American Society of Addiction Medicine

4601 North Park Avenue • Arcade Suite 101 • Chevy Chase, MD 20815-4520

MEMORANDUM

TO: Ms. Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301 827-7001; fax: 827-6801
email: topperk@cder.fda.gov

FROM: James Callahan, D.P.A
Executive Vice President and CEO
American Society of Addiction Medicine
301 656-3920; fax: 656-3815
email: jcall@asam.org

SUBJECT: June 14- 15 Meeting of the Anesthetic and Life Support Advisory Committee: Written Submission

DATE: May 23, 2001

The American Society of Addiction Medicine (ASAM) wishes to submit the attached three documents for the record, and for consideration by the FDA's Anesthetic and Life Support Advisory Committee at its June 14-15, 2001 meeting.

The three ASAM documents address the issues to be taken up by the Advisory Committee; namely:

1. Medical use of opiate analgesics for patients with chronic pain of non-malignant etiology, and

2. Abuse potential, diversion and addiction to opiate analgesics.

The first document (attachment 1), *Definitions Related to the Use of Opioids for the Treatment of Pain* is a consensus document jointly issued by ASAM with the American Academy of Pain Medicine and the American Pain Society. The document defines and distinguishes between "addiction," "physical dependence," and "tolerance," and discusses their clinical and patient management implications.

The second document (attachment 2), *The Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain*, addresses issues pertinent to the physicians in responsibly prescribing opioids, and issues regarding protections, safeguards and education for prescribing physicians.

The third document (attachment 3) is an ASAM Press Release, *Prevent misuse of pain medications, but do not withhold them from patients who need them*. This document addresses the current problem of diversion of prescription pain medication by addicted individuals, or for sale by others.

The document proposes a resolution of the problem, by a balanced approach which includes continued availability of analgesics for treatment of chronic pain of non-malignant etiology, law enforcement intervention to stop diversion, treatment of those addicted to prescription medication and other drugs, and collaboration of pharmaceutical manufacturers, the health care community and law enforcement to establish education programs and monitoring procedures.

Thank you for the opportunity to submit written comment on this important issue.

Att: (3)

- *Consensus Statement: Definitions Related to the Use of Opioids for the Treatment of Pain*
- *The Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain*
- Press Release: *Prevent misuse of pain medications, but do not withhold them from patients who need them*

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The American Academy of Pain Medicine,
The American Pain Society and the American Society of Addiction Medicine

Consensus Document

Definitions Related to the Use of Opioids for the Treatment of Pain

Background

Clear terminology is necessary for effective communication regarding medical issues. Scientists, clinicians, regulators and the lay public use disparate definitions of terms related to addiction. These disparities contribute to a misunderstanding of the nature of addiction and the risk of addiction, especially in situations in which opioids are used, or are being considered for use, to manage pain. Confusion regarding the treatment of pain results in unnecessary suffering, economic burdens to society, and inappropriate adverse actions against patients and professionals.

Many medications, including opioids, play important roles in the treatment of pain. Opioids, however, often have their utilization limited by concerns regarding misuse, addiction and possible diversion for non-medical uses.

Many medications used in medical practice produce dependence, and some may lead to addiction in vulnerable individuals. The latter medications appear to stimulate brain reward mechanisms; these include opioids, sedatives, stimulants, anxiolytics, some muscle relaxants, and cannabinoids.

Physical dependence, tolerance and addiction are discrete and different phenomena that are often confused. Since their clinical implications and management differ markedly, it is important that uniform definitions, based on current scientific and clinical understanding, be established in order to promote better care of patients with pain and other conditions where the use of dependence-producing drugs is appropriate, and to encourage appropriate regulatory policies and enforcement strategies.

RECOMMENDATIONS

The American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM), and the American Pain Society (APS) recognize the following definitions and recommend their use:

Addiction
Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

Tolerance
Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

DISCUSSION

Most specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders. However, the actual risk is not known and probably varies with genetic predisposition, among other factors. Addiction, unlike tolerance and physical dependence, is not a predictable drug effect, but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals. Most exposures to drugs that can stimulate the brain's reward center do not produce addiction. Addiction is a primary chronic disease and exposure to drugs is only one of the etiologic factors in its development.

