available to pharmacists, and other health-care providers, through which an assessment can be made of the impact of pain on quality of life).

12. Florida law now provides that health-care professionals may substitute continuing education on "end-of-life care and palliative health care" for the mandatory continuing education on AIDS/HIV, as long as the licensee has completed an approved AIDS/HIV course in the immediately preceding relicensure period. Fla. Stat. 455.604 (1999).

13. The problem of informal policies-in-practice is compounded when regulators themselves either do not know the policies-on-paper or they fail to communicate them well to the regulated industry. This problem can, at least partially, be addressed through educational programs geared for regulators. See D.E. Joranson and A.M. Gilson, "Improving Pain Management Through Policy Making and Education for Medical Regulators," Journal of Law, Medicine & Ethics, 24 (1996): 344–47.

14. See G.R. Haislip, "Impact of Drug Abuse on Legitimate Drug Use," Advances in Pain Research and Therapy, 11 (1989): 205–211 (concluding that the law is not a problem in providing an adequate supply of drugs, particularly narcotics, to patients for the treatment of intractable pain). DEA regulations formally acknowledge this perspective in a section that addresses availability of pain management medications: "This section is not intended to impose any limitations on a physician or authorized hospital staff ... to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." 21 C.F.R. § 1306.07(c) (1999).


17. 555 F.2d 258 (5th Cir. 1979).

18. 972 F.2d 395 (Utah 1998).


26. See H uang, infra notes 35–36 and accompanying text.


29. See id. at 1051.

30. See id. at 1053.

31. 642 N.E.2d 514 (Ind. 1994).

32. See id. at 519.


36. See id. at 434–444.

37. 1 S.W.3d 519 (Mo. Ct. App. 1999).

38. See id. at 524.

39. See id. at 523, n.5.

40. See Doucette et al., supra note 22.

41. See Gilson et al., supra note 23.

42. See Grainger-Rousseau et al., supra note 3.


44. See Bonomi et al., supra note 9.


46. See id.

47. See, e.g., C.N. Mitchell, "Deregulating M anatory M edi- cation Prescription," American Journal of Law & Medicine, XII, no. 2 (1986): 207–239 (arguing that public safety needs do not and cannot justify the mandatory prescription controls that are in place today).

non-prescription status, and arguing for insurance coverage of non-prescription drugs).


51. Id. at 1250.

52. See Grainger-Rousseau et al., supra note 3.


APPENDIX I

Survey Questions for State Board of Pharmacy Executive Officers

Question 1: A pharmacist in your state begins to receive a large number of prescriptions for methadone from a group of physicians who specialize in pain management. There is no question that these prescriptions are for pain, and that the patients for whom the prescriptions are dispensed are actually suffering chronic pain. The pharmacist is concerned that the large volume of prescriptions she fills for methadone will raise a “red flag” with regulators regarding the legitimacy of her dispensing. Nevertheless, she believes she has a professional responsibility to dispense these medications. The volume of her methadone dispensing increases dramatically as word gets around to patients that this pharmacist will fill methadone prescriptions without accusing them of being drug addicts. Other pharmacists become concerned about rumors they have heard that the pharmacist is dispensing large volumes of methadone. One of the other pharmacists files a complaint with the state board of pharmacy. What outcome do you believe is most likely for this pharmacist based solely on the facts as given?

_____ This pharmacist will likely not be disciplined by the board of pharmacy.
_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.
_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

Question 2: Assume the same facts as those in question #1. However, assume further that the pharmacist has filled a photocopy of a methadone prescription, presented by the niece of a patient who had a legitimate need for the drug. Five other pharmacies in the area also filled a photocopy of this prescription. Thirteen pharmacies refused to fill this photocopy. An investigation discloses that the pharmacist filled 85 prescriptions for methadone during the week in which the photocopy was filled, and 84 of these prescriptions were perfectly valid. A complaint is filed with the board of pharmacy over the filling of the one photocopy of a prescription for methadone. What outcome do you believe is most likely for this pharmacist based solely on the facts as given?

_____ This pharmacist will likely not be disciplined by the board of pharmacy.
_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.
_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

Question 3: A pharmacist in your state fills a written prescription for Demerol 50 mg on Thursday afternoon. The prescription is written by an orthopedic surgeon and is for a two-day supply of the drug to treat back pain of a patient who regularly has pharmaceutical products and services provided by this pharmacist. Two days later, on Saturday afternoon, the pharmacist is contacted by the patient and is requested to dispense a refill, which the pharmacist declines to do, citing federal law. The patient is unable to locate the orthopedic surgeon that afternoon, but the patient’s regular physician is willing to telephone in an emergency authorization to dispense a supply of Demerol 50 mg sufficient to cover the patient’s needs until Monday when the patient can visit the orthopedic surgeon. The pharmacist fills the order, but seven days later the prescriber has still not sent a written prescription to the pharmacist to cover the emergency dispensing. The pharmacist contacts the prescriber’s office five times to request that this be done. Each time the pharmacist receives assurance that the prescription will be sent, but the prescription never arrives. The pharmacist thoroughly docu-
ments each of the five attempts to contact the prescriber, and attaches this documentation to the authorization for emergency dispensing. There is no question that the drugs have not been diverted, this is simply a matter of incomplete recordkeeping. An inspector notes that the written prescription has not been received, and disciplinary action is initiated against this pharmacist based on this circumstance.

_____ This pharmacist will likely not be disciplined by the board of pharmacy.

_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.

_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

Question 4: Assume the same facts as in question #3. However, the pharmacist has not been subject to any discipline by the board. But the pharmacist has become utterly disgusted with the failure of physicians to deliver hard copies of Schedule II prescriptions subsequent to their verbal orders for emergency dispensing of Schedule II drugs. The pharmacist adopts a policy of not filling any emergency orders for Schedule II controlled substances, despite the needs of patients, because he does not want to be placed in the position of possibly not receiving the written orders later. Two patients, who are regular patients of the pharmacy, are denied narcotic analgesics under emergency circumstances by this pharmacist, despite the assurances of their physicians that a written prescription would be sent. The pharmacist states that he has simply had enough of this nonsense and will not fill emergency Schedule II prescriptions no matter what the prescriber promises. The patients file a complaint with the board of pharmacy for failure to provide complete pharmaceutical services.

_____ This pharmacist will likely not be disciplined by the board of pharmacy.

_____ This pharmacist will likely receive a minor disciplinary action by the board of pharmacy.

_____ This pharmacist will likely receive a major disciplinary action by the board of pharmacy.

Clarifying Comments:

Question 5: A pharmacist and a physician in your state come to know and trust each other very well. Together the pharmacist and physician develop a collaborative practice agreement, in which the pharmacist and physician specify how a patient’s anticoagulation therapy is to be managed by the pharmacist. The agreement contains very specific decision assistance algorithms that guide the pharmacist in monitoring the patient’s anticoagulation. The agreement contains instructions for changing the dose of prescribed drugs, initiating new drugs, and discontinuing prescribed drugs. According to the agreement, the pharmacist need not contact the prescriber prior to making changes that are authorized under the algorithm, but the pharmacist must immediately notify the prescriber following any change. Both the pharmacist and physician have signed this collaborative practice agreement. The physician begins to send to the pharmacist patients who require anticoagulation monitoring. Can this collaborative practice be done in your state?

_____ No, this collaborative practice may not be done legally.

_____ Yes, this collaborative practice may be done legally, but only within an organized health care system such as a hospital, a nursing home or a health maintenance organization.

_____ Yes, this collaborative practice may be done legally, in any community pharmacy.

Clarifying Comments:

Question 6: Assume essentially the same facts as in question 5. The pharmacist and physician in your state have come to know and trust each other very well. Together the pharmacist and physician develop a collaborative practice agreement, in which the pharmacist and physician specify how a patient’s narcotic analgesic pain therapy is to be managed by the pharmacist. The agreement contains very specific decision assistance algorithms that guide the pharmacist in monitoring the patient’s pain. The algorithm contains instructions for changing the dose of prescribed drugs, initiating new drugs, and discontinuing prescribed drugs. According to the agreement, the pharmacist need not contact the prescriber prior to making changes that are authorized under the algorithm, but the pharmacist must immediately notify the prescriber following any change. Both the pharmacist and physician have signed this collaborative practice agreement. The physician begins to send to the pharmacist patients who require pain management. Can this collaborative practice be done in your state?

_____ No, this collaborative practice may not be done legally.

_____ Yes, this collaborative practice may be done legally, but only within an organized health care system such as a hospital, a nursing home or a health maintenance organization.

_____ Yes, this collaborative practice may be done legally, in any community pharmacy.

Clarifying Comments:
APPENDIX II
Texas Board of Pharmacy Rule for Drug Therapy Management by a Pharmacist

RULE § 295.13: Drug Therapy Management by a Pharmacist under Written Protocol of a Physician

(a) Purpose. The purpose of this section is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in § 3.061 of the Medical Practice Act and § 17(x) of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act — The Texas Pharmacy Act, Texas Civil Statutes, Article 4542a-1, as amended.

(2) Board — The Texas State Board of Pharmacy.

(3) Confidential record — Any health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(4) Drug therapy management — The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standing protocol. Drug therapy management may include the following:

(A) collecting and reviewing patient drug use histories;

(B) ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;

(C) ordering drug therapy related laboratory tests;

(D) implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or

(E) any other drug therapy related act delegated by a physician.

(5) Medical Practice Act — The Texas Medical Practice Act, Texas Civil Statutes, Article 4495b, as amended.

(6) Written protocol — A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Medical Practice Act.

(c) Notification.

(1) Initial notification. Prior to initially engaging in drug therapy management, a pharmacist shall provide the board with:

(A) the name, license number, and address of the

(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of drug therapy management;

(ii) a statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management as delegated by the physician;

(iii) a statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:

(I) a statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(II) a specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority;

(iv) a statement of the activities the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) a statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist’s exercise of delegated drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient.
supervising physician; 
(B) the address where the records of such drug therapy management are maintained; and 
(C) a statement attesting to the fact that the pharmacist has within the last year: 
(i) completed at least six hours of continuing education related to drug therapy offered by a provider approved by the American Council on Pharmaceutical Education (ACPE); or 
(ii) engaged in drug therapy management as allowed under previous laws or rules. A statement from the physician supervising the acts shall be sufficient documentation.

(2) Continuing requirements. A pharmacist engaged in drug therapy management shall: 
(A) annually complete six hours of continuing education related to drug therapy offered by a provider approved by the American Council on Pharmaceutical Education (ACPE). (These hours may be applied towards the hours required for renewal of a license to practice pharmacy.) 
(B) notify the board of any change in supervising physician or change in the address where the records of drug therapy management are maintained.

(d) Supervision. Physician supervision shall be as specified in the Medical Practice Act, § 3.061 and shall be considered adequate if the delegating physician:

(1) is responsible for the formulation or approval of the written protocol and any patient-specific deviations from the protocol and review of the written protocol and any patient-specific deviations from the protocol at least annually and the services provided to a patient under the protocol on a schedule defined in the written protocol; 
(2) has established and maintains a physician-patient relationship with each patient provided drug therapy management by a delegated pharmacist and informs the patient that drug therapy will be managed by a pharmacist under written protocol; 
(3) is geographically located so as to be able to be physically present daily to provide medical care and supervision; 
(4) receives, on a schedule defined in the written protocol, a periodic status report on the patient, including any problem or complication encountered; 
(5) is available through direct telecommunication for consultation, assistance, and direction; and 
(6) determines that the pharmacist to whom the physician is delegating drug therapy management establishes and maintains a pharmacist-patient relationship with the patient.

(e) Records.

(1) Maintenance of records.

(A) Every record required to be kept under this section shall be kept by the pharmacist and be available, for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(i) the records maintained in the alternative system contain all of the information required on the manual record; and 
(ii) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(2) Written protocol.

