

PUBLIC REGULATION AND PARADIGM SHIFTS

OPIOID USE IN THE UNITED STATES

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Throughout history, opioids have been linked to both great efficacy and tragic misuse. Can we find a way to dispel irrational fears about these agents while promoting caution?

The great 17th century physician, Thomas Sydenham, once wrote, “among the remedies which it has pleased Almighty God to give to man to relieve his sufferings, none is so universal and so efficacious as opium.”¹ To this day, opioid medications remain the most effective agents available for treating severe pain.

History also shows, however, that opioids are not a panacea for all pain problems. Opioid resistance is known to occur in both cancer and noncancer pain.^{2,3} Furthermore, the drugs’ tendency to produce dependence with prolonged use gives rise to a host of medical, social, and economic problems. Aside from the impact on the individual, which can be devastating, the societal costs of

opioid dependence (such as its long association with increased criminal activities) are high.⁴

Despite more than 100 years of evolution, regulations governing the use of opioid medications in the United States have failed to curb abuse. According to 1999 National Institute of Drug Abuse data, of the approximately four million people aged 12 years and older in the United States who used prescription drugs nonmedically in the month prior to the survey, nearly two thirds misused pain relievers.⁵ And opioids continue to be diverted from authorized channels by various means, including forgery, theft, and fraud.

At the same time, these regulations may form an impediment to optimal pain management.⁶⁻⁸ Allegations of overprescribing controlled medications, such as opioids, have been a leading cause of the investigation and punishment of physicians by medical boards over many years.⁹ As a result of the fear of such punishment, many health care providers shy away from the use of opioids for pain control.⁶

Considering the public impact of undertreated pain on the one hand and opioid misuse on the other, a delicate balance between prohibition and availability of this medication class is necessary. In order to strike such a balance, however, it’s important for those who play a role in setting policy to understand the ways in which, over the past century, opioid regulations have influenced societal behavior, expectations, and norms—and, conversely, how societal value systems have determined the direction of opioid control.^{10,11} This article briefly examines the history of public opioid regulation in the United States as it affects pain control, with a view toward guiding future policies.

EVOLUTION OF FEDERAL REGULATIONS

The evidence for opium use dates back to the Assyrian poppy art from the fourth millennium BC. The Sumerians cultivated the poppy plants and isolated opium from the capsule of the seeds.¹² There also are references to opium use in the histories of ancient Egypt, Europe,

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India, and China. It was administered for several medical reasons, including the treatment of pain, diarrhea, and respiratory disorders. It was also used as a means of enhancing social interactions.¹³

In the United States, opium smoking became more visible in the mid 19th century due in part to the immigration of Chinese laborers. The practice eventually spread to other, larger populations—especially the artistic and criminal communities. This widening of the market increased demand and, thus, the smuggling of opium into the country.

Society generally regarded opium smoking as a vice, associating it with corruption, criminality, and debasement. This disapproval led to federal legislation in 1909 that banned the importation of opium for smoking into the United States (Table 1). As a result of the decreased availability, many former opium smokers turned to morphine or heroin injection.¹⁴

Perhaps an even greater force in the development of opioid dependence and addiction in the United States was medical prescription. In the latter half of the 19th century, oral administration of opioids increased as opium and morphine were incorporated into more and more remedies—including those purported to cure opium and alcohol dependence. In a world of mysterious diseases and infections, the medical profession's need for something that worked was acute, providing a major stimulus for the opium market.¹⁵ Often referred to as GOM (short for "God's Own Medicine"), opium was used to treat ailments as varied as anemia, angina pectoris, diabetes, insanity, menstrual cramps, tetanus, nymphomania, and pregnancy-related

vomiting.¹⁶ The 1885 Ebert prescription survey, which reviewed about 15,700 U.S. prescriptions, identified quinine and morphine as the most frequently used agents in medicine.¹

It became increasingly recognized that opioid addiction was mainly iatrogenic. By 1900, about one million Americans were dependent on opioids. The average opioid addict of that time was a

inclusion of opioids in over-the-counter products in the United States and introduced the nation's first legally enforceable pharmacopoeia. This act required manufacturers to indicate the amount of morphine, opium, heroin, marijuana, cocaine, and alcohol found in their products on the label of the container and made misrepresentation illegal.^{19,20}

