

Providing Relief to Those in Pain: A Retrospective on the Scholarship and Impact of the Mayday Project

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Scholarship has intrinsic value, of course; but when good scholarship can stimulate change for the better in an area as fundamental to human dignity as health care and the relief of suffering, there is a special satisfaction. This has been our experience since 1996, when the first of now four special issues of this journal focused on legal, regulatory, ethical, professional, and financial issues in medical treatment for pain.

With the generous and steadfast support of the Mayday Fund, the American Society of Law, Medicine & Ethics (ASLME) has generated a significant body of scholarship published in the *Journal of Law, Medicine & Ethics (JLME)*. This research has proven absolutely essential in changing public policy to support better care for those who suffer pain.

Over these years, the Mayday Project at ASLME has tackled many of the real and perceived barriers to effective pain relief. In pain management, both real and perceived obstacles can have a powerful negative effect. If physicians and health care institutions believe, even wrongly, that they cannot do what needs to be done for their patients — for example, because the providers believe that they will be at risk for discipline or prosecution or because payment will be denied — it seriously decreases the likelihood that patients will receive the care they need. The Mayday Project at ASLME began by listening to health care providers — in surveys, in the literature, and at meetings — talk about why pain is undertreated and what obstacles they experienced in their own practices. The research, then, mapped out the characteristics of these obstacles and always with an eye toward identifying what reflected reality, what was merely perceived, and what could be done in either case to remove barriers to pain relief.

The Mayday-funded research appearing in the four symposia of *JLME* has addressed racial and gender bias and cultural influences in the treatment of pain;¹ payment for medical care for the relief of pain;² the appropriate standards for liability for inadequate care, including criminal prosecution for decisions made in the care of patients at the end of life;³ interprofessional issues, focusing especially on the role of pharmacists;⁴ and, of course, the medical and ethical boundaries of pain management.⁵

The standards, policies, and practices relating to medical licensure and discipline have been a special emphasis of the project and formed the focus of the first symposium issue.⁶ It is in this area that we have seen the greatest change in public policy during the course of the Mayday Project at ASLME.

When we began with the first grants in 1995,⁷ we decided to examine issues in medical licensure and discipline, an obstacle that physicians claimed deterred them from treating their patients in pain most effectively.⁸ The reason we chose that area was in part because it represented a confluence of medical, ethical, and legal issues and thus was well suited to ASLME's strength in providing a forum for interdisciplinary research and education in health care.

Furthermore, the distance between the standards used by the state medical boards at that time and what medical research on the use of controlled substances for relief of chronic pain had revealed was symbolic of so many of the obstacles to effective pain relief. Most medical board members are themselves physicians; and the disconnect between customary medical practice as reflected in the standards applied by the boards and improved research-based practices demonstrated the difficulties and the lag inherent in the diffusion of new clinical knowledge into medical practice. The presumptions and attitudes exhibited by medical board members reflected larger social issues as well. These larger social

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issues included a distrust of patients in pain and, at times, of the physicians who treated them as well as the influence of the national antidrug campaign of the previous decades. As authorities in identifying the appropriate standards for medical practice, the opinions and practices of the medical boards mattered — whether or not the number of physicians actually disciplined was quite small (as was actually the case) or quite large (as was the perception).⁹

Because the boards are dominated by professionals with medical expertise who are committed to improving health care for the public, an approach for reform that focused on changing the standards used by medical boards offered great promise that they would move away from an enforcement system that operated under the influence of the “war on drugs” and saw diversion as the major evil, and move toward a more balanced approach that would prioritize effective pain relief as a central goal of their work in this area. Before that could be done, however, a question had to be answered: Was there really a problem in the policies and practices of the medical boards in relation to physicians who treated patients for pain with controlled substances; or did the doctors simply misunderstand the situation, at best; or, at worst, were they using their expressed fears of medical board action as a scapegoat for other unarticulated reasons motivating their undertreatment of patients in pain?

The first *JLME* symposium on pain relief included the results of research on disciplinary actions against physicians and state intractable pain statutes,¹⁰ as well as a case study of Texas legislation and regulations,¹¹ a state that had taken a leadership role in changing the customary disciplinary practices, and a description of how educational efforts with the state medical boards could effect change.¹² In a later issue, the executive director of a state medical board, one of the first Mayday Scholars, analyzed the ethical issues in treating pain from the perspective of how a state medical board could contribute to improving pain management practices,¹³ and two officers of the American Academy of Pain Management wrote urging a sense of balance in the application of regulatory guidelines and in the use of the intractable pain statutes.¹⁴

Many organizations, including the Pain & Policy Studies Group, the American Pain Society, the American Academy of Pain Management, and others, were working to improve the public policy environment for physicians treating patients in pain. The Mayday Project of the American Society of Law, Medicine & Ethics took a leadership role in this effort. In 1996, the Society’s National Meeting on Legal, Ethical, and Institutional Issues in Pain Relief convened the leadership of each of these groups, government officials from state attorney general offices and the state medical and pharmacy boards, pain patients, patient advocates, practicing physicians, nurses, health care administrators, and pharmacists. The grants supported the attendance of fifty policymakers and patient advocates, and this allowed pharmacists to speak with physicians and nurses; attorneys general to speak with

patient advocates; and medical board leaders to meet directly with the doctors who feared them. The workshops were enlightening, and the people in attendance were in a position to make a change.

The research published in the 1996 *JLME* issue, which followed the national meeting, documented that the standards used by medical boards at that time did not recognize the best practices in pain management and that the processes themselves had a negative impact on care. The issue also included a proposal for the Pain Relief Act.¹⁵ At the time the issue was published, only ten states had statutes that addressed the prescription of controlled substances for the treatment of intractable pain and only six of those addressed the concern of disciplinary action.¹⁶ Only six more states had guidelines or regulations on the subject.¹⁷

The proposed Pain Relief Act departed from the statutes and practices then in effect in significant ways. First, the proposed statute extended coverage beyond physicians to include other health care providers, such as pharmacists, nurses, and physician assistants. The early statutes protected physicians only.¹⁸ Second, the Act required that the state medical board support any decision to discipline a physician with expert testimony proving that the physician violated current national standards in his practice. In most states, medical boards are not required to produce expert testimony to support their decisions in every case.¹⁹ Finally, the proposed statute clearly stated that its protection applied to the care of patients who were chemically dependent. While most of the statutes in existence at that time did not specifically prohibit physicians from treating chemically dependent patients with controlled substances for pain relief, the statutes included a specific limitation relating to the treatment of such patients that was very commonly misunderstood to either prohibit or discourage the treatment of such patients for pain.²⁰

Shortly after the 1996 conference, the Federation of State Medical Boards, which is the national organization of state medical boards,²¹ established a task force to address the standards that medical boards should use in reviewing a physician’s prescribing practices. The Federation included ASLME as a participant in the task force. After several months of work and review, the task force produced new guidelines for state medical boards, which the Federation’s House of Delegates adopted as policy in 1998.²²

The new Model Guidelines for the Use of Controlled Substances for the Treatment of Pain made three very significant policy statements that responded directly to concerns that had been expressed in the published research. First, the Model Guidelines unequivocally stated that “controlled substances, including opioid analgesics, may be essential in the treatment of acute pain ... and chronic pain.” Second, the Model Guidelines stated that the legitimacy of the physician’s treatment of the patient would not be judged by “the quantity and chronicity of prescribing,” as had been the previous prac-

tice and one of the serious problems that had been identified in the Mayday Project research. Finally, like the Pain Relief Act, the Model Guidelines explicitly recognized that physicians may treat chemically dependent patients for pain with controlled substances.

There are always disputes over whether the legislature or the state medical board is in the better position to stimulate positive change in disciplinary standards and processes.²³ After all, legislatures are political bodies, not experts in medicine or professional discipline. On the other hand, medical boards, like other professional entities, can be resistant to departing from well-established custom. There is merit to both of these positions, of course. The balance between them is inherent in the structure of administrative law, with its division of power and roles between legislature and agency. In some cases, the simple threat of legislative action can effect change by stimulating an immediate response on an administrative level. In any case, the shared goal in such an effort, whether structured as statute or agency rule or policy, is to position the boards to bring their standards in line so that physicians in compliance with the best practices in pain management, rather than merely the customary practice of undertreatment in pain management, are safe from disciplinary action.

The number of states with legislation addressing concerns over the risk of discipline for the treatment of patients in pain has more than doubled since 1996. At least twenty-three states now have statutes providing legislative guidance or a mandate for the development of written guidelines on the part of the state medical board in its monitoring of physician prescribing practices in the treatment of pain.²⁴ Almost all of these statutes provide at least physicians with immunity from any disciplinary action that does not fall within the statutorily established boundaries for medical board action.²⁵

The influence of the Pain Relief Act is apparent among the new statutes and amendments passed since 1996. For example, the New Mexico Pain Relief Act, effective in 1999, is nearly identical to the Pain Relief Act as first proposed in *JLME*.²⁶ West Virginia's statute, enacted in 1998, adopts the major provisions of the statute, including coverage that extends to nurses and pharmacists, protection for health care providers who can demonstrate substantial compliance with an "accepted guideline," and a clear statement that physicians may treat chemically dependent individuals with controlled substances for pain relief.²⁷ Nebraska amended its statute in 1999 and extended its coverage to include nurses;²⁸ and Texas amended its statute in 1997 to state that its protections extend to physicians treating chemically dependent patients for pain.²⁹ A few of the new state statutes take a different approach, some of which could cause difficulties. For example, the Ohio statute, enacted in 1997, requires evaluation of the patient by a specialist.³⁰ Such a requirement could operate as a barrier to patients and a discouragement to physicians.

An additional substantial effect is observable in the activity among the medical boards themselves. In 1996, only twelve states had written policies or regulations to govern cases of disciplinary action against physicians for their prescription of controlled substances for patients in pain.³¹ The Pain & Policy Studies Group now reports that at least forty states had adopted policy statements, guidelines, or regulations as of the end of 2002.³² The influence of the Federation's Model Guidelines is clear, as most of these adopt or parallel what was recommended by the Federation, as an article by researchers with the Pain & Policy Studies Group in this issue demonstrates.³³ However, as with the legislation enacted over the past several years, medical board guidelines are not all created equal and the guidelines under which the boards operate vary in quality.³⁴

Enacting even the best legislation or adopting the most effective guidelines or policies does not necessarily mean that there has been any change in practice or attitudes on the part of the regulators. There is always the chance that all the paper in the world won't effect any real change at all. Fortunately, this does not appear to be the case here. Real change in the culture of the medical boards around this issue is documented in Diane Hoffmann and Anita Tarzian's article in this symposium.³⁵

The effort to change public policy toward improving the treatment of patients in pain cannot declare victory at this point. The challenges for public policy in health care generally, and in pain management in particular, are cyclical. New research and emerging practices in the use of opioids for the treatment of chronic noncancer pain changed the fundamental assumptions on which the disciplinary activity of the boards had been based. New learning in regard to pain treatment is bound to create serious gaps again. The resident challenge for medical licensure and discipline is its ability to distinguish "good" doctors from "bad" doctors and to rehabilitate or remove the bad doctors without driving the good doctors into defensive "safe zones" of practice that do not serve patients well.

"Sentinel events" on the national scene can significantly shift the center of emphasis in policymaking as well. For example, when the Pain Relief Act was published and the Federation's Model Guidelines were adopted, Oregon had just enacted the first statute to legalize physician-assisted suicide.³⁶ Rather than making policymakers more fearful of "drugs" and "narcotics" for the treatment of pain, however, the movement to legalize assisted suicide stimulated a nationwide focus among the states on improving the quality of care and pain relief for terminal patients, with a largely beneficial side benefit to patients in chronic pain. This certainly created a policymaking environment on both the legislative and administrative level that was receptive to the Pain Relief Act and to the Model Guidelines. More recently, however, the experience with the abuse of OxyContin threatened to shift the balance away from pain relief and toward severe restriction of access to an effective pain treatment.³⁷

Although central to its activity, the Mayday Project did not focus solely on medical licensure, and neither does this symposium. Like the earlier "Mayday" issues, this issue of *JLME* includes a range of articles in addition to the article on medical boards by Hoffmann and Tarzian. First, David Brushwood examines electronic monitoring systems for prescriptions for controlled substances.³⁸ These systems are in place in some states and are being considered in several others. The question Brushwood addresses is whether these systems will have an adverse or positive effect on the care of patients in pain. Research had indicated that the earlier "triplicate" paper-based prescription monitoring systems resulted in physicians' being hesitant to prescribe controlled substances for their pain patients even when the medications were clinically indicated.

Lars Noah then presents an analysis that explains the interaction between the two federal behemoths in regulating, either directly or indirectly, the availability of effective pain medication.³⁹ He concisely identifies the crux of the public health issues that the Food and Drug Administration and the Drug Enforcement Administration confront and how their definition of their roles determines what they can do.

Next, Stephen Ziegler and Nicholas Lovrich, Jr., have generated new data to respond to physicians' fears of legal penalty for treating patients in pain.⁴⁰ Their survey of local prosecutors in four states taps into the attitudes of the individuals who make the final decision as to whether or not to prosecute.

Finally, Jean Lazarus and Wendy Downing write about the issues presented to boards of nursing as they confront the same concerns about prescribing practices that the medical boards have been confronting.⁴¹ Their focus on the role of monitoring the prescribing practices among nurse practitioners highlights a particular issue in that effort.

The Mayday Project at ASLME has had a significant influence on the debates surrounding treatment of patients in pain because of the publication of the special issues of the *Journal of Law, Medicine & Ethics*. But the impact of the Mayday Project extends further than that of these special issues and will persist even longer. In 1997, the Mayday Project established the Mayday Scholars Program. This program had one primary goal: to create a cadre of scholars in law, ethics, finance, and the social sciences who would turn their considerable talent, creativity, and effort toward the plight of persons in pain. We thought that once individuals of their caliber had spent some substantial time researching a particular issue that negatively affected access to effective pain relief, they would "catch fire" and continue to work in the field. This has certainly been the case. Most of the Mayday Scholars have continued to research and publish on these issues, include them in their teaching, and provide critical expertise and support to individuals and institutions trying to effect change. Several of the Mayday Scholars have undertaken very significant projects with substantial funding to

change current practices within particular states.⁴² It has been a privilege to work with them and to see that there is a deep reserve of expertise and commitment that will continue to improve the situation of persons in pain.

As this issue of the *Journal of Law, Medicine & Ethics* is published, another season of the national pastime has just begun. First base, second, third, and home plate. With this fourth special symposium issue on pain management, the *Journal of Law, Medicine & Ethics*, the American Society of Law, Medicine & Ethics, and the Mayday Fund have reached home plate. Although the Mayday Scholars Program has reached its final year, the Mayday Project at ASLME continues. ASLME, again with the support of the Mayday Fund, will be convening a national conference in 2004 and a fifth special issue of *JLME* will be published, this time with a new emphasis on pain management in the emergency department. It has been a championship season, and we are ready to begin the cycle again.

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7. The first two years of the project were also supported by the Emily Davie and Joseph S. Kornfeld Foundation.

8. F.J. Skelly, “Fear of Sanctions Limits Prescribing of Pain Drugs,” *American Medical News*, August 15, 1994, at 19; R.K. Portenoy, “Opioid Therapy for Chronic Non-Malignant Pain: A Review of the Critical Issues,” *Journal of Pain and Symptom Management*, 11 (1996): 203–17, at 204; New York Public Health Council, *Breaking Down the Barriers to Effective Pain Management, Recommendations to Improve the Assessment and Treatment of Pain in New York State* (January 1998).

9. Johnson, *supra* note 6, at 321.

10. Johnson, *supra* note 6.

11. Ralston, *supra* note 6.

12. Joranson and Gilson, *supra* note 6.

13. Martino, *supra* note 5.

14. Haddox and Aronoff, *supra* note 5.

15. Johnson, *supra* note 6.

16. Hyman, *supra* note 6, at 340.

17. *Id.* at 341.

18. See *id.* at Table 1. As of 1996, California, Missouri, Nevada, North Dakota, Oregon, and Texas had enacted statutes with provisions preventing disciplinary action against physicians and/or osteopathic physicians. None of these statutes provided disciplinary protection for other health care professionals.

19. B. Furrow et al., *Health Law*, Practitioner Treatise Series, 2nd ed. (St. Paul: West Publishing Co. 2000): § 3-23(a).

20. See, e.g., Mo. Rev. Stat. § 334.106 (1995) (“The provisions of ... this section shall not apply to those persons being treated by a physician for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.”). See also N.D. Cent. Code § 19-03.3-05 (1995) (“This chapter does not authorize a physician to prescribe or administer controlled substances to a person the physician knows is using controlled substances for nontherapeutic purposes.”).

21. The Federation of State Medical Boards is composed of medical boards from the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands, and thirteen state boards of osteopathic medicine. Along with the National Board of Medical Examiners, the Federation created and administers uniform testing for medical licensing. The Federation also developed and administers assessment tools for evaluation of ongoing clinical performance and maintains the Federation Data Center, a nationally recognized system for collecting, recording, and distributing to state medical boards and other appropriate agen-

cies data on disciplinary actions taken against physicians and physician assistants by the boards and other governmental authorities. The Federation’s mission is the continual improvement in the quality, safety, and integrity of health care through the development and promotion of high standards for physician licensure and practice. Federation of State Medical Boards, *About Us*, at <http://www.docinfo.org/alp_about_us.htm> (last visited February 7, 2003); Federation of State Medical Boards, *FSMB Facts*, at <<http://www.fsmb.org/aboutus.htm>> (last visited February 7, 2003).

22. Federation of State Medical Boards, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (Euleess, Texas: Federation of State Medical Boards, 1998), available through <<http://www.fsmb.org>>.

23. Federation of State Medical Boards, *Position of the Federation of State Medical Boards in Support of Adoption of Pain Management Guidelines* (Euleess, Texas: Federation of State Medical Boards of the United States, 2000), available at <<http://www.medsch.wisc.edu/painpolicy/domestic/FSMBwp.htm>>. (“The Federation promotes a non-legislative approach in improving the regulation of physicians prescribing controlled substances in the treatment of pain. Legislative action may hinder the appropriate management of pain by physicians through unnecessary requirements and could supplant the authority of state medical boards to improve the quality of care available to patients within their jurisdictions. Thus, state medical boards should be proactive in the promotion of pain management policy initiatives to preclude legislative intervention.”).

24. Ariz. Rev. Stat. § 13-3412.01 (2002); Cal. Bus & Prof Code § 2241.5 (2003); Colo. Rev. Stat. §§ 12-36-117, 18-18-308 (2002); Fla. Stat. § 458.326 (2002); Mass. Gen. Laws ch. 94C § 9 (2003); Mich. Comp. Laws §§ 333.16204a, 333.16204b, 333.16204c, 333.16204d (2002); Minn. Stat. § 152.125 (2002); Mo. Rev. Stat. §§ 334.105–334.107 (2002); Neb. Rev. Stat. §§ 71-2418, 71-2419 (2002); Nev. Rev. Stat. §§ 630.3066, 630.135 (2002); N.H. Rev. Stat. Ann. § 318-B:10 (2002); N.M. Stat. Ann. §§ 24-2D-1 to 24-2D-6 (2002); N.D. Cent. Code §§ 19-03.3-01 to 19-03.3-06 (2002); Ohio Rev. Code Ann. § 4731.052 (2002); Okla. Stat. tit. 63 § 2-551 (2003); Or. Rev. Stat. §§ 127.800–127.897 (2001); R.I. Gen. Laws §§ 5-37.4-1 to 5-37.4-3 (2001); Tenn. Code Ann. §§ 63-6-1101 to 63-6-1109 (2002); Tex. Rev. Civ. Stat. Ann. § 4495c (2002); Va. Code Ann. § 54.1-3408.1 (2002); Wash. Rev. Code § 69.50308 (2002); W. Va. Code §§ 30-3A-1 to 30-3A-4 (2002); Wis. Stat. §§ 961.001 and 961.38 (2002). See also Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, *Data-base of State Laws, Regulations and Other Official Governmental Policies*, at <<http://www.medsch.wisc.edu/painpolicy/matrix.htm>> (last updated November 5, 2002).

25. *Id.* See, e.g., Ohio Rev. Code Ann. § 4731.052 (2001) (“A physician who treats intractable pain by managing it with dangerous drugs is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the physician treated the intractable pain with dangerous drugs. The physician is subject to disciplinary action only if the dangerous drugs are not prescribed, furnished, or administered in accordance with this section and the rules adopted under it.”).

26. Johnson, *supra* note 6; Project on Legal Constraints on Access to Effective Pain Relief, *supra* note 6; N.M. Stat. Ann. §§ 24-2D-1 to 24-2D-6 (2002).

27. W. Va. Code §§ 30-3A-1 to 30-3A-4 (2002).

28. Nebr. Rev. Stat. §§ 71-2418, 71-2419 (2002).

29. Tex. Rev. Civ. Stat. Ann. § 4495c (2002).

30. Ohio Rev. Code Ann. § 4731.052(C) (2002).

31. Hyman, *supra* note 6, at 341.

32. Pain & Policy Studies Group, *supra* note 24.

33. A.M. Gilson, D.E. Joranson, and M.A. Maurer, "Improving State Medical Board Pain Policies: Influence of a Model," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 119-29; See also D.E. Joranson et al., "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," *Journal of Pain and Symptom Management*, 23, no. 2 (2002): 138-47, at 144.

34. *Id.*

35. D.E. Hoffmann and A.J. Tarzian, "Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 21-40.

36. Or. Rev. Stat. §§ 127.800 to 127.897 (1995).

37. Two of the articles in this symposium address the OxyContin issue. See Hoffmann and Tarzian, *supra* note 35; L. Noah, "Challenges in the Federal Regulation of Pain Management Technologies," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 55-74.

38. D.B. Brushwood, "Maximizing the Value of Electronic Prescription Monitoring Programs," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 41-54.

39. Noah, *supra* note 37.

40. S.J. Ziegler and N.P. Lovrich, Jr., "Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief

Prosecutors," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 75-100.

41. J.B. Lazarus and B. Downing, "Monitoring and Investigating Certified Registered Nurse Practitioners in Pain Management," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 101-18.

42. For example, ASLME, Ben Moulton, and Mayday Scholar Diane Hoffmann conducted the Connecticut Statewide Pain Management Study, a two-year project funded by the Donaghue Medical Research Foundation. The purpose of the study was to develop baseline data on the adequacy of pain treatment in the state of Connecticut and to use the data as a basis for generating interventions and recommendations for further research to address the problem of undertreatment of pain in the state. Based on the findings from the Donaghue grant, the following were published: A. Tarzian, S. David, and D. Hoffmann, "Management of Cancer-Related and Noncancer-Related Chronic Pain in Connecticut: Successes and Failures," *Connecticut Medicine*, 66 (2002): 683-89; D. Hoffmann, Z. Lazzarini, and B. Moulton, "Constraints to Prescribing Medications for Pain Treatment in Connecticut: Part I," *The Pain Clinic*, 4 (2002): 28-35; D. Hoffmann and A. Tarzian, "Third Party Reimbursement Practices and Their Influence on Pain Management in Connecticut: Part I," *The Pain Clinic*, 4 (2002): 11-16.

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Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards

Diane E. Hoffmann and Anita J. Tarzian

Uncertainty regarding potential disciplinary action may give physicians pause when considering whether to accept a chronic pain patient or how to treat a patient who may require long-term or high doses of opioids. Surveys have shown that physicians fear potential disciplinary action for prescribing controlled substances and that physicians will, in some cases, inadequately prescribe opioids due to fear of regulatory scrutiny. Prescribing opioids for long-term pain management, particularly noncancer pain management, has been controversial; and boards have investigated and, in some cases, disciplined physicians for such prescribing. While in virtually all of these cases the disciplinary actions were successfully appealed, news of the success was not often as well-publicized as news of the disciplinary actions, leaving some physicians confused about their potential liability when prescribing opioids for pain. The confusion has perhaps increased as a result of two relatively recent cases, one where a physician was successfully disciplined by a state medical board for undertreatment of his patients' pain, and another where the physician was successfully sued for inadequate pain treatment.

In the first case, in September 1999, the Oregon Medical Board disciplined a physician for failure to adequately treat several of his patients for pain. Less than two years later, a California physician was successfully sued for his undertreatment of a patient's pain. These cases reflect a changing attitude toward pain treatment in the United States — a recognition that patients, especially patients at the end of life, have a right to adequate pain treatment. This shift in thinking appears to have begun in the late 1980s. Prior to this time, “according to established medical opinion, the likelihood of addiction to opioids was considered too great

to prescribe them to any patients but those suffering from the most serious pain.”¹ This opinion was conveyed by a number of state medical boards to physicians who were disciplined for prescribing outside of these boundaries. The “sea change” came about “as evidence mounted that patients, especially cancer patients, were being undertreated for their pain, and that addiction was not a significant problem for pain patients with no prior history of substance abuse.”² In response, physicians began to prescribe greater amounts of pain medication. In addition, professional and governmental agencies established clinical guidelines encouraging the appropriate use of opioids in the treatment of cancer pain. Many state legislatures also passed “intractable pain statutes.” These laws “were designed to provide physicians with some assurances by reducing both the real and perceived risks of being subjected to regulatory sanctions for treating pain with controlled substances.”³

Yet, at the same time that these new legal pressures would seem to counteract the pressures to undertreat, a renewed concern about drug diversion, in light of the abuse associated with OxyContin, has taken shape. Evidence of diversion of the medication from legitimate users to addicts has caught the attention of drug and law enforcement agencies that have linked OxyContin to overdose deaths, pharmacy robberies, and other criminal activities related to obtaining the drug. This turn of events has the potential for rekindling the attention of state medical boards and law enforcement agencies toward physician prescribing practices for patients suffering from pain.

In an effort to better understand how state medical boards are evaluating and balancing the need for adequate pain treatment with concerns about drug diversion and inappropriate prescribing, we undertook a survey of state medical boards across the country. This article, after briefly describing the evolution of medical knowledge regarding the treatment of

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pain, the history of efforts to regulate controlled substances used to treat pain, and the literature regarding physician concerns about legal repercussions for prescribing opioids, reports on the results of the survey.

We conclude that boards have made improvements in the way they approach physicians who prescribe large doses of opioids. Greater reliance on pain policies has given many boards clearer criteria for when to investigate and discipline physicians for opioid prescribing violations. The observed improvements involve recognition by most boards that physicians have an obligation to provide adequate pain management to their patients. This recognition has required boards to balance their concerns about opioid overprescribing with their concerns about pain undertreatment. We found, however, that boards appear to be more concerned with violation of standard of care in cases of overtreatment versus undertreatment. Respondents (speaking on behalf of their boards) viewed opioid overprescribing as a clear violation of standard of care *and* a clear example of patient harm, whereas pain undertreatment — particularly for nonmalignant chronic pain — was not so clearly perceived as a standard of care violation, and generally required a higher threshold of harm. We conclude that the boards are still trying to find the right balance between promoting adequate pain management and protecting against opioid diversion and abuse.

THE EVOLUTION OF TREATING PAIN WITH OPIOIDS

Progress in pain management has evolved over the last few decades. Beginning with the hospice movement in the 1960s, and continuing beyond the 1994 guidelines for the management of cancer pain published by the Agency for Health Care Policy & Research, opioids (in combination with other medications) have been identified as the standard treatment for moderate to severe cancer pain. In addition, opioid therapy has been shown to be effective for patients with certain types of chronic nonmalignant pain, without the occurrence of intolerable side-effects or the development of aberrant drug-related behaviors.⁴ Its use in patients with malignant and nonmalignant pain has been shown to improve functional status and quality of life.⁵ Moreover, the consensus among addiction specialists is that substance abuse history per se does not preclude the use of opioids for pain management, but it does mandate careful assessment and monitoring of such patients by a trained pain specialist.⁶

At the same time that these pain management treatment standards have evolved, there have been ongoing efforts to regulate the prescribing of opioids. These efforts began with the passage in 1970 of the Controlled Substances Act and the establishment in 1973 of the Drug Enforcement Agency (DEA). At the federal level, the Controlled Substances Act and the DEA make up the main armaments in the government's efforts to prevent drug abuse. At the state level, there are comparable laws as well as state drug enforcement agencies

and bureaus of narcotics control. Since the 1970s, the government's attitude has shifted in focus, particularly after President Reagan took office, from viewing drug abuse as a public health problem to viewing it as a political, law enforcement, and moral issue.⁷ Although the DEA and other federal laws and policies tend to be less restrictive of physician practices than state laws and enforcement practices, concerns about Medicare and Medicaid fraud and abuse and the government's "war on drugs" have put pressure on state medical boards.⁸ This has resulted in some state boards disciplining physicians for "overprescribing" opioids, including physicians who were treating pain patients.⁹ Thus, in addition to fears that patients will become addicted,¹⁰ and that doses of opioids that are too high will lead to patient deaths,¹¹ physicians avoid prescribing opioids because they believe they may face legal or regulatory sanctions or simply be the target of investigation by licensing boards or other law enforcement agencies.¹² However, research has shown that physicians' fears of legal or regulatory sanctions are more the result of a "chilling effect" than of the actual risk of disciplinary or legal liability they face if they properly prescribe opioids for pain management.¹³

Several physician surveys have provided evidence of the chilling effect of sanctions against physicians for opioid prescribing. In 1990, physician members of the Eastern Cooperative Oncology Group were surveyed and 18 percent of 897 responding oncologists rated excessive regulation of analgesics as one of the top four barriers to adequate cancer pain management.¹⁴ In a 1991 survey of members of the American Pain Society, 40 percent of surveyed physician members said concerns about regulatory scrutiny rather than medical reasons led them to avoid prescribing opioids for chronic noncancer pain patients.¹⁵ In a survey of Wisconsin physicians conducted in the same year, over half reported decreasing the dose, quantity, or number of refills, or switching to a lower scheduled medication, due to fear of regulatory scrutiny.¹⁶ And, in a 1993 California survey, 69 percent of physician respondents felt that doctors were more conservative in their use of opioids in pain management because of fear of disciplinary action, and a third felt that their own patients may be suffering from untreated pain.¹⁷

In an effort to better understand state medical board members' knowledge and attitudes toward physician prescribing of opioids for pain management, the University of Wisconsin Pain & Policy Studies Group (PPSG) conducted a survey of members of state medical boards in 1991. Joranson and colleagues found that "[w]hile most respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice, only 12% were confident in the legality of prescribing for the patient with chronic non-cancer pain; the majority of respondents (77%) would discourage this practice or even investigate it as a violation of the law."¹⁸ They also found that board members responding to the survey had a lack of knowledge about

cancer pain management and the meaning and incidence of addiction when opioids are used to manage pain. In 1997, the PPSG (which conducted workshops between 1994 and 1998 to educate board members around the country about pain management issues) repeated the survey and found some improvements in attitudes of medical board members. Specifically:

- respondents were more likely in 1997 than in 1991 to recognize that opioids are underutilized as analgesics for cancer pain;
- respondents in both surveys overestimated the incidence of addiction to pain medications, but in 1997 fewer respondents confused addiction with physical dependence; and
- medical board members in 1991 and 1997 were more skeptical about prescribing opioids for noncancer than for cancer pain, but respondents in 1997 were more likely to consider prescribing opioids to patients with chronic noncancer pain for more than several months as acceptable medical practice.¹⁹

Since 1997 there have been a number of changes in the legal landscape regarding the prescribing of opioids for pain. Recently there has been an increased focus on undertreatment of pain, influenced in part by the increased attention given to palliative and end-of-life care and the controversy surrounding physician-assisted suicide. The American Society of Law, Medicine & Ethics (ASLME), with support from the Mayday Fund,²⁰ has addressed the issue of pain undertreatment through a variety of educational initiatives and projects. In 1998, ASLME's joint work with the Federation of State Medical Boards (FSMB) resulted in 1998 in the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, thus giving clear guidance to state medical boards regarding opioid use for chronic pain.²¹ The PPSG has been tracking the adoption of the Model Guidelines as well as other state pain policies more generally for over a decade. From 1989 to 2001, there was a dramatic increase in the number of new state pain policies adopted by state boards and legislatures. Many state boards have adopted policies that are consistent with the FSMB's Model Guidelines (e.g., endorsement of a balance between preventing opioid misuse and not interfering with appropriate opioid prescribing; endorsement of multidisciplinary collaboration in treating pain patients; inclusion of treatment standards for chronic non-malignant pain as well as standards for acute and cancer-related pain).²² However, there is no literature indicating how state boards are applying the guidelines and whether they are *implementing* balanced policies for the management of both malignant and nonmalignant pain.

In addition to the efforts of the ASLME, PPSG, and FSMB, groups like Compassion in Dying have been trying to counter the chilling effect of sanctions for opioid prescribing by drawing attention to cases in which pain was undertreated.

In 1999, the Oregon Medical Board was the first in the nation to discipline a physician for failure to prescribe adequate pain relief medication. The physician, Dr. Paul Bilder, was cited for several pain undertreatment infractions, including prescribing insufficient pain medication for a terminally ill cancer patient (i.e., only Tylenol) and prescribing only a fraction of the dose of morphine that another patient needed and the hospice nurse suggested. Dr. Bilder was ordered by the medical board to complete an educational program on physician-patient communication and undergo mental health treatment.²³ In another case, in June 2001, a California jury awarded 1.5 million dollars to the surviving children of William Bergman, whose children sued their father's physician, Dr. Wing Chin, for undertreating Mr. Bergman's cancer pain before he died. Although the award was subsequently reduced by the court, it was a dramatic message to physicians. Moreover, in the same year, drug enforcement officials from the DEA and twenty-one health organizations issued a joint statement that they had begun to work together "to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need."²⁴

Almost at the same time that we experienced this shift in focus toward concerns about undertreatment of pain, a new risk surfaced that threatens the balance of providing effective pain relief while minimizing abuse and diversion of opioids — the abuse of OxyContin. OxyContin was approved by the Food and Drug Administration in 1995. It has fewer side-effects than morphine but works similarly. It contains oxycodone in a time-released formulation that works over 12 hours, making it ideal for sufferers of both malignant and nonmalignant chronic pain. However, abuse of the drug began when it was discovered that crushing the tablet and either snorting it or mixing it with water and injecting it produced a potent high. Thus, OxyContin has high addictive potential for drug abusers and a high street value. According to the DEA Office of Diversion Control, from 1996 to 1999 the number of drug abuse deaths reported to the Drug Abuse Warning Network (DAWN) that involved oxycodone more than quadrupled, with 268 deaths in 1999 compared to 51 in 1996.²⁵ Several cases were reported in the media stating that physicians who prescribed OxyContin in relatively high doses were disciplined by their state medical boards.²⁶

SURVEY OF STATE MEDICAL BOARDS

In order to better understand how state medical boards are balancing concerns about physicians undertreating pain with concerns about physicians overprescribing opioids, we undertook a nationwide survey of state medical boards. More specifically, the study sought information regarding trends in the number and nature of complaints received by boards for inappropriate prescribing of opioids (i.e., "overprescribing" or "underprescribing"), how boards evaluate such complaints, and under what circumstances boards would discipline phy-

sicians falling into one of those categories. The focus of the survey was board experience during the last 5 years (1997–2001). The survey was conducted in late 2001 and the first half of 2002, just after the high visibility given to the abuse of OxyContin in the press.

METHODS

As a first step, we developed a telephone survey tool based on available literature and input from experts in the field of pain research and state medical board staff to identify state medical board practices related to prescribing of opioids for the treatment of pain.²⁷ Survey questions included the nature of complaints the board received over the previous 5 years regarding opioid overprescribing and subsequent investigations of physicians and disciplinary action taken; the nature of complaints the board received regarding undertreatment of pain by a physician; the board's use of a pain management expert in cases involving opioid prescribing; the likelihood of the board taking disciplinary action against a physician for undertreatment of pain; and the board's educational activities directed to physicians regarding treatment of patients with pain. The study was approved by a University of Maryland institutional review board.

The survey was directed (by name) to the state board medical director, or individual with a comparable title, and that individual was asked to participate in the survey or to provide the name of someone else in the agency who would be most able to answer the survey questions. Of the fifty states and the District of Columbia, thirty-eight state medical boards participated (a 74.5 percent response rate). Seventeen respondents were state medical board directors, ten were chief investigators or prosecutors, and the remaining eleven included individuals with the following titles: "medical director," "medical consultant," "program administrator," "senior complaint analyst," "chief [or 'director'] of compliance," "consumer assistant," and "director of complaints and allegations." The respondents' average number of years in their current position was 6.0 (standard deviation = 5.7). Ten respondents were physicians, seven were lawyers, three were nurses, two were social workers, and several had other advanced degrees (e.g., in business, public administration, and public health). Ten had worked in a similar capacity before working in their current position. Thirty-four respondents completed the survey by phone, and four completed the survey in written form.²⁸ Qualitative comments were transcribed directly from phone conversations or from written comments on faxed or mailed-in surveys.

Boards of those who responded differed in two significant respects from those who did not. First, respondents were more likely not to have regulations, guidelines, statutes, or policies regarding opioid prescribing than nonrespondents. Interestingly, all of the boards without such regulations, guidelines, statutes, or policies participated.²⁹ Second, respondents

were more likely than nonrespondents to have implemented an electronic prescription monitoring program that provides access to a database of physicians' prescribing and pharmacists' dispensing practices from pharmacies in the state. A total of sixteen states have currently implemented a prescription monitoring program, all of which are electronic.³⁰ Thirteen of those sixteen states responded to the survey.

RESULTS

Opioid overprescribing: Complaints

Respondents were asked to estimate the number of complaints³¹ their board had received in 2001 related to opioid overprescribing (i.e., "physicians who allegedly prescribed opioids unnecessarily, in too high a dose, or for too long a duration").³² An estimate was requested because most boards do not formally categorize complaints that relate specifically to opioid overprescribing.³³

Twenty-five respondents were able to estimate the number of opioid overprescribing complaints in 2001. According to those estimates, the average number of complaints was 3.1 per 1,000 doctors in the state (standard deviation = 2.8, range = 0 to 13.8).³⁴ The most common sources of these complaints were pharmacies, government regulatory agencies such as the DEA, and family members of patients. Other sources included physicians, law enforcement agents, or the board itself (i.e., in the course of another investigation, the board may have discovered cases of suspected opioid overprescribing). Some qualifying comments regarding the number of complaints included: "some [complaints] run together, for example, a complaint about sexual involvement may overlap with [a complaint about] opioid overprescribing," and "we do not track it that way, but my sense is, it's extremely small. Out of 700 complaints ... under a dozen tend to be related to [opioid overprescribing, mostly criminal referral]."

Eleven respondents were not able to estimate the number of opioid overprescribing complaints their board received in 2001 and shared comments such as: "we don't keep that type of information.... [W]e categorize drug diversion, incompetence, negligence.... I really don't know"; "I know the number of complaints for inappropriate prescribing, but I don't know how many of those were for opioid overprescribing"; and "I couldn't give a fair estimate, we have codes within our tracking system, but a lot of time the tracking code we put in isn't the same as the order to show cause or the final adjudication." In this regard, one respondent reported that his board was "getting ready to add undertreatment of pain to the [complaint form] as a specific cause."

When respondents were asked their impression of whether complaints against physicians for opioid overprescribing had increased, decreased, or stayed the same in the

TABLE 1. PERCEIVED TRENDS IN COMPLAINTS, INVESTIGATIONS, AND DISCIPLINARY ACTIONS FOR OVERPRESCRIBING OPIOIDS FROM 1997–2001.

	INCREASED	DECREASED	STAYED THE SAME	NO OPINION
Complaints	14 (37%)	4 (10.5%)	17 (44.5%)	3 (8%)
Investigations	15 (39.5%)	3 (8%)	17 (44.5%)	3 (8%)
Disciplinary Actions	14 (37%)	6 (16%)	15 (39.5%)	3 (8%)

past 5 years, seventeen respondents (44.5 percent) thought complaints had stayed the same (“on average there’s a relatively fixed population of drug-seeking patients and a relatively constant population of providers willing to prescribe”), fourteen (37 percent) thought they had increased, four (10.5 percent) thought they had decreased, and three did not know (see Table 1).

Drug diversion and abuse trends: OxyContin

Respondents were asked whether the problem of drug diversion and abuse in their state, in general, had improved, become worse, or stayed the same in the last 5 years. Eighteen (47 percent) thought it had become worse, eleven (29 percent) thought it had stayed the same, and five (13 percent) thought it had improved. Four had no real impression. Some commented that the drug diversion/abuse problem was not necessarily worse, but the board was doing more (“taking a little sterner approach than before 1996”; “pursuing it more diligently; we’re more on top of it now”; and “we have more sophisticated investigatory techniques, so we may just be more aware of what’s going on”). Fifteen of the eighteen who thought drug diversion and abuse in their state had become worse (83 percent) thought that the abuse and diversion of OxyContin had contributed to that trend, while the remaining three thought it had not. Some identified the problems with OxyContin as prompting newly enacted legislation establishing a prescription monitoring program in the state. One respondent commented:

Any time you have a drug that has as much press as [OxyContin], it identifies weaknesses in systems. Then you have people who are more willing to look for new ways to identify diversion and abuse. This might be one aspect that plays into the desire of some to have this new drug monitoring system ... [to find] mechanisms to identify if a patient had been to other physicians [looking for drugs to feed an addiction], or indications of [drug] diversion/abuse, for peace of mind of the physician.

Another stated: “an electronic database system would be ideal. It works both ways: If a doctor wonders if he’s the sixth doc in the pathway, he can call the board and get the answer in a few minutes, and [vice versa].”

Some respondents thought the abuse of OxyContin had made the public more aware of diversion issues, but had “not increased [their] complaints or investigations.” Others made reference to OxyContin’s being “the drug of the month” (“20 years ago it was Dilaudid, then Percocet, once upon a time it was Demerol”; “OxyContin is a new problem, but Lortab is more abused; there’s still a diverse array of drugs”; “OxyContin is just another drug in the mix”). One respondent commented: “we don’t have issues with physicians abusing OxyContin... [O]ur problem has been with patients selling or diverting the OxyContin and physicians not tuning in to that.” A few respondents, however, described serious problems in their state with overdose deaths from OxyContin, or of people in their state breaking into pharmacies and holding pharmacists up at gunpoint, specifically requesting OxyContin (“we have seen a tremendous problem of criminal theft of OxyContin”). One respondent described local police and health care providers with an “otherwise unblemished record for 20 years ... getting addicted to OxyContin ... [and] stealing from patients.” Others reported increased prescriptions of OxyContin, but as one respondent commented: “that’s not proof of diversion.”

Investigations for overprescribing

When asked whether their board had changed its approach to investigating physicians for opioid prescribing in response to OxyContin abuse and diversion, twenty-nine (76 percent) said no and five (13 percent) said yes. Four had no opinion. Those who had not changed their approach commented that they conducted the “same thorough investigation” of all valid complaints. Others felt their investigative approach had not changed, but their attention to the issue had increased. One respondent identified drug diversion as a priority of the board, which was working more with law enforcement to “stay on top of what’s going on.” Another respondent explained that

the approach of their board included adapting to changes in drug-seeking and diversion behaviors over the years:

[The] physician's committee of the medical society ... offers very consistent counsel; they've tightened their procedures over the years because the screening tests we had in place for monitoring [opioids] needed to be beefed up. They found loopholes like ... "beat-the-piss-test.com" websites, [which led to requiring] all testing at one lab. We've gone back and identified a lot of problems. It's better to nip it in the bud before it gets too out of control.

Another respondent commented:

It's just a change in the marketplace we've taken cognizance of. We just had a huge case of overprescribing where in the testimony it became apparent the number of patients looking for this kind of prescriber. This particular doc had people coming from other states. That was his defense: "If someone is in pain, you give them drugs." But the board said, "Not necessarily. You comply with good medical practice; you assess them and follow up and keep records, etc. You don't just give them drugs."

Respondents from other boards admitted that finding the right balance between identifying physicians who overprescribe opioids and those who are appropriately treating chronic pain is not always easy. As one respondent stated: "[We're] still working on trying to figure out the appropriate balance between pain management and overprescribing. We're still looking at research to find that balance."

When asked whether board investigations of physicians' opioid prescribing practices had increased, decreased, or stayed the same over the past 5 years (1997–2001), seventeen respondents (44.5 percent) said the number of investigations had stayed the same, fifteen (39.5 percent) said they had increased, three (8 percent) said they had decreased, and three did not know (see Table 1). Respondents were asked why they thought the number of investigations had increased or decreased. For those that answered increased, the most commonly cited reasons were increased "public awareness... patients and families are more aware," and "people are more inclined to speak up than they have been in the past." Some mentioned law enforcement actions ("there have been more cases where there have been convictions [of physicians] on drug trafficking and selling [opioid] prescriptions for money").

For those that answered decreased, one respondent cited economic factors that limited the resources the board could direct toward investigations. Changes in the board's attitude toward opioid prescribing was mentioned as a reason for

increased *and* decreased investigations over the past 5 years. One respondent shared his impression that "the board is taking these cases more seriously than in the past ... [by] cracking down on doctors who are overprescribing, and wanting us to find information to back that up." Another mentioned that physicians have clearer grounds for being investigated if they do not understand the board's rules for the treatment of chronic pain and are practicing outside of their specialty area. Others pointed to their board's changed attitude toward the treatment of chronic pain and how this has resulted in fewer full investigations: "The board's attitude toward prescribing opioids has changed. If a doctor can provide documentation showing that [s]he's following pain management guidelines, the board doesn't pursue [it] further."

Respondents were asked what factors would determine whether their board would fully investigate a physician for overprescribing opioids.³⁵ A "full investigation" was defined as going beyond initial factfinding (i.e., beyond merely sending a letter of inquiry to a physician or reviewing pharmacy records). For example, one respondent explained that whenever his board received a complaint against a physician related to opioid prescribing, the board conducted a preliminary investigation during which it typically requested a two-year profile from the state pharmacy board to look at the general prescribing practices of the physician. If they saw a pattern of inappropriate prescribing or had received "a series of complaints over the years that point[ed] to there being a problem," this would trigger a full investigation. Six respondents stated that their boards fully investigate all complaints related to opioid overprescribing.

State pain guidelines, statutes, regulations, or policies were mentioned as providing guidance for when to proceed with a full investigation of a physician for overprescribing. All but six of the boards responding to the survey currently have some form of guideline (sixteen), statute (fifteen), regulation (twelve), or policy (nine) related to pain management.³⁶ For many boards, if a complaint was made against a physician who was found not to be in compliance with the board's pain rules/guidelines, this would trigger a full investigation of that physician. Comments included: "if we don't have good documentation, if it doesn't appear that the physician's following the board's guidelines with respect to prescribing for pain, then we'll investigate"; "for the most part we adhere to [our pain guidelines]... [we've made] a lot of progress ... teaching physicians how to do this appropriately. We set the minimum standard of care in any state, documentation, informed consent, proper referral, etc., so we look for that"; and "the general policy that was made known to physicians is that we leave prescribing and pain management control issues to their professional judgment, but if there is a complaint, they better have proper documentation, such as informed consent, history and physical, monitoring, etc."

Some respondents commented that the volume or amount of opioids prescribed by a physician might trigger an

investigation — for example, if there were “large numbers of patients receiving large numbers of opioids from the same individual who was seeing patients from a large geographic region, that would trigger an investigation.” Also, “if there were extremely large dosages [prescribed], that would make [the board] question if the patient could safely consume that much.” However, if there was evidence that backed up the need for the amount of opioids prescribed, most boards would not investigate further (e.g., “if we determined that they were providing therapeutic interventions, then we would close the investigation”). One respondent provided the following example:

If a person [has] had low back pain for the last 12 years and has been taking long-term increasing doses of pain medicine over the years, and the family is reporting it because [their family member is] an addict now, that would be investigated. Any allegation that the pain is not sufficient to warrant the prescribed opioid [would be investigated], so if it’s a cancer patient, no one will argue with that.

Another commented:

If we get a complaint that a doc’s prescribing OxyContin 80 mg four times a day or three times a day,³⁷ we’ll ask the pharmacist if it’s a cancer patient. Sometimes the pharmacist doesn’t know, but ... if they tell us it’s not a cancer patient, it’s more than likely the doc will get investigated. Numbers are certainly an indicator, but they’re not the only indicator — it’s hard to answer with a straightforward answer. Every case has a different twist to it.

In the absence of a board pain management policy or guideline, decisions about investigating or disciplining a physician were often based on deviations from the recognized standard of care. For example, a respondent from a state that had contemplated but not yet adopted pain management guidelines stated:

[An investigation is triggered by] the deviation from an accepted norm — if someone is prescribing differently from their peers in a specific specialty. As an example, the pain management people will write 10 times the amount of opioids as others. We wouldn’t waste time with that person. But if a physician’s billing as an internist and prescribing the same as a pain management person, we’re going to go find out why. And if the pain management person is prescribing way above others, we’d check that out too. Deviations from a norm we observe, but we don’t establish the norm.

Another commented:

[We’re] looking at complaints and poor charting, [cases where] the patient “lost the prescription” and the doctor writes another, but there’s no documentation of diagnosis or follow-up, etc. The physician’s probably gotten on lack of documentation — we can’t prove fraud or diversion, but we can prove good medical practice standards were not [maintained].

Several references were made to using judgment in each case:

You have to apply judgment; this is not an area that lends itself to cookbook approaches. You have to react to good intelligence, for example, a reliable source like a pharmacy or another health care provider — their threshold to report to the board is high. We review DEA reports for excess purchases monitored, but pure volume doesn’t necessarily indicate a problem. You have to tell whether it’s below standard of care, not just volume.

In addition to the volume of opioids prescribed, the credibility of the complaint source, and whether there is documented compliance with the pain management standard of care, board policies or guidelines, or state regulations and statutes, boards look at the egregiousness of the physician’s conduct. One instance of highly egregious conduct may be sufficient to warrant a full investigation and subsequent discipline, whereas with milder forms of physician misconduct, a board may look at the number of complaints and evaluate patterns of inappropriate prescribing or practice. The uniqueness of each case was emphasized by many respondents. Comments included: “each case is done on an *ad hoc* basis; it depends on who is reporting, what the allegations are, how egregious [the physician’s conduct was], the past history of the doctor, etc.” and “It’s not a simple answer; there’s no quota system that a specific amount of drug means you’re ripe for investigation. We’re looking at a number of aggravating factors.”

In some states, medical board investigators worked closely with law enforcement, and thus looked closely at the quality of evidence collected against a physician (e.g., witness testimony quality, corroborating evidence — for example, if anyone observed the physician improperly prescribing opioids — hospital records). One respondent stated: “partnership with law enforcement is a very productive way to run an investigation. They’re more expert on the criminal side, more able to identify witnesses — like people who get sex for drugs don’t want to testify, but police have ways to find willing victims to come forward.”

Discipline for overprescribing

When asked whether respondents thought the number of physicians in their state who had been disciplined for overprescribing opioids had increased, decreased, or stayed the same in the past 5 years, fifteen (39.5 percent) thought the number had stayed the same, fourteen (37 percent) thought it had increased, six (16 percent) thought it had decreased, and three had no real impression (see Table 1). Reasons given by those who thought the number had increased included *an increase in numbers across the board* (“our general numbers have increased” and “everything’s gone up; discipline for prescribing violations has not increased more as [a] percentage of the total, we’re clearing [backlogged cases] more quickly, we streamlined our processes”); *increased awareness* (“it has to do with increased public awareness, increased awareness on our part; OxyContin is more realized by all of us,” and “there’s generally a greater awareness in the professional community and the public about this issue now”); *an increased level of sophistication among drug diverters/abusers* (“people are more sophisticated about getting drugs”); and *increased scrutiny by the medical board* (“I think we’re more aggressive in taking action because the information is available to the doctors about proper prescribing practices”; “I would think it’s ... increased due to increased vigilance. Members of the board are on the lookout for that”; and “the board is paying more attention to these issues, investigating them more seriously, that’s my impression”).

Reasons given by those who thought the number of physicians disciplined for overprescribing had decreased over the past 5 years involved the redefinition of “overprescribing.” Respondents explained: “the board’s attitude has changed; now we have pain management guidelines and have an established way of determining if a physician is deviating from those guidelines. We’re more aware of the need for adequate pain management and how that should be documented”; “Because the quantity of opioids thought to be appropriate has increased tremendously, those who used to be disciplined now are not considered in violation. The upper limit has been raised, and we’re okaying quantities now [that are] four to six times greater than before”; and “I think we were more restrictive than we are now. Now we recognize the necessity for pain management.... [There’s] increased vigilance but an acknowledgment that pain management is necessary. We have a policy and pain management guidelines now.” Another respondent described a move by the board toward a more proactive approach that averts the need for disciplinary action:

[W]e utilize other types of informal processes to try to address a [physician] before a pattern of bad practice is established.... [W]e identify [a physician who] ... needs further education but hasn’t established the [bad] pattern or egregious conduct

— we move some of those through [a special program that is proactive rather than reactive].

One respondent identified being more proactive with opioid prescribing issues as a goal that his board was moving toward: “I don’t think the board has been looked at as being proactive; they’ve been seen as more reactive, so we’re trying to change that. It’s hard, though.”

Respondents were asked what factors would determine whether their board would discipline a physician for overprescribing opioids. Several respondents commented that each case has a unique combination and presentation of facts, making it difficult to identify specific infractions that would automatically lead to a physician’s being disciplined — use of individual judgment was necessary. Comments included: “The board doesn’t have any policies or procedures on this. We would look at it on a case-by-case basis”; and “We look for records, tests, documentation, etc., and [the board] make[s] a decision about discipline. Our practices are very subjective.” One respondent explained:

We rely on expert testimony. We would consider the harm to the patient, whether the doctor is board-certified, how long the doctor’s been in practice, whether there’s been any prior discipline, or whether [there’s been] any fraud or financial exploitation, the severity of the problem, how long it’s been going on, which drugs were used, was a patient harmed — it wouldn’t have to be more than one patient, though typically it is — and whether or not the physician was impaired. [If the latter, the physician would go to rehab and the board] might not discipline.... The goal is protecting the public and rehab’ing physicians. You don’t always need discipline to achieve that.

There was generally less subjectivity and inconsistency involved in criminal diversion cases (“[The board is] pretty consistent; we usually get a drug profile, get records, get DEA or police to investigate that, make a criminal arrest or investigate, and get an emergency suspension for 90 days”).

For many respondents, violation of a medical standard of care was enough to warrant disciplining a physician for opioid overprescribing (“there’s no need for a pattern or more than one case. One act or omission failing to meet the guidelines or standard of care is enough if the facts are corroborated,” and “the standard really is whether the physician is practicing below the standard of care and whether there’s a continued pattern of irregular or substandard care. We usually don’t have a problem with showing a pattern, and if the physician is below the standard of care, we’re quick to bring action”). Others commented: “we’d discipline based on failure to meet generally acceptable standards

of practice; usually it's based on poor recordkeeping, [rather than] 'overprescribing opioids'; "it's based on adherence to medical standards of practice, and proof of that in documentation."