(A) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist. 
(B) A pharmacist shall document all interventions undertaken under the written protocol within a reasonable time of each intervention. Documentation may be maintained in the patient medication record, patient medical chart, or in a separate log.

(C) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient. A pharmacist shall maintain a copy of any deviations from the standard protocol ordered by the physician.

(D) Written protocols, including standard protocols, any patient-specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the pharmacist’s records. Documentation of all services provided to the patient by the pharmacist shall be reviewed
by the physician on the schedule established in the protocol.

(f) Confidentiality.

1. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is not transmitted directly between a pharmacy and a physician, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this subsection.

2. Confidential records are privileged and may be released only to:
   (A) the patient or the patient’s agent;
   (B) practitioners and other pharmacists when, in the pharmacist’s professional judgment, such release is necessary to protect the patient’s health and well-being;
   (C) other persons, the board, or other state or federal agencies authorized by law to receive such information;
   (D) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act or the Dangerous Drug Act;
   (E) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person’s official duties; or
   (F) an insurance carrier or other third party payer authorized by a patient to receive such information.

3. This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, § 5.08.

(g) Construction and Interpretation.

1. As specified in the Medical Practice Act, § 3.061(e), this section does not restrict the use of a pre-established health care program or restrict a physician from authorizing the provision of patient care by use of a pre-established health care program if the patient is institutionalized and the care is to be delivered in a licensed hospital with an organized medical staff that has authorized standing delegation orders, standing medical orders, or protocols.

2. As specified in the Medical Practice Act, § 3.061(d), this section may not be construed to limit, expand, or change any provision of law concerning or relating to therapeutic drug substitution or administration of medication, including the Act, § 17(a)(5).
APPENDIX III

Central Washington Hospital

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**POLICY:** It is the policy of Central Washington Hospital Hospice Services to efficiently provide quality care to Hospice patients, and:

A. To provide quality symptom management for patients suffering distressing symptoms resulting from a terminal disease process.

B. To provide a safe and standardized approach to symptom management.

C. To improve on the timely delivery of needed interventions for symptom management (i.e. prescriptions for needed drugs obtained quickly).

D. To streamline the collaborations of the Pharmacist, Nurse and Physician by assuring communication and facilitating decision making.

E. To be cost effective while improving overall quality of care.

**GENERAL:**

The nurse is responsible for the initial and ongoing assessment of the patient’s condition and presenting symptoms. He/she will collaborate with the Pharmacist according to the algorithm.

The credentialed Pharmacist, with Washington State Board of Pharmacy Prescriptive Authority, will prescribe medications for Hospice patients in accordance with algorithms approved by a physician. The Pharmacist may continue, modify or initiate the drugs according to the process.

The Pharmacist or Hospice Nurse will consult with the physician according to the algorithm and at any time deemed necessary.

A. Algorithm Process Procedure:

1. Patient admitted to the Hospice program. A signed prescription from the attending physician, or indication on a signed Hospice Plan of Care, will be obtained to initiate the algorithm. An authorization letter from the attending physician for their patients may be used in lieu of a signed prescription.

2. A medication profile will be completed and a copy sent to the Pharmacy within 24 hours.

3. A Plan of Care will be developed by the Hospice Interdisciplinary Team and a copy sent to the Pharmacy.

4. A Plan of Care will be completed and signed by the attending physician.

5. Current medications will be continued as long as they are effective in controlling symptoms. A list of current medications will be kept by Pharmacy on a Medication Tracking Sheet. When a change occurs on a non-
algorithm medication, Hospice nurse will immediately notify Pharmacy (nurse will call if medication change accompanies algorithm change, otherwise a copy of the change will be sent to Pharmacy). The Pharmacist will use this information to update the patients profile in the Hospice Workbook.

6. When a symptom is observed and an algorithm is being considered for implementation, the Hospice nurse will consult with the Pharmacist as defined by the algorithm. The assessment data will be reviewed and a plan of action determined. The Pharmacist will prescribe per the algorithm and dispense the needed medication.

7. Within twenty-four (24) hours of an algorithm change, the Pharmacist will fax a copy of the algorithm Progress Notes summarizing the consultation process to the attending physician and Hospice nurse.

8. The Hospice nurse will perform an ongoing assessment of the patient’s condition.

9. If the current step in the algorithm is not working (i.e. not effective in relieving the patient’s distressing symptom), the Hospice Nurse will follow protocol and consult with the Pharmacist. Follow-up assessments may be performed within twenty-four (24) hours of therapeutic change, or as indicated in the specific algorithms or per clinician judgment. The Pharmacist will determine if any change in current drug therapy is needed based on the nursing assessment and prescribed according to the algorithm.

10. Once all of the steps in an algorithm are completed and symptom is unrelieved the Hospice nurse and Pharmacist will consult. The Pharmacist or Hospice Nurse will contact the attending physician.

11. For medications that fall outside of the algorithm the Pharmacist will write the new orders and dispense the medication upon a verbal order from the attending physician. This will be documented by the Pharmacist on a Algorithm Progress Note with a copy sent to the Hospice nurse and physician. The Hospice nurse may also write new orders upon a verbal order from the attending physician. The Pharmacist will dispense the medication upon a telephone order from the hospice nurse or a faxed order from the physician.

12. If the patient is admitted to the hospital, algorithms will be suspended while patient is in-house and resumed upon discharge.

B. Pharmacy Procedure:
   \hspace{10pt} The Pharmacist will:
   \hspace{10pt} 1. Prescribe the identical drug, strength, route, and instructions as outlined in the algorithm.
   \hspace{10pt} 2. Use the DEA number of Central Washington Hospital Professional Pharmacy when prescribing scheduled drugs.
   \hspace{10pt} 3. Review relevant patient information, before enacting any portion of the algorithm. Verify nurse assessment is complete. (Telephone consultation.)
   \hspace{10pt} 4. Consider for appropriate therapy, but not be limited to: accepted doses, allergy, weight, sex, age and known disease processes.
   \hspace{10pt} 5. Include monitoring parameters, such as adverse reaction, possible drug interactions, individual pharmacokinetics, as well as patient response in algorithm decisions.
**Hospice Algorithm Process**

1. **Patient Admitted to Hospice**
2. **Fax, Written, Oral Approval Given To Begin Algorithms**
3. **Assessment/Information Gathering**
4. **Plan of Care Developed**
5. **Communication With Physician**
6. **Algorithms Instituted**
7. **Ongoing Assessment and Evaluation**
   - **Current Algorithm Step Not Working** → **Start Next Step**
   - **Pharmacist Consults Physician As Needed**
   - **Pharmacist** Writes Prescription and Notifies Physician

Protocol completed.

Pharmacist/hospice nurse coordinates further care plans.

Pharmacist/hospice nurse calls physician for further drug orders and communicates information to hospice nurse/pharmacist.
APPENDIX IV

Pain Treatment Algorithm

STEP I
Mild Pain

- APAP 500 mg po/pr q4h ATC (MDD 4000 mg)
- Ibuprofen 200 mg po q4-6h ATC (MDD 2400 mg)
- Choline magnesium trisalicylate 1000 mg po bid
  * Consider adjuvant for pain syndromes

Relief

Pharmacist assess:
- Patient compliant with ATC dosing?
- Need to increase dose?
- Need to change drug?

Relief

Pharmacist-Nurse consultation to advance to Step IV

Continue medication & reassess at regular intervals

Partial or No relief

No relief

Always dispense maximum end of dosing range/frequency
Dispense 2 week supply unless otherwise instructed by R.N.

Pain Treatment Algorithm

STEP II
Moderate Pain

- Vicodin I-II po q4-6h ATC (MDD 8 tabs)
- Percocet I-II po q4-6h ATC (MDD 12 tabs)
- Oxycodone 5 mg I-II po q4-6h ATC
  If sustained release is needed:
  Oxycodin 10 mg SR po bid
  MS Contin 15 mg po bid
  (may use Vicodin, Percocet, or Oxycodone above for breakthrough pain)
  * Initiate bowel program when starting narcotic
  * Consider adjuvant for pain syndromes
  * If using Vicodin/Percocet, d/c Tylenol from Step I

Relief

Continue medication & reassess at regular intervals

Pharmacist assess:
- Patient compliant with ATC dosing?
- Need to increase dose?
- Need to change drug?

Pharmacist-Nurse consultation to advance to Step IV

No relief

Always dispense maximum end of dosing range/frequency
Dispense 2 week supply unless otherwise instructed by R.N.
Generic substitution permitted on all prescriptions
Pain Treatment Algorithm

STEP III
Severe Pain

OxyContin po bid
MS Contin po bid or Duragesic patch q3d
*Starting dose should be equianalgesic to previous narcotic agent (see equianalgesic chart). Upward titrations of 25-100%.

For breakthrough pain (25% of daily opioid use):
Morphine sublingual tabs (10, 15, 30 mg) po, sl q3h pm
OR
Dilaudid po q3h pm
OR
Roxanol liquid po q3h pm
* Initiate bowel program when starting narcotic
* Consider adjuvant for pain syndromes

Continue medication & reassess at regular intervals

Relief

Partial or no relief

Pharmacist assess:
- Patient compliant with ATC dosing?
- Need to increase dose?
- Need to change drug?

No relief

Pharmacist-Nurse consultation to advance to Step IV

Pain Treatment Algorithm

STEP IV:

- Consider morphine CADD PCA
  (If patient allergic to morphine, RPh will consult MD for other options)
- Criteria for instituting CADD PCA
  (RPh & RN to determine)
  - patient no longer able to swallow
  - patient has questionable GI absorption of meds
  - patient not well controlled with oral meds even after multiple upward titrations
- Route of administration
  - vascular access (Groshong, PICC, or Port) for IV route is preferred. On rare occasions a subcutaneous route may be used if IV is unattainable and subcutaneous route is clinically inappropriate.
- Determining starting dose
  - Starting dose of Morphine should be equianalgesic to current oral dose of opioid (see conversion formula and equianalgesic chart)
  - Usual concentration of Morphine is 10mg/mL. More concentrated solutions are used when hourly rate exceeds 10mg/hr.
    Concentration is calculated according to hourly rate.

NOTE: Subcutaneous infusion should not exceed 2mL/hr.

- Titration Parameters
  - calculate the past 24 hours total opioid usage (RN to provide information, RPh to calculate)
  - if needed, convert to equivalent dose of morphine (see equianalgesic dose chart)
  - divide total daily dose by 24 - this gives hourly rate. Drip rate may be increased (by 25-50%) Q4-6 hours if poor symptom control
  - bolus doses for breakthrough pain = 100% of hourly rate. Breakthrough dose is given every 10-15 minutes.
- Assessment
  - Relief: Continue to assess & titrate up or down pm to maintain optimal pain control.
  - No Relief: If pain rating is consistently ≥ 5 on scale of 1-10 for greater than 24 hours, in spite of repeated upward titrations, pharmacist will consult with Physician. Consider switching to another opioid or epidural infusion. Reconsider adjuvant for pain syndromes.
**APPENDIX V**

**HOSPICE/PHARMACY ALGORITHM PROGRESS NOTES**

Patient: _______________________________

Conference with _________________________ RN  Algorithm: _______________________

Date: ____________________  Time ____________________  Physician: ____________________

Nursing Assessment Completed per Protocol  □ Yes  □ No (Explain)

Summary _____________________________________________________________

_____________________________________________________________________

Plan

□ Continue Present Drug regimen with no change

□ Discontinue __________________________ (Drug/Dose)

New Rx(s)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Amount Dispensed</th>
<th>Directions</th>
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□ Refill Current Drug Therapy

Medication to be:  □ Picked up by:  □ Family  □ RN  □ Other ____________________

Faxed to: ____________________  Physician

Hospice Nurse

Review _____________________________________________________________

Review Date ____________________

Comments: __________________________________________________________

Pharmacist ____________________

7408-70  11/12/99
Federal Training Requirements for Responsible Research: Not Going Far Enough

In what is clearly an important development related to research integrity and the protection of human research subjects, the U.S. government has instituted two new training requirements as a condition of receiving federal financial support. First, the National Institutes of Health (NIH) is requiring, as a condition of funding, that key research personnel involved in human subject research complete education "in the protection of human subjects." Evidence that key personnel have completed this training must be provided in NIH grant applications or contract proposals.

