

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.*