Respondents mentioned various things they looked for when investigating physicians for violating the standard of care for overprescribing opioids, including poor maintenance of patient records/poor documentation, "upcoding third party billing from a routine to a sick visit when [the visit is] under five minutes — usually you don't even find a blood pressure [charted] — significant findings of another disease entity not being followed, like hypertension or hyperlipidemia, not monitoring or following up," "red flags in the [patient] record like lost meds.... [I]f we see a lot of that stuff, we start to think the doc doesn't know what he's doing. Especially whether the doctor refers out or not [to a pain specialist],"³⁸ "ongoing monitoring, discussion with the patient ... in general, an absence of appropriate documentation to substantiate their professional decision." One respondent reflected on how the pain management standard of care has changed:

What used to be called overprescribing 5 years ago is not that now. There's been a change in the field of pain management. Now we don't discipline for quantity only. The thinking has changed in the practice of medicine. Now we are focusing basically on any practice that could be harmful to the patient, and this is based on standard of practice, which has changed.

However, a few respondents mentioned that standard of care violations would typically not be disciplined by their board, at least not without a demonstrated pattern of infraction by a physician ("we have to see a pattern"; "it would have to rise to negligence on more than one occasion, or inappropriate treatment; we'd have a hearing, there'd be due process, it would have to be a pattern that was established"; and "obviously, any case where we see a pattern of patient harm, willful and repeated violation of prescribing laws and regulations, we'll discipline. But we'll probably try to educate the doc"). One respondent stated:

It depends on all the facts, the pharmacy printout, and we look at the patients — sometimes they doctor shop. But if it looks like the doctor was fully aware that the patient may have an abuse problem and [s]he continued to prescribe, or was asked by the board to take a prescribing course in the past ... if after that the physician is still doing the same kind of thing, we'll step up the disciplinary process.

Boards that had adopted pain guidelines referred to them in making judgments about a particular physician's actions.

One respondent stated: "We look to [our pain rules] to give us guidance as to whether there's a violation. We tend to [apply] formal disciplinary action with doctors who have shown egregious conduct or established a poor pattern of practice." Another commented:

We refer to our pain guidelines. It's not based just on dose but quantity. We realize that people are in pain and need medication for that, but there comes a point where it's not physically possible to consume so many opioids in such a short period of time.

One respondent explained the benefits of referring to a position statement when enforcing opioid prescribing standards for physicians:

We set up the position statement against legal advice, because it doesn't have the same legal standing as a law or rule, but it allows us to articulate the standard of care in each instance. Expert testimony is then used when prosecuting a physician to show that he did not follow the articulated standard. For example, the position statement says you have to see the patient before prescribing drugs for them. This rules out Internet prescribing. We've gone after four docs for prescribing over the Internet without seeing patients first, and we upheld that through the position statement. But the position statement allows us to discriminate [about] when to go after docs. We don't have to go after everybody.... The position statement allows a physician to treat pain, that's standard of care, but it does say that the physician needs to comply with the minimum of appropriate medical practice.

The most common form of sanction imposed in overprescribing cases was mandatory education/retraining. Other sanctions included (listed in order of frequency mentioned): license suspension, license revocation, probation, restriction of opioid prescribing, monitoring of prescribing practices, mentoring and supervision, reprimand/censure, and a fine. One respondent stated:

We classify our drug problems into three categories: failure to follow [standards of medical practice], diverting drugs for self-use, and diverting drugs for money, sex, or other things. We take a very different tack for all three. For the first, we retrain. For the second, we rehab. For the third, we have no patience.

Other comments included: "[the sanction] depends on the severity of the offense, frequency, contrition and recognition

on the part of the practitioner, whether he's been before the board on an offense"; "I couldn't say, there's such a range — everything from revocation to public censure to nothing [to rehab]; "the sanctions differ depending on the case"; and

I don't always get the sanctions I want. I would like to see temporary suspension of a license and mandatory attendance at an appropriate prescribing workshop. The sanction has to have enough meaning to get their attention. Many can write a \$10,000 check and they don't miss it.... You've got to take them out of the loop a little while, get their attention big time.

Another respondent explained:

If it's limited to a lack of knowledge, we have a lot of tools to evaluate what to do.... [I]f it's a pretty big problem, we send them to get a report on their skills/knowledge.... [I]f it's a minor knowledge base [problem], we send them to a remediation program.... If there are other quality of care issues, we send them to an evaluation program. Then with doctors trading drugs for sex, that's a character problem; we would invoke long-term [license] suspension or revocation.

Opioid underprescribing: Complaints

Nineteen respondents (50 percent) were aware of complaints to their board against physicians for undertreatment or inadequate treatment of pain in 2001. Based on the thirty-three respondents who were able to estimate the number of complaints, the average per 1,000 doctors in the state was 0.46 (standard deviation = 1.1, range = 0 to 5.9).³⁹ The major source of such complaints was patients (eight respondents identified nonprisoners as the major source, two identified prisoners, and five reported both prisoners and nonprisoners).⁴⁰ The other primary source of complaints was family members (nine out of nineteen). One respondent explained: "[There are] three major sections that prescribing complaints can fall under: unprofessional conduct, incompetence, and fraud. [Inadequate pain management complaints are] usually in the first two categories." Some felt this problem was underreported ("it's a very underreported problem, in my opinion"; and "I've had orthopods proudly say they've never written for a Schedule II, and my question is 'Why? Aren't you dealing with people with severe pain...?' So I'm sure there's undertreatment, we just don't see the formal complaints."). A few respondents did not perceive undertreatment of pain to warrant a serious response by the board ("[we've received] just a few [complaints about undertreatment of pain]. Normally those were dismissed or no action was taken because the board doesn't perceive that

circumstance as a real high threshold of some kind of negligence or incompetence."). Others demonstrated a commitment to the issue, despite the absence of complaints ("as a cancer survivor I'm sensitive to the issue, but I don't see complaints from cancer patients saying the doctor didn't treat my pain carefully" and "I've kind of looked for them, but haven't found any so far.").

A few respondents gave examples of inadequate pain management complaints as being revealed, through investigation, to be instances in which patients were actually receiving adequate doses of opioids or were addicted to opioids and then complaining that they were cut off from their source of drugs. One respondent explained:

We did have one doctor who was overprescribing her patients who were addicted to narcotics, and after we suspended her license, some of them called to complain they couldn't get their meds, but those were [addicts trying to get narcotics, so it's not a legitimate complaint of undertreatment for pain].

Twenty-seven respondents (71 percent) thought there had been no change in the number of complaints the board had received in the past 5 years regarding inadequate treatment of pain. Six respondents thought there had been more complaints, and two thought less. Three had no opinion. Those who thought the number of complaints had increased attributed it to increased public awareness ("on a personal level I find [awareness about this issue to have increased] in hospitals; my husband recently had surgery and they were constantly asking him about pain — having him score his pain every time you turned around").

Investigations and discipline for underprescribing

Respondents were asked to estimate the number of investigations their board had *ever* conducted related to pain undertreatment. Nineteen respondents thought their board had never investigated a physician for undertreating a patient's pain, and sixteen thought their board had. (Three did not know.) Of the latter sixteen, eleven were able to estimate the number of investigations their board had ever conducted related to undertreatment of pain. The average number of investigations was 1.7 (standard deviation = 3.4, range = 0 to 13). Six respondents said all the cases involved nonprisoners, three said they involved only prisoners, and three said both prisoners and nonprisoners. Four did not know. One respondent pointed out that physicians are not required to "treat every patient who comes in the door," so a physician may refuse to refill a new patient's request for opioids — this is different from a physician failing to treat people under his or her care. Only one board had actually disciplined a physician for undertreatment of pain.

Respondents were given facts from the case regarding Dr. Bilder, the physician who was disciplined by the Oregon Medical Board for undertreating his patients' pain. Seventeen respondents were familiar with the case, ten were not, and eleven were unsure. When asked how likely the respondent's board would be to take disciplinary action against a physician for whom the board had received similar complaints that were later corroborated, eleven respondents thought it was almost a certainty (i.e., greater than 90 percent), fourteen respondents thought it was probable (60–90 percent), three thought it possible (40–60 percent), two thought it unlikely (10–40 percent), and three gave other ranges (between 60–100 percent, and between 40–90 percent). Five could not say.

Respondents' comments added further insight. Some stated that their board is limited in the kind of disciplinary action it can take ("the law only allows us to take disciplinary action if they're grossly negligent"; "we have to use clear and convincing evidence to prosecute, and that's a pretty high standard of evidence"). Several respondents commented that each case is unique and it would be difficult to predict their board's response ("it depends on the facts" and "the board tries not to make pronouncements on types of cases because they're dependent on facts and circumstances. The doctor may be making the right judgment in that particular situation, it may be appropriate. There are no cookie-cutter answers for these cases."). Some noted that more than one instance of pain undertreatment would be necessary ("you can't establish a pattern of practice with one patient"). Others looked for level of egregiousness ("The decision would be based on the medical record, and if there was a danger to the health, welfare, and safety of the community, that would definitely be a legal basis for [disciplinary action]. If it was found that the situation was egregious, there would be a legal basis for a summary suspension.").

A number of boards appeared disinclined to consider a standard of care violation alone as a basis of disciplinary action in cases of pain undertreatment ("the board tends not to discipline based on standard of care but on [gross] negligence"). One respondent voiced frustration with this general tendency of the respondent's board:

My problem here is we see standard of care [violation] cases all the time, but we don't discipline on [violation of] standard of care. For some reason our reviewer ... says, "well, it's not the best medical care, but it doesn't rise to the level of gross negligence." I wonder, what constitutes gross negligence? ... I don't think we do a good job at all on standard of care. I'd like to think so, but we don't.

Some respondents thought that the physician's intent would be relevant ("was he trying to avoid DEA scrutiny rather than

intentionally make people suffer?"), implying that a physician's lack of knowledge about adequate pain management would be grounds to evade board sanctions for pain undertreatment ("You would almost have to show criminal cruelty. [Giving Tylenol for cancer pain, knowing it doesn't alleviate the pain,] could show that."). However, a few thought their boards would discipline if they could prove that the standard of care had been violated ("yes, standard of care would be disciplined, depending on the facts"; "we do discipline standard of care issues; it's hard to prove sometimes, but we do"; and "if the physician is just disregarding the patient's complaint [and the patient's] not getting better, standard of care dictates that a follow-up is required and, if [that does] not [happen], then standard of care is not met").

Those whose state medical boards had pain management guidelines or end-of-life legislation used those guidelines, policies, or legislation to benchmark the physician's actions. One respondent stated: "that's just cruel to those patients, and it's not in conjunction with [our] pain management guidelines." Another explained: "our state has pain rules that were made by the board that the physician is expected to follow, and if it was verified that the physician didn't follow them, as would be the case with the physician in this scenario, that physician would most likely be disciplined." Another commented:

A doctor would have to show a pattern of practice of undertreatment, and following our pain guidelines, if the patient's pain was 10 out of 10 and [he's] giving Tylenol or ibuprofen, that's really ridiculous. Our consultants are in pain management and they believe in treating for pain. [But] it's hard to gauge since we've never [disciplined for undertreatment of pain] before. There are eighteen different personalities on our board, and it's hard to say how they'd go.

Yet another respondent stated:

In [this state] you're not held criminally liable for judicious titration in cancer patients, so to get an undertreatment case, you just have to have a real lack of education, and if we saw that, we'd have to utilize some discretion. Why did it happen? Can the physician be educated without sanction and still protect the public?

Several respondents thought that, depending on the facts of the case, a physician would likely be educated about pain management before sterner sanctions were invoked. One respondent stated: "they wouldn't suspend a doctor's license probably, they would probably want re-education. Some of those programs here are very expensive, but the board doesn't let that stop them from recommending such a course." An-

other explained: “if it was an innocent mistake ... and if there was no pattern ... the remedial board would review another 10–20 charts of that doctor, in a very collegial way, and tell him what he needs to do, and [make it clear that] ‘we don’t want to see you again.’” One respondent wondered whether sanctioning a physician for undertreating pain would lead to overprescribing problems (“once you discipline someone ... they can go the other way. I’ve had physicians say, ‘Fine, I get disciplined for not doing it, I’ll give everybody drugs.’”). One respondent thought, “If you’re just coming in and spanking people, [that’s not helpful] ... doctors [need] good messages, too.... Our goal isn’t just to discipline as much as we can.” However, other respondents thought their board was too lenient in dealing with physicians for undertreating pain.

Use of pain management experts

Respondents were asked whether their board ever used a pain management expert to assist with an investigation involving the prescribing of opioids (either underprescribing or overprescribing). Thirty-one respondents said their board had used such an expert. The mean percentage estimate of cases in which a pain management expert was used was 29.2 percent (standard deviation = 35.0, range from 0 to 100 percent).⁴¹ This result must be interpreted cautiously, as some respondents qualified their answer by stating that the denominator of their estimate was investigations involving opioid prescribing for pain management, not opioid prescribing for criminal cases (e.g., physicians illegally prescribing opioids in exchange for sex or money, or self-prescribing). One respondent explained: “we have pain management guidelines that we’ve published, and it’s easy to compare a physician’s behavior to those guidelines, but I’d say we refer to a pain management expert in about 20 percent of the investigations, but they [also] use our guidelines.” Another stated: “in a case right now we’re using a pain management expert, but that’s only the second or third time. Usually the cases are pretty clear.” Some respondents stated that their boards use a pain management expert whenever disciplining a physician for opioid prescribing practices, or whenever the board has a hearing in which someone testifies against the physician for issues related to opioid prescribing. One respondent explained: “if the nexus of the case is pain management, then a pain management expert is involved.” One respondent noted that recent legislation required that a palliative care physician sit on the board. Another stated: “with our budget problems, [we don’t use a pain management expert] as often as we’d like ([only] about 20–25 percent [of the time]). [There’s] a pretty good mix of physicians on the board and subcommittee. They usually do okay, but sometimes they need the expert.”

When asked to name the credentials of the pain management expert used, five respondents mentioned board

certification in anesthesiology, twelve mentioned certification in pain management (mostly through anesthesiology pain management certification), seven mentioned experience-based expertise (“usually it’s a doctor who’s well-respected in the community and works for a pain clinic or runs a pain clinic”), and one mentioned a combination of experience-based and pain-management-credentialed expertise. Six did not know. Several mentioned that they try to match the specialty area of the physician being investigated with that of the consultant (“If it’s a family physician, we look for a family physician who also treats chronic pain patients.”). One explained: “very few physicians are board-certified in pain management, [but] there are a lot who practice pain management. We would get an internist if an internist was involved, etc.” Another reiterated: “few people are certified in pain management, though most [experts] we use, that’s their main specialty. They advertise themselves as pain management experts. Most are board-certified in their primary specialty at least. A handful are board-certified in pain management, but not a lot.”

Potential chilling effect

Several respondents commented about the potential chilling effect that could be created by the board’s investigations of and disciplinary actions against physicians for opioid prescribing. Some wondered how these fears were propagated. One commented: “the thing that surprises me is that physicians won’t prescribe because they say they will get in trouble from the state. Where do they get this idea? ... It’s always baffled me where they get that from. Urban myth.” Another stated: “there’s a perception by many GPs or internists that we are something much bigger than we really are. It’s the Big Brother syndrome, like the IRS, a bigger perception than many of us in the regulatory business are really aware of.” Others thought there might be some truth to such concerns, as is conveyed in the following comment:

It has gotten out that the board is very active and this has created the feeling of some in the medical community that we’re out to get them. And some have asked me if I’m worried that we’re being too aggressive, and I do worry about that. But I worry too that they’ll forget we’re here.

Another responded similarly, emphasizing that the interest in avoiding a chilling effect must be balanced with the board’s obligation to protect patients from harm:

Doctors like to cry foul anytime we inquire about anything, and say we’ve scared them so they’re not going to prescribe anything. It’s just a problem we have to deal with on a case-by-case basis. There are doctors out there who are harming their patients, and we have to protect the patients too.

Board-sponsored education/training

Twenty-eight respondents stated that their board had distributed educational materials regarding treatment of patients with pain. In most cases, these were articles in newsletters or publication of the board's pain management guidelines or rules. Others mentioned distributing press releases, white papers, and pamphlets on the subject. Many of the boards provided the same information on their website. One respondent stated that "our position statement on pain management is given to physicians when they're licensed, and they're interviewed by a board member to reinforce their knowledge of [the position statement]." Others covered appropriate prescribing for pain in mandatory orientation sessions for new physician licensees. In one state, "any new physician who applies has to take a written test based on all the board's rules, [including appropriate opioid prescribing]." Several respondents emphasized that the focus of these educational efforts was on proper documentation and follow-up of patients treated for pain, particularly for chronic pain, e.g., "The [emphasis] that our board has [stressed with] physicians is documenting their treatment plan, diagnosis, and rationale for what [they're] prescribing. That's where physicians will get into trouble. It's necessary for the patient and good for the doctor; for example, if the patient needs to change physicians, those records speak volumes"; and "We sent to physicians [in the state] ... a letter saying basically 'we don't want you to overtreat or undertreat [your] patients' pain, and if you ever have a complaint with us, this is what you need to have in your file, and if you don't have it, you'll probably be in trouble with us." One respondent questioned whether physicians were "getting the message":

[This state] has specific legislation in this practice [chronic pain management] and how it's supposed to be done. We have shared that with physicians in our newsletter, and we give talks, but the word doesn't seem to get out. Physicians who we find are overprescribing complain that "the board's picking on me," but we're not. It's an issue of good medical practice.

Another expressed frustration with the limitations of what could be accomplished by a nonautonomous board:

My board.... can't do a lot of things because [we're] under an umbrella agency that administers our budget and other things. We can complain but are limited in what we can do.... such as writing/distributing educational brochures and all kinds of creative things.... I work with "inside the box" type people, which you see in government agencies a lot. Creativity and innovation are not encouraged, and when you achieve them, you've had to fight hard. Everything is a struggle.

Fourteen respondents reported that their board had provided educational sessions on the treatment of patients with pain. Some were talks and presentations about pain management given at hospitals or other venues. One respondent reported: "[We've] sent staff out to give presentations and have been keeping track of those since 1999. I have a list five pages long of all the places we've gone: 137 presentations since 1998, 38 [were] pain management speeches, and 25 [were] overviews with pain management references as part of the content." Another stated: "the executive director has spoken on this.... We try to be as proactive as we can." Others mentioned full- or half-day seminars or training sessions provided by the board on pain management and proper prescribing — some were one-time sessions and others were given annually or more often. One respondent referred to a recently passed law requiring physicians in the state to take "12 hours of CME [continuing medical education] on end-of-life care and pain management" as a possible solution to the problem that "a lot of people out there are not being treated appropriately for their pain, and doctors don't recognize that." Another board was "also looking at mandatory CME in pain management for physicians."

Of the twenty-four respondents whose boards did not provide educational sessions on pain management, comments included: "this is being discussed, [but it's] available in the private sector"; "we're talking about providing CME on pain management and end-of-life hospice issues, but ... nothing has been finalized"; "we defer to Purdue and other workshops"; and "I wish we had the staff; however, there are really terrific people putting CME seminars on in the community that are excellent. There's a wealth of resources in this area, so there's no excuse for not having knowledge about pain management."

Balancing the need for appropriate treatment with preventing abuse and diversion

A few respondents thought that physicians might be hesitant to prescribe opioids to terminally ill patients out of fear that they might hasten the patient's death. One respondent said that the allegations made to the board relating to undertreatment of pain typically involved "a fundamental value system" in which physicians "have very strong feelings about not wanting to hasten a patient's death." In such cases, the board "trie[s] to assure physicians that it's within accepted practice to palliate at the end of life and this is not seen as euthanasia or physician-assisted suicide, but often physicians really struggle with that issue." Most respondents, however, felt that pain management at the end of life had seen the most improvement as far as boards being better able to distinguish adequate opioid prescribing from overprescribing, as is evident in the following comment:

The board's in a tough spot. As soon as it goes after someone for overprescribing, the first reaction is "that's chilling treatment for pain." They duck for cover under that. But those cases are apples and oranges. Those who are diverting opioids take cash only, they deal with patients who have a criminal history, they don't keep records. There's no comparison to, for example, treating a dying cancer patient. Complete apples and oranges. It's not like someone in hospice, dealing with a patient who needs pain medications. Our board has a position statement on end of life that covers all this.

Some respondents commented on the difficulty in reconciling the changing attitudes and practice standards in pain management of recent years with the ongoing problem of drug abuse and diversion. One stated: "it's a real challenge, finding that balance between under- and overtreating pain." One pointed to the difficulty of managing pain in the fragile elderly: "what might be an appropriate dose for a young person is not for an elderly frail person who's on multiple medications." For some respondents, their job was easier when there was a clearly established upper limit for prescribing opioids, as the following comments demonstrate:

[There's been a] tremendous change in the management of chronic pain and the attitude that there doesn't seem to be any upper limit on opioids. The attitude now is "whatever works." I have problems with that because I'm faced with figuring out whether opioids are being diverted or not, and I have suspicions that a lot of patients are conning a lot of doctors into giving them meds and don't get questioned because of this "whatever works" attitude. We will have to figure out how to counter that.... We used to sanction based on the PDR [*Physicians' Desk Reference*] limit (like 40 mg a day for oxycodone), but now that's almost never the basis of our sanctions. Patients are on 700 to 800 mg of oxycodone a day.

The numbers we're seeing, the doses are kind of unreal at times. You have a physician who's not educated in pain management, and this might sound bad, but there is this rhetoric about serving chronic pain patients, so physicians tend to do it. Some have good hearts and don't know how to do it well; some don't have the heart but see it as a way to have a practice. But they're not following good medical practice in prescribing, they're just prescribing. They don't have consults, they don't document about what's going on — sometimes it's not even based on good pharmacology, just "oh, this is

good." Underprescribing is still an issue, but there's also the issue of people being so overprescribed — we had one woman who was a school bus driver and she couldn't even move [because she was so drowsy from the pain medication].

The following respondent's comment concerns the same issue — how to balance treating valid chronic pain with protection against abuse of opioids:

Chronic pain in my opinion is a subspecialty. Even experts don't agree [on] what to do. The problem I have is not so much with the pain specialists, but at the ... level of general practitioners and internists who end up with patients with chronic pain. Sometimes they do a good job at handling it, sometimes they don't. A lot of these doctors don't know how to say no to patients, they don't really understand what's going on. They can get into trouble if they take everything a patient says at face value. How do you know if I really have a migraine? ... It's hard. No doctor really wants to bother with the chronic pain issues. I knew a pain management specialist who said it took 3 months for her to get a feel for whether certain chronic pain patients were lying to get meds. Everyone lies. We've had physicians lie who are under investigation, and if physicians lie, you can bet patients lie.

One respondent agreed that many physicians prefer not to treat patients with chronic pain, and that it is better for them to refer such patients to a pain specialist:

Some chronic pain patients are tough to treat and some doctors feel they don't have the time to spend with those patients. One of the things I always say is don't dabble in pain medicine. Do it right, for the sake of the patient and the doctor. It's better to refer [patients to a pain specialist] than to do it half way.

Yet, another respondent identified the problem of the lack of access to quality chronic pain treatment in pain clinics and centers:

One of the problems is that the pain clinics are undersupported, they're short of doctors willing to practice pain medicine/anesthesiology, they can't get paid. [This causes a] population of people to seek out individual physicians, some of whom lack the skill set to treat this type of patient. It's a difficult problem. One psychiatrist opened a pain clinic, no prescribing experience before. He's gone from none to the top three OxyContin prescribers

in the state. So, how does that happen? With virtually no records kept. People are walking in with money.

Another agreed:

It's the standard of care to take care of people's pain just like it's the standard of care not to be duped. That shows how colossally difficult the board's job is here. When do you cross over from appropriately treating pain to hurting patients? I think people get into trouble with this because it's easy money for doctors. I think the brass ring is a pain center connected with an academic center, where they're well-trained, well-managed, look at all problems, not just pain. Patients who are marginal and might be abusers are put on contracts and they have ways to keep them from participating in diversional activity.... I'm always impressed with these pain centers ... they make it undesirable for drug-seeking individuals to [use their services.]

Several respondents commented further about the difficulty boards have distinguishing valid chronic pain from drug-seeking behavior. One stated: "With the advent of new end-of-life legislation ... physicians ... feel freer to go ahead and prescribe the pain medications that are needed. This helps a lot. Regarding chronic pain, physicians are much more cautious about that." Another acknowledged:

It's easy if the patient is terminal. It's not so easy with intractable pain. Is this a drug-seeking patient or a patient with valid intractable pain? That's a difficult call for physicians and a difficult call for us. Maybe with time there will be more sophisticated diagnostic tools available to make it easier.

DISCUSSION

Our study results indicate significant variation among state medical boards regarding experience with and reaction to overprescribing and underprescribing opioids for pain treatment. With respect to overprescribing, states were divided on their perceptions of whether the number of complaints, investigations, and disciplinary actions for opioid overprescribing over the past 5 years had increased, decreased, or stayed the same. The largest group, in each case, indicated they thought the numbers had stayed the same. A slightly smaller, but significant, group thought they had increased, and only a few believed they had decreased. However, it appears from the data that there was consistency in responses regarding trends in complaints, investigations, and disciplin-

ary actions. That is, if the number of opioid overprescribing complaints was perceived to have increased in a jurisdiction, the number of investigations and disciplinary actions either increased or stayed the same. Likewise, if the number of complaints stayed the same or decreased, the number of investigations and disciplinary actions either stayed the same or decreased. These results were based on perceptions (rather than actual numbers), as it is still the case that most states lack systems that track complaints based on opioid prescribing.

We questioned whether the presence of a state prescription monitoring program might have had an influence on the number of complaints or investigations related to opioid prescribing. Compared to respondents from states without an electronic prescription monitoring program, we found that respondents from states with such a program were generally more likely to think the numbers of complaints, investigations, and disciplinary actions against physicians related to opioid prescribing had stayed the same over the past 5 years rather than increased or decreased (see Table 2). Regarding estimates of the number of opioid overprescribing and underprescribing complaints received in 2001, there were no statistically significant differences between boards with and boards without an electronic prescription monitoring program. Thus, based on respondents' estimates and perceptions, it does not appear that electronic data tracking mechanisms led to increased numbers of complaints, investigations, or disciplinary actions against physicians related to opioid overprescribing practices.

While nearly two-thirds of respondents reported that opioid overprescribing complaints had decreased or stayed the same, over a third of respondents perceived that opioid overprescribing complaints had increased in their jurisdiction during the past 5 years. This appeared tied to a perception that drug diversion, in general, had been increasing. A significant number of respondents believed that drug diversion on the whole was worse in their state than it was 5 years ago, although some attributed this to more diligent efforts to seek out such diversion. Of the eighteen respondents who thought drug diversion had worsened in their state, fifteen thought that OxyContin had significantly contributed to this problem. On the other hand, of the thirty-three respondents who had an opinion on this issue, fourteen (42 percent) did not think OxyContin was a problem in their state. This is likely due to the variation in abuse patterns of OxyContin across the nation. A large majority of respondents stated that their board had not changed its investigative approach in light of OxyContin concerns, but the overall tone of their comments regarding drug diversion indicated that, in general, their boards had taken more active steps to address this problem.

As regards decisions to investigate physicians for overprescribing, it appears that a number of boards are attempting to find the appropriate balance between identifying physicians who overprescribe and those who are appropriately

TABLE 2. DIFFERENCES IN PERCEIVED 5-YEAR TRENDS OF COMPLAINTS, INVESTIGATIONS, AND DISCIPLINARY ACTIONS AGAINST PHYSICIANS RELATED TO OPIOID PRESCRIBING BASED ON THE PRESENCE OR ABSENCE OF A STATE PRESCRIPTION MONITORING PROGRAM (PMP).

	INCREASED		DECREASED		SAME		DON'T KNOW	
	PMP*	NO PMP**	PMP	NO PMP	PMP	NO PMP	PMP	NO PMP
5-year trend of complaints for opioid overprescribing^A	2 (18%)	12 (44.5%)	1 (9%)	3 (11%)	7 (64%)	10 (37%)	1 (9%)	2 (7.5%)
5-year trend of complaints for pain undertreatment^B	1 (9%)	5 (18.5%)	1 (9%)	1 (4%)	9 (82%)	18 (66.5%)	0 —	3 (11%)
5-year trend of investigations for opioid overprescribing^C	5 (45.5%)	10 (37%)	1 (9%)	2 (7.5%)	4 (36%)	13 (48%)	1 (9%)	2 (7.5%)
5-year trend of physicians disciplined for opioid overprescribing^D	3 (27%)	11 (41%)	1 (9%)	5 (18.5%)	6 (56%)	9 (33%)	1 (9%)	2 (7.5%)

*“PMP” = state had an electronic prescription monitoring program before 2000 (n = 11).

**“no PMP” = state did not have an electronic prescription monitoring program before 2000 (n = 27).

A: Respondents were asked whether they thought the number of complaints regarding physicians who allegedly prescribed opioids unnecessarily, in too high a dose, or for too long a duration (“overprescribed”) had increased, decreased, or stayed the same over the past 5 years.

B: Respondents were asked whether they thought the number of complaints regarding physicians who undertreated or inadequately treated a patient’s pain had increased, decreased, or stayed the same over the past 5 years.

C: Respondents were asked whether they thought the number of investigations related to opioid prescribing had increased, decreased, or stayed the same over the past 5 years. Because the number of board investigations for opioid underprescribing was so small, answers to this question were interpreted as relating to opioid overprescribing trends.

D: Respondents were asked whether they thought the number of physicians disciplined for opioid overprescribing had increased, decreased, or stayed the same over the past 5 years.

treating patients with chronic pain. A number referred to the fact that their board had developed a policy or guidelines for prescribing for chronic pain that were a significant aid to them in deciding whether to investigate or discipline a physician. The number of boards that have adopted pain management guidelines, regulations, or policies has, in fact, increased over the last 4 years, with boards specifically addressing the issue of chronic nonmalignant (or “intractable”) pain. In 2001, the PPSG documented a total of eighty-two state pain policies in the form of statutes, regulations, guidelines, or policy statements. As of 2001, twelve states had adopted the FSMB’s Model Guidelines in full, and nine in part.⁴²

It is unclear to what degree the existence of such policies correlates with a board’s commitment to educating physicians about pain management and opioid prescribing issues (i.e., to mitigate the chilling effect that has caused physicians to avoid prescribing opioids when they are needed to treat pain). Although the findings reported here must be interpreted cautiously, it appears that boards with state pain policies that address the treatment of chronic, nonmalignant pain are more proactive, in that these boards provide more pain-management-related education to physicians than boards that do not have such policies (see Table 3). However, we do

not know whether the content of such educational efforts strives to balance education about overprescribing with that of pain undertreatment concerns. More research is needed to determine what specific messages boards are sending to physicians in these educational efforts, how physicians are interpreting these messages, and how such educational efforts are affecting physicians’ opioid prescribing practices.

Respondents’ comments indicate that boards are focusing on making their pain policies known to physicians so that physicians are aware of what is required of them to avoid scrutiny by the board. A number of boards emphasized what should be present in the patient’s chart to avoid suspicion by the board that the physician is overprescribing (e.g., patient assessment, pain diagnosis, plan of care, evaluation, follow-up, specialist referral). These efforts serve to reassure physicians that they will not be disciplined for overprescribing opioids to patients with chronic pain if they conform to standards of practice and state pain policies. On the other hand, if a physician is accused of overprescribing and lacks proper documentation of his or her practices, he or she is much more likely to be investigated and disciplined.

An encouraging result for pain management advocates is that boards appear to be moving away from volume or

quantity of opioids as a primary basis for investigating a physician for overprescribing opioids. Some respondents referred to volume as a trigger but not conclusive evidence for a decision to investigate. Many respondents indicated that these were very fact-specific cases that had to be evaluated individually; that all facts, including the diagnosis of the patient, the documentation of the prescriptions ordered, and consistency with established guidelines, had to be considered. Despite this positive trend away from using volume as a determinative factor in moving forward to investigate or discipline, a few respondent comments were troublesome in that they implied a continued reliance on volume and, in at least one case, a lack of knowledge regarding issues of dosage and volume. For example, the comment, "It's not based just on dose but quantity.... there comes a point where it's not physically possible to consume so many opioids in such a short period of time," might be accurate if referring to an opioid-naïve patient. However, it is possible that a patient with intractable pain might be administered large doses of opioids with a sharp dose escalation (i.e., large doses in a short period of time) in order to obtain pain relief.⁴³ Thus, misunderstandings still seem to exist about opioid volume and quantity upper limits (i.e., that the latter exists independently of case-specific facts, which is generally not the case).

In response to the question regarding factors that the board would consider in deciding whether to discipline for

overprescribing opioids, most respondents stated that it was a matter of judgment, that it was very fact specific, and often subjective. However, for those that had established pain management policies or guidelines, these appeared key in determining whether to discipline. Significant departures from the policies, in some cases, could be a basis for discipline. Boards varied regarding whether they would require a pattern or more than one instance of overprescribing before disciplining. Poor documentation and recordkeeping were also consistently cited as key factors in disciplining physicians in these cases. A number of boards also mentioned using pain experts to assist them in deciding whether to discipline in cases of overprescribing. A lack of availability of credentialed pain experts may interfere with some boards getting the professional guidance they need to investigate physicians for opioid prescribing practices.

Over half of the respondents (55 percent) thought the number of board disciplinary actions relating to opioid prescribing practices had either stayed the same or decreased over the past 5 years. Respondents who observed a decrease offered reasons that were encouraging for advocates of better pain management. These board representatives thought their board's attitude toward opioid prescribing had changed over the past 5 years and that their pain management guidelines helped them in a number of cases determine that the prescribing practices of the doctor under investigation were

TABLE 3. DIFFERENCES IN EFFORTS TO EDUCATE PHYSICIANS ABOUT PAIN MANAGEMENT BASED ON THE EXISTENCE OF A BOARD POLICY ADDRESSING CHRONIC, NONMALIGNANT PAIN.

PAIN MANAGEMENT EDUCATION/ TRAINING BY BOARD*	BOARDS WITH CHRONIC, NONMALIGNANT PAIN POLICY** (n = 30)	BOARDS WITHOUT CHRONIC, NONMALIGNANT PAIN POLICY** (n = 8)
Pain management content in newsletter	54% (15 of 28)	17% (1 of 6)
Written pain management materials available/sent to MDs***	40% (12 of 30; 11 sent to MDs)	14% (1 of 7; 1 sent to MDs)
Pain management content in orientation	14% (4 of 28)	0% —
Pain management sessions given by board	47% (14 of 30)	12.5% (1 of 8)

Policies addressing chronic, nonmalignant pain were identified based on the categorization of policies listed on the Pain & Policy Studies Group website. See Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, Data-base of State Laws, Regulations, and Other Official Government Policies, at <<http://www.medsch.wisc.edu/painpolicy/matrix.htm>> (last updated November 5, 2002).

*Respondents were asked: Has your board distributed any educational materials regarding treatment of patients with pain (e.g., copy of guidelines, newsletters, brochures, videos)? Has your board held any educational sessions on treatment of patients with pain? Does the board provide any additional assistance to physicians seeking guidance for the treatment of patients with pain? If respondents answered affirmatively, they were asked to describe the types of materials, sessions, or additional assistance. Information here is based on a content analysis of respondents' comments. Percentages are valid totals. Missing data are the result of respondents who completed a written survey, answered "yes" to any of the questions, but did not provide qualitative elaboration.

**These are statutes, regulations, guidelines, or policies that address treatment of or opioid prescribing for chronic, nonmalignant pain.

***These included pain-management-related brochures, copies of pain policies, position statements, and the like that were available upon request and/or distributed to physicians (e.g., by mail or other methods of distribution).

reasonable, where prior to the adoption of the guidelines they might have disciplined the physician.

The number of estimated complaints boards received for *underprescribing* were significantly fewer than those received for overprescribing (in 2001, an average of 0.46 versus 3.13 complaints, respectively, per 1,000 doctors in the state). A significant majority saw no change in the number of complaints received for underprescribing over the past 5 years. While some respondents thought the problem of pain undertreatment was real and merely underreported, others did not seem to view undertreating pain (particularly chronic, nonmalignant pain) as a significant problem.

While not equivalent to complaints received for overprescribing, it appears that the number of complaints for underprescribing has increased. Martino conducted interviews with medical board executives between November 1997 and January 1998.⁴⁴ At that time, only one board (California) of the thirty-six surveyed had received a complaint or report explicitly alleging undertreatment of chronic pain. Several had received complaints from prison inmates alleging that certain medications had been denied as a form of punishment, but they generally were not pursued as pain undertreatment cases.

As regards disciplinary action for undertreating, many boards appear disinclined to discipline simply for violation of standard of care, which is how many respondents depicted cases of underprescribing pain medication. They would be more likely to recommend education to the physicians in such cases. This appeared somewhat at odds with the responses given to questions about disciplining for overprescribing, where respondents said they were more likely to discipline for violation of standard of care, even without a pattern of poor practice. Thus, there is a lack of parity in application of standard of care and patient harm as bases for discipline in cases of undertreatment versus overtreatment. Overprescribing is more often seen as a clear violation of standard of care *and* a clear example of patient harm, while many respondents, or their boards, do not view undertreatment, particularly for chronic pain, in the same way. They appear to apply a higher threshold of harm for undertreating pain.

A number of respondents, however, did provide examples of cases they thought could be construed as gross negligence or egregious behavior regarding pain undertreatment and said that such cases might lead to disciplinary action. Consistent with this response, a significant majority of respondents (79 percent) said that if they were presented with a case where the facts were similar to those of Dr. Bilder (the physician who was disciplined for underprescribing by the Oregon Medical Board), it was either highly likely or probable that they would discipline the physician.

In regard to the potential chilling effect of the board's efforts to oversee opioid prescribing practices, some respondents showed concern that physicians might "go the other

way" (i.e., overprescribe opioids if disciplined for undertreating pain, and vice versa). Some boards were working diligently to ease physicians' fears that they would be investigated or disciplined by the board for prescribing opioids to patients. Several thought such fears were completely unfounded or perhaps a convenient excuse to avoid the added work involved in treating chronic pain patients. Others realized that the board's actions had a chilling potential, but thought there was little they could do, that it was the physician's fault for jumping to false conclusions, and that such is the price that is paid for protecting patients. These respondents were aware of the problem of inadequate pain management, but seemed to give more weight to concerns about overprescribing. Respondents spoke of "protecting patients from harm," yet did not view opioid overprescribing and pain undertreatment equally in the degree of public protection they demanded. This type of attitude may contribute to a shortage of physicians who are able and willing to treat patients who have chronic pain. While advocacy for pain management on the part of many state boards may ease physicians' fears about being disciplined for opioid overprescribing, many physicians may decide that their safest (or least burdensome) course is to refer patients with chronic pain to a pain specialist. With the number of patients suffering from chronic pain greatly outnumbering the number of qualified pain specialists, the results do not add up in favor of those with chronic pain.

CONCLUSION

In sum, we cautiously conclude from our survey results that the attitudes and practices of medical boards toward physicians' prescribing of opioids have changed for the better over the last several years. Respondents' references to the need for "balance" between ensuring appropriate treatment of pain and disciplining physicians who are inappropriately prescribing opioids are illustrative of this movement. The work of a number of individuals and agencies, including the Wisconsin Pain & Policy Studies Group, the American Society of Law, Medicine & Ethics, the Federation of State Medical Boards, through its Model Guidelines, and the recent DEA joint statement, has reinforced this message of the need for balance and may have played a role in moving boards forward on this learning curve. Moreover, boards' abandonment of opioid quantity as a marker of questionable practice, in favor of an individual assessment of whether the physician has appropriately evaluated the patient, prescribed consistent with board guidelines, and appropriately documented his or her prescribing, further indicates progress in board recognition of the need for adequate pain treatment.

At the same time, some attitudes and practices by boards remain problematic — in particular, a continued tolerance of undertreatment. While many boards are becoming more proactive in educating physicians about pain management

issues, the focus is on what physicians who prescribe opioids for pain must do to avoid board scrutiny. There appears to be a discrepancy in the weight given to violation of standard of care, patient harm, and gross negligence for overprescribing as compared to underprescribing. Ironically, boards seem to have a higher threshold for patient harm in cases involving pain undertreatment — particularly for chronic, nonmalignant pain. To this extent, physicians may be getting mixed messages from boards: on the one hand, that effectively managing their patients' pain is the expected standard of care; and on the other hand, that the board is more concerned about opioid overprescribing than underprescribing. Perhaps this is unavoidable given the realities of opioid diversion practices. In terms of lessons one might take away from these findings, reformers may have to accept that management of chronic pain inevitably carries with it a greater chance of entanglement with licensing and law enforcement authorities than management of cancer pain, given the higher risks of diversion.

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28. The survey was designed to be administered during a phone interview, but a minority of respondents opted to complete the survey in written form.

29. See Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, *Data-base of State Laws, Regulations, and Other Official Government Policies*, at <<http://www.medsch.wisc.edu/painpolicy/matrix.htm>> (last updated November 5, 2002).

30. See Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, *Prescription Monitoring Programs*, at <<http://www.medsch.wisc.edu/painpolicy/domestic/diversion.htm>> (last visited February 12, 2003).

31. In addition to formal written complaints, twenty-two of the thirty-eight respondents also accepted complaints by phone, e-mail, or anonymously, although anonymous complaints were investigated only in rare circumstances (i.e., regarding serious complaints when sufficient information was provided to investigate further). Some states first considered allegations that were transformed into complaints after a formal process in which preliminary evidence was collected.

32. This could include complaints against physicians for prescribing opioids for pain patients they were treating, prescribing for themselves, or trading opioids for money or sex.

33. This is consistent with the findings of Weiner and Pound in their "Project on Legal Constraints on Access to Effective Pain Relief," in which they interviewed medical board members (cited in Johnson, *supra* note 8, at 321), and found that the boards were "not able to separate actions against physicians treating patients for pain from the more general disciplinary category of abuse of prescription drugs."

34. The actual range of values was 0 to 250. To correct for the outlier values of 100 and 250, these values were "windsorized" to the next highest values of 57 and 58, respectively. Those numbers were then divided by the number of physicians per state (see data at <http://www.education-world.com/a_lesson/TM/WS_census_states.shtml>) and multiplied by 1,000.

35. The task of investigating and disciplining physicians was implemented by different individuals, departments, or agencies, depending on the structure of the board and whether it was part of an "umbrella" agency. When referring to boards' investigating or disciplining physicians, we are referring to whatever mechanism the individual board implements to investigate or discipline physicians in that particular state.

36. See Pain & Policy Studies Group, *supra* note 29.

37. The lowest dose of OxyContin is 10 mg. An opioid-naïve patient with chronic pain is typically started on 10 mg of OxyContin twice a day, and the dose is increased until the patient's pain is controlled (unless the pain is refractory to opioid therapy or other circumstances exist). Suggested dosing for OxyContin is twice a day or every 12 hours, not four times a day. Patients with cancer pain are more likely than patients with chronic nonmalignant pain to take larger daily doses, but there is usually no way of knowing by daily mg dosing alone whether a physician has overprescribed OxyContin for an individual patient.

38. The respondent conveyed that referral to a pain management specialist would be expected for primary care physicians treating patients with complex chronic pain.

39. Eighteen respondents thought their boards had not received any such complaints — their pain undertreatment complaint estimate was entered as zero. Of the nineteen who thought their boards had received such complaints, fifteen were able to give a 2001 estimate. If a range was given, the median of the range was entered. The actual range of values was 0 to 25. To correct for the outlier value of 25, that value was "windsorized" to the next highest value of 13. Raw values were then divided by the number of physicians per state (see data at <http://www.education-world.com/a_lesson/TM/WS_census_states.shtml>) and multiplied by 1,000.

40. We specifically asked about prisoners as a source of complaints, as they tend to file complaints with state medical boards regarding poor medical care in general. One respondent said he "tended to investigate most prisoner complaints because they're in a duress situation; they might not get the best care," while another commented, "Some department of corrections issues, like prisoners' being undertreated, we don't investigate. Even if it's true, are we going to do anything about it?"

41. Estimates for four of the five respondents whose boards had not used a pain management expert were entered as zero (one reported no cases of pain undertreatment complaints and did not know the number of opioid overprescribing complaints. We did not assume that this board had complaints about opioid prescribing to investigate, so we considered data for that board as missing). Of the twenty-three respondents whose boards had used a pain management expert and who gave an estimate of the percentage of investigations in which such an expert was used, if a range was given, the median of the range was entered.

42. Joranson et al., *supra* note 22.

43. The following scenarios may also indicate inappropriate quantities of opioids being prescribed: (1) the doctor is prescribing relatively low dose tablets but in great volume and does not know to shift the patient to a higher dose, a longer acting version, or a different drug, when the current drug is no longer effective; (2) the doctor may be prescribing in the hundreds of tabs a day. However, focusing on quantity alone is generally insufficient to determine that a physician is overprescribing.

44. See Martino, *supra* note 3.

Maximizing the Value of Electronic Prescription Monitoring Programs

David B. Brushwood

There is general agreement that the “principle of balance”¹ should guide controlled substance policy and regulation in the United States.² Although the diversion of controlled substances from medical to nonmedical purposes is a significant public health problem, overly aggressive controlled substance regulation has been shown to have an unintended deterrent effect on appropriate controlled substance use,³ including pain management with opioid analgesics.⁴ The promotion of effective pain management and the reduction of substance abuse are equally important regulatory objectives. Neither regulatory objective need be sacrificed to achieve the other. Rather, the two objectives must be balanced with each other to assure that necessary pain management is encouraged while drug abuse is curtailed.⁵

Approximately 75 million people in the United States suffer from severe pain. Fifty million of these suffer chronic pain, and 25 million suffer acute pain from trauma or surgery.⁶ Pain is not merely an uncomfortable symptom. It is a pathological condition that can adversely affect the outcome of treatment for other conditions.⁷ The direct economic cost of pain in the United States is about \$79 billion annually.⁸ This figure does not reflect the diminished quality of life as a result of suffering. Many patients in pain receive inadequate treatment or no treatment, despite the availability of safe and effective pharmacologic and nonpharmacologic treatment options.⁹

One significant barrier to the use of medications for the treatment of pain is that physicians, pharmacists, and other clinicians have difficulty discerning the difference between a patient who legitimately suffers pain and one who is pretending to be in pain for the sake of obtaining drugs.¹⁰ Pain is

a disease that cannot be ruled out by an evaluation of laboratory values, radiologic imaging, or a physical examination. Health care providers rely largely on patient interviews and histories to determine a patient’s need for pain medications.¹¹ They depend on their interpretation of what they see and hear to distinguish between pain patients and drug diverters. It is not an easy job. Conscientious and caring physicians and pharmacists have been duped into prescribing and dispensing opioid analgesics for persons who have no legitimate medical need.¹²

To gather evidence on the problem of inappropriate prescribing and dispensing of controlled substance medications, and to facilitate a resolution to the problem, seventeen states have adopted some sort of prescription monitoring program.¹³ Many early programs used ink-on-paper multiple copy prescriptions or serialized prescriptions. With the advent of computerized pharmacy systems, the recent trend has been for states to develop an electronic prescription monitoring program.¹⁴ There is currently no federal ink-on-paper or electronic prescription monitoring program. The Drug Enforcement Administration (DEA) supports the development of electronic state monitoring programs, and a bill has been introduced into the U.S. Congress that, if passed, would create the National All Schedules Prescription Electronic Reporting (NASPER) program.¹⁵

The purpose of this article is to describe the attributes of a safe and effective state or federal electronic prescription monitoring program. To be considered effective, a monitoring program must actually reduce the abuse of medicinal controlled substances. To be considered safe, the program must avoid unintended adverse consequences. Adverse consequences may include invasion of patient privacy or interference with the legitimate medical use of controlled substances for the treatment of pain or other pathological conditions. The article begins with an overview of the struc-

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ture and function of existing electronic monitoring programs. This overview includes an analysis of key policy issues. The article then questions how policymakers can know whether an electronic prescription monitoring program is achieving a reduction in substance abuse without producing a “chilling effect” on appropriate medication use. Next, the article describes how electronic monitoring programs might be included within developing pharmaceutical risk management programs. The article concludes with a summary of five key factors that can maximize the value of an electronic prescription monitoring program: comprehensiveness, expert analysis, timely and meaningful feedback, clear standards, and periodic program review.

PROGRAM FEATURES AND KEY POLICY ISSUES

The creation of electronic prescription monitoring programs is justified by the nonsystematic nature of medication acquisition and use in the United States. Although manufacturers, distributors, prescribers, and dispensers are highly regulated under the law, patients enjoy almost complete freedom to do as they please in obtaining and ingesting prescription drugs.¹⁶ Patients are free to procure prescriptions from any prescriber they wish, and to have their medication dispensed at any pharmacy they choose. Patients may use the same physician and pharmacy consistently, or they may change physicians and pharmacies as a matter of routine. There is no centralized record of the medications that any patient has received.¹⁷ Physicians and pharmacists do not regularly share information with each other. Without a centralized system, it is impossible to identify what patient has acquired what medications from what pharmacy under the authority of what physician. Drug seekers can exploit this lack of integration to acquire from different physicians and pharmacies quantities of pharmaceuticals that no single physician or pharmacist would allow.

As often occurs when states adopt systems without national standards for guidance, the approaches taken to the implementation of state electronic prescription monitoring programs vary.¹⁸ Most states begin their enabling legislation with a description of the controlled substances to which their program applies. Pharmacies in the state are then mandated to report, through electronic data transfer, the dispensing of these drugs to a centralized source. Usually drugs must be identified by name, drug code number, strength, quantity, and date. The patient and the prescriber must also be identified. The government agency to which the report is made then does an evaluation of the data. It may assess which physicians, pharmacists, and patients are associated with excessive controlled substance use. In some states, it is possible for physicians and pharmacists who have responsibility for a patient’s care to acquire from the agency a medication profile for the particular patient. From this report, physicians and pharmacists can learn whether their patients are

acquiring medications only from them or from other sources as well. Numerous policy issues have arisen over this close scrutiny of the prescribing and dispensing of controlled substances.

Accuracy of data

The lack of accuracy within these electronic monitoring programs is troubling. Pharmacists report their data using patient identifiers that are often incomplete or inconsistent, and are always subject to error. Forged or stolen identification documents may enable a drug diverter to escape scrutiny. The increasing incidence of identity theft raises the distinct possibility that a patient is not really the person she or he claims to be. Even when reported data are accurate, patients may have similar (or the same) names, similar (or the same) birth dates, or similar identification numbers. Program administrators must decide, by examining raw data only, whether patients who seem the same are in fact the same. When a physician or pharmacist requests a report for a particular person, program authorities who assemble the report must make a judgment about the inclusion or exclusion of information that may relate to that person’s medication use or may reflect medication used by a different person. If program administrators decide to emphasize specificity, they will insist on absolute concordance of received and dispersed information. This type of monitoring program will result in underreporting to those who request information. On the other hand, if program administrators decide to emphasize sensitivity, combining records that are similar to each other, then the program will overreport. In either case, the physician or pharmacist to whom a report is provided cannot assume that the information received is accurate. The report may include information for patients other than the patient for whom it has been requested, or fail to include information about the requested patient.

Confidentiality

Confidentiality issues are among the most obvious concerns when a government agency commands a private business to deliver to the agency information about many individual citizens who may have believed their information protected from such disclosure by professional ethics and legal rules restricting the release of private medical information. Legal rules of confidentiality have not evolved for pharmacy records as quickly as they have for medical records. In the not terribly distant past, pharmacy records contained only limited information. They conveyed little about the patient, and were too poorly organized to permit easy access. Pharmacists now maintain far more extensive information about patients.¹⁹ This information may convey significant facts about patients,²⁰ and be easily accessible if it is electronically maintained.²¹ Nonetheless, the law has not caught up with this increased

need for privacy in pharmacy records. Courts have generally held that pharmacy is a pervasively regulated industry, and that there is a reduced expectation of privacy in pharmacy records.²² Information that would be impossible to obtain from a patient's physician may be readily available from the patient's pharmacist.²³ Sharing private information about one's patients not only diminishes the respect inherent in the traditional provider-patient relationship, it threatens the quality of care by deterring patient disclosure to physicians of information that physicians need to know but patients prefer to keep private.

The constitutionality of ink-on-paper prescription monitoring programs was directly addressed in 1977 by the U.S. Supreme Court in *Whalen v. Roe*.²⁴ Referring to the New York triplicate copy prescription program²⁵ as "the product of an orderly and rational legislative decision,"²⁶ the Court rejected challenges from patients and physicians who claimed that the patient-identification aspect of the program would lead many patients to decline necessary therapies for fear of being stigmatized as drug addicts. The Court discussed two relevant constitutionally protected privacy interests: the interest in avoiding disclosure of private matters, and the interest in independent decision-making.

Describing the high level of security over New York's centralized and computerized patient-specific information (e.g., receiving room protected by a locked wire fence and an alarm system, access limited to a small number of people, unlawful release of information punishable by up to 1 year in prison), the Court ruled that requiring pharmacists to disclose information to representatives of the state does not automatically amount to an invasion of privacy. Acknowledging that "some individuals' concern for their own privacy may lead them to avoid or to postpone needed medication attention,"²⁷ the Court apparently viewed this reduction in the quality of care as a necessary cost to "prevent unscrupulous pharmacists from repeatedly refilling prescriptions, to prevent users from obtaining prescriptions from more than one doctor, or to prevent doctors from overprescribing, either by authorizing an excessive amount in one prescription or by giving one patient multiple prescriptions."²⁸ In a concurring opinion, Justice Brennan expressed apprehension about the computerized storage of sensitive information, a practice that was relatively new at the time: "The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity of some curb on such technology."²⁹

With the briefest of explanations, the Court dismissed the argument that the New York triplicate prescription program would interfere with the right of patients to decide independently, with their physicians, how to acquire and use needed medication. Noting that the state could prohibit entirely the use of particular controlled substances if it wished, the Court reasoned that if a drug is available, then the deci-

sion to prescribe it, or use it, is left entirely to the physician and the patient.³⁰ The Court held that neither the immediate nor the threatened impact of patient-identification requirements in the New York ink-on-paper prescription monitoring program were sufficient to constitute an invasion of any right or liberty protected by the Constitution.