The NIH education policy will eventually be superseded by a more broadly applicable instructional policy for the "responsible conduct of research," which will be promulgated by the Department of Health and Human Service's Office of Research Integrity and the Public Health Service (PHS). The instructional policy will apply to all persons engaged in any research or research training with PHS support. Presently, the only version of the policy is in draft form. The final version of the policy was, according to schedule, announced in November 2000, following a period of public comment on the draft version. However, the newly installed Bush administration suspended the final version in February, responding to criticisms that the public comment period wasn't widely known and the final version of the policy didn't respond to the few comments that were made. A review and public comment period is now underway, with a final version of the policy anticipated shortly.

Heightened concern over research integrity and human subject protection — as well as the related public policy response of requiring PHS-supported researchers to undergo responsible research training — is a welcome development that is long overdue. In 1998, several well-publicized reports and congressional testimony were released indicating, in part, that researchers and those who were responsible for research review and oversight were inadequately trained on matters pertaining to research integrity or human subject protection. A follow-up report that was recently published found that extremely little has been done to correct these and other deficiencies.

The new training requirements, coming well over two years since the findings of deficiencies, are a belated attempt to address a deceptively simple problem: educating researchers and those responsible for research oversight about research integrity and protecting human subjects. As is common with many of the federal regulations pertaining to research, however, both the interim NIH education policy and the PHS draft policy appear too ambiguous and ambivalent to solve this problem. A review of the two policies indicates that much more should be done to improve the substantive training requirements and enhance this important development in our nation’s research enterprise.

The NIH Policy

On June 5, 2000, the NIH published Notice No. OD-00-039, a policy titled, Required Education in the Protection of Human Research Participants. The new policy requires that investigators who submit applications for NIH funding must complete an educational program on human subject protection as a con-
The Journal of Law, Medicine & Ethics

The PH S Draft Policy

On July 17, 2000, the Public Health Service and the Office of Research Integrity published Draft Policy on Instruction in the Responsible Conduct of Research. The draft policy is intended by the Department of Health and Human Services to help ensure that PH S-supported researchers undergo basic instruction in responsible research conduct and related federal regulations. Unlike the NIH educational policy, this policy is intended to apply more broadly to “all staff” engaged in research training with PH S funds or working on PH S-supported research projects. For example, the term “all staff” includes not only investigators, but institutional officials who approve PH S grants as well as students, technicians, consultants, research assistants, and others who work on PH S-supported projects, whether or not these staff receive the support themselves. The policy even recommends that secretarial and other support staff receive instruction relevant to their particular responsibilities and roles.

The PH S policy also includes more substantive instructional requirements.

In response to many inquiries about what would constitute satisfactory documentation that key personnel had completed the required training, NIH has indicated that the letter must include the names of the key personnel responsible for the design and conduct of the study. Additionally, for each named individual, the title of the educational program and a one-sentence description of it must be provided. Finally, the letter must be signed by the principal investigator and co-signed by an official of the institution. To simplify matters, at least one NIH agency — the National Institute of Allergy and Infectious Disease — has gone so far as to provide a “sample” or template for the documentation letter.

Discussion

Both the NIH education policy and the draft PH S instructional policy are critical and long-overdue first steps towards furthering research integrity and, importantly, human subject protection. Just this past year, a government report indicated that almost no improvement had been made since a 1998 report from the Office of the Inspector General of the Department of Health and Human Services had concluded, among a number of important findings, that investigators as well as members of research review committees required much more training in responsible research conduct. In this respect, the NIH and PH S policies may be lauded for doing what the reports did not: galvanizing research institutions into developing training programs or making such programs accessible to research staff. There are, however, a number of concerns about the new policies.
Sad comment on state of training
First, and as a general matter, it is disconcerting that a federal mandate is necessary in order for institutions to provide their researchers and research reviewers with basic responsible research training.

Such a decree implicitly suggests that research institutions lack the wisdom or the wherewithal to adequately prepare researchers and research reviewers for responsible research conduct without external guidance or pressure — which is a troubling thought given that the widespread lack of such training and its attendant adverse consequences has been so clearly established and recognized at the highest levels of government.  

Unquestionably, responsible research institutions would not permit an investigator to perform blood draws on human subjects, excise tissue from animal subjects, or perform other laboratory experiments if the investigator lacked the requisite qualifications to do these things.

Similarly, good research practice also requires that investigators be minimally trained, for example, on matters as diverse as informed consent for human subjects, authorship responsibilities for publication, and conflicts of interest. That repeated prodding is required in order for research institutions to own up to the importance of this training or to take constructive measures to implement it is a regrettable development in light of our nation’s checkered history pertaining to research.

One small way for research institutions to mitigate the past neglect of responsible research training for staff is to exercise extreme care and diligence in conforming to the training requirements to go beyond the federal policies and require all research staff, regardless of source of funding, to be trained.

An overreliance on self-policing
A second concern about the new policies is the overreliance on self-policing by research institutions, which may, in turn, compromise the training requirements as a meaningful safeguard against unethical or irresponsible research practices. As described above, research institutions are only required to provide assurance of their compliance with the new policies through form letters or signed certifications provided to the Public Health Service prior to the award of a research grant or contract funds. These assurances are conceptually similar to those now used by research institutions to evidence compliance with other PH S requirements, such as appropriate initial and continuing review of research, adequate human and animal subject protection, and research integrity.

In essence, the Public Health Service has delegated to research institutions the responsibility for reviewing and approving research undertaken by their own investigators and promoting research integrity. Institutions are also responsible for investigating and interdicting improper research and research misconduct, as well as reporting such cases to their sponsors and to the Office of Research Integrity.

In a real sense then, institutions subscribe to a federally devised “honor code,” by which the institutions stipulate as a condition of federal funding that human and animal subjects will be protected against research risks and that research misconduct will be prevented or scourged.

While this self-policing scheme has existed for nearly two decades, it has been found lacking in important respects during just the past few years. Particular criticism of the current scheme is leveled at the research review committee process, which official reports have concluded require significant reforms.

Under federal law, a research institution must convene a committee whose members meet regularly to review research protocols involving the institution’s research staff. The committee must also perform continuing reviews of research already approved to ensure that human subjects are properly protected. Despite these requirements, official reports indicate that the committees’ ability to perform their tasks put human subjects at risk, while some commentators clearly suggest that human subjects are not adequately protected under the current scheme.

Related findings point out that these committees may:

• be unable to effectively manage the large volume of research they are expected to review;
• be unable to conduct more thorough reviews of research;
• have a lack of scientific expertise to make informed judgments about the research they review;
• have a lack of objectivity and independence because of conflicts of interest; and
• not be adequately trained to conduct reviews of research.

In its 2000 report, the Office of the Inspector General of the U.S. Department of Health and Human Services indicated that almost no improvements had been made to the research review scheme that would address the “disturbing inadequacies” discovered in its previous review in 1998.

One of the inferences that might be drawn from these findings is that many research institutions are simply incapable of effectively discharging their self-policing responsibilities under current federal regulations pertaining to the protection of human subjects or research integrity.

Another and perhaps related concern is that the absence of more precise regulatory guidance or requirements may leave too much for research institutions to interpret, leading to widely disparate adherence to the federal regulations. Perhaps a history characterized by an abject lack of enforcement of the regulations or interdiction of research abuses may be to blame. For any one of these reasons, the new PH S policy, which relies so heavily on self-policing by research institutions, may be similarly inadequate.
Too narrow in application
A third concern is that the new policies apply only to (a) persons who submit applications for NIH grants or contracts or (b) research staff who conduct research or receive research training with PH S funds. Thus, research staff who are engaged in research or research training with non-PH S support, such as those supported by other federal agencies, state governments, non-governmental agencies, or private philanthropy, are not required to undergo responsible research training.

The policies’ limited applicability is understandable: Neither the Public Health Service nor the National Institutes of Health have regulatory authority to institute policies for other federal agencies. Nevertheless, limited applicability of the new policies creates a two-tier environment in which unfortunate disparities will result. For example, human subjects in research funded by agencies other than NIH or PH S may be disadvantaged because these researchers may be less informed or less thoroughly trained — or not informed or trained at all — in human subject protection.

Similarly, the public or private investment in non-NIH or non-PH S research may be at greater risk because these researchers may be more likely to have their research suspended or terminated due to research abuses or misconduct that might have been prevented or mitigated by appropriate training.

Nature and depth of the training
Fourth, the new policies are problematic because there is little to no indication of the type of training that investigators should be required to undergo. This omission is especially unfortunate because the weaknesses in our current research oversight scheme and the gaps in research knowledge are more understood than they have ever been. The PH S draft policy does list and briefly describe ten “core instructional areas” that should be included in a training program, to the extent these areas are relevant to an institution’s research programs. The policy also recommends that research staff receive continuing education in order to keep current on updates and maintain “sensitivity to the issues.”

Left unclear, however, are several important matters, which research institutions are free to discern however they wish. These include, for example, whether and under what circumstances research staff should receive training in each of the core instructional areas, or whether and how training should be tailored to a research staff’s role or responsibility in a research project (e.g., whether a laboratory animal-care technician should receive training in data acquisition or sharing, or whether research staff who have no publication role in a project should receive training in responsible authorship). Ideally, a well-informed and trained research staff requires some immersion in each of the core instructional areas, with particular focus on those areas most relevant to the research staff’s role and responsibilities.

The NIH policy is even less informative than the PH S draft policy, relying on its proffered citations to Web-based educational resources and indicating that “a number of curricula are readily available to investigators and institutions” and that “NIH does not plan to issue a list of ‘endorsed’ programs in human subject protections.”

A related problem (about which the NIH policy is silent) is that under the PH S draft policy, the format of an institution’s training program can be “any educational activity,” such as a course, workshop, seminar, computer program, or self-study. The policy is equally permissive regarding whether or not the institution provide a certain amount of training or whether or not the research staff demonstrate some minimal competence upon completion of the training.

Without further guidance, the expansive definition of “educational activity” may lend itself to widely disparate outcomes both within and between institutions. For example, some research institutions might choose to offer only self-study training in order to minimize institutional investment in training, regardless of the needs of the research staff. Other institutions may seek the least intensive training program in order to minimize staff down time. In either case, the importance of responsible research conduct, human subject protection, and research integrity is devalued — and researchers may respond in kind when attempting to master the material (or not). Most disconcerting, the completion of an educational activity might actually be construed as competence in responsible research, which given the weakness of the NIH and PH S policies simply cannot be assured.

On the other hand, the expansive definition of “educational activity” will allow more prudent institutions to tailor training to the specific knowledge or skill deficits of each staff member and to offer a number of different types of programs. Some institutions might even offer continuing education in responsible research in order to keep their staff informed of new developments or issues in the field. More discerning institutions may choose to require that researchers demonstrate some minimally acceptable competence in any one or more of the core instructional areas, depending on the researcher’s role or responsibility. Of course, the law doesn’t require any of this.

Conclusion and Recommendations
Given the prominence assigned to human subject protection and the gravity of the deficiencies in the current regulatory scheme of research review and integrity, the NIH educational policy and the PH S draft instruction policy are important contributions to this country’s research enterprise. Nevertheless, both policies could be significantly strengthened, either through changes made in the policies or by research institutions themselves. First, research institutions should adopt procedures more stringent
than either of the policies. The new policies establish only minimal requirements for responsible research instruction and actually suggest that institutions “adopt additional goals” consistent with the policies or impose more detailed or broader research requirements.\(^{48}\) For example, institutions might require that research staff undergo training in all core areas of research, not just those areas relevant to the staff’s role or responsibility. In order to make the most effective use of training, research institutions might also carefully assess knowledge gaps among current and future research staff and tailor training requirements accordingly.