Addiction in the course of opioid therapy of pain can best be assessed after the pain has been brought under adequate control, though this is not always possible. Addiction is recognized by the observation of one or more of its characteristic features: impaired control, craving and compulsive use, and continued use despite negative physical, mental and/or social consequences. An individual's behaviors that may suggest addiction sometimes are simply a reflection of unrelieved pain or other problems unrelated to addiction. Therefore, good clinical judgment must be used in determining whether the pattern of behaviors signals the presence of addiction or reflects a different issue.

Behaviors suggestive of addiction may include: inability to take medications according to an agreed upon schedule, taking multiple doses together, frequent reports of lost or stolen prescriptions, doctor shopping, isolation from family and friends and/or use of non-prescribed psychoactive drugs in addition to prescribed medications. Other behaviors which may raise concern are the use of analgesic medications for other than analgesic effects, such as sedation, an increase in energy, a decrease in anxiety, or intoxication; non-compliance with recommended non-opioid treatments or evaluations; insistence on rapid-onset formulations/routes of administration; or reports of no relief whatsoever by any non-opioid treatments.

Adverse consequences of addictive use of medications may include persistent sedation or intoxication due to overuse; increasing functional impairment and other medical complications; psychological manifestations such as irritability, apathy, anxiety or depression; or adverse legal, economic or social consequences. Common and expected side effects of the medications, such as constipation or sedation due to use of prescribed doses, are not viewed as adverse consequences in this context. It should be emphasized that no single event is diagnostic of addictive disorder. Rather, the diagnosis is made in response to a pattern of behavior that usually becomes obvious over time.

Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.

Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications. Physical dependence may develop with chronic use of many classes of medications. These include beta blockers, alpha-2 adrenergic agents, corticosteroids, antidepressants and other medications that are not associated with addictive disorders. When drugs that induce physical dependence are no longer needed, they should be carefully tapered while monitoring clinical symptoms to avoid withdrawal phenomena and such effects as rebound hyperalgesia. Such tapering, or withdrawal, of medication should not be termed detoxification. At times, anxiety and sweating can be seen in patients who are dependent on sedative drugs, such as alcohol or benzodiazepines, and who continue taking these drugs. This is usually an indication of development of tolerance, though the symptoms may be due to a return of the symptoms of an underlying anxiety disorder, due to the development of a new anxiety disorder related to drug use, or due to true withdrawal symptoms.

A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects. For example, in the case of opioids, tolerance usually develops more slowly to analgesia than to respiratory depression, and tolerance to the constipating effects may not occur at all. Tolerance to the analgesic effects of opioids is variable in occurrence but is never absolute; thus, no upper limit to dosage of pure opioid agonists can be established.

Universal agreement on definitions of addiction, physical dependence and tolerance is critical to the optimization of pain treatment and the management of addictive disorders. While the definitions offered here do not constitute formal diagnostic criteria, it is hoped that they may serve as a basis for the future development of more specific, universally accepted diagnostic guidelines. The definitions and concepts that are offered here have been developed through a consensus process of the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

Approved by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, February 2001 (replaces the original ASAM Statement of April 1997)

AMERICAN SOCIETY OF ADDICTION MEDICINE, INC.

Public Policy Statement on the Rights and Responsibilities of Physicians in the use of Opioids for the Treatment of Pain

Background

Physicians' concerns regarding possible legal, regulatory, licensing or other third party sanctions related to the prescription of opioids contribute significantly to the undertreatment of pain.

Physicians are obligated to relieve pain and suffering in their patients. Though many types of pain are best addressed by non-opioid interventions, opioids are often required as a component of effective pain treatment. In patients complaining of pain, which is a subjective phenomenon, it is often a difficult medical judgment as to whether opioid therapy is indicated. This may be a particularly difficult judgment in patients with concurrent addictive disorders for whom exposure to potentially intoxicating substances may present special risks. It is, nonetheless, a medical judgment which must be made by a physician in the context of the doctor-patient relationship based on knowledge of the patient, awareness of the patient's medical and psychiatric conditions and on observation of the patient's response to treatment. The selection of a particular opioid medication(s), and the determination of opioid dose and therapeutic schedule, similarly must be based on full clinical understanding of a particular situation and cannot be judged appropriate or inappropriate independent of such knowledge.