The Court left open the possibility that future developments could change its perspective, but it is difficult to know whether the widespread dissemination of information under an electronic prescription monitoring program is the type of change that would influence the Court's view of the privacy issue. In contrast with the New York system reviewed in *Whalen*, most state electronic monitoring programs disseminate huge volumes of sensitive, patient-specific information to the pharmacies and clinics that request it. The high level of security associated with the New York program described by the Supreme Court could not exist for a program that not only aggregates information, but also distributes it widely. This widespread distribution of private information to public places may create the "potential for abuse" that Justice Brennan anticipated would require "some curb on such technology." A law could be written with severe criminal penalties for unauthorized disclosure of information by a pharmacy or clinic, but if imposing penalties for violations of a law were a certain method of assuring compliance with a law, then drug diversion would not be the problem it currently is.

Access to palliative care

Twenty years after its opinion in *Whalen v. Roe*, the U.S. Supreme Court decided the cases of *Washington v. Glucksberg*³¹ and *Vacco v. Quill*.³² Widely known for their rejection of a constitutionally protected right to physician-assisted death, these two cases have also become recognized for their possible creation of a constitutionally protected right to palliative care. Professor Robert Burt was the first to suggest that a majority of the justices joining in these two opinions held that "states must not impose barriers on the availability of palliative care for terminally ill patients."³³ At least partly as a consequence of this interpretation, the American Bar Association (ABA) House of Delegates passed a resolution on July 11, 2000, urging federal and state governments to avoid laws that impose barriers to the provision of quality pain and symptom management.³⁴ A background report from the ABA Commission on Legal Problems of the Elderly specifically referred to ink-on-paper prescription monitoring programs as a deterrent to the legitimate prescribing of opioids.³⁵

Professor Burt's argument requires pulling together language from footnotes to the majority opinion in both cases as well as excerpts from various concurring opinions. He concludes: "A court majority effectively required all states to ensure that their laws do not obstruct the provision of adequate palliative care, especially for the alleviation of pain and other physical symptoms of people facing death."³⁶ In

applying this conclusion to the practice of pain management, Professor Burt argues that the individual right to palliative care cannot be overridden by state actions unreasonably burdening access to a physician's assistance, and that "state laws restricting the availability of opioids for the management of pain are the most likely targets for judicial invalidation by this criterion."³⁷ He uses the example of ink-on-paper prescription monitoring programs as the type of regulatory burden that would be the most vulnerable to constitutional challenge.

An alternative view of the opinions in *Glucksberg* and *Vacco* has been provided by Professor Lois Shepherd. According to Professor Shepherd, the Court's concern about pain relief for the terminally ill does not equate to a constitutionally recognized right to palliative care.³⁸ If the justices were really concerned with state laws restricting the availability of pain management, they would turn their attention to these laws, not the laws prohibiting physician-assisted death that may have an effect on effective palliative care for the terminally ill.

Professor Shepherd offers a different understanding of a liberty-based constitutional right to relief of suffering, derived from the "meaning thesis" she advances. She proposes, purely for the sake of argument, that at the heart of liberty is meaning, and "that a person may suffer so much that she cannot, without relief, find meaning in life."³⁹ Purposefully rejecting her own proposition, Professor Shepherd concludes that the liberty-based approach she develops is too limiting, and that effective legal recognition of the right to be free from suffering will require making new law, not simply reinterpreting existing law.

Any right to be free from unreasonable government restrictions on access to palliative care, whether derived from Professor Burt's analysis or Professor Shepherd's alternative approach, has implications for electronic prescription monitoring programs. This would be the case particularly if empirical data eventually showed that electronic programs have the same deterrent effect on opioid prescribing as do ink-on-paper programs.⁴⁰ The question seems not to be whether there should be recognition of a fundamental right to pain management, but how to constitute that right within existing or newly developed law. Any barriers placed in the way of physician prescribing, or pharmacist dispensing, of appropriate pain therapies have the potential to undermine a fundamental right patients may have to effective palliative care.⁴¹

The professional standard of care

It is well-settled that physicians and pharmacists must practice consistent with the professional standard of care to avoid malpractice liability and/or administrative discipline. This rule is as true for prescribing or dispensing controlled substances in the treatment of pain, as it is for using any other treatment modality for any other condition.⁴² There is ample

evidence that physicians and pharmacists have traditionally perceived greater legal risk for prescribing or dispensing too much pain medication than for prescribing and dispensing too little pain medication.⁴³ Recent emphasis on the professional and institutional responsibility to meet pain patients' needs, and the adoption of standards of practice that provide safe-harbor to physicians who adhere to explicit guidelines in prescribing controlled substances for pain, have enabled physicians to be more aggressive in prescribing high-dose opioids and pharmacists to be more willing to fill prescriptions for high-dose opioids. Nevertheless, concerns linger regarding the specificity of the professional standard of care and the level of safety that exists within the seemingly enlightened drug regulatory community.⁴⁴

Physicians and pharmacists are required by federal law to prevent the diversion of controlled substances, and they share a responsibility to assure that controlled substance prescriptions are issued for a legitimate medical purpose within the usual course of professional practice.⁴⁵ A history of aggressive government reaction to the perceived overuse of pain medications has led to understandable reluctance by physicians and pharmacists to prescribe or dispense high doses of opioid analgesics, despite recent widely publicized emphasis on the need to relieve suffering through appropriately high dosing of opioids for chronic pain. Regulators know that clinicians cannot be perfect in their assessment of patients, and that clinicians may unwittingly be duped into prescribing or dispensing pain medication when they lack full knowledge of a patient's pattern of excessive controlled substance acquisition. However, regulators are intolerant of physicians⁴⁶ and pharmacists⁴⁷ who prescribe and dispense controlled substances when they can know from readily available information that a person is a drug seeker who should not receive these drugs.

The advent of electronic prescription monitoring programs may be relevant to the standard of care in prescribing or dispensing controlled substances. Physicians and pharmacists will have the ability to know what medications their patients have received from other physicians or pharmacists. Given the knowledge-based standard applicable to physicians and pharmacists in the past, the ability to know more about a patient's medication use may lead to a legal duty to obtain this information before prescribing or dispensing controlled substances. Perhaps it will become the standard of care to refuse prescribing or dispensing any controlled substance until first assuring complete knowledge by accessing a report made available from the agency administering an electronic monitoring program. Not only may the standard require that this newly available knowledge be obtained from the agency, it may also require that the information provided by the agency be used consistent with evidence-based and consensus-driven practice guidelines.⁴⁸ Without clear direction on the standard for use of an electronic monitoring program, physicians and pharmacists may be left in an uncomfortable quandary,

wondering what is expected of them and worrying that no matter what they do it will not be in compliance with the standard of care. Such confusion could lead to a “play it safe” decision to avoid prescribing controlled substances altogether rather than risk malpractice or professional discipline in prescribing them.

MEASURING PROGRAM OUTCOMES

Due to the recency of their implementation, it is not surprising that a comprehensive, empirical evaluation of electronic prescription monitoring programs has yet to be done. Although there are many opinions about their success, facts to support these opinions are scarce. Empirical studies about safety and efficacy that compare data from the periods before and after program implementation within a single state have not been done. Likewise, statistically valid comparisons between states that have electronic prescription monitoring programs, and those that do not, of the rates of drug diversion and the deterrent effect on prescribing pain medication have not been done. These studies would be admittedly difficult to conduct, but not impossible.

For a preliminary analysis of electronic prescription monitoring programs, one must rely on anecdotes from program administrators in the states where these programs have been in operation for many years and on inferences from the ink-on-paper programs. The absence of evidence to support the safety and efficacy of new electronic monitoring programs stands in stark contrast with the requirement for hard evidence to support the safety and efficacy of newly approved drugs. Furthermore, once they have been placed into widespread use, newly approved drugs are constantly monitored for the emergence of safety and efficacy issues that were not apparent during preapproval tests. It seems reasonable to expect that new drug surveillance systems would be subject to the same safety and efficacy standards as new drugs. The public deserves some level of assurance that electronic prescription monitoring will be a benefit to diversion control and not detrimental to pain management.

The evaluation of any program requires initial goal-setting to define the parameters against which the program will be measured. There are three reports available from which to determine general programmatic goals. The reports have been produced by the DEA,⁴⁹ the Alliance of States with Prescription Monitoring Programs (ASPMP),⁵⁰ and the Wisconsin Pain & Policy Studies Group (WPPSG), three groups that are keenly interested in electronic prescription monitoring programs.⁵¹ The WPPSG report is the capstone of a series of reviews provided over the previous decade by David Joranson and his colleagues in Wisconsin. All three of the reports recognize structure and process goals with which electronic monitoring programs should comply.⁵² More importantly, the reports recognize two key outcome goals for these programs: reducing the abuse of pharmaceutical con-

trolled substances, and not interfering with legitimate medical practice.⁵³ These two goals are fully consistent with congressional intent in the enactment of controlled substance legislation.⁵⁴ Thus, a successful electronic prescription monitoring program is one that reduces the abuse of pharmaceutical controlled substances and does not interfere with the legitimate use of controlled substances.

Evidence for the reduction of substance abuse

It may be difficult for researchers to find a direct correlation between the ultimate outcome of reduced substance abuse and the implementation of electronic prescription monitoring programs, even if such a correlation exists. Yet, despite the difficulty of outcomes research, it is outcomes to which the health care community has turned for meaningful program evaluation. For example, no longer is it deemed sufficient for a hypertension program to reduce the blood pressure of hypertensive patients without additional evidence that strokes and heart attacks have also decreased. Continuing education programs with the most highly respected speakers and the most up-to-date handouts are pointless if the professional practices of those who attend the programs do not improve as a result of their attendance. Similarly, if a state electronic prescription monitoring program only makes practitioners more aware of diversion or reports that arrests of drug seekers are increasing, then their value is limited. The expectation is that the programs are having some effect on the level of substance abuse. It is results that matter. Difficult though it may be to do, it is not unreasonable to expect program administrators to provide clear evidence of positive outcomes from their programs.

There is disagreement as to whether ink-on-paper prescription monitoring programs reduce substance abuse. Joranson and Gilson, from the WPPSG, write: “There is little evidence to demonstrate that government prescriptions actually prevent drug misuse and diversion.”⁵⁵ In contrast, the ASPMP report says: “States have found that prescription monitoring programs are among the most effective tools available to identify and prevent drug diversion at the prescriber, pharmacy and patient levels.”⁵⁶ However, there is no mention in the ASPMP report of any data substantiating a reduction in substance abuse. Of the three reports, the DEA report contains the lengthiest analysis of the effectiveness of prescription monitoring programs, but its contents warrant careful scrutiny. The editor’s note preceding the report acknowledges that the report relies on both statistics and anecdotes.⁵⁷ In fact, the report contains very few statistics and a great many anecdotes. As one might expect from anecdotes provided primarily by the administrators of state prescription monitoring programs, the language is almost uniformly descriptive of programmatic success.

Of the relatively sparse statistics included in the report, those from Oklahoma are of particular note.⁵⁸ Oklahoma

implemented its electronic prescription monitoring program in 1991, the first in the country. According to the DEA report, between 1991 and 1995 there was a significant reduction in the number of dosage units of controlled substances seized by law enforcement authorities in Oklahoma, as compared with the period between 1986 and 1990. One could conclude from this that the reduction in the number of dosage units seized by law enforcement authorities was the result of the monitoring program, and thus that the statistics support success of the program. However, the DEA report also indicates that between 1989 and 1995 there was a steady increase in the number of death certificates indicating the involvement of controlled substances (from 31 in 1989 to 109 in 1995); the majority of these deaths were from the use of pharmaceutical controlled substances. From this information, one could conclude that the abuse of pharmaceutical controlled substances actually increased dramatically during the first years of the electronic prescription monitoring program, and that the program was not a success. The point in mentioning these statistics is not to conclude with certainty that the Oklahoma program was successful or not. The point is that the statistics provided by the DEA report do not permit any definitive conclusion to be drawn.

More persuasive evidence of program success in certain metropolitan areas may be available from the data aggregated semiannually by the Drug Abuse Warning Network (DAWN), under the auspices of the federal Substance Abuse and Mental Health Services Administration (SAMHSA).⁵⁹ These data are based on “drug episodes” and “drug mentions,” as reported by a sample of hospitals operating 24-hour emergency departments across the country. The trends in major substances of abuse for a metropolitan area, as described by the DAWN data, could be correlated with the presence or absence of an electronic prescription monitoring program in the state from which the data are obtained. Trends within a state could be examined both before and after a program had been adopted. If available, other measured indicators of substance abuse also could be used to measure the success of an electronic prescription monitoring program in reducing the abuse of pharmaceutical controlled substances — for example, medical examiner data recording deaths due to diverted controlled substance abuse or data summarizing the identity of drugs seized by law enforcement “on the street.” Program administrators should be given wide latitude to study whether their programs are reducing diversion, but some evidence beyond enthusiastic anecdotes should be required.

Evidence for unintended interference with prescribing

There is also widespread disagreement over whether prescription monitoring programs deter the appropriate prescribing and dispensing of opioid analgesics to treat pain. However, there are more data available to evaluate this possible effect of prescription monitoring programs.

A background of tension exists between drug control authorities and health care practitioners regarding the enforcement of controlled substance laws.⁶⁰ The concern is that a poorly constructed electronic prescription monitoring program could exacerbate the existing tension and cause health care practitioners to prescribe less pain medication than might otherwise be clinically called for. Although prescription monitoring programs have been developed and administered by highly motivated people who genuinely wish no pain patient to be deprived of necessary pain medication, they cannot change the background against which their programs operate.

There is a large body of research documenting what has become referred to as a “chilling effect” on the prescribing of pain medications by ink-on-paper prescription monitoring programs. This literature has been reviewed elsewhere.⁶¹ In the WPPSG report, Joranson and Gilson write: “research has documented that the implementation of government prescription programs is associated with decreased prescribing of Schedule II drugs.”⁶² They conclude that “although administrators of prescription monitoring programs assert that quality of care is not compromised, empirical evidence suggests otherwise.”⁶³

Denial of a deterrent effect on prescribing by prescription monitoring programs has been the consistent message of controlled substance authorities. In 1989, a DEA official concluded that “the law is not the problem in providing an adequate supply of drugs, particularly narcotics, to patients for the treatment of intractable pain.” The official continued: “I do not think that lack of availability can be explained by a triplicate prescription system or any similar restrictions.”⁶⁴

The recent DEA report responds with sarcasm to the suggestion of a chilling effect. The agency’s position differs significantly from the report of the ABA Commission on Legal Problems of the Elderly, issued the same month as the DEA report (April 2000). The ABA report summarizes studies confirming that “drug anti-diversion policies do have an effect on the rate of prescriptions for, and perhaps increase the use of, less effective or even harmful medications.”⁶⁵ The ABA report cites other studies to support its conclusion that “the criminal law has failed to protect patients and families and has significant power to deter appropriate pain management for dying patients.”⁶⁶ Without analyzing these studies, or even referencing them, the DEA report pejoratively refers to a “parade of physicians” who have testified that regulatory scrutiny has had an adverse effect on the relief of pain.⁶⁷ Referring with disbelief to what it describes as the “alleged” chilling effect,⁶⁸ the agency report concludes that state prescription monitoring programs appear “not to have any impact on the overall consumption and prescribing of analgesic drugs.”⁶⁹

The DEA report documents that there has been a national increase in the use of pain medications over the past

decade, coinciding with the implementation of state electronic prescription monitoring programs.⁷⁰ Data from various states that currently operate these programs also show an increase in overall prescribing of pain medications during the time these states' programs have been in operation. This absolute increase in prescribing is offered as evidence that the programs have had no chilling effect on the prescribing of pain medications. It is not a persuasive argument. Tremendous efforts were undertaken during the past decade to encourage physicians to prescribe, and pharmacists to dispense, high doses of opioids and other necessary drugs to treat pain.⁷¹ These efforts were initiated in response to widely recognized deficiencies in pain management.⁷² As a result of these efforts, one would expect overall prescribing of pain medications to increase dramatically even with a significant chilling effect.

To discern the presence or absence of a chilling effect, one must consider not how many pain management medications have been prescribed, but how many pain management medications have *not* been prescribed. This is a far more difficult task than merely counting the volume of drugs distributed to a state or prescribed within a state. It is an undertaking that requires systematically asking physicians whether they have refrained from prescribing under circumstances when they otherwise would have due to the monitoring program. This is the technique used by many of the researchers who published the scientific studies that were cited in the ABA report but ignored in the DEA report.

An electronic prescription monitoring program may deter legitimate prescribing not only by raising the threat of disciplinary or criminal action, but also by creating confusion between the concepts of addiction and pseudoaddiction.⁷³ A physician who receives information from a monitoring program indicating that a patient has a history of receiving pain medication from several different physicians may conclude that the patient is an addict for whom pain medications should no longer be provided. However, the patient may instead be a pseudoaddict whose pain has not been controlled by subtherapeutic analgesic doses and who is seeking relief of pain, not support of an addiction. A description of the amount and frequency of medication use cannot, by itself, provide the richness of information that a clinician needs to accurately evaluate a patient.⁷⁴ It is a beginning, not an ending. If the availability of program reports leads physicians to seek no further information, then legitimate patients may be wrongly labeled as "addicts" and their pain medication discontinued.

Further research is needed before even preliminary conclusions can be drawn about the existence of a deterrent effect on prescribing by state electronic prescription monitoring programs. Perhaps the documented deterrent effect of ink-on-paper prescription monitoring programs is simply the result of the inconvenience caused by the required use of special forms, and the constant reminder of regulatory over-

sight that is produced by the physical presence of special forms. These are factors that would be irrelevant with an electronic program. Perhaps the only prescribing that is deterred by an electronic monitoring program is inappropriate prescribing, and the reality is that appropriate prescribing remains unaffected by these programs. On the other hand, it may be that electronic monitoring programs have a significant deterrent effect on appropriate prescribing and that patients in pain are needlessly suffering because of them. State administrators of electronic prescription monitoring programs should empirically investigate these and other relevant issues, in collaboration with health care providers and academic researchers who share the administrators' commitment to reducing substance abuse without adversely affecting patient care. Significant expenditures are being made to operate these electronic monitoring programs, and at least a tiny fraction of that amount should be devoted to scientifically valid program evaluation.

Coordinated system monitoring

The problems faced by state and federal authorities in preventing substance abuse and not interfering with legitimate medication use are in many ways similar to the problems being addressed by the federal Food and Drug Administration (FDA), state boards of pharmacy, and government prescription drug payment plan administrators (primarily Medicaid and pharmaceutical programs for the elderly) in promoting quality medication use. Each of these organizations seeks to balance providing access to appropriate and necessary pharmaceuticals with denying access to inappropriate and unnecessary pharmaceuticals. One measure of programmatic success for an electronic prescription monitoring program might be the degree to which it can show cooperation and coordination with these other programs in the development of a balanced, systematic approach to the improvement of drug therapy. Improving the quality of medical and pharmacy practice will reduce drug diversion.

The FDA has acknowledged that there are limits to what can be done centrally to protect patients from harm due to adverse drug events.⁷⁵ Currently, reporting of adverse drug events is not mandatory for health care professionals. Problems with drugs do not become evident until well after harm has already occurred in a significant number of individuals, and at that point the drastic step of withdrawal from the market may be the only recourse. The large majority of patients for whom a withdrawn drug has been safe and effective will be denied access to it, to protect the small minority for whom the drug is unsafe and/or ineffective. An expanded electronic prescription monitoring program could facilitate the early discovery of drug-related problems (at first with controlled substances and later with other newly approved drugs), through the provision of reports by pharmacists within the existing electronic prescription monitoring system. In

the future, through the use of this systematically obtained information, the FDA and the DEA could cooperate in a way that they could not have in the past.⁷⁶

State boards of pharmacy and state-administered Medicaid programs have long monitored medication use through prospective and retrospective drug use review.⁷⁷ Pharmacists are required in most states to evaluate prescriptions prior to dispensing them, to discover, among other things, potential problems such as clinical abuse or misuse. A state drug use review board periodically examines aggregate data to identify trends in the inappropriate use of medications. Surveillance programs focusing primarily on controlled substances have discovered Medicaid recipients who are overusing the program, and in some states patients can be “locked in” to a single physician or pharmacy provider to prevent duplicative care. These programs could be coordinated with electronic prescription monitoring programs to their mutual benefit. Other programs that produce data that could be usefully coordinated with an electronic prescription monitoring program include the DEA’s Automation of Reports and Consolidated Orders System (ARCOS)⁷⁸ program and data from the DEA’s mandatory reports of theft or loss of controlled substances.⁷⁹ Both of these programs significantly assist in understanding the profile of drugs released for use within the closed system of controlled substances and the ways in which they leak from the system.

The goals of enhanced drug safety and improved drug therapy are much sought after by interests both within and outside the health care professions. The concept of “pharmaceutical care” has been developed to promote a systematic, organized approach to drug therapy that correlates therapeutic outcomes from the provision of pharmaceutical products and services, with the structures and processes of their provision.⁸⁰ To the extent that deficits in knowledge or information are a part of existing problems with drug therapy, electronic prescription monitoring programs could provide part of the solution. The improved quality of patient care resulting from pharmacists’ providing patient data to a centralized oversight agency and the agency’s providing meaningful feedback to pharmacists and physicians could lead to the valuable added effect of deterred diversion and abuse. The emphasis of regulation could turn dramatically from the unintended adverse consequences of law enforcement to the intended beneficial effects of enhanced quality of care. There are synergies between drug abuse prevention programs and medical quality assurance programs. These synergies could be exploited to both promote patient health and protect public health.

ATTRIBUTES OF AN EFFECTIVE ELECTRONIC PRESCRIPTION MONITORING PROGRAM

The effectiveness of any program depends not only on the program’s own characteristics, but also on the environment within which the program operates. An effective electronic

prescription monitoring program requires law enforcement personnel who are aggressive in the prosecution of controlled substance diversion, as well as professional licensing boards that have zero tolerance for those licensees who abuse the privilege of prescribing or dispensing controlled substances. Regulated professionals will respect the integrity of the system only if system requirements are enforced meaningfully and consistently. Success will require the availability of high quality continuing education programs on pain management and the appropriate use of controlled substances for other medical conditions. Success will, above all else, require a trusting atmosphere, where regulatory authorities and health care practitioners can communicate openly to avoid misunderstandings.

A successful prescription monitoring program supplements good law enforcement and health care practices. It does not replace them. There will of course be leaks within any system. The small minority of physicians, pharmacists, and patients who are gaming the system in the absence of an electronic monitoring program will certainly find ways to continue doing so once a program is in operation. A high level of reliance on an electronic monitoring program to end diversion of controlled substances may result in disappointment if traditional law enforcement techniques are not continued.

Besides an environment that promotes consistent law enforcement, education on pain management, and openness in communication between health care professionals and regulatory authorities, an effective electronic prescription monitoring program will require comprehensiveness, expert analysis, timely and meaningful feedback, clear standards, and periodic program review.

Comprehensiveness

Information that provides only part of a story may be worse than nothing. Consequently, an effective electronic prescription monitoring program must be comprehensive in the data it collects. First, this means that the program must require the reporting and aggregation of data from the dispensing of all controlled substances. A program that requires reporting only Schedule II controlled substances cannot address problems that may result from a shift in use by abusers to Schedule III controlled substances. Likewise, a program that requires reporting only opioid controlled substances may fail to detect problems with, say, the abuse of benzodiazepines. Under federal law, any controlled substance is so classified because it has an actual or relative potential for abuse. Thus, no subgroup of controlled substances should be excluded.

Second, this means that the program must be flexible enough to allow program operators to also collect data on any other medication that is not a controlled substance but has been implicated as a substance of abuse in the particular state. For example, in some areas, the drug carisoprodol has

been identified as a substance of abuse, even though it is not classified as a controlled substance under federal law.⁸¹ In those areas, the prescription monitoring program should require reporting carisoprodol and any other drugs that are known to be associated with abuse. A complete picture of abuse may not be available if program administrators and health care practitioners are denied knowledge of the full range of abusable drugs that are being dispensed to patients.

Occasionally there are drugs that become identified with substance abuse even though they are not, by themselves, considered drugs of abuse. There is a pharmacologic quality of antihistamines, for example, that leads to potentiation of the beneficial analgesic effects of opioids. This quality has been exploited by substance abusers to enhance the abuse characteristics of certain controlled substances. Tripelennamine is an antihistaminic drug that has been used in this way. It has been combined with paregoric (for a combination known by abusers as “blue velvet”)⁸² and with pentazocine (for a combination known as “T’s and Blues”).⁸³ Both paregoric and pentazocine are controlled substances, but one might identify them as substances of abuse only if one knew that they were being used with tripelennamine. The failure to include tripelennamine as a reportable drug in an area where the drug is known to be used in combination with opioids by drug abusers would give only a partial picture of the pattern of abuse in that area.

A comprehensive electronic prescription monitoring program should include not only all controlled substances and possible substances of abuse, but all pharmacies as well. This would require that mail-order and Internet pharmacies filling prescriptions for out-of-state patients report to the electronic monitoring programs within those patients’ states.

Expert analysis

The state agency running the electronic prescription monitoring program should have sufficient expertise to evaluate the significance of a pattern of dispensing that may be evident from the aggregated data. A state department of health or a state board of pharmacy would meet this criterion. A law enforcement agency would not because those untrained in health care would not be qualified to distinguish between appropriate and inappropriate therapy. Reporting to a health care agency carries with it the added assurance for physicians and pharmacists that a health care colleague would be reviewing their practices, not a law enforcement officer. This may make it more likely that innovative pain management practices would be adopted by physicians and pharmacists, since they would be secure in the knowledge that their activities would be measured against health care standards rather than law enforcement standards.

However, simply because an agency focuses on public health care needs does not necessarily mean that someone

with special expertise in pain management or substance abuse will be available to evaluate the reported data. It will probably be necessary to appoint an expert committee to periodically review both specific cases and general trends in medication use. The expert committee should be comprised of physicians, pharmacists, law enforcement personnel, and others who can bring to the analysis their disciplinary perspectives. The expert committee should provide general policy guidance to staff, and assist with specific applications of the policy as needed.

Timely and meaningful feedback

Effective electronic prescription monitoring programs will provide timely feedback to physicians and pharmacists who have accepted responsibility for a patient’s care. The quality of a patient’s drug therapy can be vastly improved if those who prescribe, dispense, and monitor the therapy have a complete record of medications received by the patient. This information may be particularly important for a new patient, but it can also help coordinate ongoing care for a patient who is being treated by several different providers. A medication profile provided to a pharmacist or a physician by an electronic prescription monitoring program will be the most useful in constructing trends in medication use over time, rather than identifying an acute problem at a particular time. Pharmacists and physicians can discover, from a centrally reported history of medication use, those patients who are not being honest about their controlled substance acquisition, as well as those who may have forgotten the medications they have used or never realized that a controlled substance had been prescribed for them. It is important that this information be made available to the physician or pharmacist on the same day it is requested. Immediate electronic access to the information would best facilitate quality care.

The opportunity to improve therapy would be enhanced if the information aggregated were not simply a list of drugs dispensed to a patient, but also contained information about the perceived effectiveness of care. For example, pain patients could be asked to report a pain score every time a report is requested by a physician or pharmacist from an electronic prescription monitoring program administrator. Other simple questions about access to pain therapies and satisfaction with pain therapies could be included in the information being requested of the patient. The patient’s responses could then be included in the request submitted by the physician or pharmacist, and they could be entered into the database by the program administrators. A history of the responses for each patient, along with a list of the medications dispensed, could be included in the reports sent to requesting physicians and pharmacists. From this information it would be possible to evaluate not just the types and number of medications used over time, but also the patient’s perceived effectiveness of the medications over time.

Clear standards

The availability of comprehensive information about a patient's controlled substance use will enable pharmacists and physicians who fully utilize the services of an electronic prescription monitoring program to improve the quality of care they provide to their patients. The opportunity to improve medical care is both exciting and daunting. Health care providers need to know the standard of practice against which they will be judged if the care they provide is evaluated by licensing boards or in malpractice proceedings. Uncertainty of standards may lead to risk-averse medical and pharmacy practices that return pain management to the uniform "start low, go slow" approach of times past. A flexible and balanced approach to the use of program reports should encourage improvements in care and collaboration among a patient's health care providers. Standards should produce both decreased prescribing for patients who have received too many controlled substances and increased prescribing for patients who have received too few.

Patient reports transmitted to pharmacists and physicians from an electronic prescription monitoring program could include relevant clinical and regulatory guidelines for the use of controlled substances, along with legal requirements for the use of the same controlled substances. Physicians and pharmacists could then compare the patient's actual use of controlled substances with the guidelines provided by the program. As the sophistication of a state's program develops, it could individualize the included information to reflect specific parameters of a single patient's drug use. Physicians and pharmacists would be supported in their care of patients through the provision of guidelines for clinical care. They would be enabled to prescribe and dispense appropriately high doses of opioid analgesics to treat pain for patients whose report indicated a need for aggressive therapy based on the distributed guidelines.

Periodic program review

The primary goal of each state electronic prescription monitoring program is to reduce substance abuse without adversely affecting the appropriate use of controlled substances in legitimate medicine. Each state programs must be continually evaluated vis-à-vis this goal. The precise criteria for evaluation may vary from state to state, and the criteria may change over time within a state, but program evaluation must show whether specified criteria have been met within a given timeframe in each state. States with similar evaluation criteria may be able to compare their program evaluations to determine what approaches to program implementation can be expected to produce the best results. Programmatic changes within a state can be monitored from one year to the next to determine whether anticipated program enhancements actually led to the achievement of stated goals.

A benchmark for program accuracy should be established. Physicians and pharmacists should be told both the benchmark and how accurate the program actually is. Administrators should empirically measure how often they accurately include in their patient-specific reports all the information reported to them for a given patient (a specificity problem), without inaccurately including information reported for a different patient (a sensitivity problem). For example, if the program's goal is to be accurate 90 percent of the time, then program administrators should, first, learn how often that goal is met and share this information with those who request reports. Second, if empirical data show that a program's reports are completely accurate only 80 percent of the time, then physicians and pharmacists should be told that there is a one in five chance that a given report may contain an error.

The process of programmatic goal-setting should reflect the interests of both the law enforcement community and the health care community. A program that has the potential to meet the needs of both should not be satisfied with having achieved only a part of its potential. Ultimately, it will be the state legislature that determines whether the demonstrated success of the program warrants continuation.

CONCLUSION

The maximum value from electronic prescription monitoring programs will be realized in states that design them as health care programs with significant law enforcement benefits. The goals of improved drug therapy and reduced controlled substance abuse are not mutually exclusive; they can be synergistic. However, the implementation of uncoordinated programs, each pursuing one of these goals, has in the past led to distrust and antagonism between law enforcement personnel and health care providers. This antipathy has perpetuated the suffering of both pain patients and the victims of substance abuse. Properly designed and implemented electronic prescription monitoring programs have the potential to create a collaborative regulatory environment that reduces substance abuse. Rather than merely not deter appropriate pain treatment, they can actually improve the quality of drug therapy involving controlled substances, including opioid analgesics. Yet, the value of these programs should not be assumed; it should be empirically examined through systematic evaluations. Not enough is yet known about electronic prescription monitoring programs to conclude how they are best designed or implemented. Anecdotes abound, but scientific data are sparse. Existing programs should conduct evidence-based evaluations, and newly developing programs should likewise incorporate evaluations into their procedures. Programmatic changes should be made to reflect what is learned about structures and processes that are associated with positive outcomes.

REFERENCES

1. The importance of creating a balanced system in which regulatory control of medications does not interfere with legitimate medicine has long been recognized. The federal law that establishes the framework for controlled substances regulation begins with the statement, "Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American People." 21 U.S.C. § 801(1) (2001). The "principle of balance" was first articulated by David Joranson and June Dahl. See D.E. Joranson and J.L. Dahl, "Achieving Balance in Drug Policy: The Wisconsin Model," in C.S. Hill, Jr., and W.S. Fields, eds., *Advances in Pain Research and Therapy*, vol. 11 (New York: Raven Press, 1989). The principle has been promoted by the Wisconsin Pain & Policy Studies Group, which has developed guiding principles for analysis of statutes and regulations based on the principle of balance. See D.E. Joranson et al., *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (Madison: The Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000), available at <<http://www.medsch.wisc.edu/painpolicy/eguide2000/index.html>>.
2. The need for balance in pain policy regulation has been recognized in a consensus statement by health care providers, health care regulators, and law enforcement. See Drug Enforcement Administration, *21 Health Groups Call for Balanced Policy on Prescription Pain Medication Like OxyContin* (October 23, 2001), available at <http://www.deadiversion.usdoj.gov/pubs/pressrel/newsrel_102301.pdf>.
3. See D.E. Joranson and A.M. Gilson, "Regulatory Barriers to Pain Management," *Seminars in Oncology Nursing*, 14 (1998): 158–63. Widely publicized disciplinary cases have focused physician attention on the risks of controlled substance prescribing. See, e.g., *Hoover v. Agency for Health Care Administration*, 676 So. 2d 1380 (Fla. Dist. Ct. App. 1996); *Hollabaugh v. Arkansas State Medical Board*, 861 S.W.2d 317 (Ark. Ct. App. 1993). In a recent survey of physicians, 23.8 percent agreed with the statement, "I give my patients a limited supply of pain medication to avoid being investigated." In the same survey, 26.4 percent of physicians admitted that they feared an investigation by regulators if they prescribed controlled substances for a chronic pain patient. See S.M. Weinstein et al., "Physicians' Attitudes Toward Pain and the Use of Opioid Analgesics: Results of a Survey From the Texas Cancer Pain Initiative," *Southern Medical Journal*, 93 (2000): 479–87.
4. The terms "opioid analgesic" and "narcotic" are virtually synonymous, but the former term is used consistently by the health care community, while the latter term is used consistently by the regulatory and law enforcement community. Both terms refer to drugs that are derived from opium or are synthetic adaptations of opium. They depress the central nervous system, relieve pain, and are used by drug addicts to support their addiction. Contrary to popular belief, the use of prescribed opioid analgesics by pain patients rarely leads to addiction. See M. Pappagallo, "The Concept of Pseudotolerance to Opioids," *Journal of Pharmaceutical Care in Pain Symptom Control*, 6 (1998): 95–98.
5. Even in the midst of the so-called "OxyContin crisis" of 2001, the Drug Enforcement Administration reiterated the importance of balance, describing its goal as "to ensure that the legitimate users of OxyContin® continue to receive their medication while reducing its diversion and abuse." See Drug Enforcement Administration, *Working to Prevent the Diversion and Abuse of OxyContin®*, at <http://www.deadiversion.usdoj.gov/pubs/brochures/alert_oxycontin/alert_oxy.htm> (last visited April 29, 2002).
6. See American Chronic Pain Association, *Frequently Asked Questions*, at <<http://www.theacpa.org/faqs.htm>> (last visited April 29, 2002).
7. Uncontrolled pain can lead to the secretion of hormones that promote tissue breakdown and fluid retention; cardiovascular responses such as tachycardia, hypertension, ischemia, and ventricular arrhythmias; slowing of peristalsis; and immune system impairment. Uncontrolled pain is considered a significant public health issue. See C.S. Hill, Jr., "Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin," *Journal of Pain and Symptom Management*, 11 (1996): 287–98.
8. See American Chronic Pain Association, *supra* note 6.
9. Pain is the most common presenting complaint of patients seeking medical assistance. Nonpharmacologic treatment options include anesthesia interventions, behavioral counseling, transcutaneous electrical nerve stimulation, acupuncture, and massage. Pharmacologic treatments include nonsteroidal anti-inflammatory drugs, opioids, and adjuvant medications such as anticonvulsants and antidepressants. Opioids are primary therapeutic options, and are not to be saved until the bitter end when every other option has been tried and has failed. See T.J. Bauman, "Pain Management," in J.T. Dipiro et al., *Pharmacotherapy: A Pathophysiologic Approach*, 4th ed. (New York, McGraw-Hill, 1999): 1014–26. It is estimated that only about one-quarter of pain patients receive adequate pain relief. See D.E. Joranson and J.W. Berger, "Regulatory Issues in Pain Management," *Journal of the American Pharmaceutical Association*, 40 (2000): S1–S60.
10. The difficulty of distinguishing between legitimate patients and drug seekers has led to the use of pain agreements between patients and physicians. In the agreement, patients commit to specific appropriate behaviors, in exchange for which physicians commit to providing care. Sometimes inaccurately referred to as "pain contracts," these agreements are not legally binding, but they help patients understand how to behave so as to avoid being labeled a drug seeker. See S.L. Burchman and P.S. Pagel, "Implementation of a Formal Treatment Agreement for Outpatient Management of Chronic Nonmalignant Pain with Opioid Analgesics," *Journal of Pain and Symptom Management*, 10 (1995): 556–63.
11. See A.T. Patel and A.A. Ogle, "Diagnosis and Management of Acute Low Back Pain," *American Family Physician*, 61 (2000): 1779–86.
12. Nonmedical drugs such as cocaine, marijuana, and methamphetamine are significantly abused drugs, but the abuse of medical drugs is equally problematic. There is evidence that approximately 2.6 million individuals abused prescription opioids in 1999. See National Institute on Drug Abuse, *Prescription Drugs: Abuse and Addiction*, NIH Publication No. 01-4881 (July 2001), available at <<http://165.112.78.61/ResearchReports/Prescription/Prescription.html>>.
13. The Alliance of States with Prescription Monitoring Programs lists the participating states as California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New Mexico, New York, Oklahoma, Rhode Island, Texas, Utah, Washington, and West Virginia. *States with Prescription Monitoring Programs* (March 2001), available at <<http://www.nascsa.org/Rxmonitor/montable.pdf>>.
14. See D.E. Joranson et al., "Pain Management and Prescription Monitoring," *Journal of Pain and Symptom Management*, 23 (2002): 231–38.
15. See L.M. Manchikani, K.R. Brown, and V. Singh, "National All Schedules Prescription Electronic Reporting Act (NASPER): Balancing Substance Abuse and Medical Necessity," *Pain Physician*, 5 (2002): 294–319. See also S.I. Peine, ed., *Drug*

Enforcement Administration, *Prescription Accountability Resource Guide*, rev. ed. (September 1998), available at <http://www.deadiversion.usdoj.gov/pubs/program/rx_account/index.html>.

16. The federal Controlled Substances Act (21 U.S.C. §§ 801 *et seq.*) establishes a closed system of distribution for drugs classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Those who are authorized to prescribe, dispense, and otherwise control access to these drugs are required to register with the Drug Enforcement Administration (DEA). Drugs that make their way outside this closed system are said to have been “diverted” from the system and people responsible for diversion are in violation of the law. See American Society of Law, Medicine & Ethics, *Pain & The Law: Statutes & Regulation*, at <<http://www.painandthelaw.org/statutes/index.php>> (last visited April 29, 2002). In reality, there is nothing at all closed about the system. The fact that pharmaceutical products are easily available for purchase “on the street” betrays the otherwise apparent security within the system.

17. Insurance companies, prescription benefit managers, and other third-party payers may maintain centralized records of controlled substance dispensing, and they may deny payment for excessive or inappropriate prescribing. However, their focus is generally on cost containment, not on drug abuse prevention. Enrollees in such programs may pay cash for their prescriptions and avoid having the prescriptions become part of the program database. Programs managed by third-party payers may reduce the abuse of controlled substances, but that is not their primary purpose and they are not an adequate substitute for a comprehensive program that aggregates data on dispensing from all pharmacies for all drugs and all patients. See D.E. Hoffmann, “Pain Management and Palliative Care in the Era of Managed Care: Issues for Health Care Providers,” *Journal of Law, Medicine & Ethics*, 26, no. 4 (1998): 267–89.

18. A description of each state’s electronic prescription monitoring program is provided in *A Closer Look at State Prescription Monitoring Programs*. S.I. Peine, ed., Drug Enforcement Administration, *A Closer Look at State Prescription Monitoring Programs* (April 2000), available at <http://www.deadiversion.usdoj.gov/pubs/program/rx_monitor/index.html> [hereinafter cited as DEA Report].

19. Under the mandate of the Omnibus Budget Reconciliation Act of 1990 (OBRA-90), 21 U.S.C. § 1396r-8(g)(2)(A)(ii)(II) (2001), states that wish to participate in the Medicaid prescription benefit program must require that pharmacists make a reasonable effort to acquire and record information about a patient’s medical condition and medication history. This requirement clearly places pharmacists in a better position to provide care to patients and to prevent costly problems with drug therapy. However, the failure of the legislation to provide for the confidentiality of this sensitive pharmacist-maintained information is a serious omission. See B.J. Quick, “The Cost of the Omnibus Budget Reconciliation Act of 1990,” *Journal of Pharmacy Law*, 2 (1994): 145–61.

20. See *Doe v. SEPTA*, 72 F.3d 1133 (3rd Cir. 1995) (noting that it is now possible from looking at an individual’s prescription records “to determine that person’s illnesses, or even to ascertain such private facts as whether a woman is attempting to conceive a child through the use of fertility drugs”).

21. See G.M. Mowery, “A Patient’s Right of Privacy in Computerized Pharmacy Records,” *University of Cincinnati Law Review*, 66 (1998): 697–736.

22. See *United States v. Acklen*, 690 F.2d 70 (6th Cir. 1982) (concluding that pharmacists and distributors subject to the Controlled Substances Act have a reduced expectation of privacy in

their records, and that the government may inspect these records without a search warrant by obtaining only an administrative inspection warrant). See also *Stone v. City of Stow*, 593 N.E.2d 294 (Ohio 1992) (holding that “since a pharmacy is a pervasively regulated business,” the pharmacist has “a reduced expectation of privacy in the prescription records he or she keeps”).

23. The Code of Ethics of the American Pharmaceutical Association, the national professional association of pharmacists, states: “With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.” However, state laws do not recognize this requirement for pharmacists as consistently as they do a similar confidentiality requirement for physicians established by the American Medical Association. The ethical principle of confidentiality in pharmacy does not have the same level of legal authority as does the same principle for physicians. See Mowery, *supra* note 21, at 717.

24. *Whalen v. Roe*, 429 U.S. 589 (1977).

25. Within this program, all Schedule II drugs could be prescribed only through use of a government-issued triplicate form. The form identified the prescribing physician, the dispensing pharmacy, the drug and dosage, and the name, address, and age of the patient. One copy of the form was retained by the physician, the second by the pharmacist, and the third was forwarded to the New York State Department of Health. *Id.* at 593.

26. *Id.* at 597.

27. *Id.* at 602.

28. *Id.* at 592.

29. *Id.* at 605.

30. *Id.* at 601.

31. *Washington v. Glucksberg*, 521 U.S. 702 (1997).

32. *Vacco v. Quill*, 521 U.S. 793 (1997).

33. R.A. Burt, “The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care,” *N. Engl. J. Med.*, 337 (1997): 1234–35, at 1234.

34. The resolution, which was written by the ABA Commission on Legal Problems of the Elderly in April 2000, reads in its entirety as follows:

Resolved, that the American Bar Association urges federal, state, and territorial governments to construe, apply, and if necessary, amend laws regulating the health professions, controlled substances, insurance, and both public and private health benefit programs so that these laws do not impose barriers to quality pain and symptom management.

Further Resolved, that the American Bar Association urges federal, state, and territorial governments to support fully the right of individuals suffering from pain to be informed of, choose, and receive effective pain and symptom evaluation, management, and ongoing monitoring as part of basic medical care, even if such pain and symptom management may result in analgesic tolerance, physical dependence, or as an unintended consequence shorten the individual’s life.

See American Bar Association Commission on Legal Problems of the Elderly, *Report to the House of Delegates — Proposed ABA Policy on Legal Obstacles to Effective Pain Management* (April 2000), available at <<http://www.abanet.org/ftp/pub/elderly/painmanagement.pdf>> [hereinafter cited as ABA Report].

35. The report states: “Several states have enacted ‘prescription monitoring programs’ that require the physician to issue prescriptions for controlled substances in certain schedules using only special government-issued single-copy, duplicate or triplicate forms. Studies show that these policies may deter legitimate prescribing of opioids.” *Id.* at 12.

36. See Burt, *supra* note 33, at 1234.
37. *Id.* at 1235.
38. L. Shepherd, "Looking Forward with the Right of Privacy," *Kansas Law Review*, 49 (2001): 251–320.
39. *Id.* at 317.
40. See *infra* notes 60 through 72, and accompanying text.
41. See A. Meisel, "Pharmacists, Physician-Assisted Suicide, and Pain Control," *Journal of Health Care Law & Policy*, 2 (1999): 211–42 ("To the extent that the United States Supreme Court's decisions rejecting a constitutional right to physician-assisted suicide can be viewed as creating a constitutional right to palliative care, this right must also extend to pharmacists' dispensing as well as physicians' prescribing.").
42. See B.R. Furrow, "Pain Management and Provider Liability: No More Excuses," *Journal of Law, Medicine & Ethics*, 29, no. 1 (2001): 28–51. ("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.").
43. See J.B. Nist, "Liability for Overprescription of Controlled Substances: Can It Be Justified in Light of the Current Practice of Undertreating Pain?," *The Journal of Legal Medicine*, 23 (2002): 85–113 ("For years there was a general feeling in the medical community that the best way to avoid liability would be to prescribe as little pain medication as possible.").
44. S.E. Stark, "Bio-Ethics and Physician Liability: The Liability Effects of Developing Pain Management Standards," *St. Thomas Law Review*, 14 (2002): 601–40 (Referring to the rule of the Florida Board of Medicine, adopted almost verbatim from the Federation of State Medical Board's Guidelines for the Use of Controlled Substances in the Treatment of Pain, the author states: "The rule does not, as a whole, appear to provide any great comfort to physicians regarding their pain management practices and may actually result in a lack of uniformity in physicians pain management practices. Indeed, it could further chill physicians in their pain management efforts and reduce effective pain management.").
45. See 21 C.F.R. § 1306.04 (2001).
46. See *United States v. Singh*, 54 F.3d 1182 (4th Cir. 1995) (holding that to convict a physician of unlawful prescribing of controlled substances, the government must prove, among other things, that the physician acted knowingly and intentionally).
47. See *United States v. Henry*, 727 F.2d 1373 (5th Cir. 1984) (holding that to convict a pharmacist of unlawful dispensing of controlled substances, the government must prove, among other things, that the pharmacist had reason to believe that the prescription was not issued in the usual course of professional treatment).
48. See B.A. Rich, "A Prescription for the Pain: The Emerging Standard of Care for Pain Management," *William Mitchell Law Review*, 26 (2000): 1–91 (suggesting that a clinician who does not use available measures to improve the quality of care may have violated the standard of care even if the custom of the profession has not been to use such measures). See also P.C. Crowley, "No Pain, No Gain? The Agency for Health Care Policy & Research's Attempt to Change Inefficient Health Care Practice of Withholding Medication from Patients in Pain," *Journal of Contemporary Health Law & Policy*, 10 (1994): 383–403 ("As one of the AHCPR's first completed clinical practice studies the guideline on pain management is in a prime position to change the standard of care for pain treatment at the initial stages of health care reform in the United States.").
49. See DEA Report, *supra* note 18.
50. See Alliance of States with Prescription Monitoring Programs, *The Goals of Prescription Monitoring* (October 26, 1999), available at <<http://www.nasca.org/Rxmonitor/Goals.pdf>> [hereinafter cited as ASPMP Report].
51. Joranson et al., *supra* note 14.
52. The structure and process goals generally relate to non-controversial matters such as data collection techniques, security, and data management.
53. The clearest statement to this effect is from the Alliance of States with Prescription Monitoring Programs, which says: "States' laws generally must balance the promotion of the safe use of controlled substances for the provision of medical care with the need to impede illegal and harmful activities involving these pharmaceuticals. Prescription monitoring programs are tools used by states to assist in the achievement of these goals." See ASPMP Report, *supra* note 50. The report of the Wisconsin Pain & Policy Studies Group is also quite clear in saying that "[t]he purpose of PMPs [prescription monitoring programs] is to reduce the diversion of prescription controlled substances.... Prescription monitoring is not intended to interfere with medical practice and attempts are made to make it minimally intrusive." See Joranson et al., *supra* note 14, at 233. Clearly stated program goals are far more elusive in the DEA report, although one can infer from the report's extensive discussions of both the deterrent effect on abuse and the lack of deterrence of appropriate use that these are both goals of the program. See DEA Report, *supra* note 18, at "Historical Background."
54. In adopting the international treaty *Convention on Psychotropic Substances*, the U.S. Congress made its intentions clear: This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health and Human Services on the basis of a consensus of the views of the American medical and scientific community.
- 21 U.S.C. § 801a (2001).
55. Joranson and Gilson, *supra* note 3, at 160. See also R.T. Angarola and S.D. Wray, "Legal Impediments to Cancer Pain," in C.S. Hill, Jr., and W.S. Fields, eds., *Advances in Pain Research and Therapy*, vol. 11 (New York: Raven Press, 1989) (concluding from their review of a recent study of ink-on-paper prescription monitoring programs that nothing in the data "suggested that there had been any reduction in abuse of Schedule II drugs, the purpose of the triplicate prescription requirement").
56. See ASPMP Report, *supra* note 53, at 1.
57. See DEA Report, *supra* note 18, at "Editor's Note."
58. *Id.* at "Scope of the Problem."
59. See Office of Applied Studies website, at <<http://www.samhsa.gov/oas/dawn.htm>> (last visited May 2, 2002).
60. See A. Alpers, "Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying," *Journal of Law, Medicine & Ethics*, 26, no. 4 (1998): 308–31. See also *State of Oregon v. Ashcroft*, 2002 U.S. Dist. LEXIS 6695 (D. Or. 2002) (invalidating directive of U.S. Attorney General that declared that prescribing controlled substances to assist patient death is not a legitimate medical purpose); *Johnson v. Lally*, 887 P.2d 1262 (N.M. Ct. App. 1994) (civil rights action brought by a pharmacist against a local prosecutor who initiated criminal proceedings against the pharmacist after the pharmacist followed the instructions of the prosecutor and dispensed medication pursuant to a fraudulent prescription in cooperation with a drug diversion investigation).

61. See L.J. Wastila and C. Bishop, "The Influence of Multiple Copy Prescription Programs on Analgesic Utilization," *Journal of Pharmaceutical Care in Pain and Symptom Management*, 4, no. 3 (1996): 3–19; Hill, Jr., *supra* note 7.

62. See Joranson and Gilson, *supra* note 3, at 160.

63. *Id.*

64. See G.R. Haislip, "Impact of Drug Abuse on Legitimate Drug Use," in C.S. Hill, Jr., and W.S. Fields, eds., *Advances in Pain Research and Therapy*, vol. 11 (New York: Raven Press, 1989): at 209. There is certainly an element of this view that is agreed to by all. The disagreement is over whether prescription monitoring programs are one of many barriers to pain management, not whether they are the only barrier. There are many factors other than prescription monitoring programs that pose barriers to effective pain management. See A.M. Martino, "In Search of New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?," *Journal of Law, Medicine & Ethics*, 26, no. 4 (1998): 332–49.

65. See ABA Report, *supra* note 34, at 7.

66. *Id.*

67. See DEA Report, *supra* note 18, at "Chilling Effect."

68. *Id.* at "Historical Background."

69. See *id.* at "Chilling Effect."

70. *Id.*

71. See D.E. Joranson et al., "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," *Journal of Pain and Symptom Management*, 23 (2002): 138–47.

72. See D.C. Turk et al., "Physicians' Attitudes and Practices Regarding the Long-Term Prescribing of Opioids for Non-Cancer Pain," *Pain*, 59 (1994): 201–08.

73. Addiction and pseudoaddiction are easily confused, but they are very different. Addiction is a neurobehavioral syndrome that results in psychological dependence and "is characterized by compulsive use despite harm." Pseudoaddiction is a "pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction." See Federation of State Medical Boards of the United States, Inc., *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (adopted May 2, 1998), available at <<http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>>.

74. Evaluation of a physician's prescribing should be "based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing." *Id.*

75. See FDA Task Force on Risk Management, *Managing the Risks from Medical Product Use, Creating a Risk Management Frame-*

work (May 1999), available at <<http://www.fda.gov/oc/tfrm/1999report.html>>.

76. See L. Noah, "Challenges in the Federal Regulation of Pain Management Technologies," *Journal of Law, Medicine & Ethics*, 31, no. 1 (2003): 55–74.

77. See D.J. Pisano, "Controlled Substances and Pain Management: Regulatory Oversight, Formularies, and Cost Decisions," *Journal of Law, Medicine & Ethics*, 24, no. 4 (1996): 310–16.

78. ARCOS is an "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution to point of sale or distribution at the dispensing/retail level." See Drug Enforcement Administration, *ARCOS Background*, at <<http://www.deadiversion.usdoj.gov/arcos/background.htm>> (last visited December 2, 2002). ARCOS data provide a denominator for calculating the rate of diversion (or, correspondingly, the rate of appropriate use) of controlled substances within a specific zip coded geographic area.

79. DEA Form 106 must be executed by any registrant who experiences a theft or significant loss of controlled substances through means such as burglary, robbery, loss in transit, or employee theft. These leaks from the closed system of controlled substance distribution are relevant to electronic prescription monitoring programs because they may explain the sudden appearance of pharmaceutical products "on the street," and relieve any concerns that may otherwise be expressed regarding the actions of physicians and pharmacists as the source of the pharmaceutical products. All 106 forms are sent by registrants to the DEA. See Drug Enforcement Administration, "Controlled Substance Theft or Loss," *Pharmacist's Manual*, 8th ed. (January 2001), available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/secure/cs_theft.htm>

80. See C.D. Hepler and L.M. Strand, "Opportunities and Responsibilities in Pharmaceutical Care," *American Journal of Hospital Pharmacy*, 47(1990): 533–39.

81. Marketed under the tradename Soma, but also available as a generic product, carisoprodol is a noncontrolled skeletal muscle relaxant that is metabolized to meprobamate, a controlled substance. It is subject to abuse and should be used with caution in patients who have a history of substance abuse. See R.R. Reeves et al., "Caridoprodol (Soma): Abuse Potential and Physician Unawareness," *Journal of Addictive Diseases*, 18 (1999): 51–56.

82. See Drug Awareness and Relief Movement, *Antihistamines*, at <http://www.drugarm.com.au/drug_info/a-z_of_drugs/antihistamines.htm> (last updated October 21, 2002).

83. *Id.*

Challenges in the Federal Regulation of Pain Management Technologies

Lars Noah

Those who write about pain management have focused almost entirely on delivery issues, paying essentially no attention to the federal regulatory challenges that affect the development of pain relief technologies — namely, pharmaceuticals and medical devices indicated for analgesic uses. The academic literature is strangely devoid of any sophisticated discussion of the difficulties that attend, first, the product approval decisions of the Food and Drug Administration (FDA) and, second, the scheduling decisions made by the Drug Enforcement Administration (DEA). If a “bottleneck” develops upstream, it could have serious repercussions downstream — without pain relief technologies, the issues of access that have preoccupied previous commentators would have little practical consequence.