Second, competency in responsible research conduct should be demonstrated by research staff before they are permitted to undertake any research. Institutions might establish differing levels of competency for each of the core instructional areas, tailored to the role or responsibility of the research staff. For example, it may not always be necessary for a research or animal laboratory technician to have the same degree of competency in human subject protection as a principal investigator who undertakes human subject research or a research review committee member. A change in roles or increased responsibilities can be accommodated by requiring continuing or more intensive training.

Institutional review boards and research mentors should play a key role in assuring that research staff receive appropriate as well as continuing training as part of the staff’s development and privilege of conducting research.

Third, it is important that responsible research training be required for all researchers, not just those engaged in research funded by the National Institutes of Health or the Public Health Service. This would include research staff funded by other federal agencies, state governments, non-governmental organizations, and private philanthropy. The Common Rule,\(^{49}\) now applicable to federal agencies, should be revised to include responsible research training as a condition of federal sponsorship of research. Other mechanisms to encourage uniform adoption of such training should be evaluated, such as national accrediting agencies, professional societies, and licensing authorities. Most importantly, research institutions should take the initiative and require that all research staff, not just those engaged in research funded by NIH or PHS, undergo training. The opportunity to convey the highest regard for responsible conduct to all who are engaged in our country’s research enterprise should not be missed.

Acknowledgment

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References


2. Public Health Service, U.S. Dep’t of Health and Human Services, PHS Draft Policy on Instruction in the Responsible Conduct of Research, NIH Guide OD-00-045 (Washington, D.C.: U.S. Gov’t Printing Office, July 17, 2000) [hereinafter cited as PHS, Draft Policy]. For purposes of this article, the terms “responsible conduct of research” and “responsible research” will include human subject protection, which is consistent with the PHS draft policy. See id. at sec. II, VII(b).


6. NIH, Required Education, supra note 1.

7. Id. at “Implementation.”

8. Id.

9. Id.


11. Id.

12. Id.


14. PHS, Draft Policy, supra note 2.

15. Id. at sec. IV.

16. Id.

17. Id. at sec. II.

18. Id. at sec. VI(A).

19. Id. at sec. VII(1)-(10).

20. Id. at sec. III.

21. Id. at sec. VI(B).

22. Id.

23. Id. at sec. X(B).

24. Id.

25. Id. at sec. X(A).

26. Id. at sec. X(A)(2), (3).

27. Id. at sec. X(A)(4).

28. Id. at sec. IX(B).

29. Id. at n.1. Because the PHS instructional policy will eventually supersede the current NIH education policy, most analysis here is reserved for the PHS policy; any relevant differences will be mentioned.


32. See generally ACHRE, Final Re-
port, supra note 31, at 81–223 (reviewing ethics in human subject research from the 1940s to the 1970s); Beyond Consent: Seeking Justice in Research, J. Kahn, A.C. Mastroian, and J. Sugarman, eds. (New York: Oxford University Press, 1998) (providing some historical background on research exploitation involving vulnerable populations).

33. 45 C.F.R. § 46.103 (2000) (stating in relevant part that “[e]ach institution engaged in research which is covered by this policy, and which is conducted or supported by a Federal Department or Agency shall provide a written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy”). See also 45 C.F.R. § 46.109 (“IRB review of research”); 45 C.F.R. § 46.116 (“General requirements for informed consent”); 45 C.F.R. § 46.113 (“Suspension or termination of IRB approval of research”); 7 U.S.C. § 2131 et seq. (“Animal Welfare Act” (1966)); National Institutes of Health, Dep’t of Health & Human Services, Public Health Policy on Human Care and Use of Laboratory Animals (rev. 1986) (supplying the principles and procedures on the use and care of vertebrate animals in research); 42 C.F.R. § 50.101 et seq. (setting forth institutional responsibilities for investigating research misconduct).


35. OIG 1998 Report, supra note 4, at D-14 (1998) (comments by the Public Citizen’s Health Research Group); see Kahn et al., supra note 32, at 166.

36. Id. at i-iii. But see id. at app. D-20, D-30, and D-38 (comments by Applied Research Ethics National Association, the Association of American Medical Colleges, and the Consortium of Independent Review Boards, criticizing some of the generalizations made in the OIG’s report).


38. NIH, Required Education, supra note 1.

39. PH S, Draft Policy, supra note 2, at sec. IV. However, the policy “does not limit the authority of an institution to impose more detailed or broader requirements of RCR [responsible conduct of research] education.” Id. In fact, the policy provides that, as part of an institution’s certification of compliance to PH S, the institution describe how the instructional program is “being applied to those research staff not supported by PH S funds.” Id. at sec. X(A)(1).

40. See, e.g., OIG 2000 Report, supra note 5, at 3 (observing that the Common Rule (or 45 C.F.R. § 46, Subpart A), which serves as the “basis of a common Federal policy on human-subject protections,” is a significant barrier to making the recommended changes pertaining to research oversight because any change to the Common Rule requires the concurrence of all seventeen agencies adhering to the rule).


42. PH S, Draft Policy, supra note 2, at sec. VI(A). These include data acquisition, management, sharing, and ownership; mentor/trainee relationships; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; conflict of interest and commitment; and compliance with existing PH S and institutional policies.

43. Id. at sec. IX(C).

44. At least the NIH policy suggests that “some [investigators] may elect more intensive study if their work involves especially difficult topics or special populations.” NIH, Required Education, supra note 1, at “Educational Resources.” But such intensive study should be required, not elective.

45. NIH, Required Education, supra note 1, at “Educational Resources.”

46. PH S, Draft Policy, supra note 2, at sec. III.

47. Id. at sec. V(B).

48. Id. at sec. IV. V(B).

49. 45 C.F.R. § 46 (Subpart A); but see note 40, supra, regarding concerns about the Common Rule.
Pharmaceuticals:  
Conspiracy to Increase Ritalin Profits Alleged  

On May 1, 2000, three Texas parents filed a national class action suit against the American Psychiatric Association (APA) and the drug manufacturer, Novartis Pharmaceuticals Corp., which is the primary American supplier of methylphenidate, more popularly known as Ritalin.2

The suit alleges that the defendants “planned, conspired, and colluded to create, develop, promote, and confirm” the diagnoses of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD). The non-profit organization, Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD), is also named as a co-defendant for deliberately aiding Novartis in the alleged conspiracy, of which the aim was to boost Ritalin sales.

According to the complaint, filed in the Texas District Court for the 103rd District, the repeated expansion of the diagnostic criteria for ADD and ADHD by Novartis and the APA made the criteria overbroad and led to a dramatic, inappropriate increase in Ritalin sales.4 The defendants also allegedly conspired to promulgate the idea that a significant percentage of children suffer from a “disease” requiring prescription drug therapy, with Ritalin as the “drug of choice” for such therapy.5

All defendants are accused of fraudulent misrepresentation, also known as the common law action of “deceit” or “fraud,” concerning the scope and extent of the ADD and ADHD diagnoses. To recover for fraud, the plaintiffs must establish the following elements, as set forth in the Restatement (Second) of Torts: (1) misrepresentation by the defendants; (2) scienter;6 (3) an intent to induce the plaintiffs’ reliance on the misrepresentation; (4) justifiable reliance on the misrepresentation; and (5) damage to the plaintiffs, stemming from the reliance.8 Notably, if the defendants intentionally concealed a fact from the plaintiffs, they would be treated the same way as if they had affirmatively misstated that fact.9

Under the facts of the case, Michael Hernandez was diagnosed with ADHD in 1995. His parents, two of the three named plaintiffs filing the suit, claim to...
have reviewed literature published by CHADD and paid for by Novartis. Based on the information they read, the parents agreed their child should receive a prescription for Ritalin. Thus, Michael took the drug, as prescribed, from 1995 until 2000.

Michael’s parents assert that, had they known of the financial connections among Novartis, the APA, and CHADD, they would not have accepted the diagnosis of ADHD nor the prescription for Ritalin, especially given the subjective and broad nature of the criteria for the disorder. Furthermore, they state that having accepted the diagnosis, they then expended unnecessary sums of money for the Ritalin.

Dakota Butler, whose mother is the third named plaintiff, was diagnosed with ADHD in the late fall of 1997 and took Ritalin from 1997 to 2000. Dakota’s mother had not reviewed the literature published by CHADD or paid for by Novartis prior to purchasing Ritalin. However, she, too, was unaware of the financial relationship among the defendants, and she claims that she would not have accepted the diagnosis nor the prescription of Ritalin had she known about the relationship.

Allegations Against Novartis

The Diagnostic and Statistical Manual of Mental Disorders (DSM) is widely used by physicians as a compendium of psychiatric diagnoses. As a result, a new listing or change of diagnostic criteria in the DSM may generate large numbers of new prescriptions, insurance coverage, and public attention.

The plaintiffs claim that Novartis took steps to ensure a more expansive and subjective diagnostic criteria for ADHD in the most recent edition of the DSM (DSM-IV). This allegedly provided the necessary medical credibility so that diagnosis would lead to more prescriptions of Ritalin and, therefore, an increase in the sale of the drug.

The complaint names particular steps that Novartis took to increase sales: (1) actively promoting the concept that a significant percentage of children suffer from a “disease” which requires drug therapy; (2) actively promoting Ritalin as the “drug of choice” for treating pediatric ADHD; (3) actively supporting groups such as CHADD financially; and (4) distributing misleading sales and promotional literature to parents.

Furthermore, the plaintiffs allege that Novartis failed to warn physicians, parents, and schools about the drug’s risks. Risks include serious cardiovascular problems, central nervous system problems (e.g., tics), gastrointestinal problems (e.g., anorexia), and pituitary dysfunction.

Allegations Against the APA

The plaintiffs’ complaint asserts that the criteria in the DSM are so numerous and subjective that even a normal child exhibiting any number of normal childhood behaviors could be diagnosed with ADHD.

The plaintiffs assert that the APA deliberately allowed Novartis to participate in drafting the DSM criteria because of financial self-interest on the part of APA members — namely, the psychological field would benefit financially with more diagnoses and more prescriptions of Ritalin.

Allegations Against CHADD

The plaintiffs’ complaint states that CHADD has received significant financial donations from Novartis. Indeed, according to the Drug Enforcement Administration, the relationship between the drug manufacturer and CHADD “raises serious concerns about CHADD’s motive in proselytizing the use of Ritalin.”

The plaintiffs contend that the financial relationship between CHADD and Novartis explains why CHADD promotes not only the “disease” of ADHD, but also the use of Ritalin specifically. Thus, CHADD has allegedly aided Novartis by helping to boost profits from the sale of Ritalin.

The Great Debate and the Future

Since the Texas lawsuit was filed, similar suits have appeared in California and New Jersey. In California, for example, teenager Todd Vess and his mother filed a class action suit, charging Novartis and the APA with creating medical diagnoses, promoting Ritalin as the best remedy for those conditions, and failing to disclose Ritalin’s risks. The new lawsuits arise amidst a growing nationwide debate among parents, teachers, and physicians over Ritalin use. The main question is whether Ritalin is appropriately prescribed or overprescribed for children, especially those in preschool, who exhibit ADHD symptoms.

What troubles Dr. Daniel Borenstein, the APA president, the most about these lawsuits is that “they will discourage the families of children and others who need psychiatric treatment from seeking help.” Dr. Pasquale Accardo echoes this sentiment: “Parents are terrified of medicating their children, and their fears have been heightened by the recent flap over the widespread use of psychotropic drugs in preschoolers.”

Additionally, Dr. Borenstein refutes the allegation that the APA “created” the disease as a part of a conspiracy with Novartis. He comments that “as early as the 1930s physicians had discovered that stimulant medications were helpful to children” with certain behavioral problems. Thus, he feels that “the psychiatric community was aware of the therapeutic benefits of stimulant medications and was using them before ADD or ADHD appeared in any version of the DSM. This is hardly any APA conspiracy with a pharmaceutical firm.”