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middle-aged, southern, white woman who bought morphine or opium legally from the local store (or by mail order) and used it orally. These women were regarded as well adjusted homemakers and were not recognized as a significant burden on society.^{17,18} In his 1997 book, *The Greatest Benefit to Mankind*, Porter describes a cartoon from the late 19th century showing a bartender gazing enviously at a druggist and grumbling, "The kind of drunkard I make is going out of fashion. I can't begin to compete with this fellow," while happy customers walk out of the pharmacy carrying opium-based medications.¹

Opium and morphine also were incorporated into multiple pediatric remedies, including the famous Dover's Powder, Brown Mixture, and Mrs. Winslow's Soothing Syrup. These remedies were instrumental in the passage of the first Pure Food and Drug Act in 1906, which ended the unlabeled

The Harrison Act of 1914

The problem of opioid overuse and addiction remained a prominent public issue in the early 20th century. Neither the ethics rules of professional organizations nor the various state laws were sufficient to control the problem.¹⁵ The family burden of opioid addiction at that time is illustrated vividly by Eugene O'Neill's autobiographical play *Long Day's Journey into Night*, set in August 1912. The depiction of the helplessness, doubt, and sorrow generated by a mother's morphine addiction was so true to life that the author could not bear to have the work published during his lifetime.

The shame often felt by such addicts and their families helped spur the demand in the 1910s and 1920s for more stringent laws to curtail both medical and nonmedical opioid use.²¹ And as the fear of opioids grew, health care professionals began to feel the effects.²² The Harrison Act of 1914, a milestone in the

Table 1. Timeline of opioid regulation in the United States

1860: Pennsylvania passes antimorphine law	1942: Opium Poppy Control Act outlaws unlicensed opium poppy cultivation
1872: California passes antiopium law	1948: Miller Amendment applies FDCA rules to interstate transport of regulated agents
1874: Connecticut declares narcotic addicts incompetent to attend to personal affairs	1951: Boggs Amendment to Harrison Act provides severe mandatory penalties for conviction on narcotic charges
1875: The San Francisco Ordinance bans opium smoking in “dens”	1956: Narcotic Control Act allows for death penalty, if recommended by jury, for sale of heroin to anyone under age 18 by anyone over age 18
1876: Virginia City, NV bans opium smoking in “dens” or smoking houses; by 1914, there are about 27 such laws in several states and cities	1961: United Nations’ Single Convention on Narcotic Drugs ratified
1881: California establishes a separate bureau to enforce narcotic laws	1966: Narcotic Addict Rehabilitation Act enhances federal efforts to treat and rehabilitate narcotic addicts and allows treatment as alternative to jail
1883: Congress raises tariff on opium for smoking from \$6 to \$10 per pound	1968: Drug Abuse Control Amendments provide for suspension of sentence and record erasure if drug offender not convicted for another violation in one year
1890: Congress limits manufacture of opium for smoking to American citizens; tariff on opium for smoking raised to \$12 per pound	1968: Bureau of Narcotics and Dangerous Drugs created under Department of Justice
1897: Tariff on opium for smoking reduced to \$6 per pound	1970: Comprehensive Drug Abuse Prevention and Control Act creates schedule system for controlled substances based on abuse, addiction potential, and therapeutic value
1906: Pure Food and Drug Act , strictly a labeling law, addresses mainly concerns with patent medicines	1972: Drug Abuse Office and Treatment Act establishes National Institute on Drug Abuse and permits development of community-based treatment system and maintenance treatment of addicts
1906: Congress adopts District of Columbia Pharmacy Act	1973: Methadone Control Act places controls on methadone licensing
1909: Importation of opium for smoking completely banned	1973: Heroin Trafficking Act increases penalties for traffickers
1912: Hague Convention calls for international regulation of opium	1973: Drug Enforcement Administration (DEA) formed from Bureau of Narcotics and Dangerous Drugs
1913: Tennessee Narcotic Act requires addicts to register before refilling opioid prescriptions	1974: Narcotic Addict Treatment Act requires separate DEA registration for physicians to use approved opioids for drug abuse therapy
1914: Boylan Act (New York) requires physical examination and physician use of state-issued prescription pads for opioid prescription	1978: Alcohol and Drug Abuse Education Amendment creates Office of Alcohol and Drug Abuse Education in Department of Education
1914: Congress imposes \$300 per-pound tax on opium for smoking	1980: Drug Abuse Prevention, Treatment, and Rehabilitation Amendment extends prevention education and rehabilitation programs
1914: Harrison Act controls production, importation, sale, and distribution of opioids and requires physician licensing to prescribe opioids; by 1970, is supplemented by about 55 other federal laws	1984: Drug Offenders Act creates special programs for drug offenders and organized treatment
1917: Whitney Law (New York) requires state registration of addicts and monthly updates by providers; physicians allowed to treat addicts for comfort	1986: Analogue (Designer) Drug Act outlaws use of substances similar in effect and structure to substances already scheduled
1918: Second Whitney Act (New York) includes plan for elaborate system of prescription forms	1986: Executive order 12564 mandates drug-free federal workplace program
1922: Narcotic Import and Export Act intended to eliminate nonmedical use of opioids	1988: Anti-Drug Abuse Act creates Office of National Drug Control Policy
1924: Heroin Act prohibits heroin manufacture and importation (even for medicinal use)	2000: Drug Addiction Treatment Act allows qualified physicians to prescribe schedule III, IV, and V opioids for treatment of opioid dependence
1930: Federal Bureau of Narcotics formed	
1932: National Conference of Commissioners on Uniform State Laws produces draft of Uniform Narcotic Drug Act suggested for adoption by individual states	
1938: Federal Food, Drug, and Cosmetic Act (FDCA) requires that new drugs be shown to be safe before marketing and that safe tolerances be set for unavoidably poisonous agents	

