

Prescription Drug Abuse: Executive Summary of a Policy Position Paper From the American College of Physicians

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The inappropriate use and abuse of prescription drugs is a serious public health problem. The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of deaths from prescription drug overdose (1). The CDC reports that drug overdose, particularly due to the increase in nonmedical use of prescription pain-relief drugs, is the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities (2). A recent analysis of preliminary CDC data suggests that drug overdose may now be the leading cause of such deaths (3).

Prescription drug abuse is found throughout all aspects of our population. Physicians and other health professionals with prescribing privileges are entrusted with the authority to use medications in the treatment of their patients and therefore have an important role to play in helping to ensure safe and effective use of this treatment option and the deterrence of its abuse. The American College of Physicians (ACP) developed this position paper to provide guidance to prescribers and policymakers regarding measures to effectively address the problem of prescription drug abuse. This Executive Summary provides a synopsis of the full position paper (see the **Appendix**, available at www.annals.org).

BACKGROUND

A 2010 Substance Abuse and Mental Health Services Administration survey found that 16 million Americans age 12 years and older had taken a prescription pain reliever, tranquilizer, stimulant, or sedative for nonmedical purposes at least once in the previous year; 7.0 million (2.7%) had used psychotherapeutic drugs nonmedically within the past month. Of these drug abusers, 55.0% said they obtained the drug they most recently used from a friend or relative for free (4). Another 17.3% reported that they got the drug from one doctor. Only 4.4% obtained them from a drug dealer or other stranger, and only 0.4%

bought them on the Internet. The survey noted, “Among those who reported getting the pain reliever from a friend or relative for free, 79.4% reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor.” Another study found that more than 50% of teens obtained prescription drugs from their own family’s medicine cabinet (5). Also in 2010, there were 2.4 million opioid abusers in the United States—with 60% of abused opioids obtained directly or indirectly through a doctor’s prescription (6). Furthermore, the Substance Abuse and Mental Health Services Administration 2010 survey indicated that 2 million people reported using prescription painkillers nonmedically for the first time within the last year (4).

The full position paper (see the **Appendix**) includes a definition of drug abuse, information about prescription drug abuse in different age groups, variation by geographic area, prescription drug abuse and fraud in Medicare, and factors contributing to the dramatic rise in the availability and misuse of prescription drugs.

Key measures of abuse of opioid drugs increased from 2003 to 2009 (4). The largest increases were in measures of adverse health consequences, such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths (1). The adverse consequences of prescription drugs abuse are serious, and the costs are substantial. Commonly abused prescription drugs fall into 3 categories: pain relievers (opioids), sedatives and tranquilizers (central nervous system depressants), and stimulants (7).

The National Institute on Drug Abuse (NIDA) warns that opioids can be highly addictive and can depress respiration and lead to death, and that injecting opioids with unsterile or shared equipment increases the risk for HIV infection and other infectious diseases (7). Unintentional overdose deaths involving prescription opioids have quadrupled since 1999 and now outnumber those from heroin and cocaine combined. The number of overdose deaths involving opioid analgesics was more than 16 600 according to a recent report from the CDC (8). The National Survey on Drug Use and Health estimates that about 1.9 million people in the United States abuse or are dependent on prescription opioids (4). The potential for abuse is enormous because roughly 116 million patients in the

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United States have chronic pain (9). The NIDA provides a listing of commonly abused prescription drugs at www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart. Each year, drug abuse and addiction cost taxpayers nearly \$534 billion in preventable health care, law enforcement, crime, and other costs (10).

The full position paper (see the **Appendix**) includes details about the types of drugs that are abused and summarizes the current regulatory framework within the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Agency. It also discusses issues related to Medicare and Medicaid, programs that provide coverage for medically necessary prescription drugs, including opioids and other pain medications, and are dealing with the problem of increasing prescription drug abuse. It also discusses approaches taken by various state legislatures and medical boards to address this issue.

THE CHALLENGE FOR PHYSICIANS AND PUBLIC POLICYMAKERS

The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment. The physician must be up to date on the proper use of medications and treatments, including pain medications. Physicians have an ethical obligation to manage and relieve pain yet to do so responsibly and in accord with scientific evidence (11). Improvement in function through the short-term use of opioids and related substances to treat acute pain and their use to ease suffering at the end of life are well-accepted medical practices. However, long-term opioid use for chronic pain is controversial because of concerns about addiction, overuse, misuse, and adverse effects. Long-term use can also lead to opioid-induced hyperalgesia, which in turn leads to increased doses of opioids, further escalating sensitivity to pain. Furthermore, evidence for long-term efficacy is lacking (12). Concerns about pain being underdiagnosed and undertreated remain, particularly for ethnic and racial minorities (13). The result is needless suffering for patients, complications that cause further injury or death, and unnecessary treatment costs. Controlled substances include medications to treat not only pain but also sleep disorders, nerve conditions, weight loss, and other conditions. However, prescribing controlled substances, which can be addictive or abused, can subject physicians to substantial regulatory and administrative burdens. Physicians face criminal and civil penalties, including loss of licensure (and consequent inability to practice) for failure to comply with state and federal laws regulating controlled substances. On the other hand, failure to adequately medicate a patient can expose a physician to malpractice charges of negligence. Physicians can also be sued for overmedication that results in addiction or serious adverse effects (14). State medical boards also report addressing

complaints for both overtreatment and undertreatment of pain.

METHODS

The decision to develop this policy paper was made by ACP's Health and Public Policy Committee, which is charged with addressing issues affecting the health care of the U.S. public and the practice of internal medicine and its subspecialties. Recommendations developed were informed through a literature review and input from the various College constituencies and nonmember experts in the field. The policy paper and related recommendations were reviewed and approved by the College's Governing Board in July 2013.

ACP POSITION STATEMENTS AND RECOMMENDATIONS

The following statements represent the official policy positions and recommendations of the ACP. The rationale for each is provided in the full position paper (see the **Appendix**).

1. *ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.*
2. *ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.*
3. *ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.*
4. *ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing and filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.*
5. *ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.*
6. *ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.*
7. *ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding*

recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.