Others argue that the real problem is misdiagnosis, not a conspiracy between Novartis and the APA. Indeed, Dr. Elizabeth Berger, a pediatric psychiatrist, believes that a large number of children are diagnosed and taking Ritalin, but do not have the right diagnosis and should not be taking the medication. The Clinical Practice Guidelines for the diagnosis of ADHD, given by the American Academy of Pediatrics,
affirms the attitude of most physicians that ADHD is a complicated condition that should be diagnosed only after a very thorough evaluation of the child's home, school, and social life. In the era of managed care, however, physicians and nurses must make quick diagnoses and prescriptions, often to the detriment of a thorough evaluation.

Funding from drug companies to professional associations, non-profit organizations, and even doctors has become commonplace in the medical field. What are the effects of these monetary relationships on the practice of medicine? This question will no doubt be a matter of major scrutiny in Hernandez and other pending lawsuits.

Iris Lan

References

2. Ciba-Geigy Corporation was the primary Ritalin maker and supplier in the United States from approximately 1955 through 1995. The merger of Ciba-Geigy with Sandoz created Novartis Pharmaceuticals Corporation in 1996. Since 1996, Novartis has been the drug's sole manufacturer and American supplier.
3. CHADD is an unincorporated and non-profit association that currently provides information for parents with children with ADHD and adults with the disorder.
5. id.
6. The plaintiffs must show that the defendants had a culpable state of mind called “scienter.” According to the Restatement (Second) of Torts § 526 (1979), a defendant acts with scienter if he (1) knew or believed that he was not telling the truth; (2) did not have the confidence in the accuracy of his statement that he stated or implied that he did; or (3) knew that he did not have the grounds for a statement that he stated or implied that he did.
7. Thus, the plaintiffs must show that they relied on the misrepresentation and that their reliance was justifiable.
8. Restatement (Second) of Torts § 525 (1979).
9. However, if the defendant simply fails to disclose a material fact, it is harder for the plaintiff to establish the requisite misrepresentation. In courts that follow the Restatement (Second) of Torts § 551 (1979), the general rule remains that there is almost never a misrepresentation when a plaintiff merely fails to disclose. Exceptions include matters that must be disclosed because of a fiduciary relationship.
10. The complaint does not indicate how much money was spent.
11. Hernandez and Butler also claim that Novartis continually misrepresented the efficacy of Ritalin, leading them to believe that using the drug would improve academic performance. Hernandez, supra note 4.
12. More specifically, the plaintiffs listed cardiovascular problems ranging from palpitations to cardiac arrest; central nervous system problems ranging from agitation and irritability to psychosis with hallucinations and depression; and gastrointestinal problems ranging from mild ailments to vomiting and nausea.
14. The actual donation amount may be in dispute, but the plaintiffs' complaint states that $748,000 was donated from 1991 to 1994. Id.
16. The plaintiff filed the class action suit in the U.S. District Court for the Southern District of California. He seeks to represent all California residents who used or purchased Ritalin. Notably, this plaintiff also brought a claim under the California Consumer Legal Remedies Act, Civil Code Section 1750, claiming that the defendants engaged in proscribed competitive practices. The plaintiff also alleged that the defendants' misrepresentation of material facts concerning Ritalin and the failure to disclose risk-related information constitute deception under the Act. Vess v. Ciba-Geigy Corp. (S.D. Cal. [No. 00 CV 1839], filed September 13, 2000).

EM TALA: Duty Extends to Even Non-transferring Emergency Patients

In Harry v. Marchant, the U.S. Court of Appeals for the Eleventh Circuit held that the Emergency Medical Treatment and Active Labor Act (EM TALA) requires screening patients for medical emergencies and providing stabilizing treatment whether the patient will be transferred to another hospital or not. The appellant represents the decedent, who received emergency care from and was admitted to the appellee hospital. The appellant brought an action under EM TALA, 42 U.S.C. § 1395ddd, against the hospital's medical staff and the hospital for failure to screen the decedent for a medical emergency and for failure to stabilize the decedent. The appellant also brought a claim of race discrimination under 42 U.S.C. § 1981, which the court sustained because the appellant alleged sufficient facts to support the claim. Congress enacted EM TALA to protect patients from being transferred from one emergency room to another because of their inability to pay. Under EM TALA, the hospital is required to stabilize emergency room patients before transferring them to another hospital. "Patient dumping" occurs when a hospital refuses to "examine or to treat" emergency room patients because they are unable to pay. The hospital dumps the patients by transferring them to another hospital without having screened or treated the patient — thereby putting financial and medical responsibility on the next hospital. EM TALA prevents this by requiring hospitals to examine and stabilize an emergency room patient before transferring him or her to another hospital.

Not a Malpractice Claim

The decedent was brought to the hospital for emergency care. Although a recommended screening test was not available, the doctors were able to determine that the decedent faced a medical emer-
The decedent was diagnosed with a medical emergency that required her to be admitted to the intensive care unit where her condition worsened. The hospital and medical staff determined that the decedent had an emergency condition and admitted her to the intensive care unit where her condition was diagnosed. Their actions to stabilize the decedent's condition, as required by EMTALA, was not intended to “ensure ... a correct diagnosis.” The hospital and medical staff did determine that the decedent had an emergency condition and admitted her to the intensive care unit where her condition was diagnosed. Their actions thus precluded a claim for failure to provide “appropriate medical screening.”

Duty to Stabilize All Patients

The court disagreed, holding that “EMTALA was not intended to substitute for a state malpractice claim.” EMTALA requires an “appropriate medical screening examination” and is not intended to “ensure a correct diagnosis.” The hospital and medical staff did determine that the decedent had an emergency condition and admitted her to the intensive care unit where her condition was diagnosed. Their actions thus precluded a claim for failure to provide “appropriate medical screening.”

The court argued that the requirement to stabilize under EMTALA only applies to patients being transferred or admitted and that patients receive appropriate emergency care by requiring hospitals not only to screen for medical emergencies, but also to treat them so that their conditions do not further deteriorate. This duty to stabilize emergency medical conditions applies regardless of whether a patient will be transferred or admitted to the hospital providing the initial emergency care.

Sabre B. Kaszynski

References

2. See id. at *22. The plaintiff alleged facts to support the following: “(1) the plaintiff is a member of a racial minority, (2) an intent to discriminate on the basis of race by the defendant; and (3) the discrimination concerns one or more of the activities enumerated in the statute” (citations omitted).
3. See id. at *5.
6. 42 U.S.C. §§ 1395dd(a), (b).
7. See id. § 1395dd(a).
9. See id. at *10.
10. See id. at *11.
11. See id. at *12.
12. See id. at *11–12; 42 U.S.C. § 1395dd(a).
15. See id. at *18.
16. See id. at *20; 42 U.S.C. § 1395dd(b).

Research Guidelines: Changes Urged

On December 19, 2000, the National Bioethics Advisory Commission issued a draft report calling for a drastic overhaul of the federal protection granted to human research subjects. In the document, Ethical and Policy Issues in Research Involving Human Participants (hereinafter Research Involving Human Participants), the Commission argues for the creation of a centralized National Office of Human Research Oversight to supervise all federal and private clinical studies. This agency would replace the current web of “complex and sometimes overlapping, but often incomplete” regulations known as the Common Rule. These current regulations apply only to research conducted by government departments, whereas the report proposes the first federal guidelines for human research conducted at private institutions.

The Commission also recommends that the types of regulated research be increased and that the funds earmarked for oversight of research on human subjects be significantly expanded. These proposed changes are the product of more than six years of study stemming from the negative publicity surrounding the government’s 1994 admission that it had earlier exposed unknowing subjects to radioactive materials.

The federal government’s investigation of its own human research practices began in earnest in 1994 with the establishment of the Advisory Committee on Human Radiation Experiments. The Committee was charged with investigating reports of unethical Cold War era radiation experiments on humans, including “the injection of plutonium into unsuspecting hospital patients.” The Committee was also asked to assess the state of current protections for research participants.

The Committee found “evidence of serious deficiencies” in the existing regulatory framework. Among the most disturbing features of the research studies were that patients were often misled about the impact that research participation might have on their lives and that some patients with grave illnesses appeared to have harbored unrealistic expectations about the benefits of being subjects in the research. The Committee also noted the existence of extensive confusion among human research participants, who were often unsure whether they were involved in research or therapy.

Shortly after the publication of these conclusions, in October 1995, President Clinton created the National Office of Human Radiation Experiments.
Bioethics Advisory Commission to address ongoing concerns. The Commission’s Research Involving Human Participants follows up on a 1997 report that dwelled on the extent to which federal agencies found the Common Rule confusing. The earlier document noted that federal protections are often difficult to enforce and improve effectively because there is no single authority or office overseeing research protections uniformly across all government agencies and departments. The Common Rule is actually shorthand for fifteen different sets of regulations governing the sixteen federal departments and agencies that conduct research using human participants. Any change to current rules entails rewriting these fifteen different sets of regulations; thus, the Common Rule is extremely difficult to amend.

This inflexibility makes it nearly impossible for the Common Rule to be adapted to meet emerging ethical and scientific issues. For example, research involving xenotransplantation and community-based research are not easily extrapolated from the current, highly inflexible regulations. Other significant effects of this rigidity are the failures of the Common Rule to protect the specialized needs of “vulnerable groups,” including “pregnant women, prisoners, and children.” Instead, individual agencies are often compelled to issue their own guidelines — measures that “promote inconsistency and undermine the very unification the Common Rule was supposed to establish.” The Commission’s report argues that replacing the rigid Common Rule with a centralized National Office of Human Research Oversight would prevent such inconsistencies, while still leaving some latitude for individual “education, monitoring and enforcement policies” at the agency level.

While past Commission reports have confined themselves to addressing the manner in which the federal government conducts research, Research Involving Human Participants addresses for the first time the need for the protection of human subjects in studies conducted at private hospitals and universities. However, this call for an expansion of the scope of regulated research comes alongside another for an increased emphasis on education and fewer large-scale government enforcement actions. The Commission, in effect, argues for “a vastly expanded role for the research community as a whole to implement self-regulation through non-federal credentialing organizations.” Among the diverse groups called to arms are many segments of the medical community “often marginalized in the protection of research participants,” including journal editors, professional societies, and patient advocacy groups. Although the Commission does not have actual regulatory authority in this area, Executive Director Eric M. Esin noted that the final report would be sent to the President of the United States for approval and action. Both federal agencies and private sector institutions objecting to the plan will have until May to voice their concerns.

Although the vast majority of the Commission’s study addresses issues of regulatory structure, the document concludes that the principal obstacle to effective oversight of research on human subjects is a shortage of resources. Of the sixteen federal agencies conducting human subjects research, five cannot afford to allocate even one staff member to human protection. Similarly, in one private-sector trial cited in the report, fewer than three full-time staff were assigned to support 1,700 protocols a year. According to the study, most departments spend less than 2 percent of their research budgets on the protection of subjects, while the National Institutes of Health spent less than 0.5 percent of its human research budget last year on activities aimed at protecting patients. “The existing system cannot be expected to operate effectively without adequate resources,” the report concluded. “It will require an infusion of both human and financial resources at every level.”

Jacob M. Appel

References
2. Id.
4. Id.
5. Id.
7. Id.
8. Id.
9. Id.
12. Id.
13. Id.

Insurance: Exclusion of Contraception Found Discriminatory by EEOC

On December 14, 2000, the U.S. Equal Employment Opportunity Commission (EEOC) found that the exclusion of prescription contraceptives from a health insurance plan is a violation of Title VII of the Civil Rights Act of 1964, as amended by the 1978 Pregnancy Discrimination Act.