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evolution of opioid regulations, gave the federal government control over the sale of opium and related substances. With this act, opioid medications became legally available only by prescription in the course of professional practice, for the treatment of disease. The passage of the Harrison Act criminalized not only drug addiction but also its treatment by most physicians.

While this act itself did not explicitly prohibit a physician from prescribing opioids to treat an addicted patient, the Treasury officials charged with enforcing the law regarded the practice as problematic.⁴ And soon enough, opioid maintenance for addicts by a regular physician was formally outlawed—by a 1919 Supreme Court ruling. Many physicians were concerned with this encroachment of the law on medical practice. Contravention of the rule resulted in the arraignment of about 25,000 physicians, 3,000 of whom served prison terms.¹

Due to the fear of reprisal, many physicians stopped offering opioid therapy to addicted patients. In response, local governments and communities established formal clinics to treat addiction. These clinics were closed, however, when the American Medical Association in 1920 noted that there was unanimous agreement that prescription of opioids to addicts for self-administration on an ambulatory basis was an unacceptable medical practice. This viewpoint shifted the management of opioid addiction in the following decades to the criminal justice system and a few federal public health hospitals.⁴ The Federal Bureau of Narcotics was formed in 1930, a time when illicit

drugs were regarded as mankind's deadliest foe. This spirit was carried forward to the more recent "War on Drugs."

The Federal Controlled Substances Act of 1970

The Harrison Act was updated with the Comprehensive Drug Abuse Prevention and Control Act of 1970—title II of which contained the Federal Controlled Substances Act (CSA) of 1970. Together, the CSA and the Federal Food, Drug and Cosmetic Act (FDCA) of 1938 form the principal federal laws that govern the prescription of controlled substances, including opioids, today. Administered by the FDA, the FDCA mandates the evaluation and approval of drugs prior to commercial availability and medical use.²³ The CSA is a consolidation of numerous laws regulating the production and distribution of controlled substances. It establishes a security system to halt the diversion of such designated controlled medication.

The CSA places all controlled substances into one of five schedules, depending on the agent's therapeutic value, harmfulness, and potential for abuse or addiction (Table 2). Schedule I contains drugs that have a high abuse potential and no accepted medical use. These drugs are available only for research. Drugs with accepted medical uses are in schedules II through V. Those in schedule II have a high potential for abuse and may lead to severe physical or psychological dependence. Schedule III contains drugs whose abuse may lead to moderate or low physical dependence or to high psychological dependence. This class includes preparations of acetamin-

ophen or nonsteroidal anti-inflammatory drugs combined with limited quantities of schedule II opioids. Schedule IV contains drugs whose abuse may lead to limited physical or psychological dependence. For drugs in schedule V, the consequences of abuse are even more limited than those of schedule IV. This classification system doesn't necessarily reflect the drugs' street demand or providers' prescribing practices.