8. *Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of prescription drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Physicians may be required to report suspected cases of drug abuse, but should not be mandated to conduct random drug testing without the patient's consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.*

9. *ACP recommends the consideration of patient-provider treatment agreements between physician and patients as a tool for the treatment of pain.*

10. *ACP recommends the passage of legislation by all 50 states permitting electronic prescription for controlled substances (EPCS).*

CONCLUSION

The goal of this paper is to provide physicians and policymakers with a set of recommendations to address the significant human and financial costs related to prescription drug abuse. The recommendations address detection and deterrence, as well as treatment, of this condition, and also discuss the need for increased educational efforts on the issue of prescription drug abuse both for the patient population and the physicians who treat them. They touch on the importance of maintaining patient involvement, dignity, and privacy and the importance of limiting third-party administrative and regulatory mandates on physicians attempting to provide care and address this issue. These recommendations offered by the College aim to form a framework for patients to receive the care they require while effectively accounting for the problems associated with the use of prescription drugs—specifically, those with a significant potential for abuse.

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APPENDIX: PRESCRIPTION DRUG ABUSE: A POLICY POSITION PAPER FROM THE AMERICAN COLLEGE OF PHYSICIANS

Executive Summary

Prescription drug abuse is found throughout all aspects of the U.S. population and is a serious public health problem. Physicians and other health professionals with prescribing privileges are entrusted with the authority to use medications in the treatment of their patients and therefore have an important role in helping to ensure safe and effective use of this treatment option and the deterrence of its abuse. This paper is intended to provide guidance to prescribers and policymakers regarding measures to effectively address the problem of prescription drug abuse and offers the following recommendations:

1. ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.

2. ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.

3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.

4. ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.

5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.

6. ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.

7. ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.

8. Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of prescription drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Physicians may be required to report suspected cases of drug abuse, but should not be mandated to conduct random drug testing without the patient's consent. The financial cost of mandatory drug testing should

be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.

9. ACP recommends the consideration of patient-provider treatment agreements between physician and patients as a tool for the treatment of pain.

10. ACP recommends the passage of legislation by all 50 states permitting electronic prescription for controlled substances.

Introduction

The inappropriate use and abuse of prescription drugs is a serious public health problem. The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths (1). The CDC reports that drug overdose, particularly due to the increase in nonmedical use of prescription pain-relief drugs, is the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities (2). A recent analysis of preliminary CDC data suggests that prescription drug overdose may now be the leading cause of such deaths (3). This paper uses the National Institute on Drug Abuse (NIDA) definition of drug abuse, which is “the intentional use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling it causes” (15). The literature reflects an attempt to differentiate between prescription drug misuse (for example, nonsanctioned therapeutic use) and abuse (for example, specific use for recreational/intoxicating purposes) without consensus (16); thus, our use of the term “prescription drug abuse” will include both these important components.

Methods

The decision to develop this policy paper was made by the Health and Public Policy Committee of the American College of Physicians, which is charged with addressing issues affecting the health care of the U.S. public and the practice of internal medicine and its subspecialties. Recommendations developed were informed through a literature review and input from the various College constituencies and nonmember experts in the field. The policy paper and related recommendations were reviewed and approved by the College's Governing Board in July 2013.

Background

Population at Risk

A survey in 2010 by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that 16 million Americans age 12 years and older had taken a prescription pain reliever, tranquilizer, stimulant, or sedative for nonmedical purposes at least once in the previous year; 7.0 million (2.7%) had used psychotherapeutic drugs nonmedically within the past month. Of these drug abusers, 55.0% said they obtained the drug they most recently used from a friend or relative for free. Another 17.3% reported they got the drug from one doctor. Only 4.4% obtained the drug from a drug dealer or other stranger, and only 0.4% bought such drugs on the Internet. The survey noted, “Among those who reported getting the pain reliever from a friend or relative for free, 79.4% reported in a follow-up question that the friend or relative had obtained the

drugs from just one doctor" (4). Another study found that more than 50% of teens obtained prescription drugs from their own family's medicine cabinet (5).

The 2010 SAMHSA survey indicated that there were 2.4 million opioid abusers in the United States, with 60% of abused opioids obtained directly or indirectly through a doctor's prescription. Furthermore, 2 million people reported using prescription painkillers nonmedically for the first time within the past year (4).

Abuse by the Young

The 2010 SAMHSA survey indicated that individuals age 12 to 25 years report the highest rates of nonmedical use of prescription drugs. The rate of abuse of prescription drugs was 5.9% among young adults age 18 to 25 years. The survey showed that 2.7% of 8th graders, 7.7% of 10th graders, and 8.0% of 12th graders had abused Vicodin during the previous year. In addition, the survey showed that 2.1% of 8th graders, 4.6% of 10th graders, and 5.1% of 12th graders had used OxyContin for nonmedical purposes (4). Other than marijuana, prescription and over-the-counter (OTC) medications account for most of the commonly abused drugs by high school seniors (7).

Recent data from the 2011 National Survey on Drug Use and Health (17) indicates a decline in prescription drug abuse by young adults age 18 to 25 years. The number reporting that they had used prescription drugs for nonmedical purposes in the past month declined by 14%—from 2 million in 2010 to 1.7 million in 2011. The survey also found an overall 12% decline in the number of Americans abusing prescription drugs (18).

Abuse by the Elderly

Persons aged 65 years and older make up only 13% of the population yet account for more than one third of total outpatient spending on prescription drugs in the United States. Recent data also reflect that the dispensing of opioid medication has significantly increased in the past 5 years for individuals 60 years or older (19). Although illicit drug use is low in this population, the prevalence of prescription drug abuse may be as high as 11%, with female sex, social isolation, depression, and history of substance abuse increasing risk (20, 21). Older patients often are being treated for comorbid illnesses and are more likely to be prescribed long-term and multiple prescriptions, including opioid medications for pain. The elderly also are susceptible to age-related changes in drug metabolism and potential drug interactions and also use OTC medicines and dietary supplements, which (in addition to alcohol) could compound any adverse health consequences resulting from prescription drug abuse. As a result of the above, the NIDA notes that prescription drug abuse may therefore be more dangerous in the elderly than in younger populations (21). Some older persons improperly use prescriptions because of cognitive impairment. It is also possible that retirees on a fixed income may abuse leftover medications of a spouse or another person in order to save money.

The Centers for Medicare & Medicaid Services (CMS) has estimated that in 2011 as many as 225,000 Medicare Part D

beneficiaries (0.7% of the Part D population) who did not have cancer and were not in hospice received high dosages (more than 120 mg daily) of morphine equivalent dose (MED) for at least 90 consecutive days in 2011, and thus could be at risk for addiction to or abuse of these drugs (22).