The modern pharmaceutical industry traces its origins back more than a century, around the time that the German company Bayer first synthesized aspirin (acetylsalicylic acid) and began marketing it as an analgesic.¹ Federal regulation of drug products in the United States began shortly thereafter,² and it has evolved alongside the growing sophistication of the pharmaceutical industry. Although not specifically geared toward the control of pain management technologies, these various laws have had important consequences for the availability and use of analgesic products, at least in part because of certain peculiar aspects of these pharmaceuticals. In parallel, Congress has imposed special requirements on narcotics often used for analgesia because of concerns about addiction and abuse.

This article considers, in turn, the roles played by the FDA and the DEA in regulating pain management technologies. Whether a company wishes to market an over-the-counter

pain reliever containing a well-known active ingredient, a prescription drug containing a novel analgesic compound, or a medical device intended for the treatment of pain, it must satisfy a number of requirements designed to ensure the safety and effectiveness of the product. In addition, if a drug product contains a narcotic or other controlled substance, its availability will depend on the manner in which the DEA has classified that substance. Although implemented by two quite dissimilar agencies — the former preoccupied with medical and scientific questions, while the latter focuses on law enforcement matters — these two regulatory regimes operate in tandem and overlap in potentially important ways.

Several themes emerge from this discussion. First, both agencies have shown a marked resistance to making narcotics available as analgesic products, though the FDA has better appreciated the value of providing patients with a wide range of options for treating pain. Second, notwithstanding its far more limited understanding of clinical practice, the DEA has demonstrated a greater enthusiasm for efforts to keep physicians in line than has the FDA. These and similar examples of contrasting behavior by the two federal agencies in this field — reflecting their distinctly different missions and cultures — provide important lessons about comparative institutional competence and suggest that Congress might want to reconsider this sometimes unstable division of regulatory authority.

Finally, the tools currently available to both agencies may be too blunt for sensibly addressing the conflict that often arises between the needs of patients and efforts to prevent irresponsible use. Once it decides to approve a new drug, the FDA can restrict access to prescription-only and then hope to influence physician use through recommendations in labeling. For the DEA, most of the important restrictions on access to controlled substances represent an

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outgrowth of initial decisions about appropriate scheduling, which may cause the agency to overschedule substances in order to serve law enforcement purposes. Providing more refined regulatory options may allow for a more sensible resolution of the perennial tension between patient access and drug diversion.

If federal agencies become excessively concerned about misuse, they may deprive patients of valuable new analgesic agents. Indeed, depending on the stringency of the restrictions imposed, companies may be unable or unwilling to develop such products in the first place, or health care professionals may fail to make full use of them.³ Already hesitant to approve powerful analgesics, the FDA and the DEA may be forced to revisit their original clearance decisions due to the growing problems with the theft and diversion of currently marketed painkillers containing ingredients such as oxycodone and fentanyl. Any such regulatory actions — whether expressed as a refusal to allow an analgesic product to enter the market initially or the withdrawal of such a product in the face of rampant abuse — would have to grapple with the classic difficulty of choosing between the medical needs of individual patients and the broader societal hazards associated with the availability of such products. These questions do not admit of any simple answers, of course, but they cannot be avoided. This article delineates the nature of the various challenges that the federal government has faced in regulating pain management technologies before tentatively recommending a public health approach that attempts to bridge the FDA's predominantly clinical focus and the DEA's preoccupation with the potential adverse consequences for third parties.

FDA REGULATION OF ANALGESIC PRODUCTS

Before pain management technologies can reach patients, the Food and Drug Administration must assess their safety and effectiveness. If a product has not received marketing approval (or an exemption) from the agency, then it cannot be sold. Even if a company has surmounted the often difficult hurdle of proving that a product serves a therapeutic purpose without posing an undue risk, the FDA's decisions about appropriate labeling may affect how readily patients will be able to access it.

Product approval requirements

Over the course of the last century, federal regulation of medical technologies has shifted from an emphasis on policing against economic frauds to a premarket approval system mandating proof to support therapeutic claims.⁴ The FDA has, for example, expressed long-standing and largely justified skepticism about “quack” medical devices, including products indicated for pain relief.⁵ As a result, legitimate articles used for analgesia may encounter significant regula-

tory obstacles originally fashioned to protect consumers from wasting their resources on worthless remedies.

In particular, the FDA's insistence on placebo-controlled clinical trials when evaluating the effectiveness of pharmaceuticals and medical devices means that firms seeking to market pain management technologies shoulder a particularly challenging evidentiary burden given the pronounced placebo effect that researchers encounter in this context.⁶ Moreover, because of difficulties in measuring a largely subjective condition such as pain,⁷ coupled with the significant variability in patient response,⁸ the agency may struggle to interpret placebo-controlled clinical trials submitted as part of an application for new drug approval (NDA).⁹

Even if persuaded that a drug works, the agency will have to decide whether or not the inevitable side-effects pose too great a hazard to justify granting product approval. In making these risk-benefit judgments, “the FDA takes into account the significance of a targeted health condition, or the status of that condition as a treatable disease.”¹⁰ Interventions such as analgesics that provide *only* symptomatic relief may not fare as well in this process,¹¹ though some experts maintain that pain should qualify as a serious disease process in its own right.¹² A similar dichotomy, between curative and palliative care,¹³ may account for the persistent undertreatment of pain by health care professionals.¹⁴

Notwithstanding this pair of potential obstacles — namely, the heightened difficulty of establishing efficacy and the presumption that symptomatic relief represents a less compelling clinical endpoint for purposes of making risk-benefit judgments — no one has accused the FDA of overcaution in reviewing new analgesics. On the contrary, some observers have criticized the agency for approving too many new non-steroidal antiinflammatory drugs (NSAIDs) that offer no particular advantage over existing, and typically less expensive, drugs in the class.¹⁵ The FDA usually does not, however, make judgments about comparative efficacy,¹⁶ preferring to leave that task for physicians and patients based on the information supplied in the labeling dictated by agency reviewers.

In some instances, the management of side-effects associated with analgesics rather than any differential effectiveness accounts for the need to have a range of therapeutic options. In 1999, the FDA approved Vioxx[®] (rofecoxib) and Celebrex[®] (celecoxib), the first in a new class of painkillers called COX-2 inhibitors.¹⁷ NSAIDs represent peripherally acting analgesics, which means that they lessen the localized inflammation (and production of prostaglandins) that triggers a sensation of pain.¹⁸ They do this by blocking the enzyme cyclooxygenase. As it turns out, this enzyme has two isoforms, one associated with inflammation (COX-2) and the other one thought to protect the lining of the stomach (COX-1). Older NSAIDs blocked both isoforms, which may explain their association with the development of ulcers.¹⁹ By selectively blocking only the form of the enzyme linked to inflammation, COX-2 inhibitors promised to offer compa-

rable pain relief, especially in arthritis patients, without the associated risk of gastrointestinal side-effects.²⁰ These drugs appear, however, to pose a heightened risk of cardiovascular side-effects.²¹

As may happen with any new drug product, serious side-effects associated with analgesics may become evident only after approval and widespread use.²² During the 1980s, the FDA received numerous adverse event reports for three NSAIDs that led to their hasty withdrawal from the market: Zomax[®] (zomepirac), Oraflex[®] (benoxaprofen), and Suprol[®] (suprofen).²³ Zomax was, however, notable for another reason. Even though the FDA conceded that it knew at the time of approval that the drug represented a potential human carcinogen (and that some patients would use it chronically), Zomax received an NDA because agency reviewers thought that it could substitute for narcotics used in the treatment of severe pain.²⁴ This excessive concern about patient use of any controlled substances — so much so that it would displace the FDA's normal resistance to approving nonessential products that create a risk of cancer — appears repeatedly in other contexts. When patients mysteriously began dying from anaphylactic reactions, even the supposed advantage of Zomax as a substitute for narcotic analgesics could not prevent the drug's commercial demise.²⁵

In July 1997, the prescription analgesic Duract[®] (bromfenac sodium) entered the U.S. market. Less than a year later, the manufacturer withdrew the drug from the market after it had been associated with liver toxicity resulting in at least four deaths and eight liver transplants.²⁶ During clinical trials, researchers had reported an unexpectedly high incidence of elevated liver enzymes in patients who took Duract for relatively long periods,²⁷ and one FDA reviewer voiced significant concerns about the drug's potential hepatotoxicity.²⁸ Nonetheless, as happened with Zomax, the agency viewed the product as a substitute for narcotic analgesics, so it decided to approve Duract, though only for short-term use and with labeling information about the risk of elevated liver enzymes.²⁹ Many physicians, however, prescribed Duract for longer than the 10 days specified by the FDA, and the agency soon began receiving reports of liver failure.

As the FDA initially became aware of liver problems in patients taking Duract, it tried to notify physicians about the emerging safety problems.³⁰ The agency required the addition of a prominent boxed warning in the drug's labeling, and the manufacturer mailed out a "Dear Doctor" letter emphasizing the drug's dangers and providing guidelines for proper use.³¹ These efforts did not, however, completely prevent the inappropriate prescribing of Duract for long-term use. After the FDA concluded that it could not impose effective restrictions to limit the duration of use,³² the manufacturer voluntarily withdrew the drug from the market in June 1998.³³ Duract may well have offered a net benefit over other drugs in some class of patients when used as rec-

ommended, but the agency could not ignore the pattern of physician misuse causing risks to other patients.

Over-the-counter marketing

One fundamental labeling question is whether to make a product available only upon a prescription from — or through direct administration by — a licensed health care professional. Because analgesics relieve symptoms and do not purport to treat any underlying disease process, they would seem to represent natural candidates for nonprescription or over-the-counter (OTC) marketing.³⁴ Even if most consumers would not need a physician's diagnostic skills in order to decide whether to select a particular pain reliever, however, the safety profile of a product may justify some restriction on access. At least initially, most new ingredients are available only by prescription while the FDA collects additional adverse event data.³⁵ In addition, the risk of abuse has, from the outset, represented one of the primary rationales for limiting drugs to prescription-only sale.³⁶

The FDA may decide to authorize OTC marketing for drugs that do not require the supervision of a physician, have a history of safe use, and present no abuse potential. This may happen in a couple of different ways. First, a company may sell an OTC drug if it abides by the terms of the applicable "monograph," which specifies for particular categories of products the active ingredients and dosages that the FDA has determined to be safe and effective, along with the precise labeling necessary to facilitate appropriate consumer use.³⁷ The agency's OTC drug review for internal analgesics began with a call for data in 1972.³⁸ Five years later, the review panel, which had considered forty-nine active ingredients, issued its recommendations.³⁹ More than one decade later, the FDA published a tentative final monograph (TFM) for this OTC drug category.⁴⁰ In brief, this proposed rule includes aspirin and acetaminophen as permitted active ingredients and allows labeling "for the temporary relief of minor aches and pains" with directions against taking the product for more than 10 days along with an assortment of warnings.⁴¹ After more than 30 years, the OTC monograph for internal analgesics remains at least 1 year from finalization.⁴²

The second route to OTC marketing requires that a company secure supplemental NDA for a reformulation (including revised labeling) of a product previously approved for prescription use.⁴³ Among its most prominent Rx to OTC switches, the FDA authorized nonprescription sale of a lower dose product containing ibuprofen (e.g., Motrin[®]).⁴⁴ It later switched a number of other NSAIDs, including ketoprofen and naproxen, from prescription to OTC status.⁴⁵ Of course, it did not take long for consumers to realize that they could self-medicate with a prescription strength simply by exceeding the dose recommended in the OTC labeling.⁴⁶

Nonprescription marketing does not mean that a drug product entails no serious risks,⁴⁷ as again revealed by the

FDA's experience with analgesics. For instance, in the early 1980s, the agency became aware of a link between Reye syndrome and the use of aspirin by children suffering from viral infections.⁴⁸ The labels of OTC drug products containing aspirin now must include the following statement: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin."⁴⁹ Notably, the FDA rejected suggestions urging "more drastic measures such as banning use of aspirin in products for individuals under 21 years of age or limiting such products to prescription use."⁵⁰ More recently, after it received reports of an association between acetaminophen and liver toxicity, the agency imposed special warning requirements.⁵¹

DEA RESTRICTIONS ON ANALGESIC PRODUCTS

Although NSAIDs dominate both the prescription and OTC markets in terms of volume,⁵² most of the truly significant pain management technologies used by physicians qualify as "controlled substances," primarily opioid analgesics.⁵³ (Less frequently, health care professionals may try behavioral therapy, surgical interventions such as nerve blocks, or medical devices such as transcutaneous electrical nerve stimulators.⁵⁴) Unlike peripherally acting drugs, opioids relieve pain by acting directly on the central nervous system, binding with the receptors that are involved in the transmission of pain signals to the brain. These drugs must undergo the same FDA premarket review process as any other pharmaceutical product, but special authority over controlled substances resides with a separate agency, the Drug Enforcement Administration of the U.S. Department of Justice.⁵⁵

Classification of controlled substances

In 1970, Congress enacted the Controlled Substances Act (CSA), which establishes different "schedules" of narcotics and other substances prone to abuse or diversion. The most restrictive classification, Schedule I, is defined as follows:

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
- (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.⁵⁶

The statute then provides the following definition for Schedule II:

- (A) The drug or other substance has a high potential for abuse.

- (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- (C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.⁵⁷

Schedules III, IV, and V, which all have "a currently accepted medical use in treatment in the United States," contain drugs with progressively lower potentials for abuse and severity of dependence.⁵⁸ Most states have adopted parallel legislation modeled on the federal statute.⁵⁹

By way of illustration,⁶⁰ Schedule I includes substances such as heroin (diacetylmorphine) and marijuana (cannabis). Schedule II includes, for instance, drugs containing synthetic forms of morphine sold as Dilaudid[®] (hydromorphone hydrochloride) and Demerol[®] (meperidine hydrochloride). Schedule III includes products such as Tylenol[®] (acetaminophen) with codeine. Schedule IV includes products such as Darvon[®] (propoxyphene hydrochloride). Schedule V includes products such as Robitussin[®], a cough syrup which contains a limited amount of codeine.

Congress understood that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."⁶¹ This explains the central role, for purposes of distinguishing Schedule I from all other controlled substances, of the criterion that asks whether the drug has "a currently accepted medical use in treatment in the United States."⁶² Congress did not provide further guidance on this score,⁶³ but it insisted that the Attorney General request and abide by recommendations from the Secretary of Health and Human Services (HHS) when revising the schedule.⁶⁴ In amending the CSA in 1978 to implement the United Nations Convention on Psychotropic Substances, Congress announced its intent that the legislation not "interfere with ethical medical practice in this country as determined by the Secretary of [HHS] on the basis of a *consensus* of the views of the American medical and scientific community,"⁶⁵ which suggests a somewhat more restrictive standard than "a currently accepted medical use."

Under the statute, the DEA supervises the manufacturing and distribution of legal narcotics.⁶⁶ For Schedule II drugs, manufacturers must register their operations, and the DEA assigns aggregate and individual production quotas.⁶⁷ Schedule II drugs must be produced in a secure facility, transported with care, stored in a vault, tracked using a precise inventory system, supplied in response to an order form completed by a registered practitioner, and dispensed only upon a written prescription and without refills.⁶⁸ Progressively weaker restrictions apply to Schedule III, IV, and V drugs. Physicians wishing to prescribe controlled substances first must register with the DEA, which enjoys sweeping authority to suspend or revoke certificates of registration.⁶⁹ The agency has, for

instance, threatened to use this authority to discipline physicians who have done nothing more than recommend that their patients consider taking a Schedule I substance as permitted under limited circumstances in a growing number of states.⁷⁰

Legislative scheduling decisions

Congress typically makes the initial decision about how to schedule a controlled substance. In *United States v. Oakland Cannabis Buyers' Co-operative*,⁷¹ the U.S. Supreme Court showed tremendous deference to the legislature's judgment about the appropriate classification of marijuana. The dispute arose after California voters passed Proposition 215 (the Compassionate Use Act of 1996), which created a limited safe harbor from prosecution under the state's controlled substances act for the medical use of marijuana.⁷² The state law could not, of course, protect critically ill patients or their health care providers from the risk of federal prosecution for the medical use of marijuana. As part of its multipronged response to the California initiative, the Department of Justice sought to enjoin buyers' clubs from dispensing the drug to patients with severe pain and other debilitating symptoms. The U.S. Supreme Court rejected these groups' argument that a medical necessity defense might be implied under federal law. It held that persons manufacturing or distributing Schedule I controlled substances for medical uses could not avoid federal sanctions,⁷³ though three members of the Court wrote separately to emphasize that it had not decided whether a seriously ill patient could raise a medical necessity defense if prosecuted for using marijuana.⁷⁴

The Supreme Court's decision turned entirely on the notion that, in placing marijuana within Schedule I, Congress necessarily had concluded that the drug lacked any currently accepted medical use: "It is clear from the text of the Act that Congress has made a determination that marijuana has no medical benefits worthy of an exception."⁷⁵ The Court rejected the argument that, although placed within Schedule I because its medical use had not yet achieved "general acceptance," a controlled substance may offer therapeutic benefits for some narrow class of patients. It also rejected the suggestion that Congress may have placed a controlled substance into Schedule I without strictly abiding by the criteria (such as the lack of any currently accepted medical use) that it had established to govern scheduling decisions made by the DEA.⁷⁶

In fact, when it enacted the CSA, Congress had expressed a good deal of ambivalence about whether marijuana belonged in Schedule I.⁷⁷ After all, the *United States Pharmacopeia (U.S.P.)*, which Congress has cross-referenced in other statutes as a source for information about therapeutic products,⁷⁸ had listed marijuana as a drug for almost a century (until 1941), and prominent physicians had endorsed its use early in the twentieth century for treating maladies such as migraine headaches.⁷⁹ Although neither one of these

facts would establish that the drug offers genuine therapeutic benefits, subsequent research has suggested that marijuana may have analgesic and other clinically useful properties.⁸⁰ Within the last few years, both the National Institutes of Health and the Institute of Medicine have recommended further scientific work on this question.⁸¹

Although more than half a dozen states,⁸² along with Canadian health officials,⁸³ have concluded that marijuana may have legitimate medical uses, Congress has decided to abide by its earlier, contrary conclusion: A resolution passed in 1998 "oppose[d] efforts to circumvent this [federal scheduling] process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration."⁸⁴ This leaves an opening, of course, for revisiting the original scheduling judgment administratively if new research emerges to persuade regulatory officials that marijuana has medical utility, an issue taken up more fully below.

A similar controversy arose in the early 1980s in connection with the ultimately unsuccessful efforts by some in Congress to reschedule heroin. Unlike marijuana, which may have multiple therapeutic applications and an arguably exaggerated abuse potential, no one seriously doubts that heroin causes addiction, but, in common with the Schedule II drugs cocaine and morphine, it also offers a powerful analgesic effect. In fact, some have argued that it has unique properties as a pain reliever for terminally ill patients or, at the very least, offers an alternative for those who do not respond well to approved opioids.⁸⁵ For this reason, the United Kingdom continues to recognize the medical usefulness of heroin;⁸⁶ however, the CSA requires that a controlled substance have a currently accepted use *in the United States* in order to avoid classification in Schedule I.⁸⁷ In the end, fears of diversion and confidence in the effectiveness of already available opioid analgesics — coupled with the understandable political imperative against appearing to be soft on drugs — scuttled the effort to reschedule heroin.⁸⁸

In another instance, Congress decided to reclassify a drug as Schedule I even though it clearly enjoyed a currently accepted medical use. The FDA previously had approved methaqualone for treating insomnia, which concededly gave the drug a currently accepted use in treatment, but Congress concluded that methaqualone offered no advantages over other products that posed less of a risk of abuse.⁸⁹ For that reason, Congress directed the DEA to reschedule the drug and the FDA to withdraw its NDA.⁹⁰ Although this did not alter the statutory criteria generally applicable to scheduling decisions, the legislative rescheduling of methaqualone arguably set a troublesome precedent.⁹¹ In effect, Congress adopted a "one size fits all" approach, which fails to account for the possibility that this drug might provide some unique benefit to a small group of patients who are refractory to the drug of choice, whether because of their physiologic or genetic deviation from the norm, progression of disease, heightened

susceptibility to side-effects, co-morbid factors, or concomitant use of other medications. If aggregate risk-benefit balancing of this sort becomes the standard for future scheduling decisions, then the needs of individual patients will compete against the consequences of the irresponsible behavior of abusers, and the DEA may opt to sacrifice products that offer insufficiently dramatic advantages over existing alternative treatments.

Administrative scheduling decisions

In the case of newly synthesized chemicals, or in response to new information about previously scheduled controlled substances, the DEA may have to make its own scheduling decisions. As mentioned previously, Congress mandated that the agency first consult with HHS,⁹² which has subdelegated that task to the FDA, and then abide by any recommendations that the DEA receives from the Department.⁹³ In this way, Congress hoped to “strike[] a balance between the extent to which control decisions should be based upon law enforcement criteria, and the extent to which such decisions should be based on medical and scientific determinations.”⁹⁴ Given the long-running “war on drugs” in this country, it is difficult to maintain this sort of balance.⁹⁵

Such cooperative arrangements between agencies or “split enforcement” models have posed challenges in other contexts.⁹⁶ In some instances, Congress has decided against consolidating authority in a single administrative agency to counteract the tendency toward tunnel vision in regulatory decisions, or it has established a separate watchdog group for an agency,⁹⁷ as it did when assigning the responsibility for accident investigations to the National Transportation Safety Board (NTSB), which often criticizes the Federal Aviation Administration (FAA) for taking inadequate steps to improve safety.⁹⁸ In other instances, the division of authority over a field between multiple agencies does not reflect any purposeful design but instead an accident of history that subsequently leads to calls for consolidation.⁹⁹ Apart from questions of efficiency, these organizational choices can have significant impacts on substance, especially if two agencies have different sorts of expertise and missions, and respond to different constituencies.¹⁰⁰ Without meaning to exaggerate the cultural explanations for their contrasting approaches to pain management technologies, the FDA probably would have implemented the Controlled Substances Act differently than the DEA has done.

Immediately after passage of the Act, the National Organization for the Reform of Marijuana Laws (NORML), together with a couple of allied organizations, attempted to persuade the DEA and its predecessor agency to reschedule marijuana. Starting in 1972, the agency repeatedly denied these rescheduling petitions, though on four separate occasions the reviewing court remanded the dispute to the DEA for further consideration.¹⁰¹ In contrast, constitutional chal-

lenges to the DEA’s refusal to down-schedule marijuana have not fared as well in the courts.¹⁰²

Perhaps the refusal to down-schedule marijuana arises from a concern that, unlike chemicals synthesized by pharmaceutical companies, the FDA could not effectively exercise its regulatory authority to demand proof of safety and efficacy over a raw product with variable composition that individuals can grow in their homes.¹⁰³ After the FDA approved an NDA for Marinol® (dronabinol), an antiemetic drug containing synthetic tetrahydrocannabinol (THC), the principal psychoactive component in marijuana, the DEA placed this controlled substance into Schedule II.¹⁰⁴ In 1999, the DEA further down-scheduled that drug as the FDA began to approve additional indications for its use.¹⁰⁵

In 1992, 20 years after NORML first petitioned the agency, the DEA Administrator opined that “no responsible physician could conclude that marijuana is safe and effective for medical use,”¹⁰⁶ echoing his predecessor’s earlier conclusion that it was “not recognized as medicine in generally accepted pharmacopeia, medical references, journals or textbooks.”¹⁰⁷ This time around the federal appellate court upheld the agency’s decision.¹⁰⁸ Late in 1997, after receiving yet another petition for the rescheduling of marijuana, the DEA once again referred the matter to HHS for a recommendation.¹⁰⁹ In 2001, the DEA appeared to soften its stance somewhat when it authorized use by researchers at the University of California to conduct clinical trials investigating marijuana’s analgesic properties in multiple sclerosis and AIDS patients with peripheral neuropathy.¹¹⁰

The protracted effort to reschedule marijuana forced the DEA to elaborate on the meaning of the critical statutory phrase “currently accepted medical use.”¹¹¹ The agency decided to demand that there be adequate safety information coupled with adequate and well-controlled studies establishing efficacy, which are widely available and accepted by qualified experts.¹¹² These criteria closely track the FDA’s test for whether to exempt a product from new drug approval requirements. Indeed, after noting Congress’s failure to define “currently accepted medical use,” the DEA looked to the FDA’s enabling statute for guidance.¹¹³ Under that statute, a manufacturer need not secure an NDA for a drug that is “generally recognized as safe and effective” (GRASE), which the FDA has defined as requiring essentially the same proof of safety and efficacy that it demands for new drugs.¹¹⁴ In effect, a controlled substance could only avoid inclusion in Schedule I if the FDA already had approved it or exempted it from new drug approval requirements, a standard that seems overly stringent and inconsistent with the statutory design.¹¹⁵ Congress could have explicitly linked scheduling decisions to a drug’s FDA regulatory status, but it did not do so, choosing instead the arguably more flexible standard of “currently accepted medical use.”

This distribution of regulatory authority, between a traditional law enforcement agency and one that focuses on

patient health, can generate incongruities. In some instances, the DEA's desire to facilitate prosecution of drug abusers by placing a substance into Schedule I or II conflicts with the FDA's effort to promote the development of a drug potentially valuable in the treatment of a legitimate class of users.¹¹⁶ In other instances, at least where it has not already approved a drug proposed for inclusion in Schedule I, the FDA has done little more than "rubber stamp" DEA scheduling recommendations.¹¹⁷ Once placed in Schedule I, of course, it becomes exceedingly difficult to conduct the sort of research necessary to secure FDA approval and subsequent down-scheduling by the DEA.

Off-label prescribing

The DEA has overlaid another "currently accepted medical use" requirement in regulating prescriptions for narcotics. Physicians may prescribe controlled substances only for "a legitimate medical purpose."¹¹⁸ In turn, pharmacists may dispense controlled substances only pursuant to a valid prescription, which might require a comparison between the indications appearing in the FDA-approved labeling and the patient's condition.¹¹⁹

In contrast, the FDA has long recognized the legitimacy of "off-label" drug prescribing, an outgrowth of Congress's admonition against federal interference with the practice of medicine.¹²⁰ As the agency has explained, "[o]nce a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling."¹²¹ Apart from deferring to the congressional decision against undue interference with the practice of medicine, this policy acknowledges the inevitability of incomplete information, the lag time before widely accepted new uses appear in revised labeling (if they ever do), and patient variability. Thus, physicians routinely, and often appropriately, deviate from the directions contained in approved prescription drug labeling.¹²²

In the case of controlled substances, however, physicians may not have the freedom to engage in such off-label prescribing.¹²³ In contrast to the FDA, which focuses its attention on the activities of commercial entities, the DEA enjoys the power to supervise the activity of individual physicians by virtue of its registration requirements. The agency also has shown less deference to medical practitioners and the regulatory prerogative of the states, instead seeming to regard them with some suspicion. For example, when it down-scheduled THC, the DEA formally announced a policy threatening to revoke (as inconsistent with the public interest) the registration of anyone "who engages in the distribution or dispensing of dronabinol for medical indications outside the [FDA] approved [antiemetic] use associated with cancer treatment."¹²⁴

For a variety of reasons, patients respond variably to opioids,¹²⁵ which explains the need for a range of alternatives and the interest in using powerful analgesics in different

combinations. For instance, a certain genetic polymorphism found in more than 5 percent of patients makes them poor metabolizers of codeine.¹²⁶ In addition, patients may develop tolerance from chronic treatment. Would a physician or pharmacist face DEA sanctions for prescribing or dispensing a Schedule II drug approved only for nonanalgesic indications to a patient with severe pain refractory to the other available drugs? In recent testimony before Congress, the DEA Administrator seemed to imply otherwise,¹²⁷ but the agency's position remains unclear.

Contemporaneously with the Administrator's congressional appearance, and in an effort to undercut Oregon's Death with Dignity Act, the Attorney General threatened to sanction physicians who assist in the suicide of terminally ill patients using Schedule II drugs approved by the FDA for other purposes (primarily sedatives such as secobarbital).¹²⁸ In effect, the DEA decided that, notwithstanding state law to the contrary, physician-assisted suicide does not qualify as legitimately within the scope of medical practice.¹²⁹ A federal court subsequently invalidated the Attorney General's order, holding that Congress had never intended to grant the DEA such sweeping power to define the contours of legitimate medical practice.¹³⁰ If affirmed on appeal, this decision may have broader consequences for the DEA's authority to limit off-label prescribing and dispensing of other controlled substances for analgesic uses.

Formulation issues and distribution controls

Dosage forms

For the most part, scheduling decisions relate to the intrinsic characteristics of active ingredients, paying little attention to product formulation and dosage,¹³¹ though the DEA's differential treatment of smoked marijuana and THC encapsulated for ingestion may represent an exception. In contrast, the FDA routinely addresses precisely these sorts of issues when it reviews an NDA application,¹³² and the choices that it makes may have important repercussions for the threat of abuse and diversion.

Fentanyl citrate is a Schedule II controlled substance. During the last decade, the FDA approved products containing this opioid analgesic in unusual dosage forms. First, it authorized the marketing of a transdermal fentanyl patch (Duragesic®).¹³³ Within a couple of years, the misuse of these patches — for instance, a few individuals died after sucking on them — led the agency to demand stronger warnings to physicians and patients.¹³⁴ More controversially, in 1994, the FDA approved a transmucosal form of fentanyl — a lollipop intended for use by children (Oralet®) — notwithstanding objections that it had received from the DEA and others that this would promote abuse.¹³⁵ In 1997, another manufacturer received approval to market a lollipop form of fentanyl (Actiq®), though this time intended only for use by cancer

patients experiencing breakthrough pain and with special packaging designed to minimize the risk of accidental poisoning by children.¹³⁶

Recent years have seen widespread misuse of other opioid analgesics, especially OxyContin® (oxycodone hydrochloride).¹³⁷ Introduced in 1996, shortly after securing FDA approval, OxyContin quickly became the most widely prescribed narcotic painkiller, recording more than \$1 billion in sales last year. The drug's active ingredient is a synthetic form of morphine regulated as a Schedule II controlled substance. Older painkillers such as Percocet® and Percodan® also contain oxycodone, but OxyContin uses a time-released formulation designed to offer sustained relief over a 12-hour period to patients with chronic moderate-to-severe pain. In contrast, the older drug products in this class (including the related hydrocodone drugs such as Vicodin® and Lortab®) may offer uneven relief over just a 3–4 hour period.

It is difficult trying to quantify the benefits of this drug. Anecdotal reports from physicians testify to the effectiveness of OxyContin in particular patients, but these give no sense for the drug's aggregate utility. One could use the number of prescriptions written each year — now in excess of 6 million — as a rough proxy. Even if some number of physicians prescribed the drug to patients who did not actually suffer from severe pain or to those for whom the older opioids had offered satisfactory relief, the high volume of prescribing suggests that OxyContin has helped to fill a significant unmet need and that many “thousands” of patients have benefited from its availability.¹³⁸ If nothing else, the slow-release feature made OxyContin more convenient than older opioids, which patients with severe pain would have to take every 4 hours throughout the day and night.

The time-released formulation also seemed to make OxyContin less prone to abuse because it would not provide a quick euphoric effect upon initial ingestion. As a result, Purdue Pharma and Abbott Labs promoted their drug to a broader group of physicians and as presenting a lower risk of abuse and diversion.¹³⁹ The companies apparently failed to appreciate the creativity of drug abusers. To defeat the slow-release feature, these individuals chewed, crushed, dissolved, or scraped the coating off of the tablets, leaving stronger dosages of oxycodone than found in individual Percocet or Percodan tablets. They would then ingest, snort, or inject the substance. Reports indicate that hundreds of people have died after overdosing in this fashion,¹⁴⁰ usually as a result of acute pulmonary edema.

Diversion occurs in several ways. Individuals might feign pain and shop for doctors willing to prescribe the drug, or they might engage in prescription fraud and theft. These individuals then might use the drugs themselves or sell their supplies to others. A few desperate addicts have committed armed robberies at pharmacies, demanding OxyContin rather than cash.¹⁴¹ Most of the deaths and other injuries linked to the drug have occurred in persons other than legitimate patients.

Although deaths resulting from OxyContin have received significant publicity, they should be put in context: The diversion of other prescription controlled substances over the years has resulted in numerous deaths among drug abusers, and the toll pales in comparison to the injuries associated with the lawful use of nonnarcotic drugs. NSAIDs may represent a far more serious public health menace, contributing to thousands of patient deaths each year.¹⁴² The volume of use is also higher, but these comparative statistics raise an interesting policy question: Should injuries to third parties who misuse prescription drugs attract greater concern from public officials than injuries suffered by legitimate patients?

Purdue recently announced plans to investigate the possibility of including another ingredient (naltrexone) that might counteract efforts to defeat the slow-release mechanism, but it will have to conduct trials to determine the safety and efficacy of this combination and then await FDA approval of a supplemental NDA, which could take several years.¹⁴³ What if naltrexone reduces the effectiveness of OxyContin, as happened during clinical trials using a similar ingredient (naloxone),¹⁴⁴ or else causes adverse reactions in some subset of users? From the perspective of the patient with cancer or other type of intractable pain, such a new form of the drug definitely would not represent an improvement.

Moreover, what if naltrexone does not really help prevent misuse — should OxyContin never have been marketed because it poses greater risks to nonusers than some of the older opioids? Is the extended-release feature not a substantial enough utility compared to other narcotic pain relievers to justify continued marketing in light of emerging patterns of diversion (much in the same way that Congress evaluated relative risks and benefits when it decided to reschedule methaqualone)? And, finally, who should make these sorts of choices? Tentative answers to such questions appear below, after first considering some of the other possible regulatory responses.

Marketing and distribution

Just as happens with formulation issues, the abuse potential of a drug may extend beyond the intrinsic characteristics of the active ingredient to include how the manufacturer promotes the drug product to health care professionals. Some critics have alleged that Purdue Pharma overpromoted OxyContin for the treatment of temporary or less serious pain, arguing that this led to excessive prescribing and created a larger supply for potential diversion.¹⁴⁵ Even though the DEA does not regulate the marketing of controlled substances (leaving that task to the FDA), it has castigated the manufacturer for its aggressive promotion of OxyContin to physicians.¹⁴⁶

Critics also object that Purdue and Abbott made OxyContin generally available for prescribing by any physi-

cian and dispensing by any pharmacy. The companies might have decided to supply the drug only to hospital pharmacies for dispensing, and only in response to a prescription by a pain management (or similar) specialist, but such a restricted distribution network would have been unprecedented and perhaps even unlawful.¹⁴⁷ The FDA generally does not have the authority to restrict the distribution of drugs that it approves.¹⁴⁸ Although the DEA clearly enjoys the power to limit the channels of distribution for controlled substances by virtue of its scheduling decisions, it does not usually impose more precise restrictions tailored to a particular drug.¹⁴⁹ Either agency could attempt to persuade a manufacturer to accept nominally voluntary limitations that they could not mandate directly,¹⁵⁰ but that did not happen at the time of OxyContin's approval.

In whatever manner achieved, distribution restrictions would have important practical consequences for patients. Although more stringent limitations may reduce the threat of diversion and abuse, they also may complicate access for legitimate users of these drugs. For instance, with just over 1,000 pain management specialists practicing in the United States,¹⁵¹ patients would have difficulty getting prescriptions for needed drugs if only such specialists were permitted to prescribe them. Similarly, patients would find it inconvenient if they regularly had to fill their prescriptions at a hospital pharmacy. Even without distribution restrictions, of course, physicians hesitate before prescribing controlled substances,¹⁵² and local pharmacists may fail to stock them.¹⁵³ One should not lose sight of the fact that the FDA's decision to restrict access to some analgesics on prescription-only creates an important barrier,¹⁵⁴ both because physicians have ethical and legal obligations designed to limit inappropriate prescribing and because of the practical (especially financial) hurdles involved in visiting a physician. Schedule II, by further restricting physician flexibility and by insisting on repeat office visits (through the no-refill rule), enhances these barriers to patient access.

In July 2001, the FDA mandated labeling revisions for OxyContin to provide stronger warnings,¹⁵⁵ and, a few months later, it convened one of its advisory committees to provide additional recommendations.¹⁵⁶ States have gotten involved as well: A few have limited Medicaid reimbursement for OxyContin,¹⁵⁷ and members of the National Association of Attorneys General have discussed options for curbing abuse of the drug with representatives from the manufacturer.¹⁵⁸ At the same time, the DEA urged Purdue Pharma to consider restricting distribution to pain management specialists on the theory that these physicians would know to use the drug only as a last resort, if other pharmaceutical options did not help a patient.¹⁵⁹ In testimony before Congress, the acting Administrator of the DEA even threatened to slash the company's annual production quota by approximately 95 percent.¹⁶⁰

Ultimately, such responses to widespread misuse may undermine recent efforts to provide patients with better pain

management. It makes little sense to protect irresponsible physicians and illegitimate users from their own bad judgment if it means sacrificing the welfare of those in genuine need.¹⁶¹ Abuse and diversion remain unlawful, of course, and persons who violate the CSA may suffer serious legal and other consequences, but agency initiatives that attempt to restrict access by limiting supplies or channels of distribution would reflect an unfortunate pursuit of administrative expediency or a response to the failure of more precisely targeted law enforcement efforts.

It is particularly challenging, of course, to target abusers when large supplies of a drug legally move through channels of commerce. Unlike illicit substances that law enforcement officials can attempt to interdict at the source or while still moving through a distribution network, controlled substances approved for medical use do not become a law enforcement concern until diverted by drug abusers fairly late in the distribution process. Agencies will have a natural inclination to reduce the undoubted difficulty of their task by restricting supplies, but they must not lose sight of the other half of the equation.¹⁶² To its credit, the DEA recently took the unprecedented step of issuing a public statement joined by numerous public health groups to emphasize the importance of not letting concerns about abuse interfere with the legitimate use of OxyContin.¹⁶³ Although an important gesture, it remains to be seen whether this conciliatory rhetoric translates into more enlightened regulatory responses by the agency when confronted with calls for swift action to crack down on the next wave of controlled substances abuse.

The experience with antibiotics may offer an instructive contrast. Physicians continue to overprescribe these often powerful prescription drugs with attendant risks to their patients' health.¹⁶⁴ Patients also may abuse antibiotics, whether by disregarding dosage and duration of use instructions or by passing them along to family members and friends.¹⁶⁵ Unlike the abuse and diversion of controlled substances, none of this unwise behavior violates federal law. The same problems may, of course, arise with any pharmaceutical product,¹⁶⁶ but antibiotic misuse carries a societal risk as well — widespread overuse has created drug-resistant strains of infectious agents.¹⁶⁷ As with analgesics, this explains the need to continue developing new and improved antimicrobial agents even though the old stand-bys usually work well enough for most patients with simple bacterial infections.¹⁶⁸ So far, public health agencies have responded by pleading with physicians to exercise restraint in prescribing,¹⁶⁹ but some commentators would go further and restrict access to the latest compounds.¹⁷⁰ Because individual physicians and patients do not directly bear the diffuse societal risks associated with the spread of resistance, and because they do not face any real legal consequences for misusing antibiotics, a paternalistic strategy of limiting access has much to recommend it.¹⁷¹ Because law enforcement tools already exist to deal with the abuse and diversion of controlled substances, however, fed-

eral access restrictions that may interfere with legitimate use seem far less defensible.

Perhaps the central lesson from this brief discussion of antibiotics is that neither the FDA nor the DEA has approached pain management issues from the proper perspective. Traditionally, the FDA has adopted a clinical (or individualistic) mindset, leaving most of the difficult risk-benefit judgments in the hands of health care professionals and patients. Although such an attitude has much to commend it, the agency may have placed excessive faith in the good sense of physicians and the power of labeling to encourage proper use and to limit the occasions for inappropriate prescribing.¹⁷² Conversely, the DEA's law enforcement mindset goes to the opposite extreme, giving perhaps undue weight to the negative externalities associated with access to narcotics and not trusting health care professionals. A public health perspective, which the Centers for Disease Control and Prevention (CDC) has expressed in connection with antibiotics as well as vaccine programs,¹⁷³ might help to mediate between these two potentially incompatible perspectives.

A public health approach to concerns about the overuse of narcotic analgesics might bring with it a variety of intermediate regulatory responses. For one thing, the government might limit access to those medical specialists who usually encounter persons suffering severe or chronic pain — including, for instance, oncologists and orthopedic surgeons along with pain specialists — in the hopes that such specialists would better resist the tendency to prescribe Schedule II analgesics for patients for whom milder agents would work equally well. As mentioned previously, however, this would risk creating serious access problems for legitimate patients, at least if the range of specialists was defined too narrowly.

The federal government also could try to limit promotional efforts. At present, the FDA does not permit manufacturers of Schedule II drugs to advertise directly to consumers, and it might restrict the distribution of free samples to physicians. An outright prohibition on advertising directed to physicians could, however, run afoul of the First Amendment.¹⁷⁴ Enhanced tracking of prescriptions offers still another — though controversial — option worth exploring, and the DEA has encouraged more states to set up prescription monitoring programs.¹⁷⁵ Perhaps enhanced agency efforts to educate health care professionals would offer the best mechanism for achieving the ideal balance between promoting appropriate use in patients and discouraging excessive or otherwise inappropriate prescribing.¹⁷⁶

CONCLUSION

Federal agencies represent the first, but hardly the only, line of defense against the misuse of pain management technologies. Their licensing decisions should not reflect an excessive preoccupation with the potential for abuse unless the products genuinely have no value as therapeutic interventions. If

an analgesic drug or medical device offers a relatively safe and effective option for the treatment of pain in some group of patients, then any concerns about misuse and diversion need to balance the therapeutic benefit for legitimate users against the risk that individuals who act unlawfully may injure themselves and others. It would be unfortunate if an inability to deal with the latter problem by other means (including educational efforts as well as state and local policing) led to regulatory decisions that denied effective relief to those in pain. Federal officials must resist the temptation to place law enforcement imperatives ahead of genuine medical need.

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38. See 37 Fed. Reg. 14,633 (1972); see also 37 Fed. Reg. 26,456 (1972) (call for data on topical analgesics).

39. See 42 Fed. Reg. 35,346 (1977) (concluding, for instance, that a few ingredients used in then-marketed analgesics (e.g., phenacetin) were not generally recognized as safe and/or effective); see also 44 Fed. Reg. 69,768 (1979) (panel report for external analgesics).

40. See 53 Fed. Reg. 46,204 (1988); see also 48 Fed. Reg. 5,852 (1983) (TFM for external analgesics), amended, 51 Fed. Reg. 27,360 (1986).

41. The TFM includes a number of warnings applicable to aspirin. See 53 Fed. Reg. at 46,256 (to be codified at 21 C.F.R. § 343.50(c)). In addition, with the OTC drug review for internal analgesics still pending, the FDA promulgated a requirement that any nonprescription products containing aspirin include a special warning against use during pregnancy. See 55 Fed. Reg. 27,776, 27,784 (1990) (codified at 21 C.F.R. § 201.63(e)).

42. See 66 Fed. Reg. 61,555, 61,575 (2001) (semiannual unified regulatory agenda forecasting final action on this monograph by Dec. 2002). The most recent unified regulatory agenda does not provide any estimated date of finalization for this rule. See 67 Fed. Reg. 33,058 (2002).

43. See 21 C.F.R. § 330.11 (2002); 65 Fed. Reg. 24,704, 24,704–05 (2000); *Farquhar v. FDA*, 616 F. Supp. 190, 192 (D.D.C. 1985); see also S.P. Mahinka & E. Bierman, “Direct-to-OTC Marketing of Drugs: Possible Approaches,” *Food & Drug Law Journal*, 50 (1995): 49–63; L.R. Rook, “Listening to Zantac: The Role of Non-Prescription Drugs in Health Care Reform and the Federal Tax System,” *Tennessee Law Review*, 62 (1994): 107–39; P. Temin, “Realized Benefits from Switching Drugs,” *Journal of Law & Economics*, 35 (1992): 351–69.

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45. See G. Mays, “Pain-Killer Wars Can Be a Pain for Ailing Consumers,” *Chicago Tribune*, Nov. 24, 1995, at Bus. 1.

46. Cf. *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 939–40, 942 (7th Cir. 2001).

47. See S.G. Boodman, “Painful Choices: Consumers Face a Baffling Wall of Choices — and a Surprising Number of Serious Risks — When They Seek Relief from Minor Pains and Illnesses at the Drug Store,” *Washington Post*, Feb. 11, 2003, at Z1. Apart from the risks associated with the proper use of OTC products, they also may pose hazards of misuse. For example, responding to numerous instances of childhood poisoning from the accidental ingestion of aspirin and similar products, Congress enacted special child-proof packaging requirements. See Poison Prevention Packaging Act of 1970, Pub. L. No. 91-601, 84 Stat. 1670 (codified as amended at 15 U.S.C. §§ 1471–1476 (2000)); 16 C.F.R. pt. 1700 (2002). In addition, after seven people in the Chicago area suffered cyanide poisoning in 1982 from ingesting

tainted Extra-Strength Tylenol® capsules, the FDA swiftly imposed tamper-resistant packaging requirements for most OTC drugs. See 47 Fed. Reg. 50,442, 50,449–50 (1982) (codified as amended at 21 C.F.R. § 211.132); see also Federal Anti-Tampering Act, Pub. L. No. 98-127, 97 Stat. 831 (1983) (codified at 18 U.S.C. § 1365 (2000)). Although one occasionally hears complaints that such rules have made it difficult for elderly and arthritic consumers to open containers, these controls have reduced instances of dangerous misuse at relatively trivial additional cost to users.

48. See 50 Fed. Reg. 51,400, 51,401 (1985); see also *Public Citizen Health Research Group v. Comm’r, FDA*, 740 F.2d 21, 34–35 (D.C. Cir. 1984) (remanding for lower court to consider claim of unreasonable delay by the FDA in acting on a citizen petition urging it to require a warning of this risk); *American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 137–41 (S.D.N.Y. 1987) (offering a detailed account of the history behind the early Reye syndrome warning efforts).

49. 21 C.F.R. § 201.314(h)(1) (2002).

50. 53 Fed. Reg. 21,633, 21,635 (1988).

51. See 63 Fed. Reg. 56,789, 56,801–02 (1998) (codified at 21 C.F.R. § 201.322 (2002)) (warning against the use of internal analgesics in combination with heavy alcohol consumption); see also *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1387, 1389 (4th Cir. 1995) (sustaining a negligence claim and punitive damage award against the seller of Tylenol where it had delayed submitting adverse reaction reports — concerning liver toxicity resulting from interactions between acetaminophen and alcohol — to the FDA during the OTC monograph review process for internal analgesics); C. Adams, “Makers of Rival Pain Relievers Trade Jobs on Safety,” *Wall Street Journal*, Sept. 18, 2002, at B1.

52. See S.H. Roth, Editorial, “Nonsteroidal Anti-inflammatory Drugs: Gastropathy, Deaths, and Medical Practice,” *Annals of Internal Medicine*, 109 (1988): 353–54; C.M. Wilcox et al., “Striking Prevalence of Over-the-Counter Nonsteroidal Anti-inflammatory Drug Use in Patients with Upper Gastrointestinal Hemorrhage,” *Archives of Internal Medicine*, 154 (1994): 42–46, at 42; J. Foreman, “Painkillers Often Take Toll on Stomach,” *Boston Globe*, July 8, 1996, at 25; J. Weber & Z. Schiller, “Painkillers Are About to O.D.,” *Business Week*, Apr. 11, 1994, at 54. These two categories do not, however, exhaust the range of options. For example, the prescription drug tramadol (Ultram® and Ultracet®) qualifies as neither an NSAID nor an opioid analgesic. See J.E. Edwards et al., “Combination Analgesic Efficacy: Individual Patient Data Meta-Analysis of Single-Dose Oral Tramadol Plus Acetaminophen in Acute Postoperative Pain,” *Journal of Pain & Symptom Management*, 23 (2002): 121–30.

53. See N.I. Cherny, “Opioid Analgesics: Comparative Features and Prescribing Guidelines,” *Drugs*, 51 (1996): 713–37; A. Jacox et al., “New Clinical-Practice Guidelines for the Management of Pain in Patients with Cancer,” *N. Engl. J. Med.*, 330 (1994): 651–55, at 653 (“Of the many methods available to manage pain in cancer, drug therapy is the cornerstone because it entails relatively little risk, is usually inexpensive, and as a rule works quickly.”); M.H. Levy, “Pharmacologic Treatment of Cancer Pain,” *N. Engl. J. Med.*, 335 (1997): 1124–32; H. McQuay, “Opioids in Pain Management,” *Lancet*, 353 (1999): 2229–32; C. Ripamonti & E.D. Dickerson, “Strategies for the Treatment of Cancer Pain in the New Millennium,” *Drugs*, 61 (2001): 955–77; P.C. Crowley, Comment, “No Pain, No Gain? The AHCPR’s Attempt to Change Inefficient Health Care Practice of Withholding Medication from Patients in Pain,” *Journal of Contemporary Health Law & Policy*, 10 (1994): 383–403, at 391–93. See generally C. Stein, ed., *Opioids in Pain Control: Basic and Clinical Aspects* (Cambridge, England: Cambridge Univ. Press, 1999).

54. See J. Laurance, “Are We Really Born to Suffer?,” *Times of London*, Jan. 27, 1997, at 18; see also 21 C.F.R. § 882.5890 (2002) (FDA regulation classifying transcutaneous electrical nerve stimulation devices for pain relief); M.I. Johnson et al., “An In-Depth Study of Long-Term Users of Transcutaneous Electrical Nerve Stimulation,” *Pain*, 44 (1991): 221–29; cf. R.A. Deyo et al., “A Controlled Clinical Trial of Transcutaneous Electrical Nerve Stimulation (TENS) and Exercise for Chronic Low Back Pain,” *N. Engl. J. Med.*, 332 (1990): 1627–34 (finding the treatment ineffective); E.A. Ghoname et al., “Percutaneous Electrical Nerve Stimulation for Low Back Pain: A Randomized Crossover Study,” *JAMA*, 281 (1999): 818–23 (evaluating a method supplying deeper stimulation).

55. See Controlled Substances Act, Pub. L. No. 91-513, title II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–904 (2000)).

56. 21 U.S.C. § 812(b)(1).

57. *Id.* § 812(b)(2).

58. See *id.* § 812(b)(3)–(5).

59. See Uniform Controlled Substances Act of 1994; see also R.L. Brown, “Uniform Controlled Substances Act of 1990,” *Campbell Law Review*, 13 (1991): 365–74.

60. These examples come from the lists of substances appearing in each of the schedules. See 21 U.S.C. § 812; 21 C.F.R. pt. 1308 (2002). The brand-name versions of analgesic products come from the *Physicians’ Desk Reference*, 56th ed. (Montvale, New Jersey: Medical Economics Co., 2002).

61. 21 U.S.C. § 801(1).

62. See *Alliance for Cannabis Therapeutics (ACT) v. DEA*, 930 F.2d 936, 938 (D.C. Cir. 1991); see also L. Scott, “The Pleasure Principle: A Critical Examination of Federal Scheduling of Controlled Substances,” *Southwestern University Law Review*, 29 (2000): 447–500, at 455 (“The purpose of the legislation is to legalize the possession and use of certain drugs for medical purposes, and to criminalize their possession and use for any other purposes.”).

63. Congress did set out a number of factors to consider, but these relate primarily to the potential for abuse rather than what qualifies as currently accepted medical use:

- (1) [A substance’s] actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. § 811(c); see also *National Organization for the Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 747–48 (D.C. Cir. 1977) (suggesting that the potential for abuse rather than medical use distinguishes the schedules).

64. See 21 U.S.C. § 811(b) (directing HHS to consider the listed factors); 116 Cong. Rec. 33,300 (1970) (statement by Rep. Springer) (emphasizing “that purely enforcement responsibilities are placed with the Department of Justice while medical and scientific judgments necessary to drug control are left where they properly should lie and that is with the Department of Health, Education, and Welfare”); *NORML*, 559 F.2d at 745–47.

65. Pub. L. No. 95-633, § 101, 92 Stat. 3768 (1978) (codified as amended at 21 U.S.C. § 801a(3)(C)) (emphasis added).

66. See 21 U.S.C. §§ 821–829.

67. See *id.* §§ 823(a), 826; 21 C.F.R. pt. 1303; see also *MD*

Pharm., Inc. v. DEA, 133 F.3d 8, 10–11, 16 (D.C. Cir. 1998) (rejecting methylphenidate manufacturer's challenge to the registration of a competitor); *Western Fher Lab. v. Levi*, 529 F.2d 325, 330–32 (1st Cir. 1976) (affirming challenged production quotas for phenmetrazine); L. Noah, "Sham Petitioning as a Threat to the Integrity of the Regulatory Process," *North Carolina Law Review*, 74 (1995): 1–73, at 9 n.24, 69 (discussing the DEA's effort to combat the delays that result when competitors routinely file objections to each other's manufacturer registration and production quota applications).

68. See 21 U.S.C. § 829(a); 21 C.F.R. §§ 1301.72(a), 1301.73, 1301.74(e), 1304.11(e)(3)(i), 1305.03, 1306.11(a), 1306.12; *United States v. Poulin*, 926 F. Supp. 246, 249–55 (D. Mass. 1996) (concluding that a pharmacy had violated numerous requirements applicable to Schedule II drugs); D.J. Pisano, "Controlled Substances and Pain Management: Regulatory Oversight, Formularies, and Cost Decisions," *Journal of Law, Medicine & Ethics*, 24 (1996): 310–16, at 311–12.

69. See 21 U.S.C. §§ 822–824; 21 C.F.R. § 1301.36; see also *Humphreys v. DEA*, 96 F.3d 658 (3d Cir. 1996) (reversing the revocation of a physician's certificate of registration); *Kirk v. Mullen*, 749 F.2d 297, 298 (6th Cir. 1984) (noting that the DEA processed more than half a million CSA registrations annually).

70. See 62 Fed. Reg. 6,164 (1997); see also *Conant v. McCaffrey*, 2000 WL 1281174 (N.D. Cal. 2000) (invalidating one aspect of this policy as inconsistent with the CSA when read to take the First Amendment into account), *aff'd*, 309 F.3d 629 (9th Cir. 2002); G.J. Annas, "Reefer Madness — The Federal Response to California's Medical-Marijuana Law," *N. Engl. J. Med.*, 337 (1997): 435–39.