The CSA of 1970 recognizes that many controlled drugs have legitimate and useful medical purposes and are essential for the health and general welfare of the American people. It requires that prescriptions for controlled drugs be issued in the course of professional practice for a legitimate medical purpose and in such a way as not to increase or aggravate the public health problems of addiction and associated criminal activities. It gives the U.S. Drug Enforcement Agency (DEA) authority to set production quotas in order to control possible diversion from excessive production.

The Narcotic Treatment Act of 1974 amended the CSA by creating a separate Narcotic Treatment Program. Under this act, registered physicians can maintain or detoxify addicts as part of professional practice, but separate registration (in addition to that of the CSA) is needed. It also requires the DEA to prevent the diversion and abuse of methadone and other opioids used in addiction therapy.

The DEA's role

The DEA was created in 1973 by merging the Bureau of Narcotics and Dangerous Drugs with various law enforcement and intelligence

Table 2. Schedule of controlled substances, exemplified by opioids

Schedule	Description	Examples
I	High abuse potential with no accepted medical indications	Heroin, acetorphine
II	High abuse potential, leading to severe psychological or physical dependence, with accepted medical indications	Morphine, methadone, oxycodone, codeine, hydrocodone, meperidine
III	Lower abuse potential, may lead to moderate or low physical dependence or high psychological dependence	Buprenorphine, acetaminophen-codeine, acetaminophen-hydrocodone
IV	Lower abuse potential, may lead to limited psychological or physical dependence	Pentazocine, propoxyphene
V	Lowest abuse potential of controlled drugs, with more limited consequences of abuse	Codeine cough preparations

gathering agencies. Part of the Department of Justice, this agency is charged with enforcing federal drug laws. Every physician or pharmacist who prescribes or dispenses any controlled substance must register with the DEA, and license renewal is required every three years. Interns, residents, foreign physicians, and VA physicians may be covered under a hospital registration.

According to CSA requirements, the DEA uses a computerized data system called the Automation of Reports and Consolidated Order System (ARCOS) to monitor the distribution of all controlled substances in schedules I and II, as well as the opioid agents in schedule III, from the manufacturing to the retail phases. Such records can be used to identify registrants with unusual or outstanding practices.

ARCOS reports are available to states on a quarterly basis to help identify and control sources of diversion.²⁴

OPIOD REGULATION AT THE STATE LEVEL

State laws also govern the prescription and dispensing of opioids. Although federal laws usually take precedence over state laws and control situations in which both apply, states historically have regulated medical and pharmacy practice.²⁵ Some early state laws outlawed the smoking of opium, regulated the opium content of various agents, and, in some cases, set up drug treatment programs.

For example, Pennsylvania, the home of leading morphine manufacturers in the 19th century, had an antimorphine law as early as 1860.²² In 1875, the city of San Fran-

cisco adopted an ordinance prohibiting the smoking of opium in smoking houses or “dens.”²⁶ A similar ordinance was passed in Virginia City, NV the following year. Under the Tennessee Narcotic Act of 1913, addicts in that state could register and then have their opioid prescriptions refilled. The idea was “to minimize suffering among this unfortunate class” and keep “the traffic in the drug from getting into underground and hidden channels.”^{22,27} The laws enacted by different states varied considerably, however, and by 1932, the National Conference of Commissioners on Uniform State Laws set up a Uniform Narcotic Drug Act, which was adopted by many states.²⁸

Today, all states permit the use of opioids for the treatment of intractable pain. The current state laws regarding controlled substances are based on the Uniform Controlled Substances Act (UCSA) of 1970. This model regulation provided a unified framework to replace the multiple antidrug laws enacted previously by various states since the turn of the last century. Significant state-to-state variations persist, however, since some states did not repeal their previous regulations before adopting their version of the UCSA and others have added new regulations. For example, the Rhode Island UCSA included a provision dating back to 1938 that required practitioners to report to the director of health the name and the disease of any patient who was prescribed a schedule II agent for a period of three months.²⁹ South Carolina’s law prohibited the prescription of controlled substances for indications other than those approved by the FDA and restricted the analgesic

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use of methadone to hospitalized patients.³⁰ While the model UCSA of 1970, like the federal CSA of the same year, did not establish limits on the quantity of a prescription, some states (such as New Jersey and South Carolina) restricted prescription of schedule II agents to the lesser of a 30-day supply or 120 dosage units.