Abuse May Differ in Rural Areas

Prescription drug abuse is a problem throughout the United States. From 1999 to 2003, the rate of increase was higher in rural areas than in urban areas. A study of deaths in rural western Virginia between 1997 and 2003 found a 300% increase in the number of deaths in which drugs, including prescription medications, were determined to be related or a contributor to death. The rate of death from drugs in rural areas increased steadily over that period. In 58% of the cases, the deaths involved polydrugs (more than one drug or medication). Prescription opioids were identified in 74% of the cases. Although national data indicate the highest rates of prescription drug abuse among persons younger than age 25 years, this study indicated disproportionately higher rates of death from prescription drug abuse in rural areas in an older population (age 35 to 45 years). The authors (23) concluded:

Given the identification of older decedents in our study and nationally, this population may not be taking these medications as directed or may be abusing or addicted to prescription medications, instead of illicit drugs. As policymakers and researchers formulate a response to the increase in nonmedical use of prescription medications, an older population should be targeted for education as well as youths. We should educate all patients, and their families, about taking medication only as prescribed, only by the individual for whom it is intended, and the dangers of combining medications without prescriber knowledge.

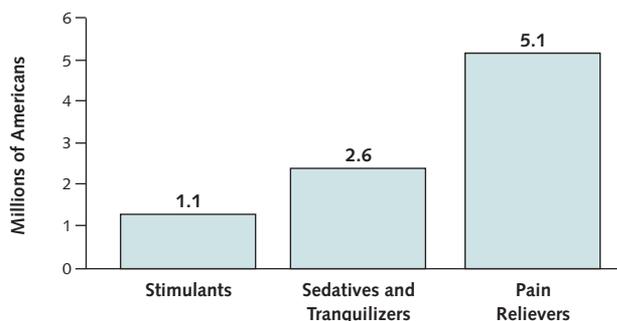
It is also notable that prescription drugs have replaced heroin and cocaine as the leading drugs involved in fatal drug overdoses in all urban–rural categories (24).

Prescription Drug Abuse and Fraud in Medicaid

Widespread cases of fraud also have been uncovered in the Medicaid program. In a review of 5 states (California, Illinois, New York, North Carolina, and Texas) in 2009, the Government Accountability Office (GAO) found 65 000 instances of Medicaid beneficiaries improperly obtaining potentially addictive drugs at a cost of about \$63 million during 2006 and 2007. The GAO also found a disturbing amount of fraud, involving thousands of prescriptions written for dead patients or by people posing as doctors (10, 25).

The 65 000 Medicaid beneficiaries identified by GAO had acquired the same type of controlled substances from at least 6 different medical practitioners during fiscal years 2006 and 2007; most had "doctor shopped" to obtain prescriptions from 6 to 10 medical practitioners. At least 400 Medicaid beneficiaries had visited 21 to 112 medical practitioners and up to 46 different pharmacies for the same controlled substances. The GAO acknowledged that although some beneficiaries may have justifiable reasons for receiving prescriptions from multiple medical practi-

Figure. 2010 Past-month use of prescription drugs for nonmedical purposes.



tioners, such as visiting specialists or several doctors in the same medical group, others “were likely seeing several medical practitioners to support and disguise their addiction or to obtain drugs to fraudulently sell” (10).

Causes and Contributing Factors

Multiple factors are believed to account for the rise in prescription drug abuse in the United States. Motivations to purposely abuse drugs include the desire to become intoxicated; to counter anxiety, pain, or sleep problems; and to enhance cognition. Unintended misuse can be due to misperceptions about drug safety, use of medications other than as prescribed, and dosage errors due to cognitive decline or impairment.

Contributing to the problem is the dramatic rise in the availability and prescription of drugs. From 1999 to 2009, the number of prescriptions increased 39% (from 2.8 billion to 3.9 billion), compared with a U.S. population growth of 9%. The average number of retail prescriptions per capita increased from 10.1 in 1999 to 12.6 in 2009. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to nearly 45 million and for opioid analgesics from about 75.5 million to 209.5 million (26). High-dose opioids also became more readily available as opioids were reformulated as extended-release medications to allow longer dosing intervals for treating patients in pain (27). After reviewing the significant growth in prescribed controlled drugs in recent years and its correlation with increases in abuse and overdose, Alexander and coworkers posited that the substantial increase in the nonmedical use of opioids and related drugs is a predictable adverse effect of substantial increases in the extent of prescriptive use (28). Furthermore, they questioned the extent to which such campaigns as “Pain as the 5th Vital Sign” (29) and other initiatives to improve the treatment of pain, the establishment of specific pain treatment professional guidelines, and the aggressive marketing of pain drugs by pharmaceutical companies have also, either directly or indirectly, contributed to this current problem.

Overprescribing of medication by physicians for treatment of limited acute or postsurgical pain is also a contributing factor (30). The surplus medications, coupled with inadequate instruc-

tions for disposal, serve as a ready source for drugs to abuse or divert for profit.

Society and the medical profession also need to reexamine how we view pain and pain relief (16). As summarized by some experts: “The problem facing the United States now is how to change the culture into one that recognizes pain without conflating pain relief with opioid therapy. The treatment of pain with any number of approaches other than opioids can be held up as compassionate care. But most of them require more time than writing a prescription” (31). The profession needs to have a broader therapeutic toolkit that starts with strong patient-physician relationships and supportive systems of care.

Adverse Consequences

Key measures of abuse of pain-relieving opioid drugs increased from 2003 to 2009. The largest increases were in measures of adverse health consequences, such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths (1).

The adverse consequences of prescription drugs abuse are serious, and the costs are substantial. Prescription drug abuse is common among both the young and the elderly, and it affects urban as well as rural areas. In 2010, about 7 million Americans reported past-month use of prescription drugs for nonmedical purposes. Commonly abused prescription drugs fall into 3 categories (Figure): pain relievers (opioids), sedatives and tranquilizers (central nervous system depressants), and stimulants (7).

NIDA warns that prescription opioids act on the same receptors of the brain as heroin and can be highly addictive. They also can depress respiration and lead to death. It further advises that injecting opioids increases the risk for HIV infection and other infectious diseases through use of unsterile or shared equipment. Unintentional overdose deaths involving prescription opioids have quadrupled since 1999 and now outnumber those from heroin and cocaine combined. The number of overdose deaths involving opioid analgesics was more than 16 600 according to a recent report from the CDC (8). The National Survey on Drug Use and Health estimates that about 1.9 million people in the United States abuse or are dependent on prescription opioids (15). The potential for abuse is enormous as there are roughly 116 million patients in the United States who have chronic pain (9).