Factual Summary
Two registered nurses filed charges with the EEOC, claiming that their employers engaged in unlawful employment practices. The plaintiffs alleged that while the employers’ health insurance plan covered numerous medical treatments and services, the plans excluded...
coverage for “prescription contraceptive drugs and devices... used for birth control or for other medical purposes.”

Both nurses charged that this lack of coverage amounted to sex and pregnancy discrimination in violation of Title VII.

Ultimately, the EEOC agreed that the plan’s coverage was discriminatory on the basis of the plain language of the statute, its interpretation of congressional intent, and prior U.S. Supreme Court rulings. The EEOC noted that the Pregnancy Discrimination Act “explicitly require[d] equal treatment of women ‘affected by pregnancy, childbirth, or related medical conditions.’”

The EEOC relied on the Supreme Court’s ruling in Int’l Union, UAW v. Johnson Controls, which found that the Pregnancy Discrimination Act covers not only a woman’s pregnancy, but also her potential pregnancy. The EEOC, therefore, found it to be discriminatory to prohibit a woman’s use of contraceptives. As oral contraceptives are only used by women, the exclusion of coverage was deemed sex discrimination.

The EEOC also noted that Congress had enacted a specific statutory exemption for abortion and that the absence of an exemption for contraceptives was proof that Congress did not mean to limit the applicability of the Pregnancy Discrimination Act to contraception.

The respondents, in rebutting the claims that their health plan violated Title VII, argued that (1) the plan covers only “abnormal” conditions; (2) the claims are preempted by ERISA; and (3) there is a legitimate cost defense. However, the EEOC rejected the “abnormal” conditions argument for two reasons.

First, pregnancy can be a medical condition that poses both risks and consequences to a woman’s health. Therefore, it could be included in an “abnormal” conditions category. Second, the EEOC did not agree that this categorization of the plan was correct, as the plan covers Viagra whether or not an individual has been diagnosed as impotent.

The EEOC also found that ERISA “explicitly exempts federal law from preemption.” Thus, federal antidiscrimination law would not be preempted. Lastly, the EEOC found the argument that prescription contraceptives were excluded for cost reasons invalid. In passing the Pregnancy Discrimination Act, Congress specifically recognized that employers may incur significant cost. Regardless, it chose not to write a defense based on cost into the law.

Therefore, the EEOC held that “[r]espondents may not discriminate in their health insurance plan by denying benefits for prescription contraceptives when they provide benefits for comparable drugs and devices.” However, limiting the coverage of contraceptives is allowed when similar limits are placed on the coverage of comparable drugs or services.

As the decision indicates a finding of reasonable cause, the two charging parties are entitled to both future costs and back pay for prescription contraceptives. In an attempt to resolve the remaining dispute over cognizable damages, the charges were returned to the appropriate EEOC district office, although the parties may still pursue the claims in federal court.

Decision Ramifications
The EEOC’s ruling only applies to the two women who initially filed charges. While not binding, agency opinions still carry weight in court. For this reason, employers fear that the decision may result in widespread litigation by women with health insurance plans that exclude prescription contraceptives. Alternately, groups such as the National Women’s Law Center laud the decision for precisely the same reason.

The National Women’s Law Center hopes that the EEOC’s decision will not only encourage more women to bring suits, but also that the decision will aid cases already pending. One such case, Erickson v. Bartell Drug Co., is the first suit to assert a violation of Title VII because of an employer’s exclusion of prescription contraceptives in its employee health plan. The case is currently pending in a Seattle federal court. The National Women’s Law Center and similar groups applauded the EEOC’s recognition that challenges on disparate impact grounds would be viable.

Business groups worry about the cost ramifications of the EEOC ruling. The decision has the potential to be an added burden on companies already struggling to deal with soaring healthcare premiums. An increase in premiums of “between 10% and 30% is expected for next year.”

Others have noted their surprise in the EEOC’s application of the Pregnancy Discrimination Act. William Kilberg, a partner with the Washington law firm of Gibson, Dunn & Crutcher, found the Act’s application in this case to be “a real stretch.”

Concluding Remarks
Thirteen states have already passed legislation that mandates coverage of contraception where a health plan covers other prescription drugs or devices. Insurance plans offered to federal employees must also meet requirements similar to those codified in these states.

Thus, the EEOC’s decision is indicative of the emerging application of antidiscrimination laws to the scope of contraception in health plans. Other pertinent parallels include recent cases that have interpreted the Americans with Disabilities Act to apply to benefit plans and cases that have used the Age Discrimination in Employment Act of 1967 (ADEA) to apply to retired employee health benefits.

Regardless of the result of pending cases, one thing is clear: Health plans and employers will continue to face increased litigation pressure as the plaintiff’s bar continues to unleash new legal theories based on the application of antidiscrimination laws.

Wendy Netter
References


2. While the EEOC typically determines in specific cases at the local level, some exceptions to the Commission's authority, such as discrimination based on age, religious beliefs, or sex, are within the purview of Title VII.

3. Medical treatment and services that were covered included prescription drugs, vaccinations, and "preventative medical care." One cannot name a few.

4. Medical treatment and services that were covered included prescription drugs, vaccinations, and "preventative medical care." One cannot name a few.


8. Decision on Coverage of Contraception, supra note 5, at 199, 211.


10. Decision on Coverage of Contraception, supra note 5.


14. Id.

15. Decision on Coverage of Contraception, supra note 5, at footnote 3.

16. Decision on Coverage of Contraception, supra note 5.


19. The Third Circuit Court of Appeals in Erie County Retiree Association v. County of Erie, Pa., 220 F.3d 193 (3rd Cir. 2000), surprised both attorneys and health benefits experts by holding that it was a violation of the Age Discrimination in Employment Act of 1967 to offer different benefits, terms, and conditions to Medicare-eligible retirees because of their age without meeting the "equal benefit or equal cost" standard. Health industry experts say the ruling "would be the death knell for retiree benefits" if it were to be upheld.


The "Stark" provisions were first introduced by U.S. Representative Fortney Stark (D-CA) as part of the Omnibus Budget Reconciliation Act of 1989 (hereinafter O BRA 1989). They are referred to as the Stark I provisions. They limited their scope to prohibiting physician referrals of Medicare patients to clinical laboratories where the physicians had a financial interest.

Stark II, as part of O BRA 1993, expanded the scope of the Stark I provisions to prohibit prohibited physician referrals of both Medicare and Medicaid patients for "designated health services" in which the physician or an immediate family member received a financial interest in the entity providing the services. Stark II also prohibits physicians from being compensated based on the volume or value of their referrals.

The Health Care Financing Administration (HCFA) issued a proposed rule to the Stark provisions on January 9, 1998 to provide further guidance in the interpretation of those provisions. On January 4, 2001, HCFA also published the first part (Phase I) of a two-part final rule.

Phase I provisions will be effective on January 4, 2002, after HCFA integrates and considers comments received by the public. In the meantime, the U.S. Department of Justice stated that it will continue to pursue alleged self-referral violations as a basis for False Claims Act cases.

The Department of Justice's aggressive stance has been criticized, as Bill Sarraile of Arent Fox Kintner Plotkin & Kahn in Washington, D.C., argues that HCFA has instituted "substantial changes" to the original statute passed by Congress. However, others argue that the department must take some action during the confusing intermission time between when the "new" provisions take effect in January 2002 and the preexisting provisions effective since 1995.

In addition to the Stark II prohibitions, Congress had enacted the Federal Health Care Program Anti-Kickback Statute that "applies to those who knowingly and willfully offer, pay, solicit, or receive remuneration to induce the furnishing of items or services under Medicare or State health care programs (including Medicaid). . . . Under this statute, Congress requires the Department of Health and Human Services to define "safe harbors," specifying those payment practices that will not be subject to criminal prosecution." Under the new statute, the physician's intent is important in determining whether the anti-kickback law has been violated, in contrast with Stark II prohibitions that ban certain referrals and payments regardless of intent. Furthermore, the Stark provisions prohibit only referrals to entities where the physician has a financial interest in "designated health services"; those not defined as such are not prohibited. Penalties for violating Stark prohibitions include being excluded as a provider from Medicare and Medicaid programs, denial of payment for referrals, and civil fines.

HCFA delineates numerous exceptions to the Stark II prohibitions, in part reflecting the medical community's criticisms that the original statute did not reflect the realities of medical practice. First, in-office ancillary services, such as x-rays and physical therapy, are exempted as long as they are provided by the physician or another employee in the "same office" under the physician's direct supervision. Second, HCFA reverses the requirement that group practices "treat costs and revenues not as a basis for False Claims Act cases." The Department of Justice's aggressive stance has been criticized, as Bill Sarraile of Arent Fox Kintner Plotkin & Kahn in Washington, D.C., argues that HCFA has instituted "substantial changes" to the original statute passed by Congress. However, others argue that the department must take some action during the confusing intermission time between when the "new" provisions take effect in January 2002 and the preexisting provisions effective since 1995.
stipulating a $25 cap on a single gift, but no maximum aggregate amount.17

The Stark II statute has been seen as “one of the government’s strongest weapons to combat perceived health care fraud,” in a new “compliance-sensitive, zero-tolerance fraud environment.”18 In turn, HCF A responded to criticisms that medicine could not be constrained by “cookie-cutter” regulations — the trend imposed by health-care organizations of modern times, such as the use of Diagnosis Related Groups (DRGs) to determine compensation — by giving physicians more discretion in determining the care of their patients. Although many still argue that HCF A’s provisions decrease the power of the statute, the final rule is consistent with the current trends of the health-care system in limiting physician autonomy.

Betty Pang

References


2. The Stark Law defines "referral" as "the request by a physician for an item or service for which payment may be made under Part B [of Medicare], including the request for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician) ... [and including] the request or establishment of a plan of care by a physician that includes the provision of a designated health service." See Epstein Becker & Green, P.C., "Proposed Stark II Regulations and Advisory Opinion Process: HCF A Seeking Public Comment on a Wide Range of Unanswered Questions" (visited March 19, 2001) <http://www.eblaw.com/article_321.html> [hereinafter cited as "Proposed Stark II Regulations"].

3. A financial interest includes ownership, investment, or another compensation relationship with the entity providing the services. See "Ban on Physician Self-Referrals," supra note 1.

4. "Designated health services" include clinical laboratory services (Stark I); physical therapy services; occupational therapy services; radiology therapy services; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Id.

5. As defined by HCF A, an "immediate family member" is a spouse; natural or adoptive parent, child, or sibling; those related by marriage (e.g., stepbrother or father-in-law); grandparent or grandchild; or a spouse of a grandparent or grandchild. See id.


7. This is true for all of the provisions except those involving physician referrals to home health agencies, which become effective on February 5, 2001. Id.

8. HCF A will be accepting these comments until April 4, 2001. See id.

9. The preexisting statutory provisions have been effective since January 1, 1995, when Congress first enacted Stark II as law. HCF A issued a proposed rule on January 9, 1998 to provide guidance concerning compliance with the provisions, but this is not binding until the final rule is promulgated in 2002. This proposed rule was published in the Federal Register (1624–1728). See "Ban on Physician Self-Referral," supra note 1.

10. Id.


13. See id.

14. This is often referred to as the physician group practice exemption. A "physician group practice" is defined as a group where two or more physicians are legally organized and recognized as a business entity, with a single corporate or federal tax number and/or Medicare billing number, with shared space, billing, staff, equipment, and facilities. These group practices also meet other strict requirements as defined by HCF A to be exempted from the statute. See "Ban on Physician Self-Referrals," supra note 1.

15. HCF A specifically states that buildings that are connected by tunnels or are within the same complex do not constitute the "same office." See Harris, supra note 6.