Although the current statutory approaches to the scheduling of controlled substances at the state level reflect, for the most part, the system set up by the federal CSA of 1970, there are variations in the number of schedules and the actual drug classifications. Instead of five schedules, Alaska, Arkansas, North Carolina, and Virginia each have six; Tennessee has seven; and South Dakota has four.³¹ Vermont lists drugs according to pharmacologic types but doesn't rank them based on danger, potential for

abuse, or medical utility. In Maine and Massachusetts, controlled substances are placed in categories (Schedules W through Z for Maine and Classes A through E for Massachusetts) that reflect the severity of penalty, rather than the abuse potential or medical utility.

STATE LAWS RAISE CONCERNS

In many cases, regulations passed by the individual states were more stringent than those enacted at the federal level and were geared toward identifying practitioners prescribing outside legitimate medical practice. For instance, until recently, the mandatory Multiple Copy Prescription Program (MCP) for selected controlled substances was in effect in the states of California, Hawaii, Idaho, Illinois, Indiana, Michigan, New York, Rhode Island, and Texas. First begun in 1913, the MCP was

a paper-based program requiring prescribers to write out prescriptions in duplicate or triplicate, using state-issued prescription pads, with one copy made available to the state. Although the MCP differed somewhat from state to state, it generally was geared toward reducing diversion and abuse of schedule II medications.

For most health care providers in participating states, the MCP was the most visible reminder of the regulatory process.⁶ It carried a perception of scrutiny, risk of sanction, burden of paperwork, substantial cost, and potential loss of patient privacy. Several studies have indicated that MCPs deter the use of controlled substances for pain management,^{29,30,32} with over a 50% decline recorded in the prescription of drugs included within the program.³⁰ At the same time, data from the Drug Abuse

Warning Network—an information gathering program used by the Substance Abuse and Mental Health Service Administration that has been in place since 1972—have not confirmed a reduction of prescription drug abuse following the institution of the MCPP.³³

Another area of concern with some state laws and regulations was imprecise terminology, which led to confusion between the concepts of addiction and physical dependence. For instance, in the New York State Controlled Substances Act, section 3302.1, page 467, an addict was defined as “a person who habitually uses a narcotic and who by reason of such use is dependent thereon.” Section 3372 of the same law required the treating physician to report any person meeting this definition to the state Department of Health. Under these provisions, a majority of patients who use opioids appropriately for pain control for more than a few weeks would qualify as “addicts” and, therefore, would need to be reported by the treating physician to the state.²⁹

PARADIGM SHIFTS BREED POLICY CHANGES

The “War on Drugs,” declared in 1971, continued throughout the 1990s into the new millennium. Statistics for the year 2000 showed that almost 25% of the 1.9 million inmates in the United States were incarcerated for drug offenses. Yet illegal drugs are cheaper, more readily available, and more powerful than ever before.³⁴

Meanwhile, years of slanted information emphasizing the potential harm of opioids has generated an irrational fear of using the drugs for pain control—sometimes termed “opiophobia”—among providers and laypeople alike.^{35–37}

In the past decade, however, we have begun to see a shift in this proscriptive view. Many organizations today are working together to identify and address the major barriers to pain management and to improve public awareness of these issues. For example, the U.S. Con-

firming the view that opioids may be used for managing chronic cancer and noncancer pain and outlining the basic expectations of the prescribers. California recently enacted legislation (AB487) that requires prescribers to complete 12 hours of continuing medical educa-

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gress has designated the years 2001 to 2010 as the “decade of pain control and research,” the Joint Commission on Accreditation of Healthcare Organizations has established standards related to the assessment and treatment of pain, and the VHA has established pain as the “fifth vital sign.”

States also have responded to increasing concerns about the undertreatment of pain, restrictive regulations, and discipline of physicians who supposedly used opioid analgesics “inappropriately” for the treatment of chronic pain, by making significant changes in their laws, medical board regulations, and guidelines.³⁸ Many states have adopted an Intractable Pain Treatment Act (IPTA), usually modeled after the Texas IPTA of 1989. This law prohibits the board of medical examiners from disciplining physicians for using opioids in their practice to treat intractable pain.

Numerous state medical boards have developed new guidelines af-

firming the view that opioids may be used for managing chronic cancer and end-of-life issues.³⁹

Computer-based, point-of-sale systems that monitor schedule II drug prescription have been introduced in some states, including Indiana and Kentucky. These systems can alert pharmacists to situations in which patients may be trying to obtain opioids from more than one provider at the same time or to refill an opioid prescription too soon. This type of electronic monitoring, in combination with the DEA’s ARCOS, makes the MCPP obsolete.