In addition to the costs of treating the addiction and other adverse health consequences associated with prescription drug abuse, there are also other costs to consider. These include not only the actual cost of drug purchases but also the costs of the doctor and emergency department visits that precede the dispensing of these medications. There is also the economic cost of death and lost productivity. As noted by the GAO, “Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be financed by insurance and public programs such as Medicaid.” Each year, drug abuse and addiction cost taxpayers nearly \$534 billion in preventable health care, law enforcement, crime, and other costs (10).

The Challenge for Physicians and Public Policymakers

The physician must be up to date on the proper use of medications and treatments, including pain medications. Physicians have an ethical obligation to manage and relieve pain yet to do so responsibly and in accord with scientific evidence (11). Improvement in function through the short-term use of opioids and related substances to treat acute pain and their use to ease suffering at the end of life are well-accepted medical practices. However, long-term opioid use for chronic pain is controversial because of concerns about addiction, overuse, misuse, and adverse effects. Long-term use can also lead to opioid-induced hyperalgesia, which in turn leads to increased doses of opioids, further escalating sensitivity to pain. Furthermore, evidence for long-term efficacy is lacking (12). Concerns about pain being underdiagnosed and undertreated remain, particularly for ethnic and racial minorities (13). The result is needless suffering for patients, complications that cause further injury or death, and unnecessary treatment costs. Controlled substances include medications to treat not only pain but also sleep disorders, nerve conditions, weight loss, and other conditions. However, prescribing controlled substances, which can be addictive or abused, can subject physicians to substantial regulatory and administrative burdens. There are criminal and civil penalties, including loss of licensure (and consequent inability to practice) for failure to comply with state and federal laws regulating controlled substances. On the other hand, failure to adequately medicate a patient can expose a physician to malpractice charges of negligence. Physicians can also be sued for overmedication that results in addiction or serious adverse effects (14). State medical boards also report addressing complaints for both overtreatment and undertreatment of pain.

The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment.

Current Regulatory Framework

The Food and Drug Administration

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety and effectiveness of medicines, including prescription drugs, generic drugs, and OTC medications. It has oversight for approval of new prescription drugs, labeling of OTC and prescription drugs, and drug manufacturing standards. It also has regulatory authority over the manufacturing, marketing, and labeling of biological products, medical devices, vaccines, food, cosmetics, and products that emit radiation. It is “responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health” (32).

The FDA provides the public with important drug safety information that is easy to read and in an interactive format. It maintains a Web page that contains the most recent Drug Safety Communications from the FDA and maintains an Index to Drug-Specific Information. The FDA shares information in the interest of informing doctors and patients about the issues that

are under review and when FDA experts anticipate completing their review. The Healthcare Professional Information (33) sheet is for doctors, pharmacists, nurses, and other health care professionals. It contains an “alert” (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.

In July 2012, the FDA approved a risk evaluation and mitigation strategy (REMS) for extended-release and long-acting opioids as part of a federal initiative to address the prescription drug abuse and related overdose epidemic (34). The REMS introduces new safety measures designed to reduce risks and improve the safe use of extended-release/long-acting opioids while ensuring access to needed medications for patients in pain. More specifically, the new REMS for extended-release/long-acting opioids will affect more than 20 companies that manufacture these opioid analgesics. These companies will be required to make education programs available to prescribers on the basis of an FDA blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. Physician participation in this training would be voluntary. In addition, physicians will be required to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to periodically assess the implementation of the REMS and the success of the program in meeting its goals. In June 2013, ACP, along with its curriculum partner Pri-Med, launched an online training program on safe opioid prescribing consistent with the FDA blueprint and funded by industry (35).

Drug Enforcement Administration

Under the Controlled Substances Act of 1970, the Drug Enforcement Administration (DEA) established a system for controlling the manufacture, distribution, and dispensing of controlled substances. This legislation requires any person who manufactures, dispenses, imports, exports, or conducts research with controlled substances to register with DEA (unless exempt); keep track of all stocks of controlled substances; and maintain records to account for all controlled substances received, distributed, or disposed. All registrants are required by the DEA to maintain records of controlled substance transactions. Pharmacies are required to maintain records but are not required to report dispensing information at the patient level to the DEA (10).

The DEA classifies controlled substances into 5 schedules on the basis of their currently accepted medical use and potential for abuse and dependence: Schedule I drugs—including heroin and hallucinogens, such as LSD—have a high potential for abuse, and no currently accepted medical uses in treatment in the United States. It should be noted that marijuana, which traditionally is included under Schedule I, has been approved for medical use in several states. Schedule II drugs have currently accepted medical uses but have a high potential for abuse and can lead to severe psychological or physical dependence. They in-

clude stimulants, such as methylphenidate, and opiates, such as morphine and oxycodone. Drugs on Schedules III through V have medical uses and progressively lower potentials for abuse and dependence. All drugs except those in Schedule I are legally available to the public with a prescription (10).

Physicians must register with the DEA to prescribe any medications that are controlled substances. The DEA maintains an online listing of criminal investigations of physicians that have resulted in arrest and prosecution. Also online is a list of administrative actions, including judicial decisions and orders.

On 31 March 2010, the DEA issued an Interim Final Rule with Request for Comment titled "Electronic Prescriptions for Controlled Substances" (EPCS). The rule revises DEA regulations to permit physicians to write prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule became effective 1 June 2010 (36).

To help deter abuse of prescription drugs, the DEA sponsors a National Prescription Drug Take-Back Day, the most recent of which was on 26 October 2013. A DEA press release (37) reported that at a similar event on 28 April 2012, citizens turned in a record-breaking 552 161 pounds (276 tons) of unwanted or expired medications for safe and proper disposal at the 5659 take-back sites that were available in all 50 states and U.S. territories. When the results of the 4 Take-Back Days to date are combined, the DEA and its state, local, and tribal law-enforcement and community partners have removed over 1.5 million pounds (774 tons) of medication from circulation.

As noted, many of the drugs abused come from family, friends, and the home medicine cabinet.

In December 2012, the DEA released a proposed rule (38) that attempts to address the issue of safe disposal of unused controlled substances. More specifically, these proposed regulations contain specific provisions that continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes; allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes; and allow authorized retail pharmacies to voluntarily maintain collection boxes at long-term care facilities.