Despite appropriate medical practice, physicians who prescribe opioids for pain may occasionally be misled by skillful patients who wish to obtain medications for purposes other than pain treatment, such as diversion for profit, recreational abuse or maintenance of an addicted state. The physician who is never duped by such patients may be denying appropriate relief to patients with significant pain all too often. It must be recognized that physicians who are willing to provide compassionate, ongoing medical care to challenging, psychosocially stressed patients may more often be faced with deception than physicians who decline to treat this difficult population.

Addiction to opioids may occur in the course of opioid therapy of pain in susceptible individuals under some conditions. Persistent failure to recognize and provide appropriate medical treatment for the disease of addiction is poor medical practice and may become grounds for practice concern. Similarly, persistent failure to use opioids effectively when they are indicated for the treatment of pain is poor medical practice and may also become grounds for practice concern. It is important to distinguish, however, between physicians who profit from diversion or other illegal prescribing activities and physicians who may inappropriately prescribe opioids due to misunderstandings regarding addiction or pain.

Physicians traditionally have received little or no education on addiction or clinical pain treatment in the course of medical training. This omission is likely a basis for inadequate detection and management of addiction and inadequate assessment and treatment of pain.

Recommendations

1. Physicians who prescribe opioids for the treatment of pain should use reasonable medical judgment to establish that a pain state exists and to determine whether opioids are an indicated component of treatment. Opioids should be prescribed in a legal and clinically sound manner, and patients should be followed at reasonable intervals for ongoing medical management and to confirm as nearly as is reasonable that the medications are used as prescribed. Such management should be appropriately documented.

2. Physicians who are practicing medicine in good faith and who use reasonable medical judgment regarding the prescription of opioids for the treatment of pain should not be held responsible for the willful and deceptive behavior of patients who successfully obtain opioids for non-medical purposes. It is the appropriate role of the DEA, pharmacy boards and other regulatory agencies to inform physicians of the behavior of such patients when it is detected.

3. Physicians who consistently fail to recognize addictive disorders in their patients should be offered education, not sanction, as a first intervention.

4. Physicians who consistently fail to appropriately evaluate and treat pain in their patients should be offered education as a first-line intervention.

5. For the purpose of performing regulatory, legal, quality assurance and other clinical case reviews, it should be recognized that judgment regarding a) the medical appropriateness of the prescription of opioids for pain in a specific context, b) the selection of a particular opioid drug or drugs, and c) the determination of indicated opioid dosage and interval of medication administration, can only be made properly with full and detailed understanding of a particular clinical case.

6. Regulatory, legal, quality assurance and other reviews of clinical cases involving the use of opioids for the treatment of pain should be performed, when they are indicated, by reviewers with a requisite level of understanding of pain medicine and addiction medicine.

7. Appropriate education in addiction medicine and pain medicine should be provided as part of the core curriculum at all medical schools.

8. Legal and/or licensing actions against physicians who are proven to profit from diversion of scheduled drugs or from other illegal prescribing activities are appropriate.

Adopted by the ASAM Board of Directors, April 1997

May 16, 2001
For immediate release:

Contact person: James F. Callahan
301-656-3920

American Society of Addiction Medicine: PREVENT MISUSE OF PAIN MEDICATIONS, BUT DO NOT WITHHOLD THEM FROM PATIENTS WHO NEED THEM.

Chevy Chase, Maryland, May 16, 2001 The American Society of Addiction Medicine (ASAM) recognizes the important role of opioids in the treatment of pain, and the necessity of having different types of opioids available to meet the needs of patients with serious pain problems. ASAM also recognizes that diversion of prescription pain medications for use by addicted individuals or for sale by others is an important public health and law enforcement problem.