71. *United States v. Oakland Cannabis Buyers' Co-operative*, 532 U.S. 483 (2001). For some of the relevant academic commentary that predated the Court's decision, see M.N. Cohen, "Breaking the Federal/State Impasse over Medical Marijuana: A Proposal," *Hastings Women's Law Journal*, 11 (2000): 59–74; J.P. Kassirer, Editorial, "Federal Foolishness and Marijuana," *N. Engl. J. Med.*, 336 (1997): 366–67; A.J. LeVay, Note, "Urgent Compassion: Prosecutorial Discretion and the Medical Necessity Defense," *Boston College Law Review*, 41 (2000): 699–753; E.R. Neusch, Comment, "Medical Marijuana's Fate in the Aftermath of the Supreme Court's New Commerce Clause Jurisprudence," *University of Colorado Law Review*, 72 (2001): 201–55.

72. See Cal. Health & Safety Code Ann. § 11362.5 (West Supp. 2002) (decriminalizing only the cultivation and possession for use based on a physician's recommendation); *People v. Mower*, 49 P.3d 1067 (Cal. 2002). See generally A.W. Bock, *Waiting to Inhale: The Politics of Medical Marijuana* (Santa Ana: Seven Locks Press, 2000).

73. See *Oakland Cannabis*, 532 U.S. at 491–94.

74. See *id.* at 500–01 & n.2 (Stevens, J., concurring in judgment) (calling the majority's suggestion to the contrary dicta).

75. *Id.* at 493.

76. See *id.* at 492–93.

77. See H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4577–79; *NORML v. Ingersoll*, 497 F.2d 654, 657 (D.C. Cir. 1974).

78. See 21 U.S.C. § 321(g)(1)(A) (2000); see also *State v. Wakeen*, 57 N.W.2d 364, 369 (Wis. 1953) (noting that the pharmacy practice statutes in most states cross-reference the U.S.P.). But cf. *United States v. Article of Drug . . . Ova II*, 414 F. Supp. 660, 665–66, 667–73 (D.N.J. 1975) (rejecting an FDA effort to assert its drug authority over a product simply by virtue of its inclusion in the U.S.P.), *aff'd mem.*, 535 F.2d 1248 (3d Cir. 1976).

79. See E. Russo, "Cannabis for Migraine Treatment: The Once and Future Prescription? An Historical and Scientific Re-

view," *Pain*, 76 (1998): 3–8. See generally L. Grinspoon & J.B. Bakalar, *Marihuana: The Forbidden Medicine*, rev. ed. (New Haven: Yale Univ. Press, 1993); M.L. Mathre, ed., *Cannabis in Medical Practice: A Legal, Historical and Pharmacological Overview of the Therapeutic Use of Marijuana* (Jefferson, North Carolina: McFarland & Co., 1997).

80. See I.D. Meng et al., "An Analgesia Circuit Activated by Cannabinoids," *Nature*, 395 (1998): 381–83; E.M. Williamson & F.J. Evans, "Cannabinoids in Clinical Practice," *Drugs*, 60 (2000): 1303–14; R.L. Hotz, "Chemicals in Pot Cut Severe Pain, Study Says," *Los Angeles Times*, October 27, 1997, at A1; see also L. Grinspoon & J.B. Bakalar, "Marihuana as Medicine: A Plea for Reconsideration," *JAMA*, 273 (1995): 1875–76.

81. See J.E. Joy et al., eds., *Marijuana and Medicine: Assessing the Science Base* (Washington, D.C.: National Academy Press, 1999): at 145 (concluding that cannabinoid drugs may have a therapeutic potential for pain relief); *id.* at 179 ("Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain. . .").

82. See *Oakland Cannabis*, 532 U.S. at 502 n.4 (Stevens, J., concurring in judgment) (noting, in addition to California's law, the passage of voter initiatives in Alaska, Colorado, Maine, Nevada, Oregon, and Washington, along with legislative action in Hawaii); M. Tiersky, Comment, "Medical Marijuana: Putting the Power Where It Belongs," *Northwestern University Law Review*, 93 (1999): 547–95, at 551, 578–84 (describing and defending these various state initiatives).

83. See E. Goodman, Editorial, "The Uses of Pot," *Washington Post*, Aug. 4, 2001, at A23.

84. Not Legalizing Marijuana for Medicinal Use, Pub. L. No. 105-277, Div. F, 112 Stat. 2681–760, 2681–761 (1998).

85. See A.S. Trebach, *The Heroin Solution* (New Haven: Yale Univ. Press, 1982): at 59–84; A. Mondzac, "In Defense of the Reintroduction of Heroin into American Medical Practice and H.R. 5290 — The Compassionate Pain Relief Act," *N. Engl. J. Med.*, 311 (1984): 532–35, at 533; E.L. Shapiro, "The Right to Privacy and Heroin Use for Painkilling Purposes by the Terminally Ill Cancer Patient," *Arizona Law Review*, 21 (1979): 41–59, at 43–48.

86. See T. Bennett, "The British Experience with Heroin Regulation," *Law & Contemporary Problems*, 51 (Winter 1988): 299–314.

87. In a related vein, the FDA at one time categorically refused to consider prior foreign use of an ingredient in food as providing evidence of the safety of a substance, but a court invalidated the policy because it found "no basis for a purely ethnocentric distinction of this kind, divorced from demographic considerations." *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1390 (9th Cir. 1983); see also L. Noah & R.A. Merrill, "Starting from Scratch?: Reinventing the Food Additive Approval Process," *Boston University Law Review*, 78 (1998): 329–443, at 354–55; R.G. Pinco, "Implications of FDA's Proposal to Include Foreign Marketing Experience in the Over-the-Counter Drug Review Process," *Food & Drug Law Journal*, 53 (1998): 105–22.

88. See S.M. Stoll, Comment, "Why Not Heroin? The Controversy Surrounding the Legalization of Heroin for Therapeutic Purposes," *Journal of Contemporary Health Law & Policy*, 1 (1985): 173–94, at 190–93; see also *id.* at 179 ("Clearly, the United States maintains a model of drug control more suited to law enforcement than to medical concerns."); P.W. Fitzgerald, Comment, "Members of Congress as Medical Experts: Heroin and the Compassionate Pain Relief Act," *St. Louis University Public Law Review*, 6 (1987): 371–90.

89. See H.R. Rep. No. 98-534, at 5 (1984) (asking “whether the adverse health effects caused by diversion of a drug outweigh its therapeutic usefulness,” and concluding that methaqualone “has no unique therapeutic advantages over other available drugs and has a significantly higher incidence of and potential for abuse”), reprinted in 1984 U.S.C.C.A.N. 540, 543-44.

90. See Pub. L. No. 98-329, 98 Stat. 280 (1984).

91. Congress may have set a similar precedent when it originally decided to classify cocaine as a Schedule II “narcotic” even though pharmacologically the substance does not qualify as a narcotic. See *United States v. Whitley*, 734 F.2d 1129, 1140-41 (6th Cir. 1984) (upholding the classification as rational in order to promote law enforcement purposes); *United States v. Alexander*, 673 F.2d 287 (9th Cir. 1982).

92. See 21 U.S.C. § 811(b) (2000).

93. See *id.*; *Touby v. United States*, 500 U.S. 160, 162, 167 (1991) (noting that the parties characterized this provision as giving a “veto power” to the Secretary of HHS); *American Pharm. Ass’n v. Weinberger*, 377 F. Supp. 824, 831 n.16 (D.D.C. 1974) (explaining that the DEA “must first call upon FDA for its recommendation. The recommendations of FDA, insofar as they concern ‘scientific and medical matters’ relating to the ‘appropriate schedule, if any, under which such drug or substance should be listed’ are binding on the Attorney General.”), *aff’d*, 530 F.2d 1054 (D.C. Cir. 1976).

94. H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4589.

95. See D.F. Musto, *The American Disease: Origins of Narcotic Control*, 3d ed. (New York: Oxford Univ. Press, 1999); R.E. Barnett, Book Review, “Bad Trip: Drug Prohibition and the Weakness of Public Policy,” *Yale Law Journal*, 103 (1994): 2593-630 (reviewing S.B. Duke & A.C. Gross, *America’s Longest War: Rethinking Our Tragic Crusade Against Drugs* (New York: G.P. Putnam’s Sons, 1993)); E.G. Luna, “Our Vietnam: The Prohibition Apocalypse,” *DePaul Law Review*, 46 (1997): 483-568; E.A. Nadelmann, “Drug Prohibition in the United States: Costs, Consequences, and Alternatives,” *Science*, 245 (1989): 939-47; M.D. Newcomb, “Substance Abuse and Control in the United States: Ethical and Legal Issues,” *Social Science & Medicine*, 35 (1992): 471-79.

96. See L. Noah, “Divining Regulatory Intent: The Place for a ‘Legislative History’ of Agency Rules,” *Hastings Law Journal*, 51 (2000): 255-323, at 301; S. Shapiro & T. McGarity, “Reorienting OSHA: Regulatory Alternatives and Legislative Reform,” *Yale Journal on Regulation*, 6 (1989): 1-63, at 57-62.

97. See Inspector General Act, Pub. L. No. 95-452, 92 Stat. 1101 (1978) (codified as amended at 5 U.S.C. app. II (2000)); M.J. Gates & M.F. Knowles, “The Inspector General Act in the Federal Government: A New Approach to Accountability,” *Alabama Law Review*, 36 (1985): 473-513; see also L. Noah, “Scientific ‘Republicanism’: Expert Peer Review and the Quest for Regulatory Deliberation,” *Emory Law Journal*, 49 (2000): 1033-83.

98. See 49 U.S.C. § 1131 (2000); M. Wald, “Two Positions on Safety,” *New York Times*, Aug. 30, 1998, at A16; “The FAA Should Inspect Itself,” *Washington Post*, May 23, 1996, at A20; see also A.J. Wood et al., “Making Medicines Safer — The Need for an Independent Drug Safety Board,” *N. Engl. J. Med.*, 339 (1998): 1851-54, at 1852-53 (advocating the creation of a similar counterweight to the FDA in order to improve postmarket surveillance of drugs approved by the agency).

99. See, e.g., R.A. Merrill & J.K. Francer, “Organizing Federal Food Safety Regulation,” *Seton Hall Law Review*, 31 (2000): 61-173; M. Allen & J. Mintz, “Homeland Department May Take a Year to Take Shape,” *Washington Post*, Nov. 21, 2002, at A8.

100. See J. Mashaw et al., *Administrative Law: The American Public Law System*, 4th ed. (St. Paul: West Group, 1998): at 21-28, 174-75; E. Meidinger, “Regulatory Culture: A Theoretical Outline,” *Law & Policy*, 9 (1987): 355-86, at 360, 372-74.

101. See 37 Fed. Reg. 18,097 (1972), *remanded*, *NORML v. Ingersoll*, 497 F.2d 654, 660-61 (D.C. Cir. 1974), *petition denied*, 40 Fed. Reg. 44,164 (1975), *remanded*, *NORML v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977), *petition denied*, 44 Fed. Reg. 36,123 (1979), *remanded*, *NORML v. DEA*, No. 79-1660 (D.C. Cir. Oct. 16, 1980), *hearing announced*, 51 Fed. Reg. 22,946 (1986), *petition denied*, 54 Fed. Reg. 53,767, 53,784 (1989) (“The administrative law judge’s conclusion that a ‘respectable minority’ of physicians is all that is necessary to establish accepted medical use in treatment in the United States is preposterous.”), *remanded*, *ACT v. DEA*, 930 F.2d 936, 940-41 (D.C. Cir. 1991).

102. See *United States v. Greene*, 892 F.2d 453, 455-56 (6th Cir. 1989); *Pearson v. McCaffrey*, 139 F. Supp. 2d 113, 120-23 (D.D.C. 2001); *NORML v. Bell*, 488 F. Supp. 123, 132-43 (D.D.C. 1980) (three-judge court); cf. *Washington v. Glucksberg*, 521 U.S. 702, 791 (1997) (Breyer, J., concurring in the judgment) (suggesting that the Court might hold it unconstitutional “were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life”); R.A. Burt, “The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care,” *N. Engl. J. Med.*, 337 (1997): 1234-36. A lower federal court once found a fundamental right to receive acupuncture treatment. See *Andrews v. Ballard*, 498 F. Supp. 1038, 1047-57 (S.D. Tex. 1980) (invalidating a state’s licensing restriction).

103. Cf. *United States v. McMahon*, 861 F.2d 8, 11 (1st Cir. 1988) (noting the “organic-synthetic distinction in Schedule I” between marijuana and THC). Of course, similar concerns did not dissuade the agency from its ill-fated effort to assert regulatory jurisdiction over cigarettes containing variable quantities of the drug nicotine from tobacco leaves. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); L. Noah & B.A. Noah, “Nicotine Withdrawal: Assessing the FDA’s Effort to Regulate Tobacco Products,” *Alabama Law Review*, 48 (1996): 1-63.

104. See 51 Fed. Reg. 17,476, 17,478 (1986) (synthetic dronabinol in sesame oil encapsulated in soft gelatin capsules); see also 47 Fed. Reg. 10,080 (1982) (announcing the FDA’s proposed rescheduling recommendation pending approval of the NDA); R.M. Cooper, “Therapeutic Use of Marijuana and Heroin: The Legal Framework,” *Food Drug Cosmetic Law Journal*, 35 (1980): 68-82, at 76-79 (defending the FDA’s earlier recommendation against down-scheduling).

105. See 64 Fed. Reg. 35,928, 35,930 (1999).

106. See 57 Fed. Reg. 10,499, 10,507-08 (1992) (adding that, “[b]y any modern scientific standard, marijuana is no medicine”); *id.* at 10,503 (“Beyond doubt, the claims that marijuana is medicine are false, dangerous and cruel.”). Although one can understand the DEA Administrator’s exasperated tone in once again denying the petition, the published explanation contains a surprising note of glibness and sarcasm.

107. 54 Fed. Reg. 53,767, 53,784 (1989). On the pitfalls of relying on the biomedical literature in this fashion, see L. Noah, “Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decisionmaking,” *University of Pittsburgh Law Review*, 59 (1998): 677-717.

108. See *ACT v. DEA*, 15 F.3d 1131, 1135-37 (D.C. Cir. 1994).

109. See *United States v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1086, 1105 (N.D. Cal. 1998). Four years later, HHS again recommended against down-scheduling marijuana. See *Gettman v. DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002) (holding that the petitioners lacked standing to challenge the DEA’s subsequent

rejection of their request).

110. See P.J. Hilts, "After Two-Decade Halt, Marijuana Research Is Set," *New York Times*, Dec. 15, 2001, at A16; see also M. Robichaux, "Would Marijuana Be OK by Prescription If You Didn't Get High?," *Wall Street Journal*, Feb. 28, 2001, at A1 ("Recent findings suggest that THC holds more potential as a painkiller than anyone ever guessed.").

111. See 21 U.S.C. § 812(b) (2000).

112. See 57 Fed. Reg. at 10,504–07 (also requiring that the drug's chemistry be known and reproducible); *id.* at 10,505 ("When a drug lacks NDA approval and is not accepted by a consensus of experts outside FDA, it cannot be found . . . to have a currently accepted medical use."). The DEA had first described these factors a few years earlier, but in combination with a few others, see 53 Fed. Reg. 5156, 5157–58 (1988) (classifying methylenedioxymethamphetamine (MDMA), commonly known as Ecstasy, as a Schedule I controlled substance), 54 Fed. Reg. at 53,783–84, which the reviewing court rejected as unworkable, see *ACT v. DEA*, 930 F.2d at 940.

113. See 57 Fed. Reg. at 10,503–04.

114. See *United States v. 50 Boxes More or Less*, 909 F.2d 24, 26–28 (1st Cir. 1990) (sustaining an FDA enforcement action against an unapproved prescription drug for the treatment of vascular headaches); *United States v. Seven Cardboard Cases . . . "Esgic with Codeine Capsules"*, 716 F. Supp. 1221, 1224–25 (E.D. Mo. 1989).

115. See *Grinspoon v. DEA*, 828 F.2d 881, 886–91 (1st Cir. 1987) (rejecting the notion that the absence of FDA approval demonstrated the lack of a legitimate medical use); *NORML v. DEA*, 559 F.2d 735, 748–50 & n.65 (D.C. Cir. 1977); see also *Reckitt & Colman, Ltd. v. DEA*, 788 F.2d 22, 24 (D.C. Cir. 1986) (describing the DEA's decision to move buprenorphine, an opiate derivative, from Schedule II to Schedule V on the recommendation of HHS after the FDA approved the drug as an analgesic). After the remand in *Grinspoon*, the DEA adhered to its decision to place MDMA in Schedule I. See *United States v. Carlson*, 87 F.3d 440, 444–45 (11th Cir. 1996); cf. R. Weiss, "On Ecstasy, Consensus Is Elusive," *Washington Post*, Sept. 30, 2002, at A7 (reporting that the FDA now has approved research — pending authorization from the DEA — into MDMA's possible efficacy as a treatment for post-traumatic stress disorder).

116. See D.D. Rohde, "The Orphan Drug Act: An Engine of Innovation? At What Cost?," *Food & Drug Law Journal*, 55 (2000): 125–43, at 138–39 (discussing the disagreement between the agencies over gamma hydroxybutyrate (GHB), which appears to be an effective treatment for narcolepsy but also facilitates date rapes); see also Pub. L. No. 106-172, § 3(a)(1), 114 Stat. 7, 8 (2000); R. Rubin, "Company Wants 'Date Rape' Drug Approved for Sleep Disorder Treatment," *USA Today*, June 6, 2001, at 10D (describing compromise legislation that placed GHB into Schedule I for most purposes but Schedule III when used in FDA-approved studies); A. Zitner, "Date-Rape Drug OK'd to Treat Sleep Disorder," *Los Angeles Times*, July 18, 2002, at A12 (reporting that the FDA approved GHB subject to stringent restrictions on patient access).

117. See *Grinspoon*, 828 F.2d at 897. In connection with the DEA's decision to up-classify methamphetamine to Schedule II, the courts have rejected objections that HHS had done too cursory a medical and scientific review. See *United States v. Lafoon*, 978 F.2d 1183, 1184–85 (10th Cir. 1992).

118. 21 C.F.R. § 1306.04(a) (2002); see also *United States v. Moore*, 423 U.S. 122, 141–42 (1975) ("[P]rovisions throughout the Act reflect the intent of Congress to confine authorized medical practice within acceptable limits."); *id.* at 126–27, 139–45 (allowing felony conviction of physician who prescribed metha-

done in an unorthodox detoxification program that more closely resembled the activities of a "pusher"); *United States v. Betancourt*, 734 F.2d 750, 757 (11th Cir. 1984) ("[T]he jury needed medical testimony as to what the drug is, how it is properly used, how it can be abused and the medical profession's view of the drug."); *Noell v. Bensinger*, 586 F.2d 554, 557–58 (5th Cir. 1978) (upholding the revocation of a physician's certificate of registration notwithstanding the fact that the only expert who testified had stated that the prescription of amphetamines to counteract fatigue comported with accepted standards of medical practice); *United States v. Green*, 511 F.2d 1062, 1069–70 (7th Cir. 1975) (upholding the DEA's regulation even though the statute did not explicitly require that a controlled substance only be prescribed for a legitimate medical use); D.J. Behr, "Prescription Drug Control Under the Federal Controlled Substances Act: A Web of Administrative, Civil, and Criminal Law Controls," *Washington University Journal of Urban & Contemporary Law*, 45 (1994): 41–119, at 61–65, 109, 112–13; Annotation, "Federal Criminal Liability of Licensed Physician for Unlawfully Prescribing or Dispensing 'Controlled Substance' or Drug in Violation of the Controlled Substances Act," 33 A.L.R. Fed. 220 (1977 & Supp. 2002).

119. See D.B. Brushwood & J.J. Carlson, "The Pharmacist's Responsibility to Evaluate Suspicious Prescriptions," *Food Drug Cosmetic Law Journal*, 46 (1991): 467–85, at 481 (noting that the DEA's *Pharmacist Manual* lists as one indicia of an illegitimate prescription "whether the purported prescription order contains an indication other than one found in the package insert"); *id.* at 475 n.45 ("Pharmacists would have to question the appropriateness of virtually every prescription that is out of the ordinary, in a way that is inconsistent with the federal framework in which physicians are allowed wide latitude in prescribing."); see also *United States v. Leal*, 75 F.3d 219, 223 (6th Cir. 1996) (upholding conviction of pharmacist); *United States v. Hayes*, 595 F.2d 258, 261 n.6 (5th Cir. 1979) ("[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.").

120. See 21 U.S.C. § 396 (2000) (medical device regulation); 42 U.S.C. § 1395 (2000) ("Nothing in [Medicare] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."); 37 Fed. Reg. 16,503, 16,504 (1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine....").

121. 48 Fed. Reg. 26,720, 26,733 (1983); see also 21 C.F.R. § 312.2(d) (explaining that the FDA's investigational new drug requirements "do[] not apply to the use in the practice of medicine for an unlabeled indication of [an approved] new drug"); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350–51 & n.5 (2001); *FTC v. Simeon Mgmt. Corp.*, 391 F. Supp. 697, 706–07 (N.D. Cal. 1975), *aff'd*, 532 F.2d 708, 717 (9th Cir. 1976) ("FDA has specifically recognized the legality of using drugs for purposes other than those for which they have been found safe and effective."); J.D. Archer, Editorial, "The FDA Does Not Approve Uses of Drugs," *JAMA*, 252 (1984): 1054–55.

122. See L. Noah, "Constraints on the Off-Label Uses of Prescription Drugs," *Journal of Products & Toxics Liability*, 16 (1994): 139–65, at 139–44.

123. See J.R. Cooper et al., "Prescription Drug Diversion Control and Medical Practice," *JAMA*, 268 (1992): 1306–10, at 1308–09.

124. 51 Fed. Reg. 17,476, 17,477 (1986) (adding, by way of explanation, that the "DEA has encountered practitioners who attempt to justify illegal or improper distribution or dispensing

by claiming unique knowledge of a drug's effectiveness for a broad range of medical indications"). One decade later, the DEA announced a similar threat against any physicians in California who simply recommended the use of marijuana. See 62 Fed. Reg. 6,164 (1997).

125. See B.S. Galer et al., "Individual Variability in the Response to Different Opioids: Report of Five Cases," *Pain*, 49 (1992): 87-91; R.K. Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective," *Journal of Law, Medicine & Ethics*, 24 (1996): 296-309, at 298-99; see also C. Ripamonti et al., "An Update on the Clinical Use of Methadone for Cancer Pain," *Pain*, 70 (1997): 109-15.

126. See S.H. Sindrup & K. Brøsen, "The Pharmacogenetics of Codeine Hypoalgesia," *Pharmacogenetics*, 5 (1995): 335-46, at 343; see also S. Olivier, "Tailor-Made Drugs?," *Times of London*, Feb. 12, 2002 (describing the impact of hormonal differences on the effectiveness of analgesics). See generally L. Noah, "The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles," *Jurimetrics Journal*, 43 (2002): 1-28.

127. See *Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations for 2002: Part 10 — OxyContin: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 107th Cong., at 19 (2001) (statement of Asa Hutchinson, Administrator, DEA) ("Federal laws and regulations do not attempt to define or set standards as to what constitutes 'legitimate medical purpose' or 'the usual course of professional practice,' the requisite elements of lawful prescriptions under the CSA and DEA regulations. Instead, DEA relies upon the medical community to make these determinations."); see also D.E. Joranson & A.M. Gilson, "Policy Issues and Imperatives in the Use of Opioids to Treat Pain in Substance Abusers," *Journal of Law, Medicine & Ethics*, 22 (1994): 215-23, at 216 (describing the dronabinol restriction as an aberration).

128. See 66 Fed. Reg. 56,607, 56,608 (2001) (adding, however, that "[p]ain management, rather than assisted suicide, has long been recognized as a legitimate medical purpose justifying physicians' dispensing of controlled substances"); see also R. Steinbrook, "Physician-Assisted Suicide in Oregon: An Uncertain Future," *N. Engl. J. Med.*, 346 (2002): 460-64; J. Cordaro, Note, "Who Defers to Whom? The Attorney General Targets Oregon's Death with Dignity Act," *Fordham Law Review*, 70 (2002): 2477-514; A. Trafford, "Don't Dismiss This as Physician Paranoia," *Washington Post*, Mar. 12, 2002, at Z1.

129. In contrast, when a group of death row inmates petitioned the FDA in the early 1980s to restrict the off-label use of Schedule II drugs for lethal injection, that agency declined to exercise its enforcement discretion in deference to the choices made by state penal officials. See *Heckler v. Chaney*, 470 U.S. 821 (1985) (rejecting a challenge to the agency's decision); see also L. Noah, Letter, "Attorney General's Intrusion into Clinical Practice," *N. Engl. J. Med.*, 346 (2002): 1918.

130. See *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002), *appeal pending*, No. 02-35587 (9th Cir. 2003).

131. In the less stringent schedules, some of the listed substances refer to particular formulations and dosage strengths. See 21 U.S.C. § 812(c)(III)(d) & (V); see also *id.* § 811(g)(1) (calling for the descheduling of any nonnarcotic substance used in an FDA-approved OTC drug product); *United States v. Martinez*, 950 F.2d 222, 223-24 (5th Cir. 1991) (construing this provision); *United States v. Caperell*, 938 F.2d 975, 978-79 (9th Cir. 1991).

132. For instance, alternative modes of delivery for other pharmaceutical products may reflect attempts to reduce pain associated with their administration. See T. Chea, "MedImmune's Pain-Free Ambitions: If Approved by the FDA, FluMist Would Become

First Vaccine Delivered as a Nasal Spray," *Washington Post*, Mar. 18, 2002, at E1.

133. See K.H. Mosser, "Transdermal Fentanyl in Cancer Pain," *American Family Physician*, 45 (1992): 2289-94; see also W. Jeal & P. Benfield, "Transdermal Fentanyl: A Review of Its Pharmacological Properties and Therapeutic Efficacy in Pain Control," *Drugs*, 53 (1997): 109-38; D.M. Neighbors et al., "Economic Evaluation of the Fentanyl Transdermal System for the Treatment of Chronic Moderate to Severe Pain," *Journal of Pain & Symptom Management*, 21 (2001): 129-43.

134. See "Deaths Are Followed by Pain Patch Restrictions," *Chicago Sun-Times*, Feb. 6, 1994, at 54 (reporting that the manufacturer strengthened warnings after several deaths were associated with misuse of the Duragesic patch); see also *Erony v. Alza Corp.*, 913 F. Supp. 195 (S.D.N.Y. 1995) (allowing an inadequate warning claim to proceed on behalf of a teenager who died after sucking on his father's used Duragesic patches).

135. See D. Brown & J. Schwartz, "The Good and Bad Sides of a Narcotic Lollipop," *Washington Post*, Jan. 31, 1994, at A3; P.J. Hilts, "U.S. Urged to Bar Narcotic Lollipop for Children," *New York Times*, Jan. 26, 1994, at A10 (describing the DEA's objections); see also J. Brody, "The Forgotten Child in Treating Pain Is the Child," *New York Times*, Oct. 25, 1995, at C11 (noting "drug companies' reluctance to develop pediatric analgesics," and explaining that doctors have resisted using the fentanyl lollipop with children).

136. See S.G. Boodman, "Narcotic Lollipop Gets Approval by FDA Panel," *Washington Post*, Sept. 23, 1997, at Z5; see also R. Payne et al., "Long-Term Safety of Oral Transmucosal Fentanyl Citrate for Breakthrough Cancer Pain," *Journal of Pain & Symptom Management*, 22 (2001): 575-83.

137. See Hutchinson statement, *supra* note 127, at 15-17; A. Kumar, "Prescription Drug Abuse Soars," *Los Angeles Times*, Jan. 17, 2003, at A30. In 2001, the National Institute of Drug Abuse (NIDA) issued a report documenting startling levels of prescription drug abuse. See K. Fackelmann, "Health Campaign Takes Aim at Prescription Drug Abuse," *USA Today*, Apr. 10, 2001, at D7; see also B. Vastag, "Mixed Message on Prescription Drug Abuse," *JAMA*, 285 (2001): 2183-84, at 2184 ("At the same time that NIDA is raising alarm bells about abuse potential, new studies point to chronic underprescribing of appropriate pain relief and a low risk of addiction to prescription drugs.").

138. See N. Aoki, "Abusing Pain Pills: Is Maker to Blame?," *Boston Globe*, July 4, 2001, at D1; Editorial, "Curbing the OxyContin Scourge," *Pittsburgh Post-Gazette*, May 30, 2001, at A11 ("OxyContin has provided long-lasting pain relief for hundreds of thousands of cancer patients and others suffering from chronic pain."); see also C. Adams, "Painkiller's Sales Far Exceeded Maker's Plans," *Wall Street Journal*, May 16, 2002, at D2.

139. See P. Tough, "The Alchemy of OxyContin," *New York Times Magazine*, July 29, 2001, at 32; cf. *Crocker v. Winthrop Lab.*, 514 S.W.2d 429 (Tex. 1974) (allowing a tort claim to proceed against the seller of the prescription analgesic Talwin® (pentazocine) for misrepresenting it as nonaddictive).

140. See B. Meier, "Overdoses of Painkiller Are Linked to 282 Deaths," *New York Times*, Oct. 28, 2001, at A20; see also D.E. Hoffmann & A.J. Tarzian, "Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards," *Journal of Law, Medicine & Ethics*, 31 (2003): 21-40.

141. See E. Mehren, "Hooks of 'Hillbilly Heroin': Abuse of Prescription Painkiller OxyContin Ravages Poor Areas in the East," *Los Angeles Times*, Oct. 4, 2001, at A1.

142. See G. Singh, "Recent Considerations in Nonsteroidal Anti-Inflammatory Drug Gastropathy," *American Journal of Medi-*

cine, 105, suppl. 1B (1998): 31–38, at 33 (estimating 16,500 deaths annually just among arthritis patients); see also G.C. Curhan et al., “Frequency of Analgesic Use and Risk of Hypertension in Younger Women,” *Archives of Internal Medicine*, 162 (2002): 2204–08.

143. See R. Rubin, “Abuse-Resistant OxyContin Planned,” *USA Today*, Aug. 9, 2001, at 2A.

144. See L. Neergaard, “Abuse-Resistant OxyContin Hits Snag,” *Associated Press Newswire*, June 18, 2002.

145. See J. White, “Va. Class-Action Suit Filed Against OxyContin Firm,” *Washington Post*, June 19, 2001, at A6; see also *McCaulley v. Purdue Pharma, L.P.*, 172 F. Supp. 2d 803, 804–05 (W.D. Va. 2001) (summarizing the plaintiffs’ allegations in the course of resolving preliminary motions); *Salisbury v. Purdue Pharma, L.P.*, 166 F. Supp. 2d 546, 548 (E.D. Ky. 2001); *McCallister v. Purdue Pharma, L.P.*, 164 F. Supp. 2d 783, 787–88, 791–92 (S.D. W. Va. 2001); R.C. Ausness, “Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?,” *Wake Forest Law Review*, 37 (2002): 97–139, at 133–35. Opponents of efforts to down-classify marijuana make a similar argument — namely, that decriminalization for medical use will create a larger supply subject to possible diversion.

146. See J. White, “OxyContin Abuse Is Increasing, DEA Says,” *Washington Post*, Dec. 12, 2001, at A10; see also C. Adams, “FDA Asks Maker of OxyContin to Pull ‘Misleading’ Print Ads,” *Wall Street Journal*, Jan. 23, 2003, at D3; J. Carter, “Senate Committee Examines Marketing Practices of OxyContin Manufacturer,” *Associated Press Newswire*, Feb. 12, 2002.

147. See D.B. Brushwood & F.H. Fern, “Clozaril and the Threat of Product Liability: Defensive Drug Distribution Invites Regulatory Reform,” *Journal of Products & Toxics Liability*, 15 (1993): 145–62, at 145–46, 150, 158–59; J.H. Krause, “Accutane: Has Drug Regulation in the United States Reached Its Limits?,” *Journal of Law & Health*, 6 (1991): 1–29, at 18–23; M.A. Hurwitz, Note, “Bundling Patented Drugs and Medical Services: An Antitrust Analysis,” *Columbia Law Review*, 91 (1991): 1188–220, at 1192–95.

148. See *American Pharm. Ass’n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974) (invalidating the FDA’s effort to restrict the distribution of methadone, primarily because Congress had assigned this responsibility to the DEA), *aff’d*, 530 F.2d 1054 (D.C. Cir. 1976); L. Noah, “A Miscarriage in the Drug Approval Process? Mifepristone Embroils the FDA in Abortion Politics,” *Wake Forest Law Review*, 36 (2001): 571–603, at 584–86; see also M. Kaufman, “FDA Reapproves Bowel Drug After Pulling It for Safety,” *Washington Post*, June 8, 2002, at A4; F.L. Kritz, “FDA to Weigh New Controls on Problematic Drugs,” *Washington Post*, Apr. 16, 2002, at Z1.

149. Methadone represents an exception. See S.P. Molinari et al., “Federal Regulation of Clinical Practice in Narcotic Addiction Treatment: Purposes, Status, and Alternatives,” *Journal of Law, Medicine & Ethics*, 22 (1994): 231–39, at 238 (“The [Narcotic Addict Treatment Act of 1974] has created a closed distribution system unique to pharmacotherapy and the practice of medicine.”).

150. See L. Noah, “Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority,” *Wisconsin Law Review* (1997): 873–941, at 881–82.

151. See T. Pasko & B. Seidman, *Physician Characteristics and Distribution in the US* (Chicago: AMA Press, 2002): at 15, 18; see also “DEA Overreaches in Effort to Stop Abuse of Painkiller,” *USA Today*, June 13, 2001, at 16A (citing an estimate that “there are fewer than 4,000 certified pain specialists” in the United States).

152. See C.S. Cleeland, Editorial, “Undertreatment of Cancer Pain in Elderly Patients,” *JAMA*, 279 (1998): 1914–15, at 1915 (noting that “the optimal management of pain and adverse effects of analgesics requires aggressive use of controlled substances, potentially raising fears of regulatory scrutiny”); C. Gillespie, “Getting OxyContin Can Be an Ordeal for Those Who Need It,” *Los Angeles Times*, Oct. 14, 2001, at A26; P. Recer, “Experts Say Cancer Pain Undertreated,” *Associated Press Newswire*, July 17, 2002 (describing the conclusions reached at a National Institutes of Health consensus conference on the subject).

153. See L. Marsa, “OxyContin Abuse May Curb Progress in Pain Field,” *Los Angeles Times*, Aug. 13, 2001, at S1; “Supermarket Chain Pulls Oxycontin,” *Associated Press Newswire*, Apr. 16, 2002.

154. See J.A. Henderson, Jr., & A.D. Twerski, “Drug Designs Are Different,” *Yale Law Journal*, 111 (2001): 151–81, at 168–72; L. Noah, “Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues,” *Georgia Law Review*, 32 (1997): 141–80, at 172–73. In fact, after the FDA authorized the reintroduction of Lotronex with restrictions on who may prescribe the drug, patients have found it difficult to secure. See F.L. Kritz, “Still Irritable, Still Waiting: After Return to Market, Lotronex Can Be Hard to Get,” *Washington Post*, Feb. 11, 2003, at Z1.

155. See J. White, “More Warnings About OxyContin,” *Washington Post*, July 26, 2001, at B2.

156. See 66 Fed. Reg. 38,713, 38,714 (2001).

157. See S. Satel, Op-Ed, “Keeping OxyContin out of the Wrong Hands,” *Boston Globe*, Aug. 11, 2001, at A15; see also D.H. Kreling et al., “The Effects of an Internal Analgesic Formulary Restriction on Medicaid Drug Expenditures in Wisconsin,” *Medical Care*, 27 (1989): 34–44, at 36–37, 42 (concluding that this approach to reducing the use of narcotic analgesics had limited success). In addition, one state has sued for reimbursement of Medicaid expenditures for overprescribing of the drug. See M.T. Reidy & M.H. Brown, “Suit Targets State Firm That Makes OxyContin,” *Hartford Courant*, June 13, 2001, at A6.

158. See “OxyContin Maker Calls Plaintiffs’ Allegations Baseless, Pledges to Ensure Supply for Patients,” *Product Safety & Liability Reporter*, 29 (2001): 666–68, at 667.

159. See B. Meier, “U.S. Asks Painkiller Maker to Help Curb Wide Abuse,” *New York Times*, May 1, 2001, at A12. Along similar lines, the DEA regulations include a rule of last resort for the use of opioid analgesics, authorizing the administration of narcotics in hospital settings “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).

160. See *Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations for 2002: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 107th Cong., at 334 (2001) (testimony of Donnie R. Marshall, Acting Administrator, DEA). Although reportedly not done at the agency’s behest, the manufacturer decided to discontinue marketing its highest dosage form (160 mg). See J. White, “Shipment of Potent Pain Pills Suspended: Company Interrupts Sales of Strongest Dosage of OxyContin Because of Abuse,” *Washington Post*, May 12, 2001, at A9.

161. See R.L. DuPont & C.M. DuPont, “The Treatment of Anxiety: Realistic Expectations and Risks Posed by Controlled Substances,” *Journal of Law, Medicine & Ethics*, 22 (1994): 206–14, at 212–13 (“When physicians and patients abuse the social ‘contract’ on drugs of abuse, they should be subjected to professional and legal sanctions because such transgressions pose potentially serious clinical and public health dangers.”); D.A.

Kessler, "Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act," *Harvard Journal on Legislation*, 15 (1978): 693–760, at 737 ("Withdrawal of a drug that has value to a certain patient population because the drug may be misused by a larger population in effect imposes an unfair hardship on those patients who could use the drug safely and profitably."); cf. *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 468, 471–72 (5th Cir. 1987) (rejecting the plaintiff's claim that, if the manufacturer could not reduce the risk that health care professionals would act negligently and administer excessive doses of fentanyl, it should have withdrawn the drug from the market).

162. See D.R. Wesson & D.E. Smith, "Prescription Drug Abuse: Patient, Physician, and Cultural Responsibilities," *Western Journal of Medicine*, 152 (1990): 613–16, at 613 ("Prescription drug abuse is more difficult to conceptualize than the abuse of cocaine, marijuana, or even alcohol because there is the need for a balance between restricting access and maintaining availability in drug control policy."); B.B. Wilford et al., "An Overview of Prescription Drug Misuse and Abuse: Defining the Problem and Seeking Solutions," *Journal of Law, Medicine & Ethics*, 22 (1994): 197–203, at 198 ("[U]nlike illicit drug abuse, programs to control prescription drug abuse appear to affect medical care as well.... Such a large collateral effect deserves careful thought...."); *id.* at 202 (calling this issue "the 'social algebra' of the system, that is, the extent to which undermedication of some individuals will be tolerated in exchange for reductions in overmedication of others").

163. See J. White, "DEA Backs Medical Use of OxyContin," *Washington Post*, Oct. 24, 2001, at A26.

164. See J.A. Linder & R.S. Stafford, "Antibiotic Treatment of Adults with Sore Throat by Community Primary Care Physicians: A National Survey, 1989–1999," *JAMA*, 286 (2001): 1181–86; L.F. McCaig & J.M. Hughes, "Trends in Antimicrobial Drug Prescribing Among Office-Based Physicians in the United States," *JAMA*, 273 (1995): 214–19. The latest surveys suggest that things have begun to improve. See L.F. McCaig et al., "Trends in Antimicrobial Prescribing Rates for Children and Adolescents," *JAMA*, 287 (2002): 3096–102.

165. See S.B. Levy, *The Antibiotic Paradox: How Miracle Drugs Are Destroying the Miracle* (New York: Plenum Press, 1992): at 209–10; L. Neergaard, "U.S. Acting to Stem Misuse and Prolong Life of Antibiotics," *Philadelphia Inquirer*, June 11, 2002, at A10; A. Zuger, "The 'Other' Drug Problem: Forgetting to Take Them," *New York Times*, June 2, 1998, at F1.

166. For instance, in response to the escalating prices of new drugs, some patients have turned to black markets (supplied by diversion and counterfeiting) as well as cross-border purchases, each of which creates potential quality control problems that have prompted federal intervention. See L. Noah, "NAFTA's Impact on the Trade in Pharmaceuticals," *Houston Law Review*, 33 (1997): 1293–326, at 1307–09, 1311–14.

167. See J. Gillis & C. Connolly, "Emphasis on Cipro Worries Officials," *Washington Post*, Oct. 19, 2001, at A17 (reporting that drug-resistant strains of bacteria may contribute to 70,000 deaths each year in the United States); see also U.S. Office of Technology Assessment, *Impacts of Antibiotic-Resistant Bacteria*, OTA-H-629 (Washington, D.C.: Government Printing Office, 1995); M.L. Cohen, "Epidemiology of Drug Resistance: Implications for a Post-Antimicrobial Era," *Science*, 257 (1992): 1050–55.

168. See S.B. Levy, "The Challenge of Antibiotic Resistance," *Scientific American*, 278 (Mar. 1998): 46–53, at 52; H.C. Neu, "The Crisis in Antibiotic Resistance," *Science*, 257 (1992): 1064–73, at 1064, 1072. Until recently, vancomycin represented the last line of defense, but resistant strains have emerged. In 2000,

the FDA approved Zyvox® (linezolid), the first of a new class of antibiotics called oxazolidinones. See T. Hayden, "Infectious Arms Race," *U.S. News & World Report*, Dec. 17, 2001, at 50.

169. See 65 Fed. Reg. 81,082, 81,095 (2000) (proposing revisions in the content of prescription drug labeling to reduce the tendency to overprescribe antibiotics); 65 Fed. Reg. 56,511, 56,518 (2000) (proposing a best practices statement in the labeling of antibiotics to remind physicians against overprescribing).

170. See S.B. Markow, Note, "Penetrating the Walls of Drug-Resistant Bacteria: A Statutory Prescription to Combat Antibiotic Misuse," *Georgetown Law Journal*, 87 (1998): 531–62, at 546–47 (suggesting that only infectious disease specialists in hospitals be permitted to use new antibiotics).

171. See 65 Fed. Reg. 24,704, 24,705 (2000) ("How should the risks and benefits to individuals and risks and benefits to the public health be assessed and weighed in any decision on OTC marketing? For example, how should the agency balance the potential benefits of OTC antimicrobial agents with the potential risks to society at large of the development of resistant organisms associated with increased, and potentially improper, use?").

172. See L. Noah, "Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community," *Arizona Law Review*, 44 (2002): 373–466, at 438–42; see also T.J. Moore et al., "Time to Act on Drug Safety," *JAMA*, 279 (1998): 1571–73, at 1572 ("[N]ew warnings about the addictive properties of propoxyphene had no effect on either prescription volume or the number of overdose deaths.").

173. See R. Gonzales et al., "Principles of Appropriate Antibiotic Use for Treatment of Acute Respiratory Tract Infections in Adults: Background, Specific Aims, and Methods," *Annals of Internal Medicine*, 134 (2001): 479–86, at 481–82 (introducing a series of CDC guidelines calling for restraint in prescribing antibiotics for adults); see also T. Brewer and G.A. Colditz, "Postmarketing Surveillance and Adverse Drug Reactions: Current Perspectives and Future Needs," *JAMA*, 281 (1999): 824–29, at 826 (describing the CDC's vaccine adverse event surveillance efforts). See generally E.W. Etheridge, *Sentinel for Health: A History of the Centers for Disease Control* (Berkeley: Univ. of California Press, 1992); L.O. Gostin, *Public Health Law: Power, Duty, Restraint* (Berkeley: Univ. of California Press, 2000); L. Noah, "Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs," *South Carolina Law Review*, 54 (forthcoming 2003).

174. See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) (invalidating a restriction on advertising by pharmacists who compound drug products); L. Noah, "What's Wrong with 'Constitutionalizing Food and Drug Law,'" *Tulane Law Review*, 75 (2000): 137–48 (discussing litigation challenging the FDA's restrictions on indirect industry efforts to promote off-label drug uses).

175. See *OxyContin — It's Use and Abuse: Hearing Before the Subcomm. on Oversight & Investigations of the House Comm. on Energy & Commerce*, 107th Cong., at 9 (2001) (statement by Terrance W. Woodworth, Deputy Director, DEA Office of Diversion Control) ("[T]he five states with the lowest number of per capita OxyContin® prescriptions all have long standing prescription monitoring programs in place."); see also D. Brushwood, "Maximizing the Value of Electronic Prescription Monitoring Programs," *Journal of Law, Medicine & Ethics*, 31 (2003): 41–54. Doctors and drug companies generally oppose such programs. See M. Petersen & B. Meier, "Few States Track Prescriptions as Way to Prevent Overdoses," *New York Times*, Dec. 21, 2001, at A1.

176. See J. Avorn & S.B. Soumerai, "Improving Drug-Therapy Decisions Through Educational Outreach: A Randomized Controlled Trial of Academically Based 'Detailing,'" *N. Engl. J. Med.*,

308 (1983): 1457–63; M.D. Cabana et al., “Why Don’t Physicians Follow Clinical Practice Guidelines? A Framework for Improvement,” *JAMA*, 282 (1999): 1458–65; R.L. Kane & J. Garrard, Editorial, “Changing Physician Prescribing Practices: Regulation vs. Education,” *JAMA*, 271(1994): 393–94; P.R. Manning et al., “Changing Prescribing Practices Through Individual

Continuing Education,” *JAMA*, 256 (1986): 230–32; S.B. Soumerai et al., “Improving Drug Prescribing in Primary Care: A Critical Analysis of the Experimental Literature,” *Milbank Quarterly*, 67 (1989): 268–317; S.B. Soumerai & J. Avorn, “Principles of Educational Outreach (‘Academic Detailing’) to Improve Clinical Decision Making,” *JAMA*, 263 (1990): 549–56.

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Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors

Stephen J. Ziegler and Nicholas P. Lovrich, Jr.

The experience of having to suffer debilitating pain is far too common in the United States, and many patients continue to be inadequately treated by their doctors. Although many physicians freely admit that their pain management practices may have been somewhat lacking, many more express concern that the prescribing of heightened levels of opioid analgesics may result in closer regulatory scrutiny, criminal investigation, or even criminal prosecution.

Although several researchers have examined the regulatory environment and the threat of sanction or harm it poses to physicians and patients, few have examined the *likelihood* of investigation or prosecution stemming from the aggressive use of opioids in physician-directed pain management. Accordingly, in an effort to assess whether the fear of prosecution is realistic and, if so, what factors contribute to its likelihood, we surveyed chief prosecutors in four states about their knowledge, opinions, and attitudes concerning opioids and the prosecution of physicians stemming from the treatment of patients who were either terminally ill or suffering from chronic noncancer pain.

Before presenting these results, we begin with the medicolegal and political background of pain treatment. We then examine the thinking of American prosecutors generally at the local level, highlighting their discretion to investigate and to prosecute, and discuss the white-collar crime literature, which helps explain the inherent difficulty associated with both the detection and successful prosecution of medical crimes. Finally, we discuss the methodology and results of our survey and draw out some of the principal implications.

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THE MEDICOLEGAL AND POLITICAL BACKGROUND

Debilitating pain has reached epidemic proportions in the United States and continues to be neglected and inadequately treated.¹ In fact, a recurring theme in the professional and lay literature concerns the undertreatment of pain and the underdispensing of opioid analgesics for both terminally ill and noncancer chronic pain patients.² Two of the most prominent reasons for the underdispensing of opioids stem from the fear of iatrogenic addiction and increased regulatory scrutiny.³ However, the use of opioids in the management of pain is a legitimate and recognized protocol;⁴ the rate of addiction is very low;⁵ and doctors who prescribe opioids for extended periods are “acting within the professional practice of medicine.”⁶ In fact, the frequency, amount, and chronicity of opioid prescriptions are not particularly indicative of inappropriate treatment protocols. Without considering the individual patient, these aspects of dispensing practice are not determinative of abuse or diversion.⁷ The physician is not limited to the prescribing levels that appear on the package insert or the companion *Physicians’ Desk Reference* (PDR);⁸ and a physician who is authorized to prescribe opioids may do so as long as it is for a legitimate medical purpose and the physician observes the procedures of good medical practice.⁹

Insufficient knowledge

Notwithstanding the above, state medical boards lack sufficient knowledge about pain management, and health care professionals sometimes overestimate the level of regulatory scrutiny to which they are exposed. In fact, studies of physicians, pharmacists, and medical regulators not only document serious gaps in knowledge, but provide evidence that many medical professionals are largely unaware of the positive role of opioids in the treatment of pain.¹⁰ Below, we briefly review the medicolegal research as it relates to the knowledge

and concerns held by physicians, pharmacists, and medical board members in the context of pain relief and opioid use. Following this discussion, we turn our attention to prosecutors and the inherent difficulties of prosecuting medical professionals, topics that provide the background for the study reported here.

Although many physicians admit that their pain management practices may be lacking, they nevertheless fear that the dispensing of heightened levels of opioids for their patients suffering from pain will result either in negative patient outcomes or in heightened scrutiny from their medical licensing boards, county prosecutors, or even the federal government.¹¹ For instance, several studies have indicated that physicians are often reluctant to prescribe opioids out of fear of iatrogenic addiction,¹² despite the fact that the documented rate of addiction is extremely low.¹³ Moreover, they are also concerned that their prescribing practices will raise suspicions of pharmaceutical diversion.¹⁴ In fact, in a recent survey of Texas physicians, 26.4 percent of the respondents agreed with the following statement: "Prescribing narcotics for patients with chronic pain is likely to trigger a drug enforcement agency investigation"; and 47.7 percent agreed with the statement: "If I follow the same prescribing practices as other doctors in my field, I will not be investigated by a regulatory agency."¹⁵ But as noted earlier, chronic pain is undertreated, and the amount of opioids that are clinically indicated for a patient is highly individualized. A dosage that works for one patient suffering from chronic pain or for a patient near the end of life may be wholly inappropriate for another, particularly when considering the length of treatment, the patient's underlying illness or condition, and the pharmacokinetics of opioids.¹⁶

Pharmaceutical diversion

Physicians and medical boards alike are concerned about the diversion of controlled substances. While pharmaceutical diversion is part of a larger national drug abuse problem, the "perception of regulatory risk far exceeds the reality."¹⁷ In fact, only a relatively small percentage of prescription drugs are actually diverted to illicit use by doctors or patients.¹⁸ Notably, of the four types of offenders involved in pharmaceutical diversion, deceptive patients are far and above the most likely source of diverted pharmaceuticals;¹⁹ dated doctors (those who are out of touch or lax in their prescribing behavior) are a distant second, followed by impaired doctors.²⁰ Dishonest doctors are the least likely source of diversion, accounting for less than 2 percent of all pharmaceutical diversion.²¹

Fear of investigation or prosecution

Although state medical boards appear to accept the use of opioids in larger doses over longer periods of time for termi-

nally ill patients, some physicians fear investigation or prosecution for aggressively treating the pain of their terminally ill patients, particularly those near the end of life. Surprisingly, physicians who treat the terminally ill concern themselves not only with many of the same issues that arise when treating chronic noncancer pain, but also with the possibility that their actions could be misconstrued as physician-assisted suicide or euthanasia should their patients expire during the course of aggressive palliative care.²² This may especially be the case when a dying patient is suffering from severe and intractable pain and distress, and terminal sedation may be indicated.²³ Briefly stated, terminal sedation involves the administration of a combination of sedatives and analgesics until the patient is palliated to the point of unconsciousness.²⁴ Often, medically provided nutrition and hydration is withdrawn or withheld at this point.²⁵ Eventually, whether the result of the underlying condition, the withholding of artificial nutrition and hydration, the effects of the medication, or a combination thereof, the patient expires.

While opioids are often effective for the treatment of pain in terminally ill patients, opioids such as morphine do carry the risk of respiratory depression and death.²⁶ However, this risk is *small* and often limited to opioid-naïve patients.²⁷ In fact, pain is a natural antagonist, and an acquired tolerance is to be expected.²⁸ Consequently, increases in dosage can occur without increased risk of respiratory depression.²⁹

Even should a death be attributable to the use of opioids for pain relief in the dying patient, the aggressive treatment of pain is supported by the ethical principle of "double effect." Under this principle, "a proportionately good effect (relief of suffering) may overcome a foreseeable bad effect (causing death) as long as the [doctor] did not intend to accomplish the bad effect."³⁰ Although an ethical principle, it is fair to say that the principle is now one of medical custom and standard of practice. In fact, the U.S. Supreme Court has endorsed this ethical principle and may have even created a defense to prosecution should a terminally ill patient die during the administration of palliative care. See *Vacco v. Quill*, 521 U.S. 793 (1997).³¹ Aside from the administration of palliative medicine, the withdrawal of medically provided nutrition and hydration during terminal sedation, if done in compliance with state law, arguably raises no separate legal or ethical issues.³²

Physician's intent: Who decides?

But if a terminally ill patient expires shortly after the administration of opioids, at what point does aggressive pain relief become a violation or suspected violation of law that would justify prosecutorial review and action? If the distinction between aggressive pain relief and hastened death is a point of contention among physicians and ethicists,³³ what can we

expect from prosecutors who are likely less knowledgeable about pain relief and end-of-life care? For instance, some scholars have argued that the use of “risky analgesics” in palliative care could incur criminal liability,³⁴ while others argue that the practice of terminal sedation is more akin to euthanasia and affords less protection than regulated physician-assisted suicide.³⁵ But under the principle of double effect, a key in distinguishing between aggressive palliative care and euthanasia remains one of *intent*.³⁶ Intent, however, often escapes exacting proof. In fact, recent attempts at legislation in the area of opioid use and terminally ill patients were unsuccessful, in part, because of opponents’ concerns regarding the difficulty in determining intent.³⁷ In the end, it is the prosecutor who must decide if criminal intent exists and whether the physician should be charged with a crime.³⁸

OUR FOCUS

Earlier research focused on the fears and knowledge commanded by physicians, pharmacists, and members of state medical boards relating to the use of opioids in the treatment of pain. Our research focuses on the knowledge and attitudes of local prosecutors. In addition to directly and indirectly assessing prosecutors’ knowledge, we also seek to determine whether physicians’ fear of investigation or prosecution is based on an accurate assessment of reality.

Research on the frequency of prosecution stemming from the aggressive treatment of pain for terminally ill patients has been problematic. Relying on published reports of health-provider prosecutions does not present an accurate picture, for example.³⁹ Consequently, we were curious about whether prosecutions involving physicians were more common than what was being reported. Accordingly, we build on earlier research by Ann Alpers (1998)⁴⁰ and Meisel, Jernigan, and Youngner (1999),⁴¹ and also incorporate the social science literature concerning prosecutorial discretion and white-collar crime.⁴² This literature not only assisted us with instrument construction and data analysis, it also provided insight into the frequency and likelihood that incidents involving physicians and pain management would be investigated or prosecuted at the local level.