Medicare and Medicaid

Medicare and Medicaid provide coverage for medically necessary prescription drugs, including opioids and other pain medications. Both programs also are dealing with the problem of increasing prescription drug abuse.

CMS has developed daily MED criteria to identify potential cases of opioid overdose and risks for adverse drug reactions. Citing findings from a study in Washington State, CMS determined that "the total daily dose of opioids should not be increased above 120 mg oral MED without either the patient demonstrating improvement in function and pain or first obtaining a consultation from a practitioner qualified in chronic pain management." CMS then examined claims for Medicare beneficiaries

enrolled in Part D at any time in 2011, excluding claims for cancer and hospice beneficiaries. CMS found that 8.8 million of these beneficiaries (28% of all Part D beneficiaries) used opioids in 2011 and that 1.765 million (5.6% of Part D beneficiaries) exceeded the MED threshold for at least 1 day. In addition, 225 000 beneficiaries (0.71% of all Part D beneficiaries) exceeded the threshold for 90 or more consecutive days and were considered to be "at high risk for potential adverse effects and have a high likelihood of inappropriately using opioids." Further refinements indicated a population of 22 222 noncancer and nonhospice beneficiaries (0.071% of all Part D beneficiaries) for further utilization review, who received opioid prescriptions exceeding 120 mg daily for 90 or more consecutive days from at least 4 prescribers and at least 4 pharmacies (22).

Using these findings, CMS established a case management pilot program to identify potentially unsafe and inappropriate use of opioids and to detect fraudulent prescriptions. Under this program, the MED clinical thresholds and prescription patterns are used to trigger case management of opioid overusers. Written communications are sent to physicians about the appropriateness, medical necessity, and safety of high opioid dosages being prescribed for specific patients under their care. The letters also indicate that, if the patient has opiate prescriptions from multiple prescribers or pharmacies, the physician must then confirm that the opioid medications and the cumulative dosage of opioid medications being prescribed are appropriate, medically necessary, and safe for the patient. When multiple prescribers are involved, the case manager will seek to facilitate a consensus.

On 31 August 2012, CMS issued a memorandum informing Medicare Part D sponsors about the case management pilot program and urging them to be on the lookout for duplicative opioid drug use by identifying beneficiaries with high dosage, sustained use, and multiple providers. CMS also provides Medicare Part D prescription drug plans a MED analysis tool to help plans identify potential overuse (22). CMS supplied supplemental information providing guidance on how to improve drug utilization reviews on 6 September 2012.

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) are statewide electronic databases that compile information from pharmacies on dispensed prescriptions for controlled substances. Information typically includes the medicine, dose, date dispensed, patient, prescriber, and pharmacy. States vary widely with regard to who is permitted to receive the data and under what conditions. The information is stored in central databases that can be accessed only by authorized users, which include health professional prescribers and pharmacists, but may also include licensure boards, law enforcement and drug control agencies, public and private third-party payers, medical examiners, drug courts, addiction treatment programs, and other public health and safety agencies. These programs are designed to detect and prevent prescription drug abuse by identifying individuals who seek to obtain prescriptions for addictive medications from multiple physicians for themselves or to sell (39).

In 2005, President George W. Bush signed the National All Schedule Prescription Electronic Reporting (NASPER) program. Under this program, federal grants were authorized for states to establish or enhance PDMPs. Review of these programs indicated that they are effective in reducing inpatient admissions for prescription opioid abuse and had “a negligible chilling effect on physician prescribing” (40).

However, funding for NASPER was initially delayed and has been inconsistent. Much of the funding for state PDMPs has come from state governments, the Bureau of Justice Assistance of the U.S. Department of Justice, and Purdue Pharma (the manufacturer of OxyContin). By June 2012, 49 states and 1 territory had passed legislation creating PDMPs, and 41 states had operating programs (40). Recently, the Department of Veterans Affairs (VA) amended its regulations to allow participation in state PDMPs (41).

State Medical Boards and the Federation of State Medical Boards

Prescribing authority in each state is under the authority of the state medical board. The Federation of State Medical Boards (FSMB) is a national nonprofit organization representing the 70 medical and osteopathic boards of the United States and its territories. The FSMB leads by promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical and osteopathic boards in their protection of the public. As part of this mission, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, opioid analgesics. These guidelines were most recently updated in July 2013 (42).

Recent Legislation and Regulatory Actions

Proposed Federal Legislation

Senator Jay Rockefeller introduced a bill (S. 348) in February 2013 to require education courses for all prescribers registering with the DEA to prescribe controlled substances. The bill would require the Department of Health and Human Services to establish a mandatory and comprehensive practitioner education program for methadone and other opioids, in collaboration with relevant professional societies (43). The FDA also supports a mandatory training program on responsible opioid prescribing practices that would be linked to DEA registration (44).

The ACP and other medical societies signed a 2009 letter opposing mandatory educational requirements but favoring voluntary efforts. The letter expressed support for adopting positive incentives to encourage physicians to complete educational requirements, such as a waiver of the \$550 DEA registration fee for those who complete a voluntary course on pain management and recognition of substance use disorders.

On 19 July 2012, Congresswoman Mary Bono Mack (CA-45) and Congressman Bill Keating (MA-10) introduced the Stop Tampering of Prescription Pills (STOPP) Act (HR 6160) bill to require manufacturers to formulate tamper-proof versions of their prescription opiate painkillers. The legislation would re-

quire drug makers to produce tamper-resistant versions of their opioid pain drugs that cannot be crushed. The legislation is intended to deter people from getting high from crushing opiate pain medications into powder, chewing them, dissolving them in water, or by injecting them (45). The bill was not brought out of committee review. Nonetheless, at least 2 manufacturers have voluntarily developed tamper-resistant versions of their pain-relief medications (46).

Recent State Legislative/Regulatory Initiatives

Many states, in recognition of the growing problem of prescription drugs abuse, have recently taken actions to address this problem and also serve as a laboratory for new approaches. Recent legislative/regulatory efforts at the state level have included the following:

1. Implementation of, improvements to, and expanded physician and dispenser duties related to prescription drug monitoring programs (for example, in Kentucky [47], Massachusetts [48], Tennessee [49], and New York [50]).

2. The defining in law of clinical documentation and treatment requirements when scheduled medications are used, which may include patient education, counseling, mandatory urine testing, and so-called pain contracts (for example, in Florida [51], Kentucky [47], and Washington [52]).