In a Statement released today, ASAM President Andrea Barthwell, M.D., FASAM said that "diversion of prescription pain medications, principally opioids, occurs because of addicted individuals who seek these drugs, or because of individuals who divert them for sale. Restriction of the availability of opioid pain medications will not reduce problems of diversion and addiction, but may deter effective pain treatment for many individuals who suffer with pain."

"ASAM," Barthwell said, "is concerned about and opposed to the diversion and abuse of opioid medications because of the threat to individuals and the public health. ASAM

supports law enforcement in its efforts to identify and intervene in medication diversion. At the same time, ASAM encourages and supports broader access to medical treatment for individuals addicted to prescription drugs, as well as to other substances.

"An important approach to curbing prescription drug diversion is to encourage the health care community, state and federal legislators, law enforcement agencies and pharmaceutical manufacturers to establish education programs and monitoring procedures to ensure that patients who need opioid medications for pain control have access to them, while individuals who would divert or traffice the pain medications do no."

The treatment of chronic pain most often requires a multidimensional approach. Opioids alone are rarely effective. If opioids are indicated as a component of treatment, they must be used responsibly and appropriately, with proper evaluation and follow up of the patient. The goals of opioid treatment of chronic pain are to decrease pain and increase the level of function of the patient.

When properly prescribed and monitored, the development of addiction to opioids in the course of pain treatment is rare in patients with no history of addictive disease. Special care is required in supporting patients with a history of addiction while using opioids for pain treatment, but effective treatment of pain should be provided to all patients, including those with addictions.

Because misunderstandings regarding the nature of addiction are often a barrier to proper pain management, ASAM seeks to educate physicians and the lay public about the proper approaches to the treatment of pain and about the fact that the appropriate treatment of pain with opioid medication does not inevitably lead to addiction. ASAM is also engaged in improving access to appropriate pain treatment for all patients, including those with addictive disorders, using either opioid or non-opioid treatment, as appropriate. ASAM has undertaken this in collaboration with the American Pain Society and the American Academy of Pain Medicine.

The American Society of Addiction Medicine (ASAM) is a national medical specialty society of physicians engaged in research on and prevention and treatment of addiction to alcohol, nicotine and other psychoactive substances. The Society's mission is to educate physicians and to improve access to treatment for individuals with addictions.

FACSIMILE

DATE: May 23, 2001

TO: Ms. Kimberly Topper, FDA

FAX NO: 301-827-6801

FROM: Joanne Gartenmann
Executive Assistant

RE: ASAM Submission for the June 14-15 Meeting of the Anesthetic and Life Support Advisory Committee

****

Dr. James Callahan, Executive Vice President/CEO of ASAM, has asked me to send the attached 4 documents to you by e-mail and by fax.

- Memorandum
- Public Policy Consensus Statement: Definitions Related to the Use of Opioids for the Treatment of Pain
- Public Policy Statement: Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain
- ASAM Press Release: "Prevent misuse of pain medications, but do not withhold them from patients who need them"

medical review officer training course, june 1-3, 2001, st. louis, mo
conference on tobacco dependence, September 13-16, 2001, atlanta, ga
november 1-3, 2001, state of the art course, washington, d.c.
2002 ANNUAL CONFERENCE
pain and addiction: common threads course, april 25, 2002, atlanta, ga
ruth fox course for physicians, april 25, 2002, atlanta, ga
33rd annual medical-scientific conference, april 26-28, 2002, atlanta, ga

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Thank you for the opportunity to submit written comment on this important issue.

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The American Academy of Pain Medicine,
The American Pain Society and the American Society of Addiction Medicine

Consensus Document

Definitions Related to the Use of Opioids for the Treatment of Pain

Background

Clear terminology is necessary for effective communication regarding medical issues. Scientists, clinicians, regulators and the lay public use disparate definitions of terms related to addiction. These disparities contribute to a misunderstanding of the nature of addiction and the risk of addiction, especially in situations in which opioids are used, or are being considered for use, to manage pain. Confusion regarding the treatment of pain results in unnecessary suffering, economic burdens to society, and inappropriate adverse actions against patients and professionals.