The New York legislature has streamlined the process of opioid prescription, clarified terminology relating to addiction, and discontinued the MCPP. Under new laws in Massachusetts, pharmacists may fill schedule II opioid prescriptions originating from any state—instead of just the six adjacent states, as was the previous practice. In addition, prescriptions for schedule II medications in Massachusetts now are valid for 30 days, rather than

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five, and physicians no longer are required to report names of patients being treated for substance abuse to the Massachusetts Department of Public Health.⁴⁰

With regard to policies for dealing with drug abusers, the tide also is turning. Many states are redirecting efforts and resources from the imprisonment-oriented “War on Drugs” to programs centered more on education and treatment. In 2001, Californians approved Proposition 36, which directs judges to require treatment instead of incarceration for most nonviolent drug users on their first or second offenses.⁴¹ A similar program passed in Arizona in 1996.

NEW QUESTIONS EMERGE

These recent changes help to address obstacles to appropriate pain management in the short term. But they also carry potential problems. Currently, there are minimal scientific, outcome-, or evidence-based data on the widespread use of opioids for long-term management of noncancer pain.⁴²⁻⁴⁴ This knowledge gap raises numerous questions: Is opioid effectiveness maintained over several years of use for pain control? Should pain relief be the sole goal of opioid therapy, or should functional rehabilitation be a yardstick? How does long-term opioid use affect patients’ ability to drive or work? What should be the role of medical practitioners in decreasing or preventing diversion under the new dispensation? Should a drug screen be required for patients receiving opioids? How should the results of such tests be used in decisions about further opioid therapy?

Furthermore, there are many who wonder whether the loosening of regulations for the purpose of im-

proving patient care could have the unintended effect of increasing abuse and diversion significantly. Reports of misuse and abuse of opioid medications are common today and the incidence of reported first time abuse of painkillers has surged in the past few years.⁴⁵ Adding fuel to the firestorm of public apprehension, several deaths between 1999 and 2001 were attributed to the abuse of opioid medications.⁴⁵⁻⁴⁷

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Reports of excessive diversion of opioids have prompted some state medical boards to initiate corrective actions. Concerns also have been raised among policy makers, and there has been increasing pressure to limit access to these medications.⁴⁸

The House Appropriations Subcommittee on Commerce, Justice, State, and the Judiciary held a hearing on the abuse of controlled-release oxycodone in December 2001, and the Senate Health, Education, Labor, and Pensions Committee held a similar hearing in February 2002. The Senate committee discussed the drug’s ability to deliver effective pain management for patients with serious or chronic pain, the need to stop the diversion and abuse of the drug, and the need for greater resources to treat opioid addiction.⁴⁹ These hearings are an indication of the government’s growing interest in the abuse of prescription opioids.

In January 2002, the FDA Anesthetic and Life Support Drugs Advisory Committee met to consider the medical use of opioids in various patient populations, the drugs’ abuse potential, and the risk-benefit ratio. The committee members agreed that opioids are essential for relieving pain and that a great deal of progress has been made in recent years to remove the stigma associated with opioid treatment.

They noted that imposing restrictions on the use of opioids could hurt patients and reverse the progress already made in the appropriate treatment of pain and suggested a balanced approach to regulation that would relieve patients’ pain and prevent diversion.

LEARNING FROM THE LESSONS OF THE PAST

“If men could learn from history, what lessons it might teach us! But passion and party blind our eyes, and the light which experience gives us is a lantern on the stern, which shines only on the waves behind us!”⁵⁰ These words, attributed to Samuel T. Coleridge in 1831, illustrate both the potential benefit and danger of examining the past to help determine the future.

Despite the significant changes that have taken place in the regulation of opioids over the past 100 years, diversion and misuse continue and the undertreatment of

pain remains a national and international concern. History suggests that the illegal demand for opioids is remarkably inelastic; that the conditions of free availability and prohibition both increase consumption; and that the current status of opioid regulation, far from being the end of the journey, simply represents a phase in the continually shifting moral paradigms that underlie public policy. To help guide such policy, we need research to define more clearly today's "average" prescription opioid abuser and the psychosocial factors associated with this abuse, patients' levels of adherence to prescribed opioid regimens, and the outcomes of long-term opioid use to manage chronic noncancer pain.