Finally, our research involving local prosecutors⁴³ demonstrates that a prosecutor’s decision to investigate or prosecute amounts to policymaking in general,⁴⁴ and health policy in particular.⁴⁵ Consequently, this study assesses what prosecutors’ policy views are in the context of pain relief and prescription drugs. Because it would be virtually impossible to determine the likelihood of prosecution without regard to the people and dynamics in the administration of justice, our next section focuses on prosecutors in general and local prosecutors in particular.

STUDIES OF PROSECUTORS AND PROSECUTIONS

The American prosecutor is a unique political actor in our system of justice. Most local prosecutors in the United States are elected to office and serve in rather rural environments.⁴⁶ Not only do they have multiple titles — ranging from district attorney to state’s attorney — they also tend to carry out multiple roles.⁴⁷ For instance, as an attorney, the prosecutor is an officer of the court who must abide by the law.⁴⁸ As an elected official, the prosecutor is often directly answerable to no one except the electorate, and may seek reelection or use his or her office “as a stepping stone to more prestigious governmental positions.”⁴⁹ Moreover, as an elected official, prosecutors are more likely to be influenced by the community, public opinion, and influential citizens who work to ensure that prosecutors’ decisions “reflect community values.”⁵⁰ In fact, according to Joan Jacoby, “the single most powerful influence on the prosecutor, his role, and the operations of his office is the nature of the population he represents, its resources, and the consequent social and cultural patterns it develops.”⁵¹ She also notes that a prosecutor’s

policy determinations should be and probably are influenced by the socioeconomic characteristics of the community and its value system. Since the prosecutor is a result of the local political process, his policy about enforcement of the law should reflect the opinions of the community at large.⁵²

The prosecutor also serves as a member of the executive branch and is vested with the authority to investigate crimes, charge offenders, offer immunity agreements, engage in plea bargains, oppose pretrial release, seek convictions, and decide what position to take concerning the sentencing of those convicted.⁵³ In fact, the power of the American prosecutor is so wide-ranging that former U.S. Supreme Court Justice Robert H. Jackson once remarked that a “prosecutor has more control over life, liberty, and reputation than any other person in America.”⁵⁴

The decision to charge a suspect with a crime

Of the many decisions that a prosecutor must make, the decision to charge a person with the commission of a crime remains one of the foremost exercises of discretion afforded the modern-day prosecutor.⁵⁵ Because each case features a unique set of factual and legal issues, a prosecutor has virtually unfettered discretion to pursue prosecution, decline prosecution, or refer the matter to other authorities. In fact, the prosecutor even has a wide variety of alternatives to charging the defendant criminally. For instance, if the defendant is already on probation or parole, a prosecutor could pursue the matter administratively as a probation violation (easier burden of proof), or let some other person or entity handle

the matter in its entirety (via civil suits, parole hearings, mental hospitals, community agencies, or other law enforcement agencies with jurisdiction over the defendant).⁵⁶

Although research concerning the charging decision is relatively sparse,⁵⁷ many have argued that the decision to prosecute is influenced by both legal and extralegal factors. For instance, probable cause must exist before a suspect can be charged with a crime.⁵⁸ Secondly, the “strength of the case, the credibility of complainants and witnesses, the existence and admissibility of corroborating proof, and the nature and strength of the defense” also serve as significant legal constraints on the exercise of a prosecutor’s discretion.⁵⁹ However, many extralegal factors also have an influence on the prosecutor’s charging decision, such as, but not limited to, the character of the organization involved,⁶⁰ the defendant,⁶¹ the victim,⁶² the surrounding environment,⁶³ the individual prosecutor’s stereotypical beliefs of what a jury would likely do with the case,⁶⁴ publicity and public opinion,⁶⁵ and the need to reduce uncertainty about the outcome of the case.⁶⁶ The primary factor influencing the decision to charge a person with a crime is the ability to secure a conviction (i.e., the defendant’s convictability — what has been characterized as a prosecutor’s “downstream orientation” regarding the processing of cases).⁶⁷ Therefore, when making the decision to charge or not charge a physician with a crime, the prosecutor essentially asks: Could this physician be convicted in this community under the existing facts?

White-collar and medical crime

Research involving white-collar and medical crime helps distinguish between detection of a violation of law and the likelihood that health care professionals will be prosecuted. The terms “white-collar crime, medical crime, and occupational crime” are merely descriptive areas of the criminal justice literature; we do not infer that the conduct of the physicians featured in our scenarios is criminal in nature.

Although several definitions exist, white-collar crime may be best defined by what it is not — namely, it is “neither street crime nor conventional crime.”⁶⁸ White-collar crimes are generally crimes that are committed by professionals who enjoy relatively high social status. Within this broad area of literature lies the subcategory of medical crime, representing offenses committed by medical professionals within the scope of their employment (also known as occupational crime).⁶⁹ As a subfield of white-collar crime, medical crime shares many of the same problems regarding detection, investigation, and prosecution associated with the broader white-collar crime category.⁷⁰

For instance, white-collar crimes are not given the same priority as street crimes despite the fact that white-collar crime/occupational crime is far more costly in human and financial terms.⁷¹ There are a variety of reasons for this misplaced attention. First, unlike street crimes, white-collar

crimes are usually not committed in public view and quite often go undetected by either the general public or the victim.⁷² Secondly, white-collar crimes are often complex and require specialized expertise in their detection, investigation, and successful prosecution.⁷³

Moreover, due to the secretive nature of white-collar crime, it is also severely underreported in both frequency of occurrence and prosecution. Because prosecutors screen cases for further investigation and prosecution, the number of cases accepted for prosecution grossly underrepresents the frequency of occurrence.⁷⁴ Even in the context of Medicare fraud, where enforcement personnel are specially trained to investigate offenses, investigators believe that the number of physicians detected represents merely the “tip of the iceberg” and those prosecuted tend to constitute only the most egregious cases.⁷⁵

Proving intent also presents a special problem, particularly when the individual conduct stems from differences in “professional opinion” (e.g., the method of treatment).⁷⁶ Moreover, the existence of civil remedies as an alternative to criminal prosecution is often considered, particularly in light of the high standard of proof that is required in a criminal proceeding.⁷⁷ Consequently, what actually constitutes a criminal case could be processed only as a civil or administrative matter, keeping it out of the crime reporting loop.

Prosecuting physicians

Physicians have been prosecuted for a wide array of conduct related to their profession, ranging from violations of controlled substance laws to Medicare fraud.⁷⁸ In fact, several commentators argue that the frequency of physician prosecutions is on the rise.⁷⁹ This increase has been attributed to a variety of factors, one of which stems from the perception that the medical profession or state medical boards and regulatory agencies are incapable of adequate monitoring and control.⁸⁰ Other commentators argue that the general decline in our level of trust in social institutions, the emergence of managed care (where medicine is perceived more as a business than a profession), and the willingness of prosecutors to prosecute when they perceive that traditional control systems are weak are also factors at play.⁸¹

Albeit limited, some research has also been conducted on what factors may contribute to charging a physician with an offense. For instance, some researchers argue that the size of the community matters (“juries are often reluctant to convict doctors, particularly in small towns where they may have built up a grateful clientele”),⁸² or the nature of the defendant’s occupation.⁸³ Two recently published studies help inform the debate over the likelihood of being prosecuted, particularly for the aggressive treatment of pain at the end of life.

In 1994, Meisel, Jernigan, and Youngner (1999)⁸⁴ examined the willingness of prosecutors to prosecute a physician for his or her care of dying patients in light of both their personal and professional opinions. Although this large-scale

and interesting study suffered from a low rate of response, several of its findings were noteworthy. For instance, over the three less controversial scenarios presented to prosecutors, “no more than one fifth of the respondents would take measures that might lead to formal prosecution, such as an indictment.”⁸⁵ Specifically, one of the scenarios involved the planned use of morphine to alleviate the pain “of a terminally ill, competent cancer patient.”⁸⁶ In the scenario’s narrative, the health care professionals were depicted as being “concerned about possible criminal liability if the morphine [was] administered” and the patient died.⁸⁷ The results indicated that 18.9 percent of the prosecutors would be willing to take formal action against the physician, 61 percent would not, and 20.1 percent were undecided.⁸⁸

Four years later, researcher Ann Alpers reviewed published material in an effort to analyze “what actions have put physicians or nurses at risk for criminal investigation or prosecution in connection with their care of dying patients, particularly their management of pain.”⁸⁹ Professor Alpers found that there were

no systematic efforts by any state or local government to target health care providers or dying patients for routine investigation or review. The treatment of terminal pain is never investigated unless someone knowledgeable about the treatment informs either a hospital supervisor, an ethics committee, or a local prosecutor.⁹⁰

Alpers found that environmental and defendant characteristics may have played a role in the decision to prosecute. For instance, excepting five physicians in Minnesota, “all of the cases [prosecuted or investigated] occurred in small towns or rural counties.”⁹¹ Moreover,

Many of the health care providers [who were prosecuted or investigated] were outsiders — either newly arrived, members of racial or ethnic minorities, or living alternative lifestyles.⁹²

Alpers ultimately concluded that the decision to investigate or prosecute health care providers was not motivated by “suspicious or overzealous prosecutors,” but rather stemmed from “intercollegial discord and miscommunication or disagreements between providers and families.”⁹³

PURPOSE OF OUR STUDY

The purpose of this pilot study is to examine empirically whether the fear of criminal investigation and prosecution is based on a realistic assessment of risk and, further, to document what factors contribute to and predict the likelihood of prosecution in the context of providing pain relief through the use of prescription drugs.

METHODS

Population and selection of states

Our population consisted of all chief prosecuting officials at the county level in the states of Connecticut, Maryland, Oregon, and Washington ($N = 112$). Although we were dealing with an exempt population (persons holding public office), we sought and received approval for studies involving human subjects from our university’s institutional review board. Oregon and Washington were chosen because the issues of pain relief and physician-assisted suicide are highly salient in Oregon due to the state’s legalization of the practice, and the neighboring state of Washington provided a means of comparison in light of its similarity in size and lack of a physician-assisted suicide statute. Connecticut was selected for three primary reasons. First, unlike the prosecutors/district attorneys in the western states, prosecutors in Connecticut (state’s attorneys) are appointed to their posts for 8-year terms. Their jurisdiction is also not set at the county level, but rather extends over a judicial district. Second, the Donaghue Medical Research Foundation had recently funded research on the barriers to pain management in that state, and our research would add to this scholarship.⁹⁴ And third, its location in the eastern part of the United States would provide contrast to the two western states. Although it was not within our budget or original plan, we also decided to include the state of Maryland in our study. As an eastern state, Maryland would not only add to the results of Connecticut, but the number of prosecutors in Maryland would increase the validity of our study by adding another twenty-four potential respondents. Moreover, although Maryland state’s attorneys usually do not endorse studies, we found that the Maryland Attorney General’s Office was very supportive of our research. Although the office had no control over the local prosecutors in that state, it became a valuable resource to our study, as did the several national and state prosecuting attorneys associations contacted during the course of our research.

Instrument

Building on prior scholarship in both the medicolegal and social science literatures, we constructed a self-administered, mailed questionnaire consistent with the Tailored-Design Method.⁹⁵ The pre-tested questionnaire consisted of forty-four items concerning the topics of pharmaceutical diversion, pain relief, physician-assisted suicide, euthanasia, and factors that would likely contribute to whether or not a physician would be charged with an offense. As did Meisel, Jernigan, and Youngner,⁹⁶ we used scenarios involving patients and physicians, but we varied the approach somewhat by asking respondents to estimate the likelihood that they would take action on a scale from 0 percent to 100 percent. By allowing answers along a range of scores rather than the traditional yes-or-no dichotomy, we gained flexibility in response range

and captured the intensity of each respondent's views. In light of our own methodological concerns, such as the ordering of the questions, we specifically designed the questions so that respondents would have to estimate the likelihood that they would take action or inaction on each particular scenario. The likelihood they would take no action can be implied from low scores on the range of 0 percent to 100 percent. We recognize that, in reality, cases presented to prosecutors have unique facts and that our scenarios are therefore somewhat artificial. However, scenarios remain a valuable tool in both research and education because each respondent gets the same scenario (stimulus), and both attorneys and physicians are accustomed to dealing with proposed scenarios during the course of their earlier training and later discussions with colleagues.

This article reports on the two scenarios in the survey instrument entailing the aggressive treatment of pain among terminally ill and chronic noncancer pain patients, and investigates questions related to addiction, pharmaceutical diversion, and the prosecution of physicians.

The first scenario in our study concerns the legitimate but aggressive treatment of chronic noncancer pain identified as a potential problem by a pharmacist (see Scenario 1). Pharmacists have a responsibility to ensure that controlled substances are dispensed for a legitimate medical purpose (although quantity, frequency, and amount of dispensing by themselves are insufficient indicia of inappropriate prescribing). Moreover, prosecutors often have to rely on informants to flag their cases since "the criminal justice system plays a passive role in policing physician behavior."⁹⁷ Consequently, we were curious if prosecutors would recommend investigation of the physician (known to have a chilling effect on opioid dispensing), refer the matter to the Drug Enforcement Administration (DEA), or refer the matter to the state medical board in lieu of investigation or prosecution.

The second scenario involves the treatment of a terminally ill patient experiencing respiratory distress who, after morphine administration, goes into respiratory arrest and dies (see Scenario 2). Although the likelihood of respiratory

arrest is negligible,⁹⁸ and with proper titration, morphine "can be used safely and effectively,"⁹⁹ opioids have the potential to "depress both the rate and depth of respiration" to the point of respiratory arrest.¹⁰⁰ This second scenario illustrates the principle of double effect.¹⁰¹ The scenario is also analogous to the testimony of Dr. William Hunter, given before a congressional committee in support of the Pain Relief Promotion Act of 1999.¹⁰² Dr. Hunter described the basic facts of Scenario 2 as a daily occurrence in the United States. He stated that he would not fear prosecution under such circumstances. Therefore, it would be quite remarkable if our study revealed that several prosecutors would indeed take action against the physician featured in Scenario 2, either by referring the matter to the state medical board or through investigation and/or prosecution.

In addition to the two scenarios, our questionnaire also included a list of factors that our literature review indicated may be important to the decision to charge. We built on the previous work of several scholars, such as Benson et al., Benson and Cullen, Ayers and Frank, and Liederbach et al.¹⁰³ To allow some means of comparison, portions of the survey made use of a format followed by several previous surveys of health care professionals, state regulators, and prosecutors on questions involving pharmaceutical diversion and addiction.¹⁰⁴

Implementation

Consistent with self-administered survey protocol, we conducted three waves of mailings, beginning in November 2001 and ending in February 2002. Several noteworthy events occurred around the time of these mailings. First, the terrorist attacks on the United States on September 11, 2001, and the subsequent Anthrax letter incidents resulted in delays. Second, less than 2 months after these tragic events, U.S. Attorney General John Ashcroft reversed the ruling of former Attorney General Janet Reno that Oregon's use of controlled substances for physician-assisted suicide did not violate the federal Controlled Substances Act. U.S. Attorney General Ashcroft opined that any physician in Oregon who used con-

SCENARIO 1

A pharmacist, who has a corresponding responsibility to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose, is concerned that a doctor who specializes in pain relief has been prescribing controlled substances in dosage amounts that often exceed what the average physician prescribes. Although the particular doctor prescribes both narcotic and nonnarcotic substances to his patients, one of his most frequently prescribed drugs are morphine tablets, a very potent and effective pain reliever. Morphine, however, has the potential for both abuse and diversion; abusers can either self-medicate beyond the dosage or frequency designated by the doctor, or they can resell the product on the street for a significant profit. The pharmacist also told the police that this particular doctor has prescribed pain medication to some of his patients for periods beyond 30 days (in fact, some of the doctor's patients have been receiving pain medication in excess of 6 months). Based on this information, the police suspect that the doctor is contributing to the drug problem by doling out too many prescriptions too frequently and at higher dosages than the average physician. The police seek your advice.

SCENARIO 2

On Monday morning a hospice doctor was summoned to the home of a 25-year-old AIDS patient. The doctor specializes in hospice care and admits that he prescribes “controlled substances with the frequency that an infectious disease practitioner uses antibiotics.” The doctor also admits that he prescribes controlled substances in his practice in doses that exceed “the standard doses utilized in drug trials mandated by the FDA to prove safety in selected populations.” The doctor is often involved in cases in which the side-effects of medications may contribute to the deaths of his patients. Upon his arrival at the patient’s home, family members told the doctor that the patient was having difficulty breathing. When the doctor entered the room he could hear that indeed the patient’s breathing was both labored and moist (excess fluid existed in the patient’s lungs). The patient was unconscious and his respiratory rate was 44 breaths per minute (the respiration rate for this particular patient should be about 20 breaths per minute). The doctor injected the patient with 40 mg of Lasix (a medication which helps rid the body of salt and water). There was no effect. The doctor then injected the patient with 10 mg of morphine and waited several minutes. There was no effect. The doctor then gave the patient 5 mg of morphine, and again there was no effect. In what the doctor describes as an attempt to sedate the patient and ease the work of breathing, he gave the patient 5 mg of Valium (which had no effect). The doctor then gave another 5 mg of morphine, waited, saw no effect, and gave another 10 mg of morphine. After a few minutes, the patient’s respirations decreased to about 20 per minute. However, instead of stabilizing at 20, the patient’s breathing rate continued to diminish, and several minutes later the patient stopped breathing and died.

trolled substances to hasten death, even if it was in compliance with Oregon state law, would risk revocation of their permit to prescribe controlled substances.¹⁰⁵

RESULTS

Respondent characteristics

Our population consisted of 112 potential respondents, representing the total number of chief prosecuting officials in all four states (Connecticut: 13; Maryland: 24; Oregon: 36; and Washington: 39). See Table 1. During the course of our survey, two Oregon district attorneys in rural, one-person offices resigned (one of the surveys was returned to us with a note that there were no physicians in the county). We subsequently eliminated these two counties from our population and reduced our population size accordingly (from thirty-six to thirty-four in Oregon, and from 112 to 110 overall). Of the 110 questionnaires mailed, eighty-four were returned and useable, resulting in a total response rate of 76.36 percent. The overall response rate was excellent, but varied somewhat among the four states (Connecticut: 61.54 percent; Maryland: 70.83 percent; Oregon: 70.59 percent, and Washington: 89.74 percent).

All questionnaires were filled out either by the chief prosecuting officials themselves (79.8 percent), or their senior deputy (20.2 percent). The number of years that respondents were in their present position ranged from 1 to 28 years, with an average (mean) of 9.69 years. The majority of our respondents were elected to their position (72.6 percent), and although some of our respondents held either appointed or nonpartisan positions, most considered themselves Democrats (42.9 percent), with the remaining group identifying themselves as Republicans (34.5 percent), Independents (15.5 percent), or other (2.4 percent).

Determining the number of full-time prosecutors in an office, annual felony caseload, and the population served by the office is important when assessing the surrounding environment. As noted earlier, Ann Alpers found that the majority of published prosecutions of health care providers occurred in small towns or rural jurisdictions.¹⁰⁶ Earlier research acknowledged the correlation between population and the number of prosecutors in an office.¹⁰⁷ In establishing a reliable method for jurisdiction classification, we believed that the number of full-time prosecutors, the office’s annual caseload, and the jurisdiction’s population figures would serve as more useful proxies for statistical analysis than the traditional triad of rural, suburban, and urban, which are often inaccurate descriptions. These proxies made logical sense on their face, and we ultimately found that the three indicators were interrelated. For example, the correlation between the number of prosecutors and population was nearly perfect (Pearson’s $r = 0.949$), as was the correlation between annual felony caseload and population ($r = 0.863$); the correlation between annual felony caseload and the number of full-time prosecutors was also highly correlated ($r = 0.905$). All correlations were significant at the 0.01 level.

In this study, the number of full-time prosecutors in an office ranged from one to 250. The average number of prosecutors in a jurisdiction was eighteen, the median eight, and the mode was two. The annual felony caseload among the offices in the four states ranged from a low of twenty to a high of 12,000. The average (mean) annual felony caseload was 1,299, and the median was 500. Finally, according to the 2000 U.S. Census, the population of each of our jurisdictions ranged from a low of 1,934 to a high of 1,737,034. Consistent with earlier research,¹⁰⁸ forty-nine out of eighty-four of our responding jurisdictions (58 percent) could be classified as rural environments with populations of less than 100,000.

TABLE 1. RESPONDENT CHARACTERISTICS.

States and Response Rates		
Connecticut	8/13	(61.54 %)
Maryland	17/24	(70.83 %)
Oregon	24/34	(70.59 %)*
Washington	35/39	(89.74 %)
<i>Total Response Rate</i>	84/110	(76.36 %)
Official Position of Respondents		
Chief Prosecutors	67	(79.8%)
Senior Deputy Prosecutors	17	(20.2%)
Number of Years in Present Position		
Range	1–28 years	
Mean	9.69 years	
Median	7.0 years	
Elected or Appointed		
Elected	61	(72.6%)
Appointed	23	(27.4%)
Party Affiliation**		
Democrat	36	(42.9%)
Republican	29	(34.5%)
Independent	13	(15.5%)
Other	2	(2.4%)
Not Provided	4	(4.8%)
Number of Prosecutors in Office		
Range	1–250 prosecutors	
Mean	18	
Median	8	
Mode	2	
Annual Felony Caseload		
Range	20–12,000 cases	
Mean	1,299	
Median	500	
Population of Jurisdictions		
Range	1,934–1,737,034	
Mean	171,802	
Median	75,328	
Number of jurisdictions under 100,000 residents	49 (49/84 = 58.3%)	

*Oregon has thirty-six counties. However, at the time of the survey, two district attorneys serving rural jurisdictions in one-person offices left their position.

**Self-identified, not all positions partisan.

Knowledge about addiction

Prosecutors were asked to express their opinion about the risk of addiction when a patient is prescribed narcotics for pain relief. See Table 2. The definition of addiction is often misunderstood even by clinicians.¹⁰⁹ The question was tailored to our respondent population by asking: "In your opinion, what is the risk of addiction whenever a patient is prescribed narcotics for pain relief?" Respondents could answer by selecting one choice along a four-point scale: 0 = No risk of addiction; 1 = Risk is low; 2 = Risk is moderate; 3 = Risk is high. Respondents could also select "Don't know." Twelve prosecutors indicated that they did not know. Of those expressing an opinion, 22.2 percent responded that the risk of addiction was high; over twice as many viewed the risk of addiction as moderate (51.4 percent), and 26.4 percent saw the risk of addiction as being low. None of the respondents indicated that there was no risk of addiction.

Questions concerning diversion

Several questions concerning pharmaceutical diversion were asked. See Tables 3–5. As noted earlier, deceptive patients are far and above the most likely source of diverted pharmaceuticals; dated doctors (those who are out of touch or lax in prescribing behavior) are a distant second, followed by impaired and dishonest doctors.¹¹⁰ Respondents were asked to rate the level of blame for diversion among these parties by assigning a value between 1 and 4. Those considered the *least* responsible for diversion would receive a score of 1; those *most* responsible would receive a score of 4. Most prosecutors correctly believed that deceptive patients were the most responsible for diversion (the average/mean score for deceptive patients was 3.35, and both the median and mode were 4). See Table 3. Based on the mode scores for the remaining parties, impaired doctors arrived a distant second, with responsibility scores of 2.19 (mean) and 2.0 for both the median and mode. Dishonest doctors received an average (mean) score of 2.28, and dated doctors received an average (mean) responsibility score of 2.20. Nine respondents indicated that they did not know who was least or most to blame for pharmaceutical diversion.

Respondents were also asked to comment on the diversion problem in their jurisdiction and state by selecting one choice along a four-point scale: 0 = Diversion not a problem; 1 = Diversion is a minor problem; 2 = Diversion is a moderate problem; 3 = Diversion is a major problem. See Table 4. Respondents could also select "Don't know." Consistent with prior research concerning proximity and citizen perceptions of problems in their neighborhood versus their city,¹¹¹ prosecutors viewed diversion as a bigger problem in their state than in their own jurisdiction. For example, when asked about the diversion problem in their own jurisdiction, 57.5 percent of those expressing an opinion viewed diversion as only a minor problem, 32.5 percent saw it as a

TABLE 2. IN YOUR OPINION, WHAT IS THE RISK OF ADDICTION WHENEVER A PATIENT IS PRESCRIBED NARCOTICS FOR PAIN RELIEF?

	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
Risk is low	19	26.4	26.4
Risk is moderate	37	51.4	77.8
Risk is high	16	22.2	100
Don't know	12		
Total	84	100	

TABLE 3. WHO IS MOST RESPONSIBLE FOR THE DIVERSION OF PRESCRIPTION DRUGS TO ILLEGITIMATE USES? (1 = LEAST RESPONSIBLE, 4 = MOST RESPONSIBLE)

CATEGORY	NUMBER OF RESPONSES	MODE	MEAN	MEDIAN
Dated doctors	69	1	2.20	2.00
Dishonest doctors	67	1	2.28	2.00
Impaired doctors	67	2	2.19	2.00
Deceptive patients	75	4	3.35	4.00

moderate problem, and only 5 percent saw diversion as a major problem or not a problem at all. Only four respondents claimed not to know what the diversion problem was in their jurisdiction. However, when asked about the extent of the diversion problem in their state, most saw it as a bigger problem than in their own jurisdiction (38.5 percent saw it as a minor problem, 53.8 percent saw it as a moderate problem, and 7.7 percent saw diversion as a major problem in the state). Although nineteen respondents admitted to not knowing what the diversion problem was outside of their jurisdiction, none of them answered that diversion was “not a problem.”

Scenario 1 (Treatment of chronic pain)

Scenario 1 concerned the treatment of chronic noncancer pain. It is now generally accepted that the dosage, frequency, and duration of opioid use alone do not constitute sufficient evidence to indicate inappropriate use. Therefore, we constructed a scenario that illustrated these principles to help determine if physicians’ fear of investigation was warranted.

Likelihood of recommending police investigation

The survey indicated the presence of a broad spectrum of opinion. Of the eighty-three prosecutors responding, thirty-eight of them (45.8 percent) estimated the likelihood of recommending a police investigation to be 40 percent or less, whereas thirty-six of them (43.4 percent) estimated the likelihood at 60 percent or more. See Table 6. However, the most common response (the mode) was 10 percent (19.3 percent of the prosecutors estimated the likelihood of recommending investigation at only 10 percent). The overall mean likelihood of recommending a police investigation was 48.8 percent. However, when examining the means of the states individually, a pattern emerged. The average likelihood of recommending a police investigation in Oregon was the lowest (34.3 percent likelihood). The average was about the same for Connecticut as it was for Washington (48.8 percent and 46.6 percent, respectively), but the average likelihood of recommending a police investigation was much higher in Maryland (72.9 percent average likelihood that the prosecutor, here a state’s attorney, would recommend a police investigation). See Figure 1.

TABLE 4. TO WHAT EXTENT DO YOU THINK THE DIVERSION OF DRUGS IS A PROBLEM IN YOUR JURISDICTION?

	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
Diversion not a problem	4	5.0	5.0
Diversion is a minor problem	46	57.5	62.5
Diversion is a moderate problem	26	32.5	95.0
Diversion is a major problem	4	5.0	100
Don't know	4		
Total	84	100	

TABLE 5. TO WHAT EXTENT DO YOU THINK THE DIVERSION OF DRUGS IS A PROBLEM IN YOUR STATE?

	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
Diversion is a minor problem	25	38.5	38.5
Diversion is a moderate problem	35	53.8	92.3
Diversion is a major problem	5	7.7	100
Don't know	19		
Total	84		

Likelihood of referring matter to the state medical board in lieu of investigation or prosecution

The prosecutors as a group were more likely to refer the matter to the state medical board than recommend a police investigation. See Table 7. The survey results relating to the first scenario indicated that 52.4 percent of the respondents estimated the likelihood of referring the matter to the state medical board to be 60 percent or greater. The mean likelihood of referral was 57.0 percent. Individually, the western states indicated a slightly higher likelihood of referring the matter to the state medical board than the eastern states (Oregon: 62.9 percent; Washington: 57.1 percent; Maryland: 51.8 percent; and Connecticut: 50.0 percent). See Figure 2.

Likelihood of DEA referral

There was little risk that prosecutors would refer this particular matter to the DEA. See Table 8. The majority of prosecutors (54.8 percent) placed the likelihood of DEA referral at 10 percent or less (35.7 percent of the prosecutors estimated a 0 percent likelihood). Remarkably, only 16.7

percent of the respondents indicated that the likelihood of referring the matter to the DEA was 60 percent or greater. The mean score was 24.1 percent (likelihood of referral). When examining the likelihood of referring the matter by each state individually, Connecticut had the highest score with an average (mean) of 32.5 percent compared to Maryland at 26.5 percent, Oregon at 27.1 percent, and Washington at 20.0 percent.

Comments by prosecutors attributable to the above scenario and diversion topics

In addition to the quantitative data, we also reviewed the comments made by prosecutors that were attributable to the preceding questions. For instance, five of the respondents indicated to us that instead of referring the matter to the state medical board in lieu of investigation or prosecution, they would retain jurisdiction and recommend a concurrent investigation of the physician.¹¹² Respondents also commented on the extent of diversion in their jurisdiction and the competency of the medical board in their state.¹¹³

TABLE 6. SCENARIO 1: WHAT IS THE LIKELIHOOD THAT YOU WOULD RECOMMEND A POLICE INVESTIGATION OF THIS DOCTOR?

	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
0%	6	7.2	7.2
10%	16	19.3	26.5
20%	8	9.6	36.1
30%	4	4.8	41.0
40%	4	4.8	45.8
50%	9	10.8	56.6
60%	2	2.4	59.0
70%	9	10.8	69.9
80%	9	10.8	80.7
90%	7	8.4	89.2
100%	9	10.8	100
Missing	1		
Total	84		

TABLE 7. SCENARIO 1: WHAT IS THE LIKELIHOOD THAT YOU WOULD REFER THE MATTER TO THE STATE MEDICAL BOARD IN LIEU OF CRIMINAL INVESTIGATION OR PROSECUTION?

	FREQUENCY	PERCENT	CUMULATIVE PERCENT
0%	5	6.0	6.0
10%	6	7.1	13.1
20%	9	10.7	23.8
30%	7	8.3	32.1
40%	3	3.6	35.7
50%	10	11.9	47.6
60%	4	4.8	52.4
70%	5	6.0	58.3
80%	12	14.3	72.6
90%	13	15.5	88.1
100%	10	11.9	100
Total	84	100	

FIGURE 1. SCENARIO 1: LIKELIHOOD OF RECOMMENDING A POLICE INVESTIGATION.

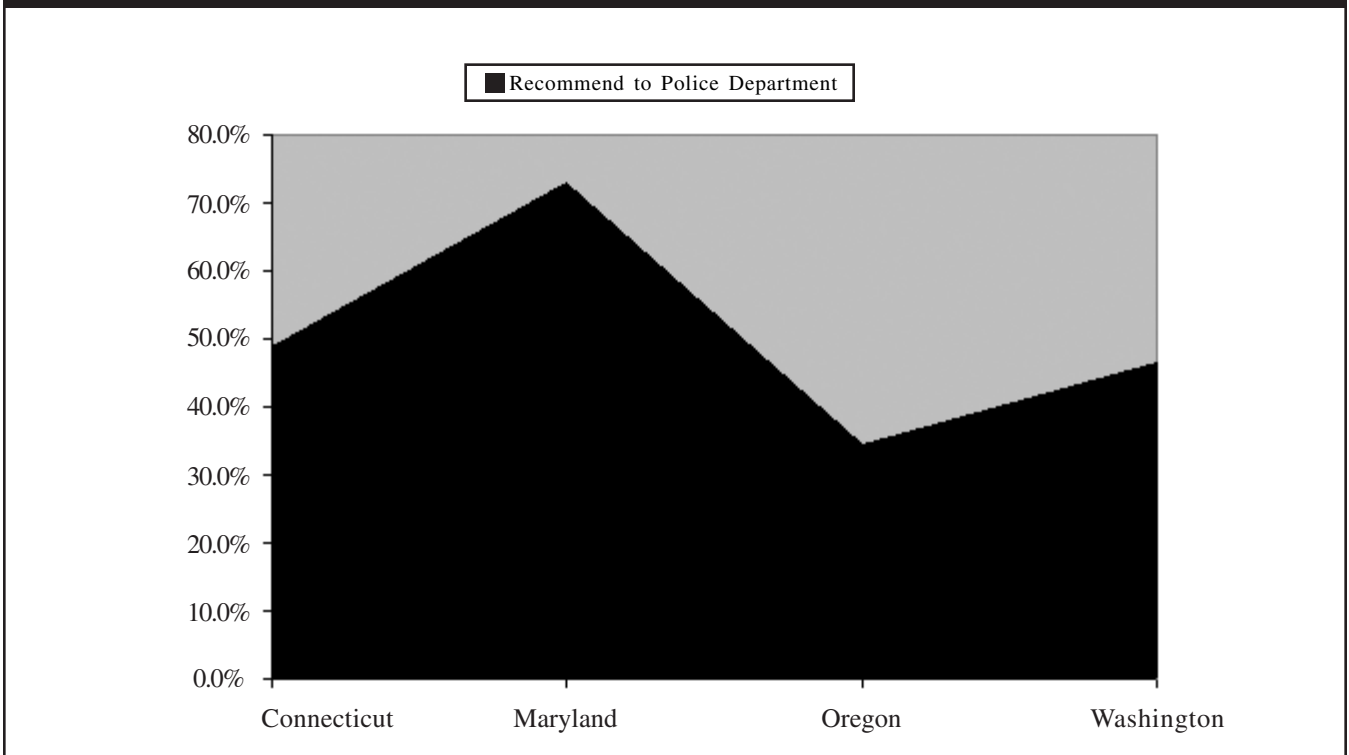


TABLE 8. SCENARIO 1: WHAT IS THE LIKELIHOOD THAT YOU WOULD REFER THE MATTER TO THE FEDERAL DRUG ENFORCEMENT ADMINISTRATION?

	FREQUENCY	PERCENT	CUMULATIVE PERCENT
0%	30	35.7	35.7
10%	16	19.0	54.8
20%	10	11.9	66.7
30%	6	7.1	73.8
40%	2	2.4	76.2
50%	6	7.1	83.3
60%	1	1.2	84.5
70%	4	4.8	89.3
80%	3	3.6	92.9
90%	4	4.8	97.6
100%	2	2.4	100
Total	84	100	

Likelihood of referring matter to the state medical board in lieu of investigation or prosecution

The survey results indicated that exactly half of the respondents estimated the likelihood of referring the matter to the state medical board in lieu of investigation or prosecution at 60 percent or greater. See Table 9.

The average score was 56.5 percent (likelihood of state medical board referral). However, as with the first scenario, we found that opinions differed widely by state. For example, whereas Connecticut prosecutors (state’s attorneys) estimated the likelihood of referring the matter to the state medical board to be 38.8 percent, Oregon prosecutors (district attorneys) estimated the likelihood at 49.2 percent, Washington at 56.7 percent, and Maryland at 75.9 percent. Maryland prosecutors (state’s attorneys) differed considerably between the two scenarios (they recommended investigation in the first, yet were content to refer the matter to the state medical board in lieu of investigation in the second). See Figure 2.

Whether a prosecutable offense was committed

Prosecutors were also asked whether they believed an offense had been committed in Scenario 2. See Table 10. Sixteen prosecutors (19 percent) answered yes, 26.2 percent responded no, and 52.4 percent said “Don’t know.” The sixteen prosecutors who indicated that an offense had been committed were also asked to specify what offense (or offenses) oc-

Scenario 2 (Pain and the dying patient)

Scenario 2, based upon the testimony of Dr. William Hunter, a hospice physician, concerned the commonly accepted use of morphine in the treatment of terminally ill patients and the concurrent risk of respiratory depression.

TABLE 9. SCENARIO 2: WHAT IS THE LIKELIHOOD THAT YOU WOULD REFER THE MATTER TO THE STATE MEDICAL BOARD IN LIEU OF CRIMINAL INVESTIGATION OR PROSECUTION?

	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
0%	8	9.8	9.8
10%	9	11.0	20.7
20%	4	4.9	25.6
30%	3	3.7	29.3
40%	4	4.9	34.1
50%	7	8.5	42.7
60%	6	7.3	50.0
70%	5	6.1	56.1
80%	14	17.1	73.2
90%	15	18.3	91.5
100%	7	8.5	100
Subtotal	82	100	
Missing	2		
Total	84		

curred.¹¹⁴ Responses included homicide/murder (10), manslaughter (6), endangerment (1), and a violation of controlled substances laws (1). See Table 10.

Recognizing that there is a distinction between classifying something as an offense and prosecuting it, we also asked respondents to estimate the likelihood that they would actually prosecute. Most who considered it an offense would have prosecuted. Specifically, of the sixteen respondents who answered yes, eight of them estimated the risk of prosecution at 60 percent or more. The average (mean) likelihood of prosecution was 55.0 percent (as was the median).

As before, several of our respondents provided us with some noteworthy comments regarding the scenario, including a need for a more fact-intensive inquiry.¹¹⁵ Additionally, the prosecutors indicated deference to experts in these areas and the difficult standard of proof.¹¹⁶

Factors influencing the decision to prosecute physicians

Three question categories addressed the prosecution of physicians directly. The first question concerned the effectiveness of the medical profession in policing its members. See Table 11. Responses ranged from a low of 1 (not effective) to a high of 7 (very effective).¹¹⁷ Earlier research indicated that the risk of prosecution of physicians may be related to a prosecutor’s perception of the ability of the medical profession to monitor its own.¹¹⁸ Our second set of questions concerned the number of physicians prosecuted in their jurisdiction over the past 12 months (see Table 12), and the third set focused on what factors would play a significant

role in the decision to charge a physician with a crime (see Table 13).

Ability of profession to police its own

Most prosecutors did not believe that the medical profession was particularly effective in policing its own members. See Table 11. Of those offering an opinion, 52.7 percent assigned an evaluation score of 3 or less (whereas only 20.3 percent gave a score of 5 or better), and the mean effectiveness score was 3.28. Roughly one-in-ten of the prosecutors indicated that they did not know how effective the medical profession was in policing its own members.

Number of physicians prosecuted

The majority of prosecutors reported that no physicians in their jurisdictions were prosecuted over the past 12 months for offenses relating to prescription drugs (88.1 percent of the prosecutors reported zero; and 10.7 percent reported prosecuting one to two physicians). See Table 12. Only one jurisdiction of the eighty-four that responded reported prosecuting three or more physicians for offenses relating to prescription drugs (likely an aberration for that jurisdiction).

Important factors in the decision to charge a physician with an offense

Our final question concentrated on what specific factors would contribute to the decision to charge a physician with an offense relating to prescription drugs. See Table 13. Earlier research by Benson and Cullen; Jesilow, Pontell, and Geis;

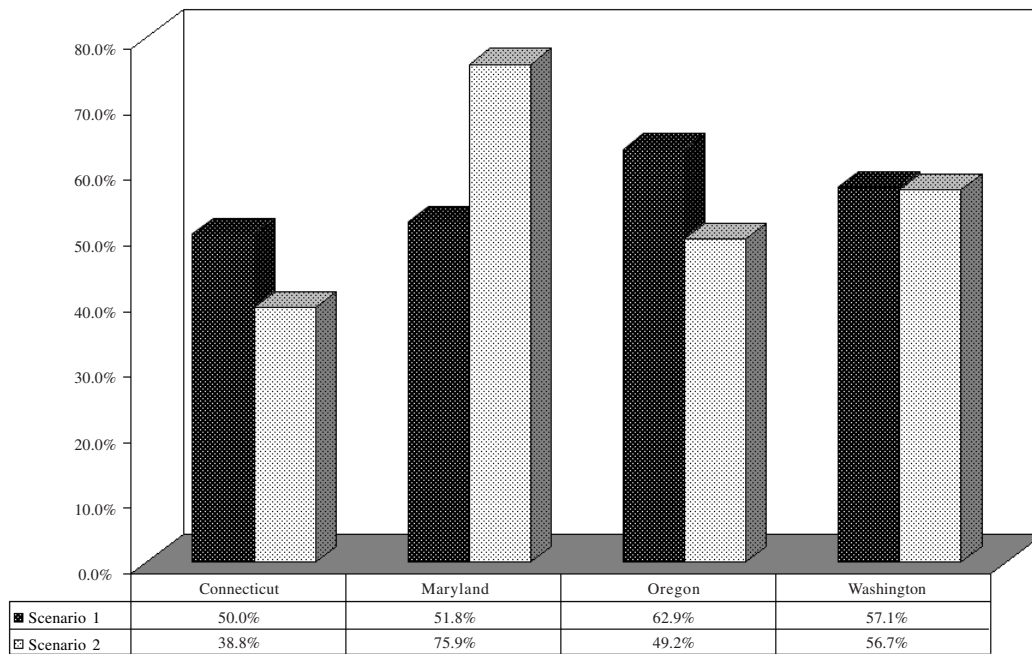
TABLE 10. SCENARIO 2: BASED ON THE SCENARIO, DO YOU BELIEVE THAT AN OFFENSE(S) HAS BEEN COMMITTED?

RESPONSE	FREQUENCY	PERCENT	CUMULATIVE PERCENT
Yes	16	19.0	19.0
No	22	26.2	45.2
Don’t know	44	52.4	97.6
Missing	2	2.4	100
Total	84	100	

IF YES, WHAT WOULD THE OFFENSE(S) BE?

LIKELY OFFENSE	FREQUENCY
Homicide/Murder	10
Manslaughter	6
Endangerment	1
Drug violation	1

FIGURE 2. SCENARIOS 1 AND 2: AVERAGE LIKELIHOOD OF REFERRAL TO MEDICAL BOARD.



Benson et al.; and Ayers and Frank¹¹⁹ greatly informed this area of our own research. We adapted their approaches to the prosecution of physicians and compiled a list of sixteen potentially influential factors on the decision to charge. Respondents were asked to rate the significance of each factor by assigning a value on a Likert scale of 0 to 3, where 0 = Not important; 1 = Somewhat important; 2 = Important; and 3 = Very important.

Prosecutors believed that several factors were “very important” to the charging decision, such as: (1) whether the medical board had investigated and handled the matter appropriately (41 percent of the respondents); (2) whether the board investigated but failed to take appropriate action (36.1 percent); and (3) whether the doctor emphasized his own financial interests over patient care (56.6 percent).

Respondents also found several factors to be “important” to the charging decision: (1) whether the state medical board is currently investigating the case (36.1 percent); (2) whether federal criminal or regulatory action has already been filed against the defendant (39.8 percent) (a total of 78.4 percent of the respondents thought this was either an important or very important factor); (3) whether the police actively seek prosecution of the defendant (47 percent); (4) whether the case is extremely complex (38.3 percent); (5) what the victim or family’s preference regarding prosecution is (54.9 percent); (6) whether the doctor’s conduct was moti-

vated by compassion (43.9 percent); and (7) whether the prosecution would likely deter future misconduct by doctors (55.6 percent).

Surprisingly, prosecutors regarded the following to be only “somewhat important” factors in the decision to charge: (1) the amount of media attention on the case (51.2 percent) (92.6 percent of the respondents thought that the amount of media attention on the case was only either somewhat important or not important); (2) the lack of public support for prosecuting the defendant (51.2 percent); and (3) the fact that the doctor was not a pain specialist (43.8 percent) (e.g., general practitioner).

Finally, respondents regarded three of the remaining factors to be “not important” at all: (1) whether a civil suit had already been filed against the defendant (57.8 percent); (2) whether there was a scarcity of physicians in the area (84.3 percent); and (3) whether the decision to charge would adversely affect their professional career (63.4 percent).

PREDICTING A PROSECUTOR’S DECISION TO TAKE ACTION

We found several variables to be strong predictors of how our respondents assessed the likelihood of taking action against doctors portrayed in the two scenarios. The following section reports on those factors found to be statistically significant predictors of whether the prosecutor would either recom-

mend a police investigation of the physician in Scenario 1, or refer the matter to the state medical board in Scenario 1 or 2. We note from the outset that human behavior is extremely complex and variable. It is best to think in terms of tendencies and probabilities instead of absolute certainties when predicting behavior for little is certain in our world (except, of course, death and taxes). Moreover, in light of this journal's interdisciplinary readership, we present a straightforward, uncomplicated statistical analysis, focusing only on those variables that demonstrated significant predictive potential. Subsequent theory-driven statistical modeling and additional qualitative research are indicated to fully explore the data collected in this survey.

Analysis

We began our analysis by converting our dependent variable — the likelihood of recommending or referring — from a percentage scale to a yes-or-no dichotomy (this was for methodological reasons since the statistical approach taken here, T-tests, requires a dichotomous dependent variable). Responses from a 0 percent to 40 percent likelihood were re-coded as no (would not recommend/refer); those indicating a likelihood of 60 percent or above were re-coded as yes (would recommend/refer). Because the middle response (50 percent) was at the halfway point and did not show a tendency either way in our dichotomy, it was omitted from the computation (and consequently reduced the likelihood of bias were we to attribute the middle response to either a yes or a no). Relying on the use of T-tests to compare means,¹²⁰ we identified several factors that were statistically associated with the respondents' answers in our survey.¹²¹ These variables were then reported along with their statistical

TABLE 11. TO WHAT DEGREE DO YOU BELIEVE THAT THE MEDICAL PROFESSION IS EFFECTIVE IN POLICING ITS OWN MEMBERS?

EFFECTIVENESS SCORE (1-7)	FREQUENCY	VALID PERCENT	CUMULATIVE PERCENT
1 (Not effective)	11	14.9	14.9
2	13	17.6	32.4
3	15	20.3	52.7
4 (Uncertain)	20	27.0	79.7
5	10	13.5	93.2
6	4	5.4	98.6
7 (Very effective)	1	1.4	100
Subtotal	74	100	
Don't know	9		
Missing	1		
Total	84		

Average score: 3.28

TABLE 12. WITHIN THE PAST 12 MONTHS, HOW MANY DOCTORS WERE PROSECUTED IN YOUR JURISDICTION FOR OFFENSES RELATED TO THE PRESCRIBING OF DRUGS?

	0	1-2	3-6
Connecticut	5	2	1
Maryland	16	1	0
Oregon	22	2	0
Washington	31	4	0
Total	74 (88.1%)	9 (10.7%)	1 (1.2%)

significance (*p*-values) in Table 14. Statistical models were then constructed with these variables, and we relied on discriminant analysis to achieve a multivariate assessment of how well each one of the variables, taken in combination with each other, helped us predict whether a prosecutor would recommend a police investigation in Scenario 1 or refer the matter to the state medical board in either Scenario 1 or 2. Those results are listed in Table 15.

Significant predictors

The ability to predict our respondents' decision to recommend a police investigation of the physician or refer the matter to the state medical board varied across the states and between hypothetical scenarios. Specifically, in Scenario 1 we found nine factors (variables) that exercised a statistically significant influence on whether the prosecutor would recommend a police investigation of the physician. See Table 14. In fact, one of the strongest predictors of whether the prosecutor would recommend such an investigation was related to his or her opinion concerning the *risk of addiction* when narcotics are used to treat pain. See Table 15. The predictor's standardized coefficient was 0.614, indicating a tendency to recommend an investigation. Moreover, as our tables indicate, it also mattered if the prosecutor hailed from Maryland or Oregon, the likelihood he or she would refer the matter to the medical board in Scenario 2, whether the prosecutor was a Republican, and how important he or she considered the following factors in the decision to charge: the amount of media attention, the lack of public support for prosecuting the doctor, and whether the doctor's conduct was motivated by compassion. Based on these several predictors, the multivariate statistical model for survey findings in Scenario 1 was able to correctly predict the decision to recommend a police investigation 69 percent of the time (i.e., the model correctly predicted that the prosecutor would have estimated the likelihood of investigation at 60 percent to 100 percent in 69 percent of the cases). See Table 15.

The models concerning the likelihood of referring the matter to the state medical board featured fewer predictors, but they were more efficacious. Specifically, regarding the

TABLE 13. HOW SIGNIFICANT WOULD THE FOLLOWING FACTORS BE IN YOUR DECISION TO CHARGE A DOCTOR WITH AN OFFENSE RELATING TO THE PRESCRIBING OF DRUGS?

	NOT IMPORTANT 0	SOMEWHAT IMPORTANT 1	IMPORTANT 2	VERY IMPORTANT 3
A. Involvement of State Medical Board				
The Board is currently investigating the case	10.8%	30.1%	36.1 %	22.9%
The Board investigated and handled the matter appropriately	9.6%	14.5%	34.9%	41 %
The Board investigated the matter and failed to take appropriate action	13.3%	20.5%	30.1%	36.1 %
B. Involvement of Other Agencies or Jurisdictions				
Civil suit has already been filed against defendant	57.8 %	30.1%	8.4%	3.6%
Federal criminal or regulatory action has already been filed against defendant	4.8%	16.9%	39.8 %	38.6%
Police actively seek prosecution of defendant	3.6%	36.1%	47 %	13.3%
C. Case and Community Factors				
Case is extremely complex	22.2%	29.6%	38.3 %	9.9%
Victim or family’s preference regarding prosecution	2.4%	26.8%	54.9 %	15.9%
Scarcity of physicians in area	84.3 %	7.2%	4.8%	3.6%
Evidence that doctor emphasized his own financial interests over patient care	3.6%	3.6%	36.1%	56.6 %
Amount of media attention on the case	45.7%	46.9 %	6.2%	1.2%
Lack of public support for prosecuting defendant	25.6%	51.2 %	18.3%	4.9%
Possible adverse consequences to your career	63.4 %	28.0%	8.5%	0%
Doctor’s conduct was motivated by compassion	2.4%	30.5%	43.9 %	23.2%
Prosecution would likely deter future conduct by doctors	3.7%	22.2%	55.6 %	18.5%
Doctor is <i>not</i> a pain specialist (e.g., general practitioner)	28.7%	43.8 %	23.8%	3.8%

likelihood of referring the matter to the state medical board in Scenario 1, five factors (variables) were found to be statistically significant and the model correctly classified cases 74.2 percent of the time ($p < 0.01$). In the case of Scenario 2, nine factors (variables) were found to be statistically significant predictors and the model correctly classified (predicted) whether the prosecutor would have referred the matter to the medical board 78.2 percent of the time ($p < 0.01$). All findings, including the relative strength and direction of each variable, have been reported in Table 15. Although the application of both linear and logistic regression statistical analyses to these survey data is indicated, the more elementary statistical analysis presented here serves well to highlight some of the key factors that influence a prosecutor’s decision regarding investigation or case referral for physicians suspected of abusing their opioid prescribing privileges.

DISCUSSION

As social scientists, rather than advocates, we must strive continually to remain impartial and above the fray, particu-

larly when the topic of research involves highly charged issues.¹²² During the review process, some colleagues suggested that our findings could be spun in different directions by the media or by health care professionals who seek to shift the blame for their undertreatment of pain. We do not wish to discourage this independent interpretation; we would hope only that those interpreting our results do so in an open-minded manner. With this hope in mind, we turn now to a discussion of our results.

Are physicians’ fear of investigation or prosecution justified?

One of the central questions that we sought to address in our study was whether medical practitioners’ pervasive fear of being investigated or prosecuted for the aggressive treatment of pain is a realistic fear. Our findings indicate that in some circumstances an investigation stemming from the aggressive treatment of pain is indeed likely. However, this conclusion must be understood within its proper context. For instance, although the likelihood of investigation in Sce-

TABLE 14. T-TEST RESULTS.

PREDICTING LIKELIHOOD OF RECOMMENDING A POLICE INVESTIGATION IN SCENARIO 1	
Scenario 1: Variables Having Significant Effects	p-value (2-tailed)
Refer to medical board in Scenario 2	0.004
State of Maryland	0.006
Opinion concerning risk of addiction	0.007
Whether lack of public support was a factor (see Table 13)	0.009
State of Oregon	0.024
Deceptive patients as a source of diversion	0.032
Whether doctor motivated by compassion	0.048
Identified self as a Republican	0.082
Whether amount of media attention was important (see Table 13)	0.101
PREDICTING REFERRAL OF CASES TO STATE MEDICAL BOARD (SCENARIOS 1 AND 2)	
Scenario 1: Variables Having Significant Effects	p-value (2-tailed)
Prosecutor requested summary of our findings	0.001
Number of part-time prosecutors in office	0.018
Likelihood would refer matter to DEA in Scenario 1	0.037
State of Oregon	0.066
Opinion regarding risk of addiction when narcotics are used to treat pain	0.090
Scenario 2: Variables Having Significant Effects	p-value (2-tailed)
Prosecutor requested summary of our findings	0.001
Likelihood would recommend police to investigate in Scenario 1	0.004
State of Maryland	0.013
State of Oregon	0.048
Identified self as a Republican	0.074
Doctor emphasized financial interest over patient	0.081
Dated doctors source of diversion	0.087
Identified self as an Independent	0.089
Lack of public support for prosecuting defendant (see Table 13)	0.101

nario 1 is greater in Maryland than it is in Oregon, there was a great deal of variation among prosecutors within each state. Moreover, although Maryland prosecutors were more likely to recommend an investigation in Scenario 1, they were also more likely to refer the matter to the state medical board in lieu of investigation in Scenario 2. Any increased likelihood of investigation is likely the result of insufficient knowledge regarding the legitimate use of opioids in the aggressive treatment of pain and the limited experience of prosecutors when dealing with such matters.

Scenario 1

Our first scenario involved the aggressive treatment of chronic pain. As we noted earlier, the dosage and frequency of opioid prescribing are insufficient grounds to trigger an investigation. Additionally, the facts in the scenario are not indicative of inappropriate treatment protocols. Nevertheless, almost half of our respondents indicated that the likelihood of rec-

ommending an investigation of the physician was 60 percent or greater. However, when we separate the results, there are distinct differences between the states. For example, the average risk of investigation among three of the states did not exceed 48.8 percent (Connecticut), and Oregon had the lowest average risk score of 34.3 percent. In contrast, the average risk of investigation in Scenario 1 in Maryland was 72.9 percent—29.67 percent higher than the average of the three other states combined (see Figure 1). This mean difference between the states was statistically significant both here and in our earlier section on predicting a prosecutor's decision to take action (where both Maryland and Oregon were statistically significant predictors of whether the prosecutor would recommend a police investigation of the physician). See Tables 14 and 15.