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Behaviors suggestive of addiction may include: inability to take medications according to an agreed upon schedule, taking multiple doses together, frequent reports of lost or stolen prescriptions, doctor shopping, isolation from family and friends and/or use of non-prescribed psychoactive drugs in addition to prescribed medications. Other behaviors which may raise concern are the use of analgesic medications for other than analgesic effects, such as sedation, an increase in energy, a decrease in anxiety, or intoxication; non-compliance with recommended non-opioid treatments or evaluations; insistence on rapid-onset formulations/routes of administration; or reports of no relief whatsoever by any non-opioid treatments.

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Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.

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Despite appropriate medical practice, physicians who prescribe opioids for pain may occasionally be misled by skillful patients who wish to obtain medications for purposes other than pain treatment, such as diversion for profit, recreational abuse or maintenance of an addicted state. The physician who is never duped by such patients may be denying appropriate relief to patients with significant pain all too often. It must be recognized that physicians who are willing to provide compassionate, ongoing medical care to challenging, psychosocially stressed patients may more often be faced with deception than physicians who decline to treat this difficult population.

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Physicians traditionally have received little or no education on addiction or clinical pain treatment in the course of medical training. This omission is likely a basis for inadequate detection and management of addiction and inadequate assessment and treatment of pain.

Recommendations

1. Physicians who prescribe opioids for the treatment of pain should use reasonable medical judgment to establish that a pain state exists and to determine whether opioids are an indicated component of treatment. Opioids should be prescribed in a legal and clinically sound manner, and patients should be followed at reasonable intervals for ongoing medical management and to confirm as nearly as is reasonable that the medications are used as prescribed. Such management should be appropriately documented.

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3. Physicians who consistently fail to recognize addictive disorders in their patients should be offered education, not sanction, as a first intervention.

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5. For the purpose of performing regulatory, legal, quality assurance and other clinical case reviews, it should be recognized that judgment regarding a) the medical appropriateness of the prescription of opioids for pain in a specific context, b) the selection of a particular opioid drug or drugs, and c) the determination of indicated opioid dosage and interval of medication administration, can only be made properly with full and detailed understanding of a particular clinical case.

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Adopted by the ASAM Board of Directors, April 1997

ASAM AMERICAN SOCIETY OF ADDICTION MEDICINE

PRESS RELEASE

May 16, 2001
For immediate release:

Contact person: James F. Callahan
301-656-3920

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supports law enforcement in its efforts to identify and intervene in medication diversion. At the same time, ASAM encourages and supports broader access to medical treatment for individuals addicted to prescription drugs, as well as to other substances.

"An important approach to curbing prescription drug diversion is to encourage the health care community, state and federal legislators, law enforcement agencies and pharmaceutical manufacturers to establish education programs and monitoring procedures to ensure that patients who need opioid medications for pain control have access to them, while individuals who would divert or traffice the pain medications do no."

The treatment of chronic pain most often requires a multidimensional approach. Opioids alone are rarely effective. If opioids are indicated as a component of treatment, they must be used responsibly and appropriately, with proper evaluation and follow up of the patient. The goals of opioid treatment of chronic pain are to decrease pain and increase the level of function of the patient.

When properly prescribed and monitored, the development of addiction to opioids in the course of pain treatment is rare in patients with no history of addictive disease. Special care is required in supporting patients with a history of addiction while using opioids for pain treatment, but effective treatment of pain should be provided to all patients, including those with addictions.

Because misunderstandings regarding the nature of addiction are often a barrier to proper pain management, ASAM seeks to educate physicians and the lay public about the proper approaches to the treatment of pain and about the fact that the appropriate treatment of pain with opioid medication does not inevitably lead to addiction. ASAM is also engaged in improving access to appropriate pain treatment for all patients, including those with addictive disorders, using either opioid or non-opioid treatment, as appropriate. ASAM has undertaken this in collaboration with the American Pain Society and the American Academy of Pain Medicine.

The American Society of Addiction Medicine (ASAM) is a national medical specialty society of physicians engaged in research on and prevention and treatment of addiction to alcohol, nicotine and other psychoactive substances. The Society's mission is to educate physicians and to improve access to treatment for individuals with addictions.