As the search continues for an equitable balance between availability and restriction of opioid medications, the guideposts of history suggest a multifaceted approach that includes education, professional peer pressure, clinical guidelines, and law enforcement. Finally, policies need to be backed up with a sustained commitment to information dissemination and dialogue, so as to be perceived and understood for what they truly represent. ●

REFERENCES

- Porter R. Medicine, state and society. In: *The Greatest Benefit to Mankind*. London, England: Harper Collins; 1997:628-667.
- Hanks GW, Forbes K. Opioid responsiveness. *Acta Anaesthesiol Scand*. 1997;41(1 pt 2):154-158.
- Mercadante S, Portenoy RK. Opioid poorly-responsive cancer pain. Part 1: Clinical considerations. *J Pain Symptom Manage*. 2001;21:144-150.
- Effective medical treatment of opiate addiction. National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction. *JAMA*. 1998;280:1936-1943.
- National Institute on Drug Abuse. *Research Report Series: Prescription Drug Abuse and Addiction*. Bethesda, MD: National Institute on Drug Abuse; July 2001. NIH Publication No. 01-4881.
- Portenoy RK. The effect of drug regulation on the management of cancer pain. *NY State J Med*. 1991;91(suppl 11):13S-18S.
- Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management. A survey from the Eastern Cooperative Oncology Group. *Ann Intern Med*. 1993;119:121-126.
- Longo LP, Parran T Jr, Johnson B, Kinsey W. Addiction: Part II. Identification and management of the drug-seeking patient. *Am Fam Physician*. 2000;61:2401-2408.
- Parran T Jr. Prescription drug abuse. A question of balance. *Med Clin North Am*. 1997;81:967-978.
- Mendelson JH, Mello N. Introduction. In: Sanberg PR, Bunsey MD, eds. *Prescription Narcotics: The Addictive Painkillers*. New York, NY: Chelsea House Publishers; 1986:13-18.
- Hanson GR, Venturelli PJ, Fleckenstein AE. Introduction to *Drugs and Society*. 7th ed. Sudbury, MA: Jones and Bartlett Publishers, Inc.; 2002:2-33.
- Brownstein MJ. A brief history of opiates, opioid peptides, and opioid receptors. *Proc Natl Acad Sci USA*. 1993;90:5391-5393.
- Grossman A. Opioid peptides and pain. In: Mann RD, ed. *The History of the Management of Pain*. Lancs, England; CRC Press-Parthenon Publishers; 1988:127-140.
- Frank B. An overview of heroin trend in New York City: Past, present and future. *Mt Sinai J Med*. 2000;67:340-346.
- Musto DF. The American Disease. In: *The American Disease. Origins of Narcotic Control*. 3rd ed. New York, NY: Oxford University Press; 1999:1-23.
- Breecher EM. Opiates for pain relief, for tranquilization and for pleasures. In: *Licit and Illicit Drugs*. Boston, MA: Little, Brown and Company; 1972:8-16.
- Sanberg PR, Bunsey MD. The history of the opiates. In: *Prescription Narcotics: The Addictive Painkillers*. New York, NY: Chelsea House Publishers; 1986:31-38.
- Hanson GR, Venturelli PJ, Fleckenstein AE. Narcotics (opioids). In: *Drugs and Society*. 7th ed. Sudbury, MA: Jones and Bartlett Publishers, Inc.; 2002:236-261.
- Street JP. The patent medicine situation. *Am J Pub Hlth*. 1917;7:1037-1042.
- Hanson GR, Venturelli PJ, Fleckenstein AE. Drug use, regulation, and the law. In: *Drugs and Society*. 7th ed. Sudbury, MA: Jones and Bartlett Publishers, Inc.; 2002:64-89.
- Musto DF. The burden of morphine. In: *Drugs in America. A Documentary History*. New York, NY: New York University Press; 2002:251-252.
- Musto DF. State and local narcotic control. In: *The American Disease. Origins of Narcotic Control*. 3rd ed. New York, NY: Oxford University Press; 1999:91-120.
- Angarola RT, Mendelsohn CB. Pain and health policy. In: Ashburn MA, Rice LJ, eds. *The Management of Pain*. New York, NY: Churchill Livingstone Inc.; 1998:199-204.