3. A requirement for physicians who prescribe scheduled substances to demonstrate competence in the area; take related continuing medical education courses; or, under certain conditions, consult a recognized authority (for example, in Kentucky [47], Wisconsin [52], Georgia [53]).

4. Removal of dispensing privileges for scheduled drugs from physicians (for example, in Florida [51]).

5. Mandating the electronic prescribing (e-prescribing) for all controlled substances (for example, in New York [50]).

Penalties for failure to adhere to defined physician obligations under these regulations vary with each state and may include monetary penalties, criminal charges, and/or suspension or loss of medical license.

Although the medical community has generally been supportive of state efforts to address this growing problem, various physicians and medical societies have expressed concerns that excessive documentation, reporting, and treatment requirements may have the adverse effects of discouraging the appropriate use of these medications and/or patients deciding not to seek needed care (54).

ACP Policy Positions

1. *ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.*

Since 1998, ACP has advocated for a medical model, as opposed to the criminal justice approach focused on interdiction and incarceration, to address the problem of drug abuse. The medical model favored by ACP focuses on addiction as the underlying pathophysiology of the problem. ACP found that treatment and prevention are cost-effective ways to combat the drug

abuse epidemic. Interdiction and incarceration are expensive and yield only minimal results. ACP concluded that treatment and, most of all, prevention are essential to eradicating drug abuse in our society. The College has advocated for development of treatment guidelines to provide the best-quality treatment of all who need it. ACP has recognized that addiction is a chronic condition that must be treated continuously throughout the life of the abuser. Aftercare and other support are crucial to keeping people off drugs. Adequate funding must be provided to ensure that treatment is available. Public perceptions of the drug user must be changed. As the society for internists, ACP seeks to educate our members to ensure that they recognize the signs of substance abuse, are prepared to appropriately counsel and treat their patients, and support public and patient education (55). Furthermore, the College supports research efforts toward meeting all of these goals—including the development of guidelines on how to best provide needed care to patients with a high potential for abuse.

For fiscal year 2012, about \$25.2 billion was provided for drug control programs across 17 federal departments and independent agencies, an increase of \$5.9 billion (about 31%) from 2004. Of these funds, \$10.1 billion was allocated by federal agencies for drug abuse prevention and treatment programs. Approximately 14% of this, or almost \$1.4 billion, was allocated for drug abuse prevention services, and more than 86% of these funds, or greater than \$8.7 billion, for drug abuse treatment services (56).

ACP is pleased to see that NIDA is supporting research to better understand how to effectively treat people with chronic pain because they may be predisposed to addiction to prescription pain relievers. NIDA research is also exploring ways to prevent addiction among those at risk and is leading efforts to develop pain medications that have less potential for abuse, such as those that bypass the reward system of the brain (56). The College is concerned that recent budget cuts mandated by the Budget Control Act of 2011 will adversely affect these efforts (57).

2. ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.

ACP has been a long-time supporter of a comprehensive national policy on drug abuse. National Drug Control Strategies have been produced annually since 1989, and ACP formally supported the goals of the 1998 National Drug Control Strategy (55).

The Office of National Drug Control Policy (ONDCP) was established in the executive branch by the Anti-Drug Abuse Act of 1988 to enhance national drug control planning and coordination. It provides advice and government-wide oversight of federal drug programs and is responsible for coordinating drug control activities. The Office is required annually to develop the National Drug Control Strategy, which sets forth a plan to reduce illicit drug use through prevention, treatment, and law enforcement programs. The first strategy was issued for 2010. It sought to provide “a comprehensive approach to drug policy, including an emphasis on drug abuse prevention and treatment efforts and the use of evidence-based practices—approaches to

prevention or treatment that are based in theory and have undergone scientific evaluation” (56).

The Obama Administration developed a Prescription Drug Abuse Prevention Plan in 2011 that expands on the National Drug Control Strategy. Under the plan, action is to be taken in 4 major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. Education will seek to increase awareness about the dangers of prescription drug abuse. Education will be directed at parents, youth, patients, and health care providers. Education of health professionals will include information on ways to appropriately dispense, store, and dispose of controlled substance medications. Drug monitoring programs will be enhanced to help identify “doctor shoppers” and detect therapeutic duplication and drug–drug interactions. Consumer-friendly and environmentally responsible prescription drug disposal programs will be developed to reduce abuse of prescription drugs obtained from family and friends. The plan also includes support for law enforcement agencies in their efforts to shut down “pill mills” and to stop “doctor shoppers” (58). The College supports this and similar comprehensive efforts to address prescription drug abuse.

3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.

The literature reflects (6, 31), as a result of cultural trends, patient demands, and the time restraints of a typical patient visit, the observation that many physicians tend to respond too quickly to patient pain relief with controlled substances, particularly opioid medications. The College encourages physicians to consider the broad set of therapies available for the effective treatment and management of pain. This “toolkit” starts with strong patient–physician relationships and supportive systems of care, and further can include nonaddictive medications (such as acetaminophen, nonsteroidal anti-inflammatory drugs, and antidepressants); controlled medications; physical therapy; psychotherapy and counseling; mind–body approaches (such as relaxation therapy, biofeedback, hypnosis, and yoga); and various alternative therapies (such as acupuncture).

4. The ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.

ACP encourages physicians to use screening tools to identify possible drug abuse in their patients and to voluntarily use PDMP databases. Physicians should check before writing initial prescriptions for medications containing controlled substances. To deter prescription drug abusers from obtaining prescriptions from multiple physicians, pharmacies should be required to check the database before filling any prescriptions for controlled substances. A national PDMP structured under NASPER could be much more effective in addressing prescription drug abuse

than programs administered by the states, which are not accessible to pharmacies or prescribers in other states and have different as well as redundant reporting requirements. A national program could be standardized so that data would be uniformly reported to a single secure database that would be accessible across state lines to pharmacies, prescribers, and researchers on a confidential basis with appropriate privacy protections. Data on controlled medications dispensed by the VA should be included in the national database to detect potential drug abuse among the large population of veterans who are treated with them. As noted above, the VA recently modified its regulations to allow participation in state PDPM programs (41). Data in a national PDMP should be highly secure, with protections for confidentiality and privacy and strong penalties for violations or misuse. Funding for the national program should also be more stable than funding has been for the state-administered NASPER program and should include data for all states and the VA.

A national PDMP program would facilitate detection of attempts by drug dealers and drug abusers seeking to obtain controlled substances from multiple sources, including in different states, and would eliminate the administrative burden of checking multiple state databases for physicians and pharmacies.