Regarding Scenario 1, we also asked prosecutors to determine the likelihood of referring the matter to the state medical board in lieu of investigation or prosecution. Although a few of the prosecutors remarked that they would

retain jurisdiction over the matter and conduct an investigation *in addition to* making the referral to the state medical board, prosecutors were generally content to refer the entire matter to the state medical board. However, there were striking differences across the individual states here as well. Whereas Maryland was more likely (and Oregon least likely) to recommend a police investigation, Oregon was more likely (and Connecticut least likely) to refer the matter in its entirety to the state medical board (see Figure 2). More specifically, 62.9 percent of Oregon district attorneys would refer, compared to an average of 52.96 percent for the other three states combined. In fact, in comparison to the other three states, Oregon was found to be a statistically significant predictor of whether the matter would be referred to the state medical board.

Finally, although we found a broad range of viewpoints regarding both investigation and referral to the state medical board, there was consensus among local prosecutors that referral to the DEA was extremely unlikely.

We were surprised by our results in Scenario 1, particularly as they related to the likelihood of recommending a police investigation of the physician. Although most prosecutors indicated a low to moderate risk of investigation, some prosecutors (particularly those in Maryland) indicated a high likelihood. It is unclear what factors account for the high scores. Even though the police are often obligated to follow up once they receive a complaint, the eventual police investigation may amount to nothing more than a telephone call. Moreover, one of the more plausible explanations stems from the realization that opinions held by prosecutors are not all that different from those held by health care providers, physicians, and pharmacists concerning the regulation of opioids. As mentioned above, 26.4 percent of Texas physicians agreed with the statement: “Prescribing narcotics for patients with chronic pain is likely to trigger a drug enforcement agency investigation”; and 47.7 percent agreed that “If I follow the same prescribing practices as other doctors in my field, I will not be investigated by a regulatory agency.”¹²³ In another survey, only 16.6 percent of New Jersey pharmacists saw the practice of prescribing opioids for more than several months as lawful and generally acceptable, and 47.2 percent thought that, albeit lawful, such prescribing was generally not acceptable and should be discouraged.¹²⁴ Although Joranson and Gilson’s survey of Wisconsin pharmacists indicated an overall greater level of legal and medical acceptance of extended opioid prescriptions, a “significant minority” believed that the use of some opioids described in the study “should be discouraged or investigated.”¹²⁵ Finally, in a survey of medical board members, Gilson and Joranson ultimately concluded that “most medical board members continued to view prolonged prescribing of opioid analgesics for chronic non-cancer pain as inappropriate medical practice and something to be discouraged or even investigated.”¹²⁶

Concerning the risk of addiction, the views held by prosecutors are also similar to those held by many physicians. For instance, although the risk of addiction when narcotics are used to treat pain is generally low, 20 percent of prosecutors estimated the risk of addiction as “high” and 43 percent estimated the risk as “moderate.” These same misperceptions were shared by many physicians and medical board members (see, e.g., the study that found that 27.9 percent of Texas physicians agreed with the statement: “Any patient who is given narcotics for pain relief is at a significant risk for addiction”;¹²⁷ as well as the studies involving state medical board members who “overestimated the incidence of addiction”¹²⁸). Notwithstanding these similarities in viewpoints, some of the opinions held by prosecutors did differ from the medical establishment, particularly when considering the scope and extent of the pharmaceutical diversion problem.

Most prosecutors correctly noted that the primary source of pharmaceutical diversion was deceptive patients, not physicians. Moreover, when prosecutors were asked about the extent of the diversion problem in their jurisdiction and state, most saw diversion as a bigger problem elsewhere. Their perception that pharmaceutical diversion was not a big problem in their own jurisdiction was buttressed by the fact that 88 percent of the respondents reported that no physicians had been prosecuted in their jurisdiction during the past 12 months for offenses stemming from the prescribing of drugs (11 percent reported prosecuting one to two physicians, and only 1 percent reported between three and six physicians). The opinions held by prosecutors concerning the extent of the diversion problem are in contrast to studies involving pharmacists and medical board members. For example, the Wisconsin survey of pharmacists found that 46 percent “viewed diversion and abuse of prescription opioid analgesics as a problem in their community” (55 percent of them saw diversion as “a moderate problem”).¹²⁹ The survey of New Jersey pharmacists found that 36 percent believed that both diversion and addiction were “serious problems,”¹³⁰ and the Gilson and Joranson study of medical board members found that “most respondents in [1991 and 1997] considered diversion to be a minor to moderate problem.”¹³¹

Prosecutors appear to recognize that deceptive patients are the primary source of diversion, few have prosecuted physicians for offenses relating to prescription drugs, and they generally do not consider pharmaceutical diversion to be a significant problem in their jurisdiction. Therefore, it is not likely that prosecutors would devote much attention to identifying or prosecuting doctors suspected of diversion unless the investigation arises from a complaint by a medical practitioner or family member related to a case.¹³² Admittedly, prosecutors deal with such matters on an infrequent basis, and therefore it is logical that they would recommend a police investigation in Scenario 1 when even health care professionals lack sufficient knowledge about what constitutes legitimate opioid use.

TABLE 15. DISCRIMINANT ANALYSIS RESULTS.**PREDICTING LIKELIHOOD OF RECOMMENDING A POLICE INVESTIGATION IN SCENARIO 1****Scenario 1 (Chronic Pain)****Model Fit:** Chi-square: 16.940 (degrees of freedom = 9) Statistical Significance: $p < 0.05$ (two-tailed)**Model Elements & Standardized Canonical Discriminant Function Coefficients**

Refer to Medical Board in Scenario 2	0.508
State of Maryland	0.412
Risk of addiction when narcotics are used	0.614
Lack of Public support for prosecuting doctor	-0.319
State of Oregon	-0.356
Deceptive patients as a source of diversion	-0.113
Doctor's conduct motivated by compassion	-0.047
Republican	-0.076
Amount of media attention	-0.296

Model Efficacy: 69.0% of cases correctly classified with this model**PREDICTING REFERRAL OF CASES TO STATE MEDICAL BOARD (SCENARIOS 1 AND 2)****Scenario 1 (Chronic Pain)****Model Fit:** Chi-square: 19.679 (degrees of freedom = 5) Statistical Significance: $p < 0.01$ (two-tailed)**Model Elements & Standardized Canonical Discriminant Function Coefficients**

Prosecutor requested summary of our findings	0.595
Number of part-time prosecutors	-0.496
Likelihood would refer matter to DEA in Scenario 1	0.546
State of Oregon	0.306
Risk of addiction when narcotics are used	-0.345

Model Efficacy: 74.2% of cases correctly classified with this model**Scenario 2 (Terminally Ill Patient)****Model Fit:** Chi-square: 27.129 (degrees of freedom = 9) Statistical Significance: $p < 0.01$ (two-tailed)**Model Elements & Standardized Canonical Discriminant Function Coefficients**

Prosecutor requested summary of our findings	0.625
Likelihood would recommend investigation in Scenario 1	0.569
State of Maryland	0.016
State of Oregon	-0.148
Republican	0.180
Doctor emphasized financial interest over patient care	-0.071
Dated doctors as source of diversion	0.452
Independent	-0.136
Lack of public support for prosecuting defendant	-0.055

Model Efficacy: 78.2% of cases correctly classified with this model*Scenario 2*

Whereas the first scenario concerned the aggressive treatment of chronic noncancer pain and physicians' fear that they could be prosecuted for pharmaceutical diversion, the second scenario addressed physicians' fear of prosecution for physician-assisted suicide or euthanasia should a terminally ill patient expire immediately following aggressive

opioid administration. We found that although the risk of *prosecution* was indeed quite low, the likelihood that the matter would be *referred* to the state medical board varied significantly across states.

Most prosecutors did not know if an offense had been committed (51.4 percent); almost a third indicated that no offense had occurred, and less than 20 percent believed that

an offense had taken place. In terms of referring the matter to the medical board in lieu of prosecution, over 50 percent of the respondents estimated the likelihood of referring the matter at 70 percent or greater. However, as noted previously, there were several significant differences among the states. For example, whereas prosecutors in Maryland were more likely to recommend a police investigation in Scenario 1 (72.9 percent likelihood), Maryland prosecutors were also the most likely to refer the matter in its entirety to the state medical board in Scenario 2. Specifically, for Maryland prosecutors (state's attorneys) the average likelihood of referring the matter to the state medical board was 75.9 percent as compared to 56.7 percent in Washington, 49.2 percent in Oregon, and 38.8 percent in Connecticut. Although a few of the prosecutors in our study remarked that they would not refer the matter *in lieu of* investigation or prosecution,¹³³ it was clear that prosecutors were not particularly interested in handling the matter themselves.

Predicting prosecutorial action using both descriptive and inferential statistics

The final part of our survey addressed prosecutions of physicians. Earlier research found that the prosecution of physicians for end-of-life treatment was relatively rare, and most prosecutions occurred in "small towns or rural counties."¹³⁴ With the exception of Connecticut, criminal prosecution of physicians for offenses related to the prescribing of drugs during the past 12 months was virtually nonexistent. The few physicians who were prosecuted for prescribing practices in our sample practiced or resided in larger, more urbanized areas. Specifically, in the ten offices that reported prosecuting a physician during the past 12 months, the number of prosecutors in each of these offices were as follows: 1, 5, 12, 17, 23, 26, 30, 70, 86, and 250. Because the number of full-time prosecutors in an office is highly correlated with the jurisdiction's population (Pearson's $r = 0.949$, $p < 0.01$), population and the number of full-time prosecutors are useful proxies for categorizing the type of jurisdiction/environment. When we recall that the median number of prosecutors in an office across all four states was eight, and jurisdictions over 100,000 citizens had at least twelve prosecutors in an office, it is apparent that most of the prosecutions of physicians came from large jurisdictions in populous areas. Although we found a moderate statistical correlation between the population size and the number of physicians prosecuted (Pearson's $r = 0.359$, $p < 0.01$), further research and formal modeling are necessary before any firm conclusions can be drawn in this regard.

Surprisingly, among the many factors offered, the scarcity of physicians in the area was *not* an important factor in the charging decision for almost all of the prosecutors surveyed. See Table 13. The score on this contextual environmental variable was in contrast to what has been ar-

gued in the past concerning doctors¹³⁵ and corporations (particularly, the impact of corporate prosecutions on the local economy).¹³⁶ Contrary to our expectations, the lack of public support, the amount of media attention, and the possible adverse consequences to their career were reported to have little bearing on the decision to charge (rated as either not important or somewhat important). While most prosecutors are elected officials who need to be at least somewhat responsive to the local citizenry, the consistent downgrading of what factors were and were not important over four states is too strong to dismiss as bias related to the strategic decision-making of elected prosecutors.

Of the factors that were rated by prosecutors as important in the charging decision, deterrence of other physicians was expected, particularly in light of scarce resources. However, in the context of prescription opioids for the treatment of pain, such a policy could lead to overreaction in the medical community, which already perceives an unrealistically high threat of regulatory scrutiny.¹³⁷ We were also not surprised by the importance given to whether a doctor emphasized his own financial interest over patient care in the charging decision, as well as whether the doctor's actions were motivated by compassion. On the other hand, we were surprised by the fact that 43.8 percent of the prosecutors considered whether the doctor was a pain specialist to be "somewhat important" in the decision to charge, and another 23.8 percent considered it to be "important." Any physician who is a DEA registrant may prescribe controlled substances for pain so long as it is for a legitimate medical reason in the usual course of his or her medical practice.

Aside from the numbers generated by the survey, some prosecutors commented that prosecutions involving doctors were complex and, absent outrageous circumstances, it was unproductive to prosecute them. One prosecutor even commented that the courts should probably keep out of the area entirely. In fact, a majority of prosecutors indicated that the complexity of a case was either somewhat important or important in the decision to charge. If the courts do stay out of this area, the alternative forum would likely be the state medical boards. In fact, two of the three most important factors upon which the prosecutors reportedly relied in the decision to charge a physician were (1) whether the state medical board had investigated and handled the matter appropriately (41 percent), and (2) whether the board had failed to take appropriate action (36.1 percent). (The third most important factor was whether the physician emphasized his own financial interests over patient care.)

Arguably, many prosecutors would be more than happy to let one centralized agency — here the state medical board — handle the matter (or at least be given an opportunity to do so). However, as our findings and the literature would suggest, this result is unlikely because most prosecutors tend to hold a rather dim view of the ability of the medical profession to police its own, and research has demonstrated that

medical boards may be lacking the requisite knowledge about pain relief.¹³⁸

Nevertheless, the involvement of, and appropriate handling of these matters by, state medical boards is an opportunity for these boards to assume a leadership role in improving the standard of care in pain relief and reducing the likelihood of police investigation in proper pain management. They could become the one source that prosecutors look to for guidance. In fact, one prosecutor even emailed us and remarked:

I would like to have the results of your survey. I'm also interested in other ways you can help our office. I guess it bothers me that we operate unilaterally and get all our outside information from the Feds. Let me know how we can help each other.

Being able to defer to the state medical board is not only sound from an informational and practical sense, it makes good political sense. Prosecutors have limited resources and must resolve problems with the wisest possible expenditure of those resources. When prosecutors can pass matters off to a competent regulatory entity, caseloads are reduced, thus saving prosecutorial resources for other areas.

STUDY LIMITATIONS

All research designs have weaknesses and potential for error. Although some of our case scenarios were based on actual events and all respondents received the same scenarios, real cases have their own unique problems and characteristics. The opinions provided by the respondents only accurately reflected their position at the time.¹³⁹ Moreover, as a pilot study we limited our examination to four states, and the possibility exists that the opinions of these prosecutors do not reflect those of similarly situated individuals in the remaining forty-six states.

CONCLUSION

The purpose of our study was to determine whether physicians' fear of criminal investigation or prosecution stemming from the prescription of opioids in the treatment of pain was realistic and, if so, what factors could predict a likely investigation. Although earlier well done research indicated that the risk was low, these few studies either relied on published data or primarily concerned the withdrawal or withholding of medical care.¹⁴⁰

Our survey questionnaire was designed to achieve five goals: (1) to solicit a high rate of response; (2) to set forth *meaningful* and *engaging* scenarios; (3) to present a number of questions designed to permit the testing of hypothesized predictors of prosecutorial action against doctors who are

aggressive in the treatment of pain; (4) to provide variation in responses; and (5) to show whether any of the hypothesized factors or variables *do predict* prosecutorial action. All five goals were accomplished.

In reality, each case presented to a prosecutor has a unique set of facts and applicable law. However, each one of our respondents received the same questionnaire and not all responded in the same way. Although our pilot study was limited to four states, our literature review and findings have yielded insight concerning the detection and prosecution of offenses involving physicians and the prescribing of controlled substances. While the likelihood of detection is rare,¹⁴¹ in the event that the conduct is discovered, the likelihood of investigation or referral to the state medical board depends considerably on which scenario and state are involved. As Figures 1 and 2 demonstrate, there was a great deal of variation (particularly when examining Oregon, a state where public policy on pain relief is highly salient). Moreover, we found several case factors that many prosecutors thought to be either very important or not important at all in their decision to charge a physician with a crime. Several variables, if known in advance, could actually predict whether the prosecutor would refer the matter to the state medical board or recommend a police investigation.

Our research can also serve as an assessment and educational tool for the legal, regulatory, and medical communities. For instance, we found that many of our respondents held views similar to those held by pharmacists, drug regulators, and physicians concerning drug addiction and the diversion of pharmaceuticals. But unlike pharmacists, drug regulators, and physicians who are in the business of health care, prosecutors do not think about the dispensing of prescription drugs on a frequent basis. Consistent with the conclusions of Ann Alpers, we also found that a prosecutor's decision to investigate, refer, or prosecute is not motivated by overzealousness,¹⁴² but most likely stems from a lack of knowledge concerning appropriate prescribing practices and opioid use. In fact, many of our respondents shared their own personal stories involving pain experienced by loved ones, and not only praised our research efforts but wanted to know whom they should consult in the future should similar scenarios arise. Several state and national prosecutor associations encouraged our research and expressed an interest in both our findings as well as in contributing to future studies of these issues.

In conclusion, while physicians' fear of prosecution or investigation is a barrier to pain relief in our society, as the social science literature and our results indicate, both the likelihood and frequency of either are extremely low. True, some doctors have abused their prescribing authority and have been prosecuted, but oftentimes the situations were patently illegal, such as the selling of prescriptions for cash or sex.¹⁴³ Overall, prosecutions surrounding the prescription of opioids are rare. When confronted with the scenarios in

this survey, many prosecutors were found to suffer from the same gaps in knowledge held by health care professionals and their regulators. A significant opportunity exists for state medical boards to take a leadership role in the proper treatment of pain and become a reliable resource to both the legal and medical communities. Instead of enacting more statutes, efforts should be directed toward the adoption of informed “guidelines or policy statements” by medical boards regarding the treatment of pain and the legitimate use of opioids.¹⁴⁴ Balancing the need to treat patients who are suffering from pain against the need to prevent the incidence of opioid abuse remains a challenge.¹⁴⁵ And while there are no simple solutions, sensitizing the legal, regulatory, and medical communities about the impact of their decisions on the treatment of pain is a step in the right direction.

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29. Fohr, *supra* note 26; Quill et al., *supra* note 1; Whitecar, Jonas, and Clasen, *supra* note 5.

30. Cantor, *supra* note 23, at 186.

31. See also Alpers and Lo, *supra* note 23; Meisel, Jernigan, and Youngner, *supra* note 26; D. Orentlicher, "The Supreme Court and Physician-Assisted Suicide: Rejecting Assisted Suicide but Embracing Euthanasia," *N. Engl. J. Med.*, 337, no. 17 (1997): 1236–39, at 1236–37.

32. See generally A. Meisel, L. Snyder, and T. Quill, "Seven Legal Barriers to End-of-Life Care: Myths, Realities, and Grains of Truth," *JAMA*, 284, no. 19 (2000): 2495–501; Cantor, *supra* note 23.

33. Steinbrook, *supra* note 22, at 463; L. Gostin, "Drawing a Line Between Killing and Letting Die: The Law, and Law Reform, on Medically Assisted Dying," *Journal of Law, Medicine & Ethics*, 21, no. 1 (1993): 94–101, at 94; Orentlicher and Caplan, *supra* note 22.

34. N. Cantor and G. Thomas, III, "Pain Relief, Acceleration

of Death, and Criminal Law,” *Kennedy Institute of Ethics Journal*, 6, no. 2 (1996): 107–28.

35. Orentlicher, *supra* note 31. See also Billings and Block, *supra* note 23; Alpers and Lo, *supra* note 23.

36. Orentlicher and Caplan, *supra* note 22, at 256; Cantor, *supra* note 23; Cantor and Thomas, III, *supra* note 34; Alpers and Lo, *supra* note 23.

37. Lethal Drug Abuse Prevention Act, H.R. 4006, 105th Congress, 2d session (1998); Pain Relief Promotion Act (PRPA), H.R. 2260, 106th Congress (1999); Conlan, *supra* note 22, at 86; Orentlicher and Caplan, *supra* note 22; C. Baron, “Assisted Dying,” *Trial*, 35, no. 7 (1999): 44–50. See also Ziegler and Lovrich, *supra* note 22; Steinbrook, *supra* note 22 (voicing concern that an intent to comfort terminal patients with the administration of opioids could be viewed by law enforcement as intent to hasten death).

38. Concerns over determining physicians’ intent were raised by the Hospice Patients Alliance, which at one time encouraged people to report physicians to the Drug Enforcement Administration if a terminally ill patient died and prescription drugs were involved. See Hospice Patients Alliance, *When Narcotics Are Misused in Order to Kill a Patient You Can Report the Crime to the U.S. Drug Enforcement Administration*, at <<http://www.hospicepatients.org/usdoj-dea-ofclist.html>> (last visited October 4, 2000).

39. Alpers, *supra* note 1, at 309. Pamela Bucy notes that it “is unfortunate that the only mechanism readily available to study prosecutions of health care providers is through reported cases. This is inadequate for two reasons. First, courts are reporting fewer and fewer of their opinions.... Second, significant cases are often settled. These two deficiencies in the sample make it difficult to detect trends, especially in an area changing as rapidly as health care.” P. Bucy, “The Poor Fit of Traditional Evidentiary Doctrine and Sophisticated Crime: An Empirical Analysis of Health Care Fraud Prosecutions,” *Fordham Law Review*, 63 (1994): 383–528, at 386 n.6.

40. Alpers, *supra* note 1.

41. Meisel, Jernigan, and Youngner, *supra* note 26.

42. See, e.g., M.L. Benson and F.T. Cullen, *Combating Corporate Crime: Local Prosecutors at Work* (Boston: Northeastern University Press, 1998); M.L. Benson et al., “District Attorneys and Corporate Crime: Surveying the Prosecutorial Gatekeepers,” *Criminology*, 26, no. 3 (1988): 505–18; M.L. Benson, F.T. Cullen, and G. Geis, “Local Prosecutors and Corporate Crime,” *Crime and Delinquency*, 36, no. 3 (1990): 356–72; Jesilow, Pontell, and Geis, *supra* note 21; K.A. Ayers, Jr., and J. Frank, “Deciding to Prosecute White-Collar Crime: A National Survey of State Attorneys General,” *Justice Quarterly*, 4, no. 3 (1987): 425–39.

43. Although the knowledge and opinions held by U.S. Attorneys are important as well, particularly since they work so closely with the Drug Enforcement Administration and have federal jurisdiction over conduct occurring in Veterans Administration (VA) hospitals, empirical research necessarily proceeds in steps. Consequently, in light of resource and time constraints, coupled with the realization that there are ten times more local prosecuting officials than appointed U.S. Attorneys, we narrowed our focus in this instant study to local prosecutors.

44. J.E. Jacoby, “The Charging Policies of Prosecutors,” in W.F. McDonald, ed., *The Prosecutor* (Beverly Hills: Sage Publications, 1979): 75–95, at 76–77; J.E. Jacoby, *The American Prosecutor: A Search for Identity* (Lexington, Massachusetts: Lexington Books, 1980): at 195; C.W. Thomas and W.A. Fitch, “Prosecutorial Decision Making,” *American Criminal Law Review*, 13, no. 3 (1976): 507–59, at 509; G.F. Cole, *Politics and the Administration of Justice* (Beverly Hills: Sage Publications, 1973).

45. Alpers, *supra* note 1, at 308.

46. Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44, at *xix*.

47. *Id.* at *xv*; Jacoby, “The Charging Policies of Prosecutors,” *supra* note 44, at 75. The chief prosecuting attorneys in our study carry different titles: prosecuting attorney (Washington), district attorney (Oregon), and state’s attorney (Connecticut and Maryland).

48. Cole, *supra* note 44, at 113–14.

49. Cole, *supra* note 44, at 112, 150; Jacoby, “The Charging Policies of Prosecutors,” *supra* note 44, at 75.

50. F.W. Miller, *Prosecution: The Decision to Charge a Suspect with a Crime*, Report of the American Bar Foundation’s Survey of the Administration of Criminal Justice in the United States (Boston: Little, Brown and Company, 1969): at 295; G.F. Cole, “The Decision to Prosecute,” *Law and Society Review*, 4, no. 3 (1970): 331–43.

51. Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44, at 47.

52. Jacoby, “The Charging Policies of Prosecutors,” *supra* note 44, at 78.

53. S.J. Cox, “Prosecutorial Discretion: An Overview,” *American Criminal Law Review*, 13, no. 3 (1976): 383–434; Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44; Miller, *supra* note 50; Thomas and Fitch, *supra* note 44.

54. R. Jackson, “The Federal Prosecutor,” *Journal of the American Judicature Society*, 24 (1940): 18–20, at 18.

55. C. Spohn, D. Beichner, and E. Davis-Frenzel, “Prosecutorial Justifications for Sexual Assault Case Rejection: Guarding the Gateway to Justice,” *Social Problems*, 48, no. 2 (2001): 206–35; Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44.

56. M.R. Gottfredson and D.M. Gottfredson, *Decision Making in Criminal Justice: Toward the Rational Exercise of Discretion*, 2nd ed. (New York: Plenum Press, 1988): at 113–14. See also R. Teslik, *Prosecutorial Discretion — the Decision to Charge: An Annotated Bibliography* (Washington, D.C.: U.S. Department of Justice, Law Enforcement Assistance Administration, National Institute of Law Enforcement and Criminal Justice, 1975); J. Kaplan, “The Prosecutorial Discretion — A Comment,” *University of Northwestern Law Review*, 60, no. 2 (1965): 174–93; Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44; Miller, *supra* note 50; R.S. Frase, “The Decision to File Federal Criminal Charges: A Quantitative Study of Prosecutorial Discretion,” *University of Chicago Law Review*, 47 (1980): 246–330; Thomas and Fitch, *supra* note 44; Cox, *supra* note 53.

57. C.A. Albonetti, “Prosecutorial Discretion: The Effects of Uncertainty,” *Law and Society Review*, 21, no. 2 (1987): 291–313, at 291; J. Eisenstein, “Unsettled Territory: An Overview of Research on The Legal Process,” *Law & Courts* (newsletter of the Law and Courts Section of the American Political Science Association), 11, no. 1 (2000): 1–32, at 5 (part of symposium issue on *Politics and Prosecutors*).

58. M.E. McGhee, “Prosecutorial Discretion,” *Georgetown Law Journal*, 88 (2000): 1057–69, at 1057.

59. B.L. Gershman, “A Moral Standard for the Prosecutor’s Exercise of the Charging Discretion,” *Fordham Urban Law Journal*, 20 (1993): 513–30, at 513 n.3. Aside from the role that convictability plays in the decision to charge, both Miller, *supra* note 50, and Gottfredson and Gottfredson, *supra* note 56, recognized that there are reasons beyond legal concerns for not charging a suspect. For instance, although a prosecutor may decline to charge a suspect for legal reasons, such as insufficient evidence, a closer examination may indicate that the legal reason is merely a facade for an outright discretionary action. Specifically, a review of the case may reveal that there is sufficient legal

evidence to convict; however, prosecution of the offender is "otherwise undesirable" in light of extralegal factors. Miller, *supra* note 50, at 155. In fact, this "insufficient evidence" designation is often a convenient way out for the public prosecutor. Miller, *supra* note 50, at 156.

60. Cole, *supra* note 44.

61. J. Schmidt and E.H. Steury, "Prosecutorial Discretion in Filing Charges in Domestic Violence Cases," in G.F. Cole and M.G. Gertz, eds., *The Criminal Justice System: Politics and Policies*, 7th ed. (Belmont, California: Wadsworth Publishing, 1998): 187-201.

62. D. Hirschel and I.W. Hutchison, "The Relative Effects of Offense, Offender, and Victim Variables on the Decision to Prosecute Domestic Violence Cases," *Violence Against Women*, 7, no. 1 (2001): 46-59; Miller, *supra* note 50; E.P. Baumer, S.F. Messner, and R.B. Felson, "The Role of Victim Characteristics in the Disposition of Murder Cases," *Justice Quarterly*, 17, no. 2 (2000): 281-307; L. Frohmann, "Convictability and Discordant Locales: Reproducing Race, Class, and Gender Ideologies in Prosecutorial Decisionmaking," *Law & Society Review*, 31, no. 3 (1997): 531-55; Schmidt and Steury, *supra* note 61.

63. Cole, *supra* notes 44, 50.

64. Frohmann, *supra* note 62; Spohn, Beichner, and Davis-Frenzel, *supra* note 55.

65. Miller, *supra* note 50; D. Pritchard, "Homicide and Bargained Justice: The Agenda-Setting Effect of Crime News on Prosecutors," *Public Opinion Quarterly*, 50 (1986): 143-59; S.L. Haynie and E.A. Dover, "Prosecutorial Discretion and Press Coverage," *American Politics Quarterly*, 22, no. 3 (1994): 370-81.

66. Albonetti, *supra* note 57.

67. Frohmann, *supra* note 62, at 535 (citing R.M. Emerson and B.P. Paley, "Organizational Horizons and Complaint-Filing," in K. Hawkins, ed., *The Uses of Discretion* (New York: Oxford University Press, 1992)). See also L. Frohmann, "Discrediting Victims' Allegations of Sexual Assault: Prosecutorial Accounts of Case Rejections," *Social Problems*, 38, no. 2 (1991): 213-26, at 224.

68. D.O. Friedrichs, *Trusted Criminals: White-collar Crime in Contemporary Society* (Boston: Wadsworth Publishing Company, 1996): at 10.

69. G.S. Green, *Occupational Crime*, 2nd ed. (Chicago: Nelson-Hall Publishers, 1997): at 15; Friedrichs, *supra* note 68, at 102; Jesilow, Pontell, and Geis, *supra* note 21.

70. Jesilow, Pontell, and Geis, *supra* note 21, at 160.

71. Friedrichs, *supra* note 68, at xvii; Green, *supra* note 69, at xiii (quoting Gilbert Geis).

72. Friedrichs, *supra* note 68, at 2, 22.

73. C.A. Albonetti, "Direct and Indirect Effects of Case Complexity, Guilty Pleas, and Offender Characteristics on Sentencing for Offenders Convicted of a White-Collar Offense Prior to Sentencing Guidelines," *Journal of Quantitative Criminology*, 14, no. 4 (1998): 353-79, at 357; Jesilow, Pontell, and Geis, *supra* note 21; Ayers, Jr., and Frank, *supra* note 42.

74. Friedrichs, *supra* note 68, at 50-53. See also Johnson, "Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act," *supra* note 1, at 320-21.

75. Jesilow, Pontell, and Geis, *supra* note 21, at 161.

76. Green, *supra* note 69, at 184; Jesilow, Pontell, and Geis, *supra* note 21.

77. Jesilow, Pontell, and Geis, *supra* note 21, at 154.

78. Jesilow, Pontell, and Geis, *supra* note 21; Behr, *supra* note 9; P. Van Grunsven, "Criminal Prosecution of Health Care Providers for Clinical Mistakes and Fatal Errors: Is 'Bad Medicine' a Crime?," *Journal of Health and Hospital Law*, 29, no. 2 (1995): 107-20; Jost, *supra* note 11.

79. F.P. Bense and B.D. Goldberg, "Prosecutions and Punitives for Malpractice Rise, Slowly," *National Law Journal*, January 22, 1996, at B7; Alpers, *supra* note 1; Van Grunsven, *supra* note 78; J. Liederbach et al., "The Criminalization of Physician Violence: Social Control in Transformation," *Justice Quarterly*, 18, no. 1 (2001): 141-70.

80. Van Grunsven, *supra* note 78, at 112; P. Van Grunsven, "Medical Malpractice or Criminal Mistake? An Analysis of Past and Current Criminal Prosecutions for Clinical Mistakes and Fatal Errors," *DePaul Journal of Health Care*, 2 (1997): 1-54, at 51; Liederbach et al., *supra* note 79, at 148-49.

81. Liederbach et al., *supra* note 79, at 145-50; Benson, Cullen, and Geis, *supra* note 42, at 364.

82. Jesilow, Pontell, and Geis, *supra* note 21, at 160.

83. *Id.* at 161. "U.S. Attorneys are extraordinarily kind to doctors, because even if they are crooks, theoretically they are still providing some useful services to the community."

84. Meisel, Jernigan, and Youngner, *supra* note 26.

85. *Id.* at 1092.

86. *Id.* at 1090.

87. *Id.*

88. *Id.* at 1092.

89. Alpers, *supra* note 1, at 308.

90. *Id.* at 311.

91. *Id.* at 315.

92. *Id.*

93. *Id.* at 311.

94. See Donaghue Medical Research Foundation, *II. Assessment of Pain Management and Obstacles to Adequate Pain Management in Connecticut*, at <http://www.aslme.org/research/proposal_pt2.php> (last visited February 18, 2003).

95. D.A. Dillman, *Mail and Internet Surveys: The Tailored Design Method*, 2nd ed. (New York: John Wiley and Sons, Inc., 2000).

96. Meisel, Jernigan, and Youngner, *supra* note 26.

97. Alpers, *supra* note 1, at 315.

98. Fohr, *supra* note 26; Quill et al., *supra* note 1.

99. Whitecar, Jonas, and Clasen, *supra* note 5, at 761.

100. Fohr, *supra* note 26, at 316.

101. See Cantor, *supra* note 23; Alpers and Lo, *supra* note 23; Orentlicher and Caplan, *supra* note 22; *Vacco v. Quill*, 521 U.S. 793 (1997).

102. *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. (June 24, 1999) (written testimony of Walter R. Hunter, Associate National Medical Director, VistaCare Hospice), available at <<http://www.house.gov/judiciary/hunt0624.htm>>.

103. Benson et al., *supra* note 42; Benson and Cullen, *supra* note 42; Ayers, Jr., and Frank, *supra* note 42; Liederbach et al., *supra* note 79.

104. Meisel, Jernigan, and Youngner, *supra* note 26; Gilson and Joranson, *supra* note 1; Benson and Cullen, *supra* note 42; Benson et al., *supra* note 42; Ayers, Jr., and Frank, *supra* note 42; Weinstein et al., *supra* note 3; Liederbach et al., *supra* note 79. Special thanks to Aaron Gilson, Ph.D., and Stuart Youngner, M.D., who helped further refine our thinking.

105. Steinbrook, *supra* note 22. See also S.J. Ziegler and N.P. Lovrich, Jr., *Pain Relief and Prohibiting PAS: The Saga Continues* (September 2001), Pain and the Law Website, at <http://www.painandthelaw.org/mayday/ziegler_lovrnich_110101.php>.

106. Alpers, *supra* note 1.

107. Jacoby, *The American Prosecutor: A Search for Identity*, *supra* note 44.

108. See, e.g., *id.*

109. Sees and Clark, *supra* note 5, at 258.

110. Wilford et al., *supra* note 18.

111. M. Gaffney and N.P. Lovrich, Jr., *Perceptions of Crime: Differential Citizen Views of Problems of Public Order at the City and Neighborhood Level*, paper presented at the Annual Meeting of the Academy of Criminal Justice Sciences, New Orleans, March 24, 2000. See also Benson and Cullen, *supra* note 42.

112. Prosecutor #1: [I would refer] in conjunction with [the police investigation].

Prosecutor #2: I would not only prosecute, but *also* refer to the state medical board.

Prosecutor #3: Your question had us consider the state medical board in lieu of investigation. When I have had these cases [involving medical practice], we have had police and [the state medical board] investigate together. The police do not have the background for these investigations.

Prosecutor #4: The questions asking if we would send matters to the medical board *in lieu* of police investigation are not well taken. We would likely [undertake] *parallel* investigations.

113. Prosecutor #5: In our jurisdiction we have a significant drug problem, including prescription drug abuse. Most prescription drugs enter the criminal arena via forged prescriptions or sales by a patient. Additionally, a large number of prescription drugs are stolen from disabled and elderly patients and then diverted into the drug world.

Prosecutor #6: In our state, there is a problem with the medical [board not] being vigilant enough. They need to be “harder lined.” More severe sanctions, etc., would help with the “pill pushing” (some dole it out like candy). But you could not realistically prosecute most of this, nor would I want to. We don’t have the resources nor do the cops.

Prosecutor #7: Unless the doctor’s conduct is extremely outrageous, I think it is not productive to prosecute doctors.

Prosecutor #8: I realize that there is a problem [with health professionals who self-medicate] but also believe with treatment that these persons can be rehabilitated. Also realize that certain types of doctors should prescribe more pain-killers but are afraid to because of [their medical] license. The biggest problem [are patients who abuse the drugs and who are eventually able to find] older doctors (legal suppliers) who need the money.

Prosecutor #9: Prescribing drug cases: for profit? [I have no anxiety when deciding to prosecute]. [Doctor has] lax controls? Punish for stupidity or do we want a knowing violation? If the physician is impaired [and diverting, I] would treat [the case] as if [it were motivated by] profit, but would treat differently for sentencing purposes. Evidence issues also present a problem — hired experts on each side would describe typical dosages — result in reasonable doubt? What about witnesses? Credibility issues are present because they may be addicted patients who are now cut off or co-defendants who assisted in street sales. If I get an undercover officer, that would be better, but [that would be] a problem if the jurisdiction is small.

114. Due to variation in the names of offenses among the states, we classified offenses using a generic classification scheme. Moreover, to avoid double counting, we counted only the highest offense when respondents provided lesser included offenses as alternatives (e.g., when both murder and manslaughter were offered, only murder was counted).

115. Prosecutor #1: It would be referred to the state medical board in addition to, but never in lieu of, prosecution.... Don’t know, need all the facts to make a determination.

Prosecutor #2: I would need more information about the dosages and whether the administration [of the drug] met a criminal mental state.

Prosecutor #5: Homicide or manslaughter. Note that Oregon is a PAS [physician-assisted suicide] state. If the patient was in [the]

last hours of life, I would not file. Need more facts.

Prosecutor #6: Need more information. What is a medically acceptable dosage.... Negligence? Was he [the doctor] unaware of the risk that he should have been aware of?

Prosecutor #7: [I don’t know]. Some variables not provided — timing, the patient’s prior use of narcotics, etc.

Prosecutor #8: [I don’t know]. We would need more facts.

Prosecutor #16: It would be good to know if the doses administered were clearly beyond norms (something I assumed). This is an interesting and thought-provoking survey.

116. Prosecutor #3: Wait for autopsy results.

Prosecutor #4: Manslaughter would require “gross negligence” (would need numerous doctors to say so and that he would not have died then because he was dying anyway — soon?? [It is not that an offense has been committed, I just] do not think an offense could be proven.

Prosecutor #9: Would depend upon information from medical experts.

Prosecutor #10: Unless someone tells me this was negligent or reckless conduct, then would pursue further [I did not think an offense had been committed].

Prosecutor #11: Depends on level of proof.

Prosecutor #12: Homicide cases, especially those involving the members of the medical profession as defendants, are extremely complex and, depending on the facts, difficult to prove.

Prosecutor #13: Difficult area that I have not yet had to address. My answers are wishy-washy mainly because I have not given much practical thought to the issue. In simple terms, I would likely not prosecute a doctor whose main purpose is to [relieve] a person’s suffering provided they have not “actively” committed euthanasia.

Prosecutor #14: [This may be] best answered through a coroner’s inquest jury. [It] will arrive at a decision based on standards in the community.

Prosecutor #15: [A few of my family members] were hospice patients. My experience of their deaths completely determined my answers to your great questions. I was surprised about how strongly I *feel* on these issues. Because rational analysis played no part, I would have to refer this matter to another prosecutor in my office should the situation present itself.

117. We also drew a distinction between “uncertain” (the respondent was taking a middle ground as to whether the profession was effective or not in policing its own) and “do not know.” Those choosing “uncertain” would correspond with a score of 4 along the seven-point scale, and those who did not know checked the box labeled “Don’t Know.”

118. See Van Grunsven, *supra* note 80; Liederbach et al., *supra* note 79.

119. Benson and Cullen, *supra* note 42; Jesilow, Pontell, and Geis, *supra* note 21; Benson et al., *supra* note 42; and Ayers, Jr., and Frank, *supra* note 42.

120. We recognize that there are other parametric and non-parametric tests that we could have selected that would have contributed further to our analysis.

121. All variables were reviewed, and those which posed a risk of tautology were omitted.

122. See, e.g., P. Goodwin, “Oregon’s Physician Assisted Suicide Law: An Alternative Viewpoint,” *Archives of Internal Medicine*, 157, (1997): 1642–44; S.J. Ziegler and N.P. Lovrich, Jr., *Examining the Link Between Physical Pain and Requests for Hastened Death: Different Results or Different Values?* (July 2, 2002), Pain and the Law Website, at <http://www.painandthelaw.org/mayday/ziegler_070202.php>; R.J. Bonnie and B. Guyer, “Injury as a Field of Public Health: Achievements and Controversies,” *Journal of Law, Medicine & Ethics*, 30, no. 2 (2002): 267–80, at 278.

123. Weinstein et al., *supra* note 3, at 481.
124. Greenwald and Narcessian, *supra* note 4, at 373.
125. Joranson and Gilson, *supra* note 7, at 217.
126. Gilson and Joranson, *supra* note 1, at 235.
127. Weinstein et al., *supra* note 3, at 480.
128. Gilson and Joranson, *supra* note 1, at 230.
129. Joranson and Gilson, *supra* note 7, at 215.
130. Greenwald and Narcessian, *supra* note 4, at 371.
131. Gilson and Joranson, *supra* note 1, at 230.
132. See Alpers, *supra* note 1; Jesilow, Pontell, and Geis, *supra* note 21.
133. See notes 112 and 115, *supra*.
134. Alpers, *supra* note 1, at 315.
135. Jesilow, Pontell, and Geis, *supra* note 21, at 161.
136. See Benson and Cullen, *supra* note 42; Benson, Cullen, and Geis, *supra* note 42.
137. See Martino, *supra* note 17. For a related context, see A.G. Lawthers et al., "Physicians' Perceptions of the Risk of Being Sued," *Journal of Health Politics, Policy and Law*, 17, no. 3 (1992): 463–82.
138. Gilson and Joranson, *supra* note 1. See also *Hoover v. Agency for Health Care Admin.*, 676 So. 2d 1380 (Fla. Dist. Ct. App. 1996).
139. J. Zaller and S. Feldman, "A Simple Theory of the Survey Response: Answering Questions versus Revealing Preferences," *American Journal of Political Science*, 36, no. 3 (1992): 579–616.
140. Alpers, *supra* note 1; Meisel, Jernigan, and Youngner, *supra* note 26.
141. Alpers, *supra* note 1.
142. *Id.* at 311.
143. See, e.g., Behr, *supra* note 9; Jesilow, Pontell, and Geis, *supra* note 21.
144. D.E. Joranson et al., "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," *Journal of Pain and Symptom Management*, 23, no. 2 (2002): 138–47, at 144; Hyman, *supra* note 11, at 338.
145. For a comprehensive examination of state and federal policies relating to the medical use of opioids, see D.E. Joranson et al., *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (Madison: The Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000), available at <<http://www.medsch.wisc.edu/painpolicy/eguide2000/index.html>>.

Not for
Distribution

Monitoring and Investigating Certified Registered Nurse Practitioners in Pain Management

Jean B. Lazarus and Belinda (Wendy) Downing

The Mayday Scholars Program for 2001–2002 provided an opportunity to boards of nursing to present their experiences in monitoring the prescribing practices of advanced practice nurses and to research ways for improving their own investigation processes as professional disciplinary agencies for prescribing practices related to pain management.¹ The Alabama Board of Nursing was interested in participating in the program based on its commitment to accountability for public protection. A gradual increase in disciplinary cases involving violations of prescribing practices by certified registered nurse practitioners (CRNPs)² prompted our inquiry as to whether a proactive monitoring system was needed to determine compliance with regulations for advanced practice nurses in collaborative practice.

In this article, we discuss selected elements related to pain management and regulatory factors, including nursing, that affect the treatment of pain. We present a brief overview of the evolution of advanced practice nursing, with an emphasis on the nurse practitioners movement, and prescription practices and pain management by nurse practitioners. Next, we present research results about nurse practitioners approved for practice in Alabama, their perceptions of their preparation for prescriptive practice in pain management, and their experiences in collaborative practice related to prescriptive authority for pain management. Then, we share the experiences of the Alabama Board of Nursing in monitoring and investigating nurse practitioners for compliance with prescriptive authority. Finally, we show how evidence obtained from research can have rapid application to regulatory concerns, and conclude with an open agenda for future research related to pain management and regulation.

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The survey presented in this article employed an evidence-based approach using an action research design to address the survey's priorities.³ Research questions centered on:

- barriers to pain management experienced by nurse practitioners;
- autonomy exercised by nurse practitioners in making decisions for dosage and administration of controlled substances when operating under a protocol for collaborative practice; and
- opportunities to improve the investigation process of a board of nursing when collaborative practice is required for prescribing practices related to pain management.

FACTORS IN PAIN MANAGEMENT

The nature of health care delivery is inextricably linked to conditions that demand intervention for pain relief. Unfortunately, pain is often undertreated in all systems of health care delivery. Numerous scholars have described the reasons for failure to effectively treat pain comprehensively. The reasons most frequently referenced in relation to physicians include lack of education, threats of litigation or discipline for accusations of overuse of opiates, lack of support from insurance companies, and fear of tolerance and addiction to opioids.⁴ While there is no evidence that large numbers of physicians are being sanctioned for their treatment practices in pain management,⁵ the mere threat of disciplinary action by regulatory agencies serves as a stimulus for undertreatment or conservative treatment of pain.⁶ Nurses have cited reasons similar to those given by physicians for inadequate treatment of pain, although with less emphasis on concerns related to overprescribing opiates.⁷ Organizational variables also contribute to inadequate treatment of pain. These include low

prioritization of pain management; lack of written standards, policies, or procedures for assessment and management of pain; lack of accountability for pain management; lack of criteria for pain management in quality assurance programs;⁸ and provider attitudes about the connection between pain and illness, summed up in the adage that pain is part of illness and should be “toughed out.”⁹

Economic factors such as limitations on third-party reimbursement practices have been implicated in matters of inadequate pain management. Most research in this arena has focused on institutional and physician reimbursement.¹⁰ Although the literature indicates that limitations on reimbursement by insurers affect access to care,¹¹ no research has clearly established that constraints on reimbursements to nonphysician health care professionals result in undertreatment of pain.

Statutory mandates at federal and state levels for the regulation of controlled substances play a significant role in pain management.¹² Securing a reasonable balance in allowing for effective interventions for pain, while enforcing laws designed to control illegal prescribing practices, continually challenges regulators. Monitoring for compliance is complicated by privacy concerns in the patient-provider relationship and laws regulating confidentiality.¹³

Nursing as a factor in pain management

Nursing is the largest health care labor market in the United States, with approximately 2.6 million registered nurses and approximately 700,000 licensed practical nurses.¹⁴ Of the registered nurses, there are estimates that approximately 130,000¹⁵ have additional education and skills that qualify them as advanced practice nurses in one of four categories: clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and nurse practitioners. Almost 45 percent (88,186) of advanced practice nurses have reported preparation as nurse practitioners.¹⁶

The majority of all licensed nurses, including advanced practice nurses, are involved in the direct care of patients, and therefore must address some aspects of pain management. Advanced practice nurses are also authorized by law or regulations in a majority of states to prescribe medications for conditions requiring pain management.¹⁷ Prescriptive authority by nurse practitioners is restricted through scope of practice regulations by the state, particularly in relation to controlled substances.¹⁸

Accountability in pain management

In today's health care delivery system, physicians are charged with considerable accountability for pain management.¹⁹ The scope of pain management, however, exceeds the boundaries of a single profession's practice. The following definition by the American Academy of Pain Management indicates

that adequate pain management requires an amalgamation of knowledge and techniques by a number of professionals:

[Pain management is the] systematic study of clinical and basic science and its application for the reduction of pain and suffering; the blending of tools, techniques and principles taken from the discrete healing art disciplines and reformulated as a holistic application for the reduction of pain and suffering; and a newly emerging discipline emphasizing an interdisciplinary approach with a goal of reduction of pain and suffering.²⁰

This definition indicates a shared accountability for pain management. Those with prescriptive authority, including physicians, advanced practice nurses, pharmacists, and psychologists, are necessarily accountable for their prescribing practices.²¹ Health care organizations, such as the Joint Commission on Accreditation of Health Care Organizations, also share the responsibility for assuring sound practices in the management of pain.²²

The Alabama Board of Nursing adopted an Accountability Model in 1999 that places the consumer as its central focus. Licensees, health care organizations, professional associations, educators, and the Board of Nursing interrelate and are held accountable for upholding standards of practice for public safety and welfare.²³ The essentials of collegial collaboration and accountability between physicians and pharmacists for pain management have aptly been analyzed and synthesized in recent research.²⁴ In nursing, accountability is often coupled with autonomy and authority to act,²⁵ not only as individual professionals, but in relation to organizational structures.²⁶

In pain management, all practitioners in health care who are legally authorized to prescribe controlled substances are accountable for upholding federal and state regulations. Although the states have laws that set parameters for the prescribing and dispensing of controlled substances, only seventeen states have adopted formal monitoring programs to promote adherence to laws governing the prescriptive practice of professionals.²⁷ Other efforts at monitoring stem primarily from the Drug Enforcement Administration's authority to enforce regulations for controlled substances under the Controlled Substances Act of 1970.²⁸

The accountability role that regulatory boards of professional health care providers play in relation to monitoring for pain management practices by health care professionals has not been clearly defined. The situations faced by medical boards to assure compliance with prescriptive practice while providing treatment for pain now confront other regulatory agencies. Nursing boards are no exception, particularly in matters concerning advanced practice where nursing has assumed greater authority in areas previously reserved under the domain of medical practice.

REGULATION OF NURSING PRACTICE

The first permissive nursing practice law was enacted in North Carolina on March 3, 1903. By 1952, all states and territories had such laws. In 1938, New York enacted the first mandatory licensure statute, which became effective in 1947. All states had mandatory licensure laws for professional and practical nurses by 1990.²⁹

Currently, agencies in sixty-one jurisdictions of the United States regulate nursing; fifty-five are located in the states, one in the District of Columbia, and five in U.S. territories. Five of those located in the states have separate boards that regulate licensed practical nurses. Thirty-one of the agencies are described as independent or autonomous boards of nursing; twenty-six are classified as units within umbrella regulatory agencies, and two have varying structures with cooperative functions with other agencies.³⁰ Laws regulating nursing, often referred to as “nurse practice acts,” typically specify an administrative authority (such as a board); define the authority, composition, and powers of the board; define nursing and the scope of practice; identify types of licensees and titles; specify state licensure requirements; protect titles; and identify grounds for disciplinary action.³¹ In most jurisdictions, the statutes also have provisions for the regulation of advanced practice nurses.

Advanced practice nurses are generally described as registered nurses, with a current license to practice, who are authorized for advanced practice by one or more regulatory agencies by virtue of having completed a formal educational program containing theory and skills practice that go beyond basic education.³² All advanced practice nurses share three essential characteristics: high degrees of autonomy in decision-making; direct accountability to patients or to the members of the health care team, or both; and advanced theoretical and practical knowledge gained at the graduate and postgraduate levels.³³

The four types of advanced practice nurses (nurse anesthetist, clinical nurse specialist, certified nurse midwife, and nurse practitioner) all evolved separately. With the exception of nurse practitioners, advanced practice nurse roles stemmed from clinical origins, at times in the laity, then evolved into formal disciplines with structured educational programs. The nurse anesthetist role is credited with being the first in advanced practice, originating in the 1870s. There are approximately 27,000 certified registered nurse anesthetists in the United States approved for practice by boards of nursing;³⁴ it is estimated that they administer 65 percent of all anesthetics given in the United States each year.³⁵

Beginning in the 1960s, the clinical nurse specialist role evolved from a registered nurse with advanced knowledge to a clinical specialty obtained by individuals pursuing a master’s degree in nursing. Five clinical nurse specialist roles seem to dominate: direct practice, education, consultation, administration, and research.³⁶ According to the American Nurses Association’s 2000 Prescriptive Authority Chart,³⁷ twenty-

nine states have authorized prescriptive practice for clinical nurse specialists, all except two with limitations on independent practice. The Health Resources and Services Administration report³⁸ states that there are approximately 70,000 clinical nurse specialists.

The certified nurse midwife’s roles are generally limited to family planning; health care of women during pregnancy, childbirth, and postpartum; and health care of newborns. Specifications for licensure include being a registered nurse, education that is certified by the American College of Nurse-Midwives (usually a master’s degree, although fourteen states allow a bachelor’s degree),³⁹ and, depending on the state, approval for collaborative practice.⁴⁰ Forty-two state licensing jurisdictions acknowledged for practice 6,895 certified nurse midwives.⁴¹ Approximately 4.4 percent of the births in the United States were attended by board-approved nurse midwives in 2001.⁴²

Although each of the four roles of advanced nurse practice is considered significant in health care delivery, including pain management, this paper focuses primarily on the nurse practitioner role. The role of nurse practitioner was initiated in 1965⁴³ as a certificate program to prepare pediatric nurse practitioners under the collaborative work of a nurse, Loretta Ford, and a physician, Henry Silver, at the University of Colorado.⁴⁴ This program was initiated to increase access to care. The curriculum focused on health and wellness and prepared the nurses to identify symptoms and to diagnose and manage health care problems in children. The project was evaluated for effectiveness and resulted in federal appropriations, so that by the mid-1970s there were over 500 programs, mostly certificate programs, preparing nurse practitioners to deliver primary care. The programs shifted gradually from certificate programs to graduate-level education. By the 1980s, a majority of the nurse practitioner programs required a master’s degree.⁴⁵

Today, over 500 graduate-level programs in more than 200 colleges and universities prepare nurse practitioners in at least fourteen specialty areas, such as acute care, adult health, child health/pediatrics, college health, emergency nursing, family nursing, geriatric nursing, neonatal nursing, obstetrical and/or gynecological and/or women’s health, and psychiatric and/or mental health.⁴⁶ The result is, as stated above, over 88,000 nurse practitioners.

Nurse practitioners and prescriptive authority

Until the 1970s, statutes regulating nursing applied only to a relatively narrow and dependent scope of practice. The laws precluded independent treatment by nurses, and specified that nurses “carry out treatment and medications as prescribed by a licensed physician.”⁴⁷ Up until this time, advanced practice nursing was covered under general nursing regulations.⁴⁸

Absent specific statutory or regulatory recognition, the legitimate scope of practice for advanced practice nurses was

established in *Sermchief v. Gonzales*.⁴⁹ The Missouri Board of Registration for the Healing Arts, which licensed physicians and osteopaths, recommended the criminal prosecution of two nurse practitioners for the unlawful practice of medicine. Physicians who worked at the clinic with the nurses were also alleged by the board to be aiding and abetting the unauthorized practice of medicine. At the clinic, the nurses worked under standing orders and protocols signed by the clinic physicians and performed a variety of diagnostic and treatment functions. The circuit court upheld the board's findings, and the nurses and physicians appealed the court's order to the Missouri Supreme Court. In reversing the circuit court's decision, the Supreme Court judge ruled that the nurses were acting within their scope of practice and education as provided for by the Missouri Nurse Practice Act.⁵⁰

In 1971, the statutory definition of a registered nurse was expanded in Idaho to include advanced practice nursing.⁵¹ Other states followed suit. Presently, fifty-three of fifty-six boards that regulate registered nurses also regulate or recognize advanced practice registered nurses as a separate group

within the jurisdiction.⁵² Of these boards, forty-four have regulatory oversight of nurse practitioners, while in six jurisdictions nurse practitioners are jointly regulated by the board of nursing and the board of medicine.⁵³ Nurse practitioners have prescription authority in forty-eight jurisdictions, although the levels of authority are restricted primarily to protocols between advanced practice nurses and collaborating physicians.⁵⁴ Of these, thirty-nine jurisdictions provide nurse practitioners with prescriptive authority for controlled substances, along with other legend drugs. Table 1 provides a breakdown of prescriptive authority for nurse practitioners⁵⁵ according to drug schedules for controlled substances.⁵⁶

Collaborative practice and protocols

Although nurses have always practiced in collaboration with other professionals in health care delivery, the early nurse practice acts were written to avoid conflict in professional practice. The statutes provided for a narrowly defined independent role, with dependent roles dominating. As nursing

TABLE 1. NURSE PRACTITIONERS AND REGULATORY SCOPE OF PRESCRIPTIVE AUTHORITY FOR CONTROLLED SUBSTANCES.