16. See Harris, supra note 6.

17. Id.


Bioethics: Court Strikes Down Arizona Ban on Fetal Tissue Experiments

On December 29, 2000, the Ninth Circuit affirmed the Arizona District Court’s decision in Forbes v. Napolitano to strike down Arizona’s ban on fetal tissue research.1 Arizona’s law banning fetal tissue experimentation dates back to 1975 and is the last such state restriction in the country to fall.2 The Ninth Circuit wrote that the law was unconstitutionally vague — the same basis used to strike down fetal tissue research bans in three other federal circuits.3

The Arizona law prohibited experimentation or investigation involving fetal tissue from induced abortions. Physicians who violated the law were subject to eighteen months in prison and fines of up to $150,000, as well as revocation of their licenses.4 The law provided exceptions for routine pathological exams to determine the cause necessitating the abortion.5

The initial suit was brought by patients suffering from Parkinson’s disease and doctors in Arizona who feared prosecution for performing services for their patients. They were assisted in the litigation by the Center for Reproductive Law and Policy. According to the plaintiffs, experts believe that transplants of fetal brain tissue into those suffering from Parkinson’s disease offer promising avenues for treatment.6 Fetal tissue transplants give these patients cause for hope because the cells can change their shape to conform to the transplant environment where, in the case of Parkinson’s disease, they assume the functions of destroyed cells. This is the same method by which fetal tissue is purported to slow or eliminate other diseases. Fetal cells are preferable to adult cells because they are less likely to be rejected by the host and, more
practically, because adult donation is necessarily minimal. Medical experts believe that fetal tissue from elective abortions is superior to tissue from ectopic pregnancies or miscarriages because they are more likely to contain healthy cells. In Forbes, the plaintiff doctors declared that they were unwilling to perform fetal tissue transplants into their Parkinson’s disease patients because they feared prosecution. To bolster their case for allowing fetal tissue research, the doctors cited other beneficial uses of the research, such as the development of the polio vaccine. One plaintiff doctor had been the subject of an investigation several years ago when he attempted to study the effects of a particular drug in women who had had abortions. The doctor was a specialist in fertility treatments. Although the investigation was dismissed, the doctor stated that he was still uncertain about the proper interpretation of the ban as applied to his situation.

The legal framework under which the case was decided stems from the Fourteenth Amendment’s prohibition on any state’s attempt to “deprive any person of life, liberty, or property, without due process of law,” which provides for fair notice of whether one’s actions will not be permitted under the law. The court found that not all uses of fetal tissue were outlawed under the statute, but that doctors did not have fair notice about which uses were legal. Although statutes need not be written with “mathematical precision,” they “must be intelligible, defining a ‘core’ of proscribed conduct that allows people to understand whether their actions will result in adverse consequences.”

The court also decided that the Arizona law banning fetal tissue research was unconstitutionally vague because it failed to properly define the terms “investigation,” “experimentation,” and “routine.” The court wrote: “Under the Arizona statute, doctors might undertake a procedure involving fetal tissue that they consider to be primarily therapeutic, perhaps even routine, but under the statute, the state might consider such a procedure illegal. The distinction between experiment and treatment in the use of fetal tissue is indeterminate...”

Other circuit courts have held similarly. Statutes in Utah and Louisiana prohibiting “experimentation” on “live unborn children” or post-abortion fetal tissue were said to be unconstitutionally vague. The terms “experimentation” and “therapeutic” in an Illinois law were also deemed vague in a statute that prohibited experimentation on human fetuses unless the activity was therapeutic. The Arizona Attorney General’s office argued that the ban in Arizona should not be similarly struck down because the other states’ statutes did not specifically refer to only post-abortion fetal tissue, but the Ninth Circuit found that the terms were vague in reference to any fetal tissue.

Judge Sneed, concurring, wrote that fetal tissue research holds promise for advances in medical technology, such as safer abortion methods and improved diagnostic tests. He wrote that the statute was part of the regulation of abortion; therefore, it could only withstand constitutional scrutiny if it furthered a compelling state interest. In his analysis, he found no compelling state interest; thus, the statute was unconstitutional.

Political Undercurrents
Because of the link between abortion and fetal tissue research, as discussed by Judge Sneed, fetal tissue research has been a political hot button. Federal funding for fetal tissue research was banned in the Reagan and Bush administrations, but one of the Clinton administration’s first acts was to lift that ban by executive order on the twentieth anniversary of Roe v. Wade.

The current President Bush, when asked about his view on fetal tissue research in his first week of office, said “I’ll deal with that issue later.” While a candidate, however, President Bush did pledge to oppose federally funded fetal tissue research.

Pro-life supporters also oppose the research due to its link with the performance of abortions. The National Right to Life Committee ran campaign ads against U.S. Senator John McCain during his presidential bid, citing his support for fetal tissue research as an affront to the unborn.

Supporters of fetal tissue research point to a 1997 General Accounting Office study that says that guidelines about fetal tissue research help separate the tissue donation issue from the initial decision to abort. The study reported that donating women may not decide who will receive the tissue and that payments to donating women are illegal. Former director of the National Institutes of Health, Harold Varmus, has said that studies with embryonic and fetal tissue constitute “research that all leading medical authorities agree offer tremendous promise in the next decade or two for treating cancer and diabetes and neurological disorders.”

In Nebraska, the debate over fetal tissue research has recently become heated. After it was revealed that the University of Nebraska was using fetal tissue from induced abortions to research Parkinson’s disease, Alzheimer’s disease, and AIDS-related dementia, a bill was introduced in the last session of the Nebraska legislature to ban the use of fetal tissue. While its sponsor eventually withdrew that bill, it is expected that several new bills will be introduced in the new term. Supporters of the ban believe that they are one vote away from having enough legislators to terminate a filibuster on the bills.

The new secretary of the Department of Health and Human Services, Tommy Thompson of Wisconsin, has drawn fire from pro-life organizations for his support of stem cell research at the University of Wisconsin. Based on his stance on stem cell research, the president of the American Life League commented: “We don’t believe he is pro-life, or should be con-
firmed." Stem cell research, however, differs from fetal tissue research. Stem cells are typically harvested from destroyed embryos, not aborted fetuses. This distinction may be irrelevant to those who believe that life begins at conception and, therefore, either procedure involves killing human life. However, because only fetal tissue research requires actual abortions of implanted fetuses, the distinction may be determinative in reaching a compromise in the heated abortion debate. Furthermore, stem cell and fetal tissue research have traditionally been governed by different rules. While federal funding of fetal tissue research was permitted under the Clinton administration, funding for stem cell research was forbidden. Quite recently, the National Institutes of Health decided to permit federal funding of stem cell research if the federal funds were not used in any part of embryo destruction.

The Bush administration seems likely to withdraw federal funds from both the stem cell and fetal tissue research arenas. The recent Ninth Circuit decision, however, will still have a powerful impact, since the decision prevents Arizona from prosecuting for fetal tissue research at public and private facilities. Thus, while the federal government can withhold public funds, private funds can still be used to pursue therapies for disease treatment without fear of prosecution.

Arizona legislators could try to rewrite the ban, defining terms more precisely, in an attempt to pass the vagueness test. They could, for example, forbid all testing on any fetal tissue, thereby removing the concern about the word “routine” in the exception for routine pathological examinations. They could also define the line between treatment and experimentation or investigation. However, Louisiana, Illinois, and Utah did not attempt to re-write their fetal tissue research bans after the courts in their jurisdictions declared their laws unconstitutionally vague, and Arizona may follow their inertia.

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References
3. Jane L. v. Bangert, 61 F.3d 1493 (10th Cir. 1995); Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986); Lifchez v. Hargit, 914 F.3d 260 (7th Cir. 1990).
5. Forbes, supra note 1, at 1.
6. Id. at 2.
8. Id., at 1283.
10. Id. at 2.
13. Id. at 2.
14. Id. at 2.
15. Id. at 4.
16. Id. at 4.
17. Id. at 4.
18. Id. at 5.
19. Zion, supra note 7, at 1281.
26. Id. at 9.
28. J. Olson, “Stem-Cell Debate Picks Up: The embryonic material is different from fetal cells, but its use in research raises similar ethical concerns,” Omaha World-Herald, September 17, 2000, at 1A.

Malpractice: Ruling on State-Agent Immunity Overturned in Alabama

On September 1, 2000, the Alabama Supreme Court held that two state-employed medical residents were not entitled to state-agent immunity from malpractice lawsuits after they delivered a baby now affected by a seizure disorder. By finding that state-employed physicians may be sued by their patients, the court retracted its previous decision.

Factual summary

Nearing parturition, plaintiff Christy Lee Johnston arrived on June 29, 1994 at the University of South Alabama Medical Center, a state-owned hospital. Dr. Felicia Stella, a fourth-year resident, and Dr. Scott Striplin, a first-year resident/intern, helped deliver her daughter, Kaytlin Wimpee. As residents in training, both Dr. Stella and Dr. Striplin were working as employees of the state of Alabama.

While in labor, Johnston was given a drug called Pitocin to aid in the delivery process. She claimed that the electronic devices monitoring the fetus indicated that the Pitocin be discontinued. The residents disagreed because they felt there was no evidence of fetal distress. According to Johnston, Dr. Stella initially informed her that a cesarean section was required, and Johnston was moved to a delivery room where such a delivery could be performed. Once there, however, the child was delivered vaginally using a vacuum extractor. Within two hours of her birth, baby Kaytlin began experiencing seizures, which one physician ascribed to “perinatal asphyxia and ischemia,” or suffocation and decrease in the blood supply during birth. Kaytlin presently suffers from a seizure disorder and has motor defects on her left side.

Johnston filed a medical malpractice action against Drs. Stella and Striplin. In particular, she contended that Kaytlin suffered serious injuries because the doctors negligently or wantonly...
failed to perform a Cesarean section. The trial court upheld motions for summary judgment by both doctors because they were immune from suit as state employees engaging in discretionary functions. Johnston and her child, Kaytlin, appealed.

State-Agent Immunity
State immunity involves immunity available to the state in an action against the state itself. In contrast, state-agent immunity is immunity available to individual defendants sued for actions taken on behalf of the state. State immunity is far broader than state-agent immunity because the government cannot be sued without its consent.

In Alabama, state immunity is based on the state’s own constitution and may not be waived by the state legislature or courts. State-agent immunity, on the other hand, is not as sweeping. All acts committed by agents of the state are not immune simply because the agents are authorized by the state to act.

Subsequent Rulings
The Alabama Supreme Court issued its original ruling in Wimpee v. Stella in November 1999. It concluded that physicians paid by the state were entitled to immunity as state agents. However, in June of the following year, the same court in Ex parte Cranman withdrew its previous decision, holding that plaintiffs could bring suit against state-employed doctors if those doctors were not engaged in conduct commonly affiliated with state-agent immunity.

In Cranman, the plaintiff’s deceased son had visited the student health center at his state university ten times without being diagnosed with cancer. The court held that the health center physicians were not entitled to immunity because their conduct in treating the son was not conduct commonly affiliated with state-agent immunity—that is, they are not protected when they act willfully, fraudulently, in bad faith, beyond their authority, or under a mistaken interpretation of the law.

In its final decision, the Alabama Supreme Court recanted its first decision in Wimpee and cited its updated decision in Cranman. The court concluded that Dr. Stella and Dr. Striplin’s treatment of the plaintiff did not fit within any of the categories allowing for state-agent immunity. Despite being state-employed physicians, the two doctors were not immune from liability.

Public Policy Considerations
The question of whether physicians are protected from claims by the doctrine of state-agent immunity raises complicated policy issues. First, since state doctors are no longer immune from malpractice in Alabama and are thereby no longer shielded from liability costs, many physicians may choose to pursue higher paying private-sector jobs.

Second, denial of state-agent immunity might hinder the educational purposes of the university responsible for the training of residents, since the residents could now be held as responsible as seasoned physicians for any mistakes they might make. Doctors that oversee the work of the residents may also be held vicariously liable for the mistakes of their trainees. Lastly, the increased cost to the government resulting from litigation and damages paid to tort victims will probably result in either higher taxes or increased medical care costs in Alabama.