Prescription data, particularly sensitive information on use of controlled substances, must be securely protected from violations of confidentiality. Access must be limited to those with legitimate needs for the data and must strictly adhere to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule requirements. Physicians, as well as anyone with access to confidential data in PDMP databanks, have an ethical obligation to “follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools” (11).

In states where physicians are mandated to check or report on PDMP databases when prescribing a controlled substance, efforts should be made to limit the administrative burden of this task. These efforts can include allowing the physician to delegate this responsibility to designated staff, defining reasonable exceptions to this mandate (for example, exempt mandate for patients receiving end-of-life care), and limiting when such checks are required to be made during a course of care (for example, limit to initial prescription and any new controlled substance prescription provided after 18 months).

The capability of electronic medical records systems to be connected to PDPMs and automatically check and report to these databases would also facilitate physician participation in these programs. The recent approval by the DEA of the electronic prescribing of controlled substances (36) (discussed below) makes this a viable goal.

5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.

Drug abuse or misuse can be challenging to detect. Resources and education for better management of drug addiction and misuse should be part of any comprehensive plan for appropriate use and prescribing of controlled substances. Physicians

must learn to recognize the signs of drug abuse and addiction. Protocols should be developed for the diagnosis and treatment of the conditions, including how to successfully wean patients off addictive medications.

ACP advocates development of evidence-based clinical guidelines and other tools to facilitate appropriate opioid prescribing (55).

Drugs that are classified by the DEA as controlled substances are particularly dangerous, and physicians should be cautious in prescribing them. In ordering any prescription drug, the prescriber must be knowledgeable about the drug's properties, potential benefits, efficacy, dosages, adverse effects, and potential drug interactions. To provide palliative care, physicians must be up to date on the proper use of opioids and the legality and propriety of using high doses of opioids as necessary to relieve suffering (11).

ACP encourages physicians, medical students, and residents to become well informed about the appropriate use and dangers of abuse of prescription drugs, particularly concerning controlled substances, and relevant training and learning opportunities should be available at all levels of practice. Medical school curricula, residency education and service obligations, and physician requirements for continuing medical education teach physicians about pharmacology and how to safely and appropriately prescribe medications. Medical education and training are comprehensive and continue throughout a physician's career.

Prescription drug abuse has only recently been recognized as a national crisis, so many physicians may not have received formal and systematic training regarding drug abuse and controlled substances. The prevention, identification, and treatment of prescription drug abuse take time, and the significant extra time required to adequately perform this task is not reimbursed. Although the College encourages physicians to voluntarily seek to update their knowledge about prescription drug abuse and responsible prescribing practices for controlled substances (particularly opioids), it does not support additional legislative mandates or DEA registration prerequisites specifying education requirements regarding prescribing controlled substances.

Public education should emphasize that all prescription drugs, especially those containing opioids and other controlled substances, should not be used for anything other than medical purposes. Public education should also include warnings not to take medications that are prescribed for someone else. Although patients may have similar ailments, self-medicating with someone else's unused medications, such as leftover drugs from a friend or deceased spouse, can be very dangerous. Patients should not use drugs that are not specifically prescribed for them by a physician who is knowledgeable about other drugs that they are taking, determines appropriate dosages, and is aware of potential for drug interactions. Perhaps most important, public education must raise awareness to approaches to pain management other than drugs.

This public education effort should also focus on ways to safeguard (for example, lock up) medications in use and how to dispose of medications no longer being prescribed.

6. ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.

ACP is particularly concerned that some current state drug abuse programs involve excessive practice requirements and enforcement methods. In addition to federal penalties that involve loss of DEA licensure and state disciplinary actions that can result in suspension or loss of medical licensure, some states impose criminal sanctions for failure to comply with documentation and treatment requirements. Excessive administrative/regulatory requirements create substantial and costly unfunded burdens for prescribers and pharmacies and can have the further unintended negative effect of interfering in effective delivery of care.

Sedatives, tranquilizers, stimulants, and pain relievers should be available for appropriate treatment of all patients as needed. Yet overly burdensome regulatory requirements may deter some physicians and other prescribers from using the most appropriate medications, causing patients to endure avoidable pain and unnecessary suffering.

7. ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.

Physicians must be responsive to the specific and unique needs of their patients. They must be able to adjust medication dosages according to individual needs that may vary over time and are not the same for all patients. Consequently, ACP opposes arbitrary maximum dosages by payers and health plans. These guidelines are instructive, but like any guidelines, they should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages and length of treatment reflecting physician judgment.

The FDA, in an effort to combat the “crisis of misuse, abuse, addiction, overdose, and death” from extended-release and long-acting opioid analgesics, recently narrowed their indicated use to the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (59). The FDA regulates drug companies, not clinicians and their prescribing, so this does not prohibit physician judgment in prescribing decisions. It does prohibit off-label promotion that is inappropriate given current evidence and that may be encouraging overprescribing.

There has also been controversy over funding of educational efforts around pain management by industry and links between industry and pain groups. ACP favors establishment of evidence-based, nonbinding guidelines, including on recommended maximum dosage and duration of therapy for controlled substances, by unbiased bodies. Physicians should practice with consideration of such guidelines.

ACP does not oppose establishing criteria for targeting efforts to identify potential cases of drug abuse or risks for adverse drug reactions, such as the case management pilot program using

MED criteria being tested by CMS to identify potential cases of opioid overdoses and risks for adverse drug reaction (22). These approaches should be coupled with research to assess their effectiveness.

8. Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Although physicians may be required to report suspected cases of drug abuse, they should not be mandated to conduct random drug testing without the patient's knowledge or consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.

The epidemic of prescription drug abuse necessitates that physicians cooperate with efforts by health insurers and government entities to identify and thwart attempts to obtain prescriptions for drugs that will be abused or used illicitly. Programs in some states require patients identified as being at “high risk” for drug abuse to submit to random drug testing. Physicians are mandated to order these random drug tests for patients suspected of being abusers because of repeated requests for early refills, multiple requests to replace “lost” prescriptions, and unauthorized dose escalation. When a physician is mandated to order random drug testing or suspects that a patient is abusing drugs, the patient should first be informed that testing will occur on a random basis, patient consent should be obtained, and the procedure should be implemented in a manner that helps maintain the patient's dignity. The participating physician should also be aware of the limitations of the monitoring procedure used and how various factors (such as a patient's physical condition and use of other medications) can affect the validity of the findings.