- Collins TM. Multiple copy prescription programs and alternative monitoring programs: Cost issues. *NY State J Med*. 1991;91(suppl 11):28S-31S.
- Clark HW, Sees KL. Opioids, chronic pain, and the law. *J Pain Symptom Manage*. 1993;8:297-305.
- Breecher EM. Opium smoking is outlawed. In: *Licit and Illicit Drugs*. Boston, MA: Little, Brown and Company; 1972:42-46.
- Tennessee Narcotic Act, Public Acts of Tennessee, 58th General Assembly, ch. 11, pp. 403-407, September 25, 1913.
- Hanson GR, Venturelli PJ, Fleckenstein AE. Federal agencies with drug abuse missions. Appendix A. In: *Drugs and Society*. 7th ed. Sudbury, MA: Jones and Bartlett Publishers, Inc.; 2002:519-520.
- Joranson DE. Federal and state regulation of opioids. *J Pain Symptom Manage*. 1990;5(suppl 1):S12-S23.
- Joranson DE, Gibson AM. Controlled substances, medical practice and the law. In: Schwartz HI, ed. *Psychiatric Practice Under Fire. The Influence of Government, the Media and Special Interests on Somatic Therapies*. Washington, DC: American Psychiatric Press; 1994:173-194.
- ImpacTeen Illicit Drug Team: Controlled substances scheduling. In: *Illicit Drug Policies: Selected Laws from the 50 States*. Berrien Springs, MI: Andrews University; 2002:15.
- Shapiro RS. Legal bases for the control of analgesic drugs. *J Pain Symptom Manage*. 1994;9:153-159.
- Jacob TR. Multiple copy prescription regulation and drug abuse: evidence from the DAWN network. In: Wilford BB, ed. *Balancing the Response to Prescription Drug Abuse*. Chicago, IL: American Medical Association; 1990:205-217.
- Drucker E. Drug prohibition and public health: 25 years of evidence. *Pub Health Rep*. 1999;114:14-29.
- Schuster CR. Does treatment of cancer pain with narcotics produce junkies? In: Hill CS, Fields WS, eds. *Advances in Pain Research and Therapy*. Vol. 11. York, NY: Raven Press; 1989:1-3.
- Morgan JP. American opiophobia: Customary underutilization of opioid analgesics. *Adv Alcohol Subst Abuse*. 1985;5(1-2):163-173.
- Weinstein SM, Laux LF, Thornby JI, et al. Physicians' attitudes toward pain and the use of opioid analgesics: Results of a survey from the Texas Cancer Pain Institute. *Southern Med J*. 2000;93:479-487.
- The use of opioids for the treatment of chronic pain. A consensus statement from the American Academy of Pain Medicine and the American Pain Society. *Clin J Pain*. 1997;13:6-8.
- AB487: California approves important pain legislation. *Pain Med Netw*. Winter 2002;17(1):3.
- Strassels S. Summary of recent changes in Massachusetts law. *Am Pain Soc Bull*. November/December 1998;8(6):3, 14.
- Alvord V. Calif. tries treatment for drug users. New law offers prison alternative. *USA Today*. July 2, 2001:1.
- Eriator I. Narcotic analgesics for chronic pain management. *Current Rev Pain*. 1998;2:193-200.
- Eriator I. Evidence based practice, reasoning and statistics. *Pain Forum*. 1998;7:172-173.
- Harden NR. Chronic opioid therapy: Another reappraisal. *Am Pain Soc Bull*. January/February 2002;12(1):1, 8-12.
- Kalb C. Playing with pain killers. *Newsweek*. April 9, 2001:45-48.
- Fielin DA, O'Connor PG. Office-based treatment of opioid-dependent patients. *N Engl J Med*. 2002;347:817-823.
- Hanson GR, Venturelli PJ, Fleckenstein AE. Holding the line: The law and prescription narcotics. In: *Drugs and Society*. 7th ed. Sudbury, MA: Jones and Bartlett Publishers, Inc.; 2002:243.
- Ashburn MA. President's message: APS must advocate for policy improvements. *Am Pain Soc Bull*. March/April 2001;11(2):2.
- APhA legislative and regulatory update. Washington, DC: American Pharmacists Association; February 15, 2002. Available at: www.cpha.com/aphupdate02152002.html. Accessed October 15, 2003.
- Goodman T. *The Forbes Book of Business Quotations: 14,173 Thoughts on the Business of Life*. New York, NY: Blackdog and Leventhal Publishers; 1997:263.