On the other hand, the court’s ruling does hold those at fault responsible for their actions, which may contribute to an increased standard of medical care in state medical enterprises. Allowing state agents full immunity for their actions would eliminate the right to a civil remedy against an individual state-agent defendant. Without a remedy for a possible malfeasance, individuals might be compelled to avoid state health care altogether. Since patients may not always have the opportunity to choose between public and private medical care, holding state-agent physicians liable for their actions would ensure that they exercise proper care during the course of their work.

Thus, considering that health care and well-being in general are prime concerns of both individuals and states, the most recent decision in Wimpee v. Stella will most probably produce beneficial results, despite curtailing physicians’ autonomy.

Neeta Toprani

References
2. Id.
4. Specifically, the court in Cranman determined that the physician is protected by the doctrine of state-agent immunity only when his or her actions involve (1) formulating plans or policies, (2) exercising judgment in the administration of a department or agency of government, or (3) discharging duties imposed by statute, rule, or regulation. Id. at 11.

Evidence: Admissibility of Attorney’s Health Record
In Olszewski v. Bloomberg LP,1 the U.S. District Court for the Southern District of New York vacated an order compelling an attorney to produce his confidential health-care records in his defense against a former client’s claim that he suffered from a mental disorder.2

Samuel Abady was Mary Ann Olszewski’s attorney in a sexual harassment lawsuit against her former employer, Bloomberg LP, and her former manager, Bryan Lewis (“the defendants”). After discovery in that suit was completed, the defendants moved for summary judgment. Despite the court’s reminders to Abady and a four-month delay before the motion was granted, Abady failed to file papers opposing the motion on Olszewski’s behalf. The court granted the unopposed summary judgment motion and entered a default judgment against Olszewski.3
Olszewski moved to quash the default judgment against her on the grounds that Abady was suffering from a mental disorder when he represented her, resulting in his inexcusable neglect. The court denied the motion without prejudice, giving Olszewski additional time to show, through supporting affidavits, that Abady was suffering from a mental disorder, and to further establish that Olszewski had made diligent efforts to monitor the attorney's actions.

Olszewski's new attorney issued a subpoena duces tecum and ad testificandum to Abady, seeking his medical, psychological, and disciplinary records. When Abady failed to produce these records, Olszewski moved to compel his compliance with the subpoena. Abady did not file papers opposing the motion and the court granted a default order. Abady then moved to quash the subpoena on the grounds that his privacy interests protected his health and disciplinary records from discovery.

The court examined Abady's privacy interest in his medical records, noting that the courts have recognized a privacy interest in the confidentiality of medical and mental health records. Additionally, New York state law “specifically provides for a physician-patient privilege of confidentiality.” Abady did not waive this right to confidentiality and, in such circumstances, the court can only compel discovery of confidential records if there is a societal interest in the records which outweighs the individual's privacy interest. Because Olszewski did not advance any societal interest argument, the court did not further examine this question.

The court also implied that if Abady had introduced his physical or mental health as an issue, this may have constituted a waiver of confidentiality.

The court next examined whether Abady could be compelled to produce his disciplinary records. Olszewski requested documents that Abady possessed relative to disciplinary proceedings before the New York Supreme Court, Appellate Division, First Department. The court had earlier rejected Olszewski’s request for discovery of these documents under the New York Judiciary Law § 90(10), which states that all such documents are sealed, private, and confidential.

Olszewski argued that documents in the individual’s possession rather than in the hands of the Disciplinary Committee are not covered by this rule and are therefore discoverable. Rejecting Olszewski’s argument, the court ruled that Abady could not be required to produce the documents if he had not waived his right to confidentiality.

Finally, the court addressed Abady's failure to contest the motion to compel before it was granted. Although Abady filed the motion to quash under Federal Rule of Civil Procedure 60(b)(1), the court instead examined the timing of his motion under Rule 45(c)(3)(A)(iii) because Olszewski’s motion was filed pursuant to Rule 45.

Under Rule 45, the motion to quash or modify a subpoena is within the district court's discretion if it requires discovery of privileged information. Because the subpoena required discovery of confidential information, the court granted Abady's motion to quash even though it was untimely.

This decision will have an impact on the discoverability of medical records, as medical records may not be subpoenaed unless the defendant has waived confidentiality or the defendant has raised the medical issue himself. While it limits the mental health claims that might be successfully brought by disgruntled clients against their former attorneys, it also frees attorneys to seek help for their physical and mental ailments without fearing that any such visit to a doctor might later be used against them without their consent. Ultimately, and most importantly, though, the decision further strengthens the doctor-patient confidentiality rules.

Ruth Miller

References
2. Id. at *14.
5. See id.
6. See id. at *8.
7. See id. at *9.
8. See id. at *10–11.
9. See id. at *12.
12. See id. at *13.
15. See id.

Antitrust: Hospitals may grant C-section privileges only to obstetricians

In County of Tuolumne v. Sonora Community Hospital, the Ninth Circuit held that a hospital's denial of Cesarean section privileges to general family practitioners was neither a federal or state antitrust conspiracy nor tying claims violation. The plaintiffs, Dr. Runte and California’s Tuolumne County, appealed the district court’s grant of summary judgment for the defendants, Sonora Community Hospital and three obstetricians. The plaintiffs alleged that the hospital's credentialing was a violation of the Sherman Act for tying, trade restraint, and conspiracy to boycott.

In 1994, Sonora Community Hospital, a private, non-profit hospital, revised the criteria regarding obtaining Cesarean section privileges when Dr. Runte, a general family practitioner, applied for such privileges. As the hospital was about to adopt the new criteria restricting privileges to Board-certified or Board-eligible obstetricians, Dr. Runte was denied Cesarean section privileges. Despite Dr. Runte’s efforts over the next two years, the hospital officially approved the criteria in 1996.

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The hospital had a policy of providing a physician with privileges only if the Medical Executive Committee, of which two of the three defendant obstetricians were members, and the Governing Board approved. The first step was for the committee to make recommendations to the board. The board, of which none of the defendant obstetricians were members, then made the final decision regarding privileges.

No Conspiracy to Boycott
First, the plaintiffs claimed the defendants engaged in a conspiracy to boycott in violation of Section 1 of the Sherman Act. The court granted summary judgment in the defendants' favor because there was no direct or circumstantial evidence that there was a conspiracy.

The plaintiffs produced a letter written by a defendant obstetrician to the hospital asserting that the "Obstetricians and the Department of Obstetrics and Pediatrics" would reevaluate their relationship with the hospital if the new credentials were not approved. The court found that this was not direct evidence since the letter was signed by only one doctor and there was no indication that the other doctors knew about this "threat." Further, there was no circumstantial evidence of a conspiracy since the hospital had a "plausible and justifiable reason" for establishing new criteria. The hospital's reasons included providing quality care and keeping insurance costs low. Also, the court determined that ample evidence existed to show that approval of the credentials was an independent decision of the board, rather than a conspiracy with the obstetricians.

No Illegal Tying
Additionally, the plaintiffs asserted such behavior constituted an illegal tying arrangement. The plaintiffs alleged that the hospital's obstetric services tied in the Cesarean section privileges, forcing a patient at the hospital who needed a Cesarean section to choose from only the defendant obstetricians. The court found that there was no tying under both a "per se" violation analysis and a "rule of reason" analysis.

Under the per se violation analysis, the court examined whether the defendants had an economic interest in obtaining Cesarean section privileges. In addition, any indirect economic benefits were too attenuated to be considered a per se violation of antitrust laws.

Assessing the situation under a rule of reason analysis, the court held that the plaintiffs' claim did not fail because the privileges only eliminated a single competitor. The court reasoned that a whole class of general family practitioners would be precluded from performing Cesarean sections and conceded that "[a]ntitrust laws apply with equal force in small communities." However, the defendants had a justifiable objective in restricting privileges. The plaintiffs could not show there was a less restrictive, but equally effective, alternative. By balancing both positive and negative effects of such an arrangement, the court concluded that any harm to competition was outweighed by the positive competitive effects of providing quality care.

No Antitrust Claim
The court also examined whether the plaintiff had a valid state antitrust claim. Since the state law was so similar to the federal Sherman Act, the previous analysis was determined to apply to state as well as federal antitrust law. Therefore, the court affirmed the district court's summary judgment on the federal and state antitrust claims.

The holding will allow hospitals to restrict certain privileges without fear of an antitrust violation.

Kate Romanow

References
2. See id. at *3.
3. See id.
4. See id. at *1.
5. See id. at *2
6. See id.
7. See id. at *4.
8. See id.
9. See id. at *6.
10. See id.
11. See id.
12. See id. at *7.
13. See id.
14. See id. at *8.
15. See id.
16. See id.
17. See id.
18. See id.
19. See id. at *9–10.
20. See id.
21. See id.
22. See id.

Malpractice: Damages Limited to Amount that Edicare Paid Out
The Pennsylvania Supreme Court in Moorehead v. Crozer Chester Medical Center held that compensatory damages for medical malpractice are limited to the actual amount paid out by M edicare and private insurance for medical services, rather than the fair and reasonable value of the services.

The decedent, Catherine Baxter, was a former patient at Crozer Chester Medical Center; before she died, she brought a medical malpractice suit after sustaining injuries in a fall at the hospital. At the time of the injury, Baxter was covered by Medicare and a “Blue Cross 65” supplemental plan. The hospital, as a voluntary participant in the Medicare program, accepted the Medicare allowance for the services, totaling $12,167.40. Baxter contended that the hospital should be liable for the sum agreed upon by both parties as the fair and reasonable value of the services required after the fall, $108,668.31. The parties stipulated this sum as part of the “Agreed Upon Statement of Facts Pursuant to Pa. R.A.P.1925.” In spite of the agreement, the hospital maintained that
Baxter was only entitled to the Medicare allowance accepted as full payment for the services.

The court agreed, holding that the agreement was only as to the facts of the case and did not supplant or preclude the court's evaluation of the legal issue of the amount of damages that Baxter was entitled to. The court held that Baxter's compensatory damages for past medical expenses was limited to the $12,167.40 paid by Medicare and accepted by the hospital as payment in full. In support, the court cited Goodhart v. Penn. R.R. Co., which established that a plaintiff may recover only those expenses that have actually been paid or are "reasonably necessary to be incurred." The court determined that in instances where a plaintiff is reasonably expected to continue to incur medical expenses, a finder of fact may determine the amount of damages. In cases in which the amount of the expenses has been pre-determined by contract, however, compensatory damages are limited to the amount paid. Once the pre-determined sum has been satisfied, the amount of expense that the plaintiff will be liable for is no longer an issue. In this instance, awarding $96,500.91 more than the actual amount paid to the hospital would result in a windfall for Baxter.

Additionally, the court held that the collateral source rule did not apply in this case. The rule provides that "payments from a collateral source shall not diminish the damages otherwise recoverable from the wrongdoer." Reasoning that no collateral source was obligated to issue — or, in fact, had issued — an amount that equaled the fair and reasonable value of the medical services in this case, the court ruled that a charge of $96,500.91 was "illusory" and the collateral source rule was inapplicable.

As a state court ruling, the impact of this case is ostensibly limited to Pennsylvania. Whether there are any wider effects depends on the degree to which other jurisdictions adopt the Pennsylvania court's decision. What is clear, however, is that hospitals that fall within this jurisdiction will benefit from the circumscribed liability for compensatory damages. At the same time, it may discourage legitimate plaintiffs from filing medical malpractice claims.

Kate Welti

References
2. The plaintiff, Catherine Baxter, died after commencing suit. Jaynet Moorhead, as administratrix of Baxter's estate, was substituted as the plaintiff. See id. at 378.
3. Id.
4. Id. Medicare paid 80 percent of this figure. Bluecross 65 paid 20 percent. Id.
5. Id.
7. 177 Pa. 1 (1896).
8. See id. at 380.
9. Id.
10. Id.
11. Id.
12. See id. at 381.
13. Id.
14. Id.