Drug testing can cost patients up to several hundred dollars for each episode, and some states require multiple random tests a year. These costs may not be covered by insurance because they are not generally considered medically necessary (60). The costs of mandatory drug testing can thus be high for patients and possibly for the uncompensated physicians who order the tests. When drug testing is mandated by legal authorities, health insurers, or government programs, that authority should bear the cost of the tests.

This recommendation is focused on the specific situation when a third party mandates urine testing (or other forms of monitoring), rather than a situation in which a physician includes monitoring (with consent) as part of an overall treatment plan developed to meet the evaluated needs of a given patient.

9. ACP recommends the consideration of patient-provider treatment agreements between physicians and patients as a tool for the treatment of pain.

Patient-provider pain treatment agreements, also referred to in the literature as pain management agreements, opioid treatment agreements, and pain medication contracts, have become common in the field of pain management. The FSMB recommends that physicians consider using these agreements (42).

A growing number of states (such as Florida and Washington) currently require physicians to use these treatment agree-

ments under specified conditions. Few evidence-based data reflect the overall effectiveness of these pain agreements or the most effective provisions to include (42, 61). Benefits attributed to use include facilitating patient understanding regarding the risks and benefits of treatment—particularly when controlled substances are part of the treatment plan—and facilitating increased adherence through an explicit statement of expectations and responsibilities of both the patient and physician during the treatment process.

A review of the opioid agreements used at 38 major academic pain centers contained the following general elements: terms of treatment, prohibited behaviors, points of termination, patient responsibilities, issues about education, addiction treatments, emergency issues, goals, prescription limitations, legal considerations, discouraged behavior, and responsibilities of staff (62).

Recent literature has raised concerns regarding potential negative unintended consequences and ethics and legal concerns regarding these agreements—particularly when the agreements are imposed on the patient as opposed to being coordinated with him or her in a manner that recognizes individual needs and preferences. These consequences/concerns include erosion of the patient–physician relationship as well as the promotion of an environment that discourages patients from seeking pain treatment or physicians from using controlled substances within the treatment plan (63). An ACP article titled “The Difficult Patient: Should You End the Relationship?” (64) addresses issues related to these agreements, including treatment termination provisions, and highlights the ethical and legal obligations related to avoiding patient abandonment.

10. The ACP recommends the passage of legislation by all 50 states permitting the electronic prescription of all scheduled controlled substances.

The literature is replete with the benefits of electronic prescribing (e-prescribing) compared with traditional paper prescriptions and includes a seminal report recommending full adoption throughout health care by the Institute of Medicine (65). Benefits purported include improved safety, quality, efficiency, and patient/consumer convenience. These benefits are highlighted when related to the prescribing of controlled substances. The benefits of electronic prescribing of controlled substances include the following:

A. Improved safety in the delivery of these medications when connected with clinical decision support technology. Prescribing physicians can receive at the site of care real-time, drug–drug interaction, drug–allergy interaction, dosing, and clinical guideline information to ensure the appropriateness of the prescription. The physician’s history of prescribing for this patient is also readily obtainable.

B. Facilitated real-time communication with payers and pharmacies to help ensure safe and appropriate prescribing of these substances. Prescribers can receive up-to-date, system-wide information regarding the patient’s medication history, including his or her receipt of prescriptions for controlled substances from other physicians, and safety and potential abuse information de-

rived from REMS and Drug Utilization Review Controls used by payers and pharmacists.

C. Facilitated real-time communication with state (and potentially nationwide) controlled-substance monitoring systems to ensure the safe and appropriate prescribing of these substances.

D. Decreased likelihood of diversion resulting from the security features embedded in the DEA final rule permitting EPCS (summarized below).

Recent surveys reflect significant increases in adoption of EPCS capability throughout the health care system. The Office of the National Coordinator for Health Information recently published a report (66) indicating that 48% of physicians are currently e-prescribing. This report only included physicians doing so through an electronic medical record system. A second survey (67) found that 58% of office-based physicians were e-prescribing, either through an electronic medical record or a stand-alone system, by the end of 2011. A significant impetus for increased implementation of e-prescribing is the use of incentive and penalty initiatives by the federal government—particularly the Medicare eRx and the Medicare and Medicaid “Meaningful Use” electronic medical record programs.

Beginning with the Medicare Modernization Act of 2003, the federal government provided support for the general development of an e-prescribing infrastructure and encouraged implementation of this technology for noncontrolled medications. In contrast, the EPCS has been prohibited by the DEA until recently. The DEA contended that as a result of the increased likelihood of abuse and diversion of controlled substances (compared with other prescription medications), additional safeguards needed to be included within systems before the e-prescribing of these medications could be approved. As noted, in 2010 the DEA released an interim final rule that defined an approved set of regulations for e-prescribing of controlled substance (36). Safeguards to decrease the likelihood of abuse and diversion include use of a certified e-prescribing application; prescriber identity proofing (that is, an approved credential issuer validates sufficient information to uniquely identify a person applying for the privilege); a 2-factor authentication procedure (the prescriber requires 2 forms of identification to e-prescribe the controlled substance—for example, password and thumbprint); defined local access procedures; and a certified, secure transmission network.

The DEA regulations permitting EPCS do not exempt existing related state laws. An informal survey by Surescripts (68), a provider of secure e-transmission information and e-prescribing networks, indicates that more than 40 states have laws consistent with EPCS, although they vary regarding approval of the EPCS of Schedule II through V or III through V medications. The College historically has supported the concept of e-prescribing and as a result of the recently approved DEA regulations (with embedded safeguards), recommends the passage by all 50 states of legislation permitting e-prescribing of all scheduled medications. Progress remains to be made toward the development of required infrastructure, ready availability of certified e-prescribing systems and modules, and expansion of pharmacies capable of

receiving these electronically transmitted controlled substance prescriptions.

Conclusion

The goal of this paper is to provide physicians and policy-makers with a set of recommendations to address the significant human and financial costs related to prescription drug abuse. The recommendations address detection and deterrence, as well as treatment, of this condition, and also discuss the need for increased educational efforts on the issue of prescription drug abuse both for the patient population and the physicians who treat them. They touch on the importance of maintaining patient involvement, dignity, and privacy and the importance of limiting third-party administrative and regulatory mandates on physicians attempting to provide care and address this issue. These recommendations offered by the College aim to form a framework for patients to receive the care they require while effectively accounting for the problems associated with the use of prescription drugs—specifically, those with a significant potential for abuse.

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