SCOPE OF PRESCRIPTIVE AUTHORITY BY SCHEDULE*	NUMBER OF STATES/JURISDICTIONS	STATES/JURISDICTIONS BY NAME	COMMENTS
I-V	3	District of Columbia, Kansas Minnesota	
II-V	22	Alaska, Arizona, Colorado, Connecticut, Delaware, Idaho, Indiana, Iowa, Maryland, Massachusetts, Montana, New Hampshire, New Mexico, New York, North Carolina, Oregon, Rhode Island, Tennessee, Utah, Vermont, Washington, Wisconsin	
III-V	4	Arkansas, California, Oklahoma West Virginia	Although Illinois, Nebraska, and South Dakota also allow nurse practitioners to prescribe Schedules III-V, they do so with stipulations as to time
All other states that allow prescriptive authority for controlled substances do so with strict limitations, such as Louisiana, which requires individual application and justification of the need for such authority.			

*Examples of drugs included in each schedule include: Schedule I: Agents that are not usually acceptable for medical use and have a high potential for abuse and addiction (heroin, hallucinogens such as LSD and PCP, and marijuana (although some states allow marijuana to be used for medicinal purposes)). Schedule II: Agents that have a high potential for abuse but are used for pain management (hydromorphone (Dilaudid), methadone, meperidine (Demerol), cocaine, oxycodone (Percodan), and methylphenidate (Ritalin)). Schedule III-V: Agents regarded as having less potential for abuse and addiction (III: anabolic steroids, codeine and hydrocodone with aspirin or Tylenol, and some barbituates; IV: depressants such as diazepam (Valium), clonazepam (Klonopin), and alprazolam (Xanax); V: antitussives, antidiarrheal, and analgesics that may contain codeine).

progressed into recognized advanced practice, roles previously considered to be dependent began to develop into legally independent roles.⁵⁷ Collaboration occurred as a result of professional interaction between health care professionals in the mutual assessment, diagnosis, and treatment of patients.

Today, "collaboration" is a legally defined term in at least fifty statutes governing nursing practice.⁵⁸ These statutes vary widely among the states. The requirements may also vary according to the particular activity. In some states, for example, a more liberal level of collaboration is designated for general advanced practice, and a more structured level for prescribing drugs and devices. Some requirements vary according to the educational level of the nurse. Whatever the arrangement, under the newer statutes, medicine continues to play a significant role in the prescriptive authority allocated to nurse practitioners and, in some states, prescriptive authority is allowed only under the supervision of a physician.⁵⁹

Alabama is considered to be restrictive in its statutory limitations on independent practice for nurse practitioners. Although nurse practitioners have been authorized to practice under the Alabama Nurse Practice Act regulations since 1984, a specific law governing advanced practice nursing was not passed until 1995.⁶⁰ The statute requires collaborative practice with physicians for nurse practitioners and certified nurse midwives. Alabama's Board of Nursing and Board of Medical Examiners promulgated the regulations under the Act.⁶¹ The regulations for prescriptive authority allow nurse practitioners to practice under jointly approved protocols when prescribing legend drugs. The statute does not give nurses authority to prescribe drugs scheduled under the Alabama Uniform Controlled Substances Act.⁶² Furthermore, the collaborating physician has authority to limit the nurse practitioner's prescriptive privileges for noncontrolled substances without stating any reasons.

In Alabama, review of protocols is integral to approval for collaborative practice. The Board of Nursing and the Board of Medical Examiners review and act on recommendations by the Joint Committee of the State Board of Medical Examiners and the Board of Nursing for Advanced Practice Nurses, including recommendations on prescriptive authority.⁶³ Protocols, as designed by the Joint Committee, consist of accepted procedures for advanced nursing practice.⁶⁴ They also include a list of thirty legend drugs that may be approved for the nurse practitioner to prescribe.⁶⁵ Each applicant must have an agreement with a collaborating physician on the precise legend drugs that the nurse practitioner will be allowed to prescribe as well as any procedures beyond the ones authorized by the Joint Committee, usually procedures of an invasive nature, that the nurse practitioner will be able to perform. Neither the collaborative practice specialty nor education seems to have any bearing on the Joint Committee's approval. The support of the collaborating physician appears

to be the deciding factor, except for invasive procedures. Here, the Joint Committee asks for validation of expertise.

The protocol application requires a specific plan for monitoring protocol compliance.⁶⁶ Monitoring, however, may be conducted primarily in-house by the nurse practitioner and collaborating physician, or by the collaborating physician alone. Criteria for monitoring are not specified on the protocols nor are practices routinely audited for compliance by the Board of Nursing or the Board of Medical Examiners.

Effectiveness of nurse practitioners

Over a 30-year period, several studies have been conducted to evaluate the effectiveness of nurse practitioners as providers of primary care. All of the studies have shown that nurse practitioners achieved clinical outcomes equivalent to physicians on most variables. Patients have given high satisfaction ratings regarding the technical competence of nurse practitioners. Patients have also shown more compliance with nurse practitioners' health care promotion/treatments than with some physicians'.⁶⁷ A recent study was conducted involving advanced practice nursing authority and prescriptive practice.⁶⁸ Data were analyzed on 1,708 patients over a 2-month period using twenty-five different primary sites in one state. In no instances were patients harmed by advanced practice nurses, and in the majority of cases, patients benefited. Ninety-eight percent of the patients were positive about their care. All of the collaborating physicians rated the prescriptive authority of advanced practice nurses as beneficial to their patients and their practice.

The American Academy of Nurse Practitioners has, for several years, declared the entry educational level of nurse practitioners to be the master's degree, with courses of study in pathophysiology and pharmacology to prepare them to diagnose and prescribe medications and treatments within their specialty area. The Academy espouses the following position:

The ability of nurse practitioners to prescribe, without limitation, legend and controlled drugs, devices, adjunct health/medical services, durable medical goods, and other equipment and supplies is essential to provide cost-effective quality health care for diverse populations across the life span.⁶⁹

Although nurse practitioners have been held accountable in the courts for scope of practice matters,⁷⁰ a Westlaw computer search, using descriptors "nurse practitioner," "pain management," and "prescribing," generated six cases, none of which named a nurse practitioner as the sole defendant or plaintiff at the trial level.⁷¹ Also, none of the cases actually referenced controlled substances or the prescribing practices of nurse practitioners.

In Alabama, nurse practitioners may prescribe unscheduled drugs that are in an approved protocol with a

collaborating physician and on the formulary adopted by the Board of Medical Examiners and Board of Nursing.⁷² To date, the Alabama Board of Nursing has had only one disciplinary case involving a nurse practitioner directly related to writing a prescription. In this case, the nurse practitioner was reported to the Board of Nursing by a pharmacist who was asked to fill a prescription for an agent containing a controlled substance.⁷³ Upon investigating the report, the nurse practitioner admitted to prescribing the drug, but denied knowing that the drug was on the controlled schedule. This situation, plus exchange of information with in-state nurse practitioner educators regarding how specific core curriculum is not defined, raises questions about the educational preparedness of nurse practitioners in pharmacology and prescribing practices.⁷⁴ Such questions parallel concerns about the quality of nurse practitioner preparation in other states, as the numbers of new programs have increased in recent years.⁷⁵ Similar concerns have also been expressed by the National Advisory Council on Nurse Education and Practice in its report to the Secretary of Health and Human Services in 1997.⁷⁶

ALABAMA NURSE PRACTITIONERS' EXPERIENCES IN RELATION TO COLLABORATIVE PRACTICE, PRESCRIPTIVE AUTHORITY, AND PAIN MANAGEMENT

Findings from a previous study conducted by the Alabama Board of Nursing indicated concerns expressed by the nurse practitioners that limited prescribing authority affected their ability to provide adequate pain management.⁷⁷ Collaborative practice limitations regarding the prescription of controlled substances have not, however, been empirically established as actual barriers to pain management. This issue, as well as other factors related to regulations and prescribing practices, was reintroduced in this project. One aim was to establish a foundation for monitoring and investigating prescriptive practices for pain management in the future.

Seventy-two percent ($n = 771$ of 1,065) of all Alabama-approved nurse practitioners at the time of the survey had specialties in family health, acute care, and adult nursing. Of those, 46 percent ($n = 356$ of 771) responded to a questionnaire on pain management and prescriptive authority in fall 2001. Results from this survey are reported below. Valid percents were calculated separately for each data item according to the number of responses (i.e., missing responses were not included).

RESULTS

Characteristics of the study group

Of 356 respondents, 344 provided information on their areas of specialty. Family nurse practitioners constituted the

majority of the sample at 252 respondents (73.3 percent of those providing information on their area of specialty); 51 (14.8 percent) practiced as adult health practitioners; and 41 (11.9 percent) accounted for the remainder in acute care. Respondents' educational level varied depending on the year that they were recognized as nurse practitioners. For instance, one held only the diploma from a noncollegiate program and was grandfathered in under current regulations from an earlier recognized certificate program. A small group held the bachelor's degree in nursing and a certificate. Of the 346 respondents who provided information on the type of degree they held, 311 (89.8 percent) held a master's degree in nursing; 278 (80.3 percent), in particular, held the Master of Science degree in nursing. Ten respondents (2.9 percent) held a doctorate in nursing. Forty-nine (14.1 percent) were prepared in programs that awarded certificates for preparation as nurse practitioners beyond their basic education and, in some cases, beyond graduate education.

Of the 289 respondents who volunteered additional information about their education, 57 (19.7 percent) held post-baccalaureate nonnursing degrees in addition to their nurse practitioner educational preparation.

A majority of the participants, 305 (or 87.6 percent of the 348 respondents who provided information about the states in which they acquired their educational preparation) attended educational programs in Alabama. The remainder, 43 (12.4 percent), attended one or more of twenty-four educational programs in other states.

Of the 346 respondents who reported their sex, 315 (91.0 percent) were female. The number of males, 31 (9 percent), corresponded closely with the total male population of registered nurses in Alabama.⁷⁸ The average age of nurse practitioners in Alabama was 43, slightly younger than the average age of the national working registered nurse population at 45.2.⁷⁹

Educational preparation of nurse practitioners

Five of six graduate nursing education programs in Alabama provided outlines of pharmacology courses or information about the pharmacological content included in their certified registered nurse practitioner curricula.⁸⁰ All five stated the curriculum required satisfactory completion of a course in pharmacology. Four of the five declared the inclusion of content in pain management, prescriptive authority and practice, and controlled substances. Additionally, the same four offered opportunities to practice writing prescriptions, including pain management agents, that were not on the controlled substance list.⁸¹

Findings revealed the educational preparation for pharmacology and prescriptive authority was fairly consistent with the degree received. Of the 355 who responded to this question, 317 (89.3 percent) stated they had completed individual courses in pharmacology. Chi-square was significant, $p =$

0.001, for respondents who stated their individual courses covered pain management, prescriptive authority, and controlled substances. A slight variance was noted in those who stated they had an individual course in pharmacology. Chi-square was significant, $p = 0.000$, in relation to the 306 of the 356 responding (86.0 percent) who said yes, and the 50 (14.0 percent) who indicated no.

Significant variance was noted in the participants' preparation for decision-making when working under protocols related to controlled substances. Of the 349 responding, 193 (55.3 percent) answered they had no preparation. The 156 (44.7 percent) who answered yes did not comment on whether their preparation was in formal class or in their preceptor experience.

When asked if their curriculum adequately prepared them for prescribing controlled substances for pain management, 194 of the 347 respondents to this question (55.9 percent) said yes, and 153 (44.1 percent) said no. Chi-square was significant, $p = 0.028$. Table 2 provides a summary of how the respondents rated their educational preparation in pharmacology for prescriptive practice.

The respondents practicing as nurse practitioners were asked to rate their educational preparation as very comprehensive, comprehensive, somewhat comprehensive, and inadequate. Although 196 of the 346 respondents to this question (56.6 percent) rated their preparation as comprehensive to very comprehensive, 63 (18.2 percent) stated their preparation was inadequate in preparing them to independently exercise prescriptive authority for controlled substances for pain management. Chi-square was significant, $p = 0.004$, in relation to those who indicated they had a comprehensive preparation versus those who did not. Examples of deficits in their curricula were given individually by 156 of 256 respondents. The major recurring deficits were identified as pain management protocols; controlled substances (pharmacodynamics); titrating dosages; acute versus chronic pain management; drug abuse, detection of drug abuse, and management of drug abuse; and prescriptive practice procedures.

Summative statements expressed the need to improve the curricula in the respondents' educational programs. Several were explicit in saying they needed more concrete facts on pharmacology and less on taking histories. Some stated that their instructor did not insure their competence and that the instructor was not current in pain management treatment. (This included using out-of-date references.) Some said they got most of their knowledge through drug representatives. Others indicated poor support from instructors who were pharmacists; one respondent commented that the instructor "made us feel like criminals regarding controlled substances." Respondents did make positive comments about their preceptors, collaborative physicians, and formal clinical experiences rather than their other curricula.

Continued competence is a concern to regulatory agencies. To this end, the survey asked respondents to describe their approach to continuing education for prescriptive practice, particularly as related to pain management (see Table 3).

The inquiry about continuing education revealed that 151 of the 348 who responded to this question (43.4 percent) obtained updates on current pain management and prescriptive authority practice through formal continuing education courses; however, the remainder of the respondents (the majority) stated they updated their knowledge through informal means. Of this group, 116 (33.3 percent) answered that they updated their knowledge of pharmacology and prescriptive practice informally with "no continuing education"; 68 (19.5 percent) answered "casually, through work-related literature or casual exchange." Four (1.1 percent) stated "rarely, through social exchange." Nine (2.6 percent) gave responses that were categorized as "other." Examples included methods such as research and formal academic study.

The rate of occurrence for updating their knowledge of pain management and prescriptive authority was fairly evenly divided between "more than annually" (123 of 349 respondents to this question, or 35.2 percent); "at least annually"

TABLE 2. ALABAMA NURSE PRACTITIONERS' CONSIDERATION OF THEIR EDUCATIONAL PREPARATION IN PHARMACOLOGY FOR PRESCRIPTIVE PRACTICE.

	RATING	FREQUENCY	VALID PERCENT
Valid	Very comprehensive	62	17.9
	Comprehensive	134	38.7
	Somewhat comprehensive	87	25.1
	Inadequate	63	18.2
	Total	346	100
Missing		10	
Total		356	

TABLE 3. METHOD OF OBTAINING CONTINUING EDUCATION ON PHARMACOLOGY AND PRESCRIPTIVE PRACTICE FOR PAIN MANAGEMENT.

	METHOD OF OBTAINING CONTINUING EDUCATION	FREQUENCY	VALID PERCENT
Valid	Formally, through continuing education courses	151	43.4
	Informally, no continuing education courses	116	33.3
	Casually, through work-related literature or casual exchange	68	19.5
	Rarely, through social exchange	4	1.1
	Other	9	2.6
	Total	348	100
Missing		8	
Total		356	

(95 respondents, or 27.2 percent); and “occasionally, as opportunities arise” (109 respondents, or 31.2 percent). Another 22 (6.3 percent) indicated they “seldom or never” updated their knowledge on pain management.

Collaborative practice and pain management

A majority of the respondents, 316 of 350 (90.3 percent), identified themselves as being in collaborative practice.⁸² When those in collaborative practice were asked if they believed that collaborative practice, as permitted by the regulations, was too restrictive to effectively manage pain for their patients, 164 of the 311 responding (52.7 percent) replied no. The remaining respondents said yes (147 respondents, or 47.3 percent).

When asked if a lack of prescriptive authority for controlled substances delayed treatment for management of pain, 258 of the 311 responding (83.0 percent) said yes; 53 said no. Of the 258 who reported delays, 150 (48.2 percent of the 311 respondents) reported brief delays; 83 (26.7 percent), moderate delays; 25 (8.0 percent), long delays.

The participants were asked what effect adding controlled substances to their prescriptive authority would have on patient outcomes. There were 314 responses given. Of these, 78 (24.8 percent) stated that adding controlled substances would greatly enhance outcomes; 114 (36.3 percent) evaluated the addition as moderately enhancing outcomes; 85 (27.1

percent) reported the addition as slightly enhancing outcomes; and 37 (11.8 percent) said there would be no effect on outcomes. Chi-square was significant, $p = 0.000$, regarding the outcomes on patients’ health.

Respondents were asked to report on what methods of pain management they used. As shown in Table 4, the methods included working under approved protocols with collaborating physicians, providing comfort measures, prescribing noncontrolled substances, and referring patients to physicians. Many respondents used more than one method.

Of the 356 respondents to the survey, 288 (80.9 percent) indicated they operated under protocols related to pain management that were established when they applied for collaborative practice. Of the 288 so responding, 149 (51.7 percent) stated the protocols for pain management were jointly developed between the collaborating physician and themselves; 54 (18.8 percent) reported by the physician alone; 38 (13.2 percent) said by themselves with the collaborating physician concurring; and 47 (16.3 percent) indicated other arrangements were made.

The respondents were asked to list the top five medications they prescribe for pain (controlled substances are not allowed by law to be prescribed by nurse practitioners in Alabama). The majority of the 304 responding, 243 (79.9 percent), listed a host of nonnarcotic agents prescribed, including Ibuprofen, Naproxen, Tylenol, Celebrex, and Vioxx

TABLE 4. METHODS OF PAIN MANAGEMENT EMPLOYED BY NURSE PRACTITIONERS LICENSED IN ALABAMA.

WORKING UNDER AGREED-UPON PROTOCOLS WITH COLLABORATING PHYSICIANS	PROVIDING COMFORT MEASURES	PRESCRIBING NON-CONTROLLED SUBSTANCES	REFERRING PATIENT TO PHYSICIAN
77.4% (n = 223/288)	94.5% (n = 259/274)	96.5% (n = 276/286)	81.2% (n = 212/261)

The figures shown represent the number of nurse practitioners who provided “yes” responses to each method that they used in managing pain as a percentage of those who said they did or did not use the particular method.

TABLE 5. DEGREE OF AUTONOMY EXERCISED IN PRESCRIBING MEDICATIONS BY NURSE PRACTITIONERS LICENSED IN ALABAMA.

	FREQUENCY	VALID PERCENT
No protocol exists for decision-making about controlled substances. Physician orders must be secured; no latitude is allowed.	144	47.8
Controlled substance is specified by the physician; protocols are dosage and route specific.	56	18.6
Controlled substance is specified; a dosage range and route are specified. The nurse practitioner exercises independent judgment on the specific amount within the range to be given and proceeds without consulting the physician.	32	10.6
Controlled substance and dosage range are specified; route for administration is left to the discretion of the nurse practitioner, who proceeds without consulting the physician.	5	1.7
Controlled substance is specified; dosage and route are left to the discretion of the nurse practitioner, who proceeds without consulting the physician.	18	6.0
Other	46	15.3
Total	301	100

as their top five. The remainder, 61 (20.1 percent), stated they ordered, with their collaborating physicians' approval, controlled substances ranging from schedules II to IV. The top ten scheduled medications "ordered" by these respondents were Lorcet, Lortab, OxyContin, Tylenol with Codeine, Barbitol preparations, Demerol, Morphine Sulphate, Vicoden, Stadol, and Mepergan (in-house only).

Data indicated that while the nurse practitioners stated they ordered the medications, some type of protocol was followed. For some, considerable latitude was allowed for the management of pain for their patients. Table 5 provides a breakdown of the responses regarding the autonomy exercised by the nurse practitioners.

As shown in Table 5, 144 of the 301 responding (47.8 percent) stated they do not operate under protocols but on physician orders for controlled substances, with no latitude given for prescribing the substance, dosage, or route of medication. All others have some latitude for making decisions about dosage and route for administration. For most, the controlled substance is physician-specified and protocols that are physician-developed are used by the nurse practitioner in making decisions about the range of dosage and route. Forty-six respondents (15.3 percent) provided other descriptions relative to autonomy exercised in managing pain. In general, these "other" comments showed that considerable latitude was given to the nurse practitioners, but in consultation with the physician. The consultation may have been retrospective. For instance, one said, "I make all decisions about the drug, route, frequency, amount dispensed, then my M.D.

writes the prescription for me." Another stated, "while no protocol exists, my request for specific controlled substances is almost always what we do. I cannot ever remember being overruled." "Protocols" were reported as both written and unwritten. Some stated that their collaborating physician left signed prescription pads for emergencies.

Barriers to pain management, as perceived by educators and nurse practitioners

Educators from nurse practitioner educational programs in Alabama were asked to provide, in addition to information about curricula, input regarding their perceptions about barriers to pain management. Three responded and listed the first barrier as restrictions that prohibit the prescribing of narcotic analgesics. This was clarified by one respondent, who stated, "Without the collaborating physician on-site, there are delays in securing medications for pain management." Collaborating physicians may practice at sites that are remote from their primary practicing location. Thus, physicians are not always on-site, nor readily available to respond to situations requiring direct intervention, such as acute pain management. Prescribing authority is limited by nursing regulations.⁸³ Another offered an aside: "Some physicians use unlicensed or non-specific credentialed persons to call in prescriptions due to the limitations on CRNP practice. This is not desirable [from] a public safety perspective."

Another barrier to practice listed was ineligibility for third-party reimbursement. This particular comment may

TABLE 6. TOP FIVE BARRIERS TO EFFECTIVE PAIN MANAGEMENT AS PERCEIVED BY ALABAMA NURSE PRACTITIONERS.

BARRIER	FREQUENCY	VALID PERCENT
Educational deficit	23	7.5
Denial of third-party payment	28	9.2
Physician resistance to prescriptive authority	35	11.5
Limitations on scope of practice	42	13.8
Restrictions by regulatory agencies: Boards of Nursing, Pharmacy, Medical Examiner	147	48.2
All others	30	9.8
Total	305	100

have merit when considering previous research⁸⁴ on lack of coverage by insurance companies related to treatment for pain.

We also surveyed nurse practitioners regarding their perceptions about barriers to pain management. Table 6 provides a summary of the top five perceived barriers. Barriers were primarily attributed to restrictions imposed by external sources, such as regulatory agencies that place limitations on the scope of authority for prescribing controlled substances. However, qualitative analysis revealed that some barriers were primarily intrinsic. For instance, approximately 50 percent of the respondents indicated hesitancy to assume independent responsibility and accountability for prescribing controlled substances. Chi-square was significant, $p = 0.051$, when cross-tabulating the degree of autonomy allowed in use of protocols with adequacy of preparation to independently assume responsibility and accountability for prescribing controlled substances for pain management. Reasons varied for those who responded "other." Among the most prominent were lack of preparation and experience in educational programs, a need for updated protocols, fear of liability, and curriculum deficits in areas such as chronic pain management.

Legal scope of practice for prescriptive authority

The nurse practitioners were asked to provide information about potential or actual violations of the legal scope of practice in relation to prescriptive authority and other relevant data. There were 314 respondents who had observed their colleagues operating outside the lawful scope of practice. Forty-eight (15.3 percent) stated they were actually aware of nurse practitioners who went beyond their approved scope of practice. Fifty-three individual comments were made about infractions. Most involved exceeding the scope of authority on prescriptive practice for controlled substances for pain management. In such cases, the collaborating physician was implicated. Examples were cited in which the collaborating physician signed a blank prescription pad to cover emergencies in pain management. Others called in prescriptions using the physician's Drug Enforcement Administration number.

Other infractions were noted, including distributing samples without written prescriptions.

When asked if they believed practicing outside one's scope of practice was necessary for effective pain management, 220 of the 302 responding (72.8 percent) said no; and 82 (27.2 percent) said yes. A significant association was determined, $p = 0.000$, when cross-tabulating the quantitative results with those related to an inquiry about whether operating outside the scope of practice could cause harm to the public. Of the 290 responding, 190 (65.5 percent) said that exceeding the legitimate scope of practice could result in potential harm. Qualitative responses were unique. While the questions addressed potential harm to the public, responses primarily specified potential harm to the nurse practitioners' professional well-being. Legal liability plus the potential for having charges brought (even without harm to the patient) could negatively affect their colleagues and the profession. For example, one respondent wrote, "not specifically a harm to the public but very definitely potential harm to CRNPs' license and ability to practice at all." Other comments focused on how nurse practitioners did not feel adequately prepared to do more than they were doing for pain management (e.g., "Since CRNPs are not fully educated regarding the use of controlled substances, they may be inappropriately prescribing, ultimately causing potential harm.").

When asked if they believed whether a nurse practitioner should be subject to disciplinary action by the Board of Nursing for operating outside his or her scope of practice, 203 of the 267 responding to this question (76.0 percent) stated yes. A majority commented that nurse practitioners should function within the law, but they declined to readily invite the board's intervention. For instance, one said, "These matters should be settled between the CRNP and the physician." Another said, "I believe a 'warning' should be given and this should suffice. The Board of Nursing has never proven to be 'trustworthy' or 'working nursing' friendly in my personal experience. The [Board of Nursing] seems to be too eager to discipline and not eager enough to be supportive and understanding!!!"

The 82 respondents who stated that practicing outside one's scope of authority was necessary for pain management

provided 108 qualitative responses to clarify or amplify their position. A majority of these said they deferred to the law but had concerns about the inadequacy of treatment. A few admitted to ordering drugs and then getting physician coverage. One clarified his or her practicing outside the scope: "As explained above, let me reinforce that when I do this, I make every effort to inform the [doctor] ASAP. All [doctors] that I have dealt with are supportive in this practice. Most have difficulty understanding the limits placed on my practice." Another commented, "The scope and prescriptive authority need to be changed. I cannot do all for my patients and give maximum care with my hands tied in pain management."

The respondents who did not believe nurse practitioners should operate outside their practice expressed concern about abiding by the law, but they also worried about their patients' well-being. One stated, "Legalities force me to stay in my scope." Another stated, "As it stands now in Alabama, [nurse practitioners] don't even have narcotic analgesics as an option. I see patients who need better 'narc' control, but am not allowed to provide due to physician's legal concerns — directly due to recent Oxycontin concerns." Another said, "I do not prescribe outside my scope of authority, but it is sometimes hard to sleep at night when I know that my patients are not getting enough to relieve their pain."

Some indicated that the addition of drugs, previously unscheduled, to scheduled lists have impaired their pain management drastically. Another pointedly implicated a major insurance company and the medical association: "The biggest barrier in the state is BlueCross BlueShield and the Alabama Medical Association." Still another said, "It may be in the patient's best interest for a [nurse practitioner] to practice outside the scope of practice. That makes a major catch 22 for the patient and the [nurse practitioner]. Currently there is no right answer." Another stated, "I think CRNPs are doing their best to provide care to patients. The legal rules always lag behind practice in this state. CRNPs have always practiced beyond their scope of authority in the state." Some admitted there are times the Board of Nursing should intervene: "Situationally[,] based on what is done, the harm caused, and how far outside the scope of practice." Another capped it by saying, "What is the point of a rule if it is not enforced." This was reinforced by one who said, "We must have a governing body that is in place to provide a clear scope of practice and who protects the public."

Although 203 of 267 respondents supported disciplinary action by the Board of Nursing, 196 of 270 respondents (72.6 percent) also stated there are incidents in which leniency should be granted. Chi-square was significant, $p = 0.002$, for those who supported disciplinary action to those who perceived a need for leniency. Qualitatively, this group described a need for case-by-case consideration based on the circumstances, education of the nurse practitioner, the type of practice, the role of the collaborating physician, patient

harm, isolated versus repetitive situations, and whether there was any substance abuse involvement.

Only 6 of 312 respondents reported that they had been involved in a disciplinary process. Three reported having been named in a malpractice suit. Only one of these cases also involved the physician. The same case also resulted in disciplinary action by a governmental agency. Chi-square was not significant relative to education, or nurse practitioner or pharmacology preparation, regarding those who had disciplinary action relative to pain management preparation.

Monitoring and investigating of nurse practitioners in pain management

In this section, we address monitoring as a means of promoting compliance with laws and regulations that affect pain management. A brief synopsis of the "state of the states" on monitoring by boards of nursing is included. Results are then presented from interviews with investigators for the Alabama Board of Nursing and the Board of Medical Examiners that focused on monitoring and investigative procedures regarding prescriptive authority. These findings are then linked to perceptions of the Alabama nurse practitioners on accountability and quality assurance for pain management.

State of the states and monitoring for compliance with prescriptive authority

Thirty-five of 50 state nursing boards regulating registered nurses responded to an e-mail inquiry regarding monitoring processes for prescriptive practice.⁸⁵ Twenty-eight of the respondents indicated that they do not have a formal monitoring program. Six specified that they act primarily on complaints. West Virginia reported plans to initiate, in February 2002, an on-site audit program involving random sampling of advanced practice nurses to determine conformity of collaborative practice agreements with actual practice in prescriptive authority.⁸⁶ Idaho also indicated plans for an audit program to begin in 2002. Both of these programs will be subject to evaluation.

Interviews with Board of Nursing investigators

Three Alabama Board of Nursing investigators were interviewed based on fifteen questions related to the investigative process and monitoring for prescriptive practice compliance.⁸⁷ An introductory statement as to the purpose of the project was provided by the interviewers. The investigators collectively accounted for ten cases over the past 7 years that involved nurse practitioners. Six of the cases had been investigated in the years 2000–2001; three in the past 6 months. They described their roles in the investigative process as follows: The process is initiated with the receipt of a complaint. Typically, complaints are generated from a variety of sources, such as an anonymous call, sometimes a dissatisfied patient,

spouse, physician, or pharmacist. The individual reporting the concern or complaint is asked to submit the complaint in writing (no name is required). When the complaint is received in writing, it is docketed and an investigator is assigned to the case. In cases involving drugs, whether for abuse or violation of prescriptive authority, a subpoena is issued for a prescription profile. Once the profile is received from the pharmacy, a determination is made as to whether a patient's medical record is required for additional investigation (if it is a legitimate patient). Illegal prescriptions are sometimes written for friends, and in these cases there may be no medical records to review. If required, the nurse is interviewed. Upon completion of the investigation, the findings of fact are submitted to the board's legal counsel (the state assistant attorney general) for review and recommendations, including possible prosecution. The investigation may be extended if legal counsel perceives a need for additional information.

The desirable outcome of the investigation was described as assuring that facts and evidence are properly documented so that the complaint can be substantiated or disproved. In cases that related to the prescriptive authority of nurse practitioners, investigators indicated a need to assure that all individuals responsible for the nurse's practice are interviewed, including the collaborating physician.

Violations by nurse practitioners that required investigation included treating a patient without the physician's knowledge; exceeding the scope of practice in prescribing; acts of omission, such as failing to adequately assess a patient's condition; and failing to keep up-to-date knowledge of drugs.

The investigators emphasized that in their view the Board of Nursing does not adequately monitor prescriptive practice in pain management. One stated, "We just wait for the complaint; then when we do get the complaint, we must wait until it is submitted in writing." "The only way we monitor CRNPs is on application for approval [of the collaborative practice] or complaints from another source."

Another investigator stated:

When working cases, the CRNPs just seem to be out there working without specific protocols being followed. They seem to be doing what they do with or without a physician. When reviewing data related to a complaint you can find incomplete information on the prescription; an example of this would be the physician not signing off on the prescription; however, I haven't seen an overwhelming amount of complaints regarding CRNPs and prescriptive authority. We don't know, they may or may not be going by the book. There is not enough monitoring to know.

Still another of the investigators stated, "We have to depend on somebody else to let us know what is being done." For instance, a case was being investigated on one of the

alternative disciplinary participants⁸⁸ whose drug screen was positive. The outcome was that another nurse practitioner had prescribed phenobarbital for her. The nurse allegedly did not know that the drug was on a controlled substance schedule.

Each investigator had stories relative to problems arising out of collaborative practice. In one case, a nurse practitioner was having a relationship with the collaborating physician that had ended. This also ended the collaborative arrangement, yet she continued to practice. Investigators reported that in two cases, physicians were not cooperative about providing patients' records. In other cases, physicians claimed that they did not know of problems with the nurse practitioner. One of the investigators described a situation with "out the back door" treatment. The nurse practitioner was writing prescriptions using the physician's signature for friends without making a record. Apparently, a pharmacist became suspicious and reported his concern to the Board of Nursing.

The investigators described the greatest barrier to conducting an investigation as the inability to obtain records in a timely manner, or even at all. One stated, "It is very hard getting national pharmacies to release records even when subpoenaed." The locally owned pharmacies usually provided a rapid response, but apparently the national pharmacies have considerable steps to go through before releasing the records, even under subpoena. Also, obtaining records from physicians sometimes proved difficult in that the physicians do not wish to be involved. Board of Nursing investigators must have a specific patient's name to issue a subpoena. Nurse practitioners have been equally uncooperative. At times, the Board of Medical Examiners and the Board of Nursing investigators have been able to work together when both a collaborating physician and nurse practitioner were jointly implicated.

When asked if the Board of Nursing was addressing the magnitude of violations regarding prescribing controlled substances in collaborative practice, one stated, "yes, all allowed by the law." Two others expressed that "we have not touched the tip of the iceberg." One was highly supportive of having a monitoring system; "We could try it at least. We have nothing now." Another was cautious, saying, "It would be good to find out if a true problem exists."

Two of the investigators did not perceive their role as one of quality monitoring. The third was open to this role, saying, "Quality management would mean everyone would have to work close together as a team; we would have a more thorough process; we could concentrate on specific assignments/tasks and not have to try and look at the entire picture with every violation."

When asked if a formal continuous monitoring process was needed, two of the investigators again asked if a true problem exists. All three of the investigators stated emphatically that they believed that extending prescriptive authority

for controlled substances would create more problems for public safety and welfare.

The investigators delineated operational necessities for effective monitoring of prescriptive practice in collaborative arrangements, such as authority to review medical files; obtaining pharmacy records in a timely manner, preferably without subpoenas (this one was clarified as requiring legislative authority to act); authority to interview both the physician and nurse practitioner if needed; and having interstate sharing on complaints.

Investigators also thought it would be necessary to inform/teach collaborative physicians about collaborative practice; require nurse practitioners to follow specific/proper protocols; establish proper protocols; and do random checking to determine if physicians and nurse practitioners were following protocols (e.g., surprise visits to check records).

Interviews with Board of Medical Examiners investigators

Five of the six Alabama Board of Medical Examiners investigators participated in a group interview, with questions from the interviews with the Board of Nursing investigators modified to accommodate the collaborating physician role.⁸⁹ The investigators concurred that they had investigated only four complaints involving controlled substances and prescriptive authority by nurse practitioners in collaborative practice since 1995. One investigation was currently in process. In all cases, the investigators contacted the Board of Nursing and reported the nurse practitioner's involvement. The Board of Nursing assumed responsibility for investigating and taking action against the nurse practitioners involved in the case, while the Board of Medical Examiners continued the investigative process involving the physicians. One of the four complaints was settled informally due to insufficient evidence to file a formal complaint. In another case, charges were brought against the physician and the nurse practitioner by their respective boards. In another, the Board of Nursing revoked the nurse practitioner's license. Action against the physician was reserved due to his leaving the state. The third case was continued. All of the cases involved violations of prescriptive authority, such as forging prescriptions, altering prescriptions, and using presigned prescriptions. In two cases, the physicians were implicated in condoning the practice. Another did not provide appropriate supervision.

According to the investigators, when the investigation exhausts all leads and there is sufficient evidence to establish probable cause, the case is presented to the Board of Medical Examiners. The board may then seek consultation from the Joint Committee for additional information or clarification regarding the collaborative practice. Final actions are delivered by the board.

Although the Board of Medical Examiners investigators stated that they investigate every complaint they receive, they

do not believe that their board or the Board of Nursing are adequately monitoring prescriptive practice in pain management. One of the investigators put it this way: "We don't have a firm handle on pain management. Only one in ten physicians strictly follows the pain management guidelines."⁹⁰

All of the investigators agreed that there is a need for a formal continuous monitoring process for case detection, but cited lack of manpower as a deterrent to instituting such a program. They generally conceded that having a quality monitoring system may help capture violations relative to prescriptive practice of controlled substances in collaborative practice.

When asked how they perceived their role in implementing a quality management system, two of the investigators said almost simultaneously that the role of their board and the Board of Nursing is regulatory. As such, the monitoring role would essentially be investigative. For that reason, the quality management program for compliance would fall under their jurisdiction.

The investigators delineated components and methods essential for instituting a quality management program. These included sufficient finances to provide equipment (e.g., computer hardware), personnel sufficient to support the investigative staff, and increased numbers of investigators to implement the program. Paramount to the program would be having legislative authority with rules and standard operating procedures to carry out the program efficiently and effectively. The investigators specified that the necessary personnel would possess investigative knowledge and experience, and possibly have a medical background.

The investigators stated emphatically that the Board of Nursing investigators were severely restricted in their ability to do a good job because they did not have the legislative authority to access records without subpoena. The investigators saw a need for conducting a shared program in monitoring as long as collaborative practice exists. As with the Board of Nursing investigators, these investigators were strongly opposed to granting nurse practitioners prescriptive authority for controlled substances.

Nurse practitioners' perceptions about monitoring and accountability

Opinions from the nurse practitioners in our survey regarding compliance monitoring were generally positive. Of the 283 respondents who expressed an opinion, 226 (79.9 percent) supported mandatory monitoring for quality control in the event that prescriptive authority for controlled substances should be granted. Numerous comments were given relative to how the monitoring should be conducted. The most common approaches were monitoring by the Drug Enforcement Administration; holding the collaborating physician accountable; Board of Nursing programs; and self-regulation by the nurse practitioners themselves. Several made a point of say-

ing that monitoring should be conducted by random sampling. Some were explicit in procedural options, such as making copies of all charts, computer tracking of prescriptions, and chart audits.

Three questions were asked of survey participants relative to accountability:

- For what should boards of nursing be held accountable in regulating pain management?
- What are concrete ways for a state board of nursing to promote quality of care in pain management?
- For what should the nurse practitioner be held accountable?

Certain themes dominated the responses to the first question about board accountability for pain management. Respondents said that the boards of nursing should be accountable for regulation of prescribers, including establishing laws and rules for qualifications (with background checks); compliance evaluation and monitoring; and discipline for failure to comply. Respondents stated that the boards should establish standards for education programs and require continuing education for nurses to update their knowledge on prescriptive authority and pain management; monitor prescriptive practice through audits, site visits, and random sampling; and establish protocols for pain management, including meeting national standards for pain management.

Regarding the second question, qualitative comments were received from 279 respondents, each specifying concrete ways for a board of nursing to promote quality of care in pain management. Six themes emerged that corresponded, from an operational perspective, with the areas for which the respondents thought the boards of nursing should be held accountable. Respondents recommended that the board should require continuing education in pharmacology, pain management, and prescriptive authority, with a mandate for updating pharmacology knowledge on an annual (or more frequent) basis. They also believed that the board should make classes available, as well as develop standard protocols, for pain management and prescriptive practice in controlled substances for physicians and nurse practitioners. Respondents desired specific guidelines for the substances allowed and the appropriate dosage and refill amounts in relation to specific conditions. Respondents called for the board to endorse pain management protocols developed by national regulatory boards. Several specified that the boards of nursing should be responsible for monitoring compliance with the guidelines. Respondents thought the board should improve formal education in prescribing in the nurse practitioner curricula, including a standardized curriculum. Respondents suggested that their state board allow nurse practitioners the full range of prescriptive authority to treat pain. This would align Alabama's regulations with those of other states. Respondents also argued that the board should use progressive disciplinary measures for violations.

In response to the third question regarding accountability by nurse practitioners, 262 respondents provided written comments. Major themes included upholding standards of care; working within protocols of collaborative agreement; relieving pain for patients; protecting patients from harm; and maintaining and updating knowledge through continuing education.

A few respondents commented that it is the nurse practitioner who is accountable for his or her practice, not the Board of Nursing. Numerous other comments, however, placed joint accountability on the practitioner and others, such as the Board of Nursing. Three independent comments demonstrate this point. They also corresponded well with the Board of Nursing's Accountability Model:

All treatments rendered by the CRNP are her/his responsibility. [The] Board of Nursing can set minimum requirements in education and continuing education for pain management and controlled substances, but practice should be up to the CRNP and her/his collaborating physician. Prescribing controlled substances should be allowed for complete care to the patient.

The CRNP should always be held accountable for his/her actions. I believe the employing agency should be responsible/accountable for teaching and regulating pain management.

CRNP: Continuing education and literature review. Board of Nursing: provide update on new meds.

DISCUSSION AND CONCLUSIONS

This project was initiated as a result of the Alabama Board of Nursing's interest in assuring competent pain management and compliance by advanced practice nurses with regulations for prescriptive authority in collaborative practice.

The survey results support recommendations that boards that regulate advanced practice nurses direct considerable attention to bringing about improvements in curricula in the area of pain management. We further recommend that all boards that regulate advanced practice nursing become proactive in mandating continuing education in prescriptive practice, including knowledge of pharmacology that affects pain management. The survey data indicate that nurse practitioners are concerned about the well-being of their patients, and that a majority of the nurse practitioners in the study are willing to be accountable for their actions either jointly with other stakeholders or individually.

This project revealed minimal published data on monitoring and investigation processes employed by other boards of nursing. Data obtained by the brief informational e-mail

survey indicated that few boards of nursing have formal monitoring systems in place to determine compliance with practice protocols, including those protocols with prescriptive authority. All respond only to complaints of potential statutory violations. Further research is recommended in the area of monitoring.

The current monitoring of certified registered nurse practitioners in Alabama is limited to the biennial monitoring of continuing education compliance, reviewing of credentials and protocols during the application process for approval to practice, and conducting an investigation when a complaint specifying a potential violation is received. Monitoring for compliance with prescriptive authority is complaint-driven. Given the responses of the Alabama nurse practitioners in our survey and the statements of the investigators from the Board of Nursing and the Board of Medical Examiners, careful consideration should be given to state boards' instituting a monitoring system to determine compliance with protocols for collaborative practice. An analysis of the cost to the potential return on the investment should be considered, including the likely manpower allocations that would be needed to execute a monitoring system. Potential advantages of such a program should be weighed against potential disadvantages. Already there is an admitted undertreatment of pain due to a fear of regulatory intervention into medical practice. Also, questions are asked about the need to have another overseeing agency monitor the practice of health care providers when considerable effort is already extended in documentation of prescribed controlled substances to meet federal Drug Enforcement Administration mandates and those of accrediting bodies for quality management that address pain management. Questions are also raised about invasions of privacy and of professional practice without cause.

The primary investigation process used by state regulatory agencies is complaint-driven. While concern is expressed for assuring that patients receive quality treatment, the primary focus of the regulatory agencies has been on assuring compliance with controlled substance regulations. Now, a new focus is developing for assuring compliance with pain management policies.

A number of problems were identified in the investigation process when complaints involve collaborative practice. The most frequently mentioned problem was the inability to obtain the records essential to building a case for adjudication. This has occurred because of a lack of cooperation from physicians and nurse practitioners. Health care organizations and corporate pharmacies were also implicated in causing delays due to legal or administrative barriers restricting immediate release of records, even under subpoena. Investigators reported collusion between collaborating physicians and nurse practitioners when investigations were conducted that involved nurse practitioners operating outside the scope of authority or beyond the accepted standard of practice for protocols. Securing sufficient evidence to sub-

stantiate complaints regarding nurse practitioners' prescriptive practice was also described as a problem.

The solutions offered to address these problems ranged from "trying" a quality monitoring approach to securing legislative approval for obtaining records expediently and unannounced. The latter was described as essential. Developing a shared responsibility between the Board of Medical Examiners and the Board of Nursing in planning and implementing a structured monitoring and investigative program was also recommended. Although restrictive, the investigators of both boards definitively opposed extending prescriptive authority for controlled substances to advanced practice nurses.

Over the last 30 years, the effectiveness of nurse practitioners has been established in terms of clinical outcomes and patient satisfaction. This study confirmed the belief, identified by previous studies, that the lack of prescriptive authority has delayed patient treatment for pain. However, this study also showed that almost half of Alabama nurse practitioners did not feel adequately prepared by their educational programs for prescribing controlled substances for pain, and currently there is inconsistency in the methods by which nurse practitioners update their knowledge of pain management. Many nurse practitioners did feel a high degree of collaboration and autonomy in their practices and did not feel they would need to practice outside their scope of practice to adequately address patients' pain. The investigators from the Board of Nursing and the Board of Medical Examiners indicated that the current state of events does not allow for quality monitoring, as investigations are complaint-based only. However, the majority of nurse practitioners welcomed increased quality monitoring should prescriptive authority for controlled substances be granted.

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32. G.D. Sherwood et al., "Defining Nurse Practitioner Scope of Practice: Expanding Primary Care Services," *The Internet Journal of Advanced Nursing Practice*, 1, no. 2 (1997), at <<http://216.39.195.244/ostia/index.php?xmlFilePath=journals/ijanp/vol1n2/scope.xml>>.
33. M.L. Gray, "Advanced Practice Nursing Roles: Preparation and Scope of Practice," in N.L. Chaska, ed., *The Nursing Profession Tomorrow and Beyond* (Thousand Oaks, California: Sage Publishers, 2001): 515–26, at 517.
34. Crawford et al., *supra* note 15.
35. C. Curtis, *The ABC's of Advanced Practice Nursing*, Wild Iris Medical Education Website, available at <<http://www.nursingceu.com/NCEU/courses/advpraccc/>> (last visited April 3, 2002).
36. *Id.*
37. W.Y. Carson, American Nurses Association, *2000 Prescriptive Authority Chart* (revised February 1, 2000), available at <<http://www.nursingworld.org/gova/charts/dea.htm>>.
38. Spratley et al., *supra* note 14.
39. Gray, *supra* note 33, at 518.
40. Curtis, *supra* note 35.
41. Crawford et al., *supra* note 15.
42. Curtis, *supra* note 35.
43. P.A. Kalish and B.J. Kalish, *The Advance of American Nursing* (Boston: Little, Brown and Company, 1978): at 660.
44. Sherwood et al., *supra* note 32.
45. Gray, *supra* note 33, at 520.
46. National Advisory Council on Nurse Education and Practice, *Report to the Secretary of Health and Human Services: Federal Support for the Preparation of the Nurse Practitioner Workforce through Title VIII* (Rockville, Maryland: U.S. Department of Health and Human Services, Health Resources and Services Administration, 1997): at 14–15. See also Crawford et al., *supra* note 15.
47. Safriet, *supra* note 18, at 417.
48. Gray, *supra* note 33, at 517.
49. *Sermchief v. Gonzales*, 660 S.W.2d 683 (Mo. 1983).
50. Kelly and Joel, *supra* note 29, at 476–77; C.P. Cournoyer, *The Nurse Manager and the Law* (Rockville, Maryland: Aspen Publishers, 1989): at 118.
51. Cournoyer, *supra* note 50, at 109.
52. National Council of State Boards of Nursing, *supra* note 17, at 230.
53. *Id.* at 241.
54. Carson, *supra* note 37.
55. Ala. Code § 34-21-81 (4)(a) (2002). Nurse practitioners in Alabama demonstrate by certification the "advance knowledge and skills" necessary for "consultation, collaborative management, or referral as indicated by the health status of the client" and thereafter practice as certified registered nurse practitioners.
56. Peine, *supra* note 13, at "Historical Background." In this section, a historical background is given relative to the Controlled Substances Act (1970) and subsequent regulations.
57. "Collaboration and Independent Practice: Ongoing Issues for Nursing," *Nursing Trends and Issues* (column), *Nursing World*, 3, no. 5 (May 1998), available at <<http://www.nursingworld.org/readroom/nti/9805nti.htm>>.
58. Carson, *supra* note 37.
59. *Id.*
60. Ala. Code § 34-21-80 (2002).
61. Ala. Admin. Code r. 610-X-9 (2002).
62. Ala. Code § 34-21-81 (8) (2002).
63. Ala. Admin. Code r. 610-X-9 (2002).
64. Alabama Board of Nursing, *Application for Approval to Practice as an Advanced Practice Nurse in Alabama* (December 2002), available at <<http://www.abn.state.al.us/downloads/applications/apn-1.pdf>>.
65. *Id.* The list of approved legend drugs for consideration by the Joint Committee for nurse practitioners to prescribe is as follows: antihistamine and decongestant drugs; analgesics and antipyretics; blood derivatives; coagulation agents; central nervous system agents; agents of electrolytic, caloric, and water balance; expectorants and cough preparation; gastrointestinal drugs; prosthetics/orthotics; local anesthetics; pulmonary drugs; spasmolytics; vitamins; antiinfective agents; autonomic drugs; blood formation; cardiovascular drugs; diagnostic agents; enzymes; ophthalmic drugs; antiinflammatory drugs; hormone and synthetic substitutes; birth control drugs and devices; serums, toxoids, and vaccines; antineoplastic agents; heavy metals; radioactive agents; gold compounds; oxytoxics; and an "other" category.
66. Alabama Board of Nursing, *supra* note 64.
67. Sherwood et al., *supra* note 32.
68. A.B. Hamric et al., "Outcomes Associated with Advanced Nursing Practice Prescriptive Authority," *Journal of American Nurse Practitioners*, 10, no. 38 (March 1998): 113–118, at 118.
69. American Academy of Nurse Practitioners, *Position Statement on Nurse Practitioner Prescriptive Privilege* (revised 2002), available at <<http://www.aanp.org/NR/rdonlyres/endrj7vquyvfoiqes72iehws4trvz43ualmwdmkmn6qrnidad62mapicxl5zcortuqv2pghxohzte/Position%2bStatement%2bPrescriptive%2bAuthority.pdf>>.
70. Carson, *supra* note 37.
71. A Westlaw search of the ALLSTATES and ALLFEDS databases was conducted by the Alabama State Supreme Court Library research attorney on January 11, 2002, using the following: Nurse =2 Practitioner/P Prescript! "Pain Management".
72. Ala. Code § 34-21-86 (a)(1–2) (2002).
73. Personal communication from Alabama Board of Nursing and Alabama Board of Medical Examiners investigative staff regarding a case under investigation (November 2002).
74. "We met with about 15 CRNP educators. They wanted the Board to do something about third party payment. They wanted to talk about barriers to practice but they did not have a core curriculum...." Comment made by N.G. Lee, executive officer of the Alabama Board of Nursing, in her March 21, 2001 report to the board at its March 21–23, 2001 meeting.
75. Sherwood et al., *supra* note 32.
76. National Advisory Council on Nurse Education and Practice, *supra* note 46, at 23.
77. C.J. Dickson and J.B. Mann, *Nurse Practitioners in Alabama, A Synthesis of Perceptions of Role and Regulatory Accountability*, Concurrent Educational/Research Sessions, (Chicago: National Council of State Boards of Nursing, 1995): at 163–203.
78. J.B. Lazarus and N.G. Lee, *Alabama Board of Nursing*

Initial Report Findings of the RN Workforce 2000 (Montgomery: Alabama Board of Nursing, 2000), report presented at the *Alabama Board of Nursing Regulatory Invitational Summit*, Prattville, Alabama, October 19, 2001.

79. Spratley et al., *supra* note 14.

80. This information was obtained from an Alabama Board of Nursing survey conducted in October 2001 of those educational programs offering master's degrees with specialties for family nurse practitioners, adult nursing practitioners, and acute care practitioners. While eight educational institutions offer master's degrees with nurse practitioner tracks, only six offer the specialties described. Due to assurances of confidentiality, neither the programs nor their respondents are named.

81. While the curriculum plans stated that there were clinical experiences in prescriptive practice, individual respondents, in their qualitative responses, commented that their clinical experience was conducted under preceptors and not instructors. Some indicated that their courses were taught online rather than in the classroom or a clinic.

82. Several of the nurse practitioners indicated they were not in collaborative practice at the time of the survey. Reasons were not given; however, when nurse practitioners seek a new collaborative practice, application for approval must again be requested from the Board of Nursing. The request must again be processed through the Joint Committee.

83. This is technically correct. The Alabama Administrative Code, r. 610-X-9, specifies collaborative practice parameters for physicians and nurses.

84. Hoffmann, *supra* note 10.

85. E-mail survey, Alabama Board of Nursing (December 18, 2001).

86. Information provided by Cyndy Haynes, director of education and practice, West Virginia Board of Examiners for Registered Professional Nurses (January 22, 2002).

87. *Interview Guide for Investigators* (November 2002):

What is needed to improve the investigative process of the Alabama Board of Nursing when collaborative practice is required for prescriptive practices relative to pain management?

1. How many incidents or complaints have you investigated that involve any aspect of prescriptive practice of CRNPs?
2. What does the investigative process involve? (steps, methods)
3. What outcome must be produced in the investigative process?
4. What was the nature of the complaints?
5. Do you perceive that the Board of Nursing is adequately monitoring prescriptive practice in pain management?
6. Why or why not?

7. Did any problems arise specific to the investigations as related to collaborative practice?

- Non-specific protocols
- Practicing beyond the scope of practice
- Both physician and nurse were noncompliant
- Physician's privileges for prescribing controlled substances, asking CRNP to exceed protocols
- Physician is uncooperative on investigation
- Not reporting of noncompliance
- Patient came to harm, no cooperation from agency, physician or nurse in providing data
- Unavailability of records
- Inadequate records
- Other

8. What barriers have you encountered in conducting investigations involving collaborative practice for prescriptive practice in pain management?

9. Are we as a regulatory agency addressing the magnitude of violations of legally authorized prescriptive practice of controlled substances in collaborative practice?

10. Would, in your opinion, having a quality management system in place help capture violations?

11. How would you, as an investigator, perceive your role in implementing a QM [quality management] system?

12. Is a formal continuous monitoring process needed for case detection?

13. What components and methods are needed to institute such a process?

14. Do you believe that extending prescriptive practice for controlled substances to CRNPs will compound problems of regulation for public safety and welfare?

15. If you could design a plan for effective monitoring of prescriptive practice in collaborative practice, what would you include?

88. "Alternative disciplinary participants" are nurses enrolled in an alternative disciplinary program who have voluntarily acknowledged substance abuse or a physical or mental condition rendering them unable to meet the standards of the nursing profession, and are monitored without their licenses being placed on probation or revoked subsequent to § 34-21-25(j) of the Alabama Code (2002).

89. The interview with the Board of Medical Examiners investigators was conducted on January 16, 2002.

90. The guidelines being referenced are the "Guidelines for the Use of Controlled Substances for the Treatment of Pain," Ala. Admin. Code r. 540-X-4-.08 (2002). The investigator who made this comment specifically monitors for compliance with the protocols and uses a standard questionnaire.