



ASAMNews

Newsletter of The American Society of Addiction Medicine

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**Voting for ASAM
officers takes place
in November.**

**Remember to
cast your ballot!**



Course on Best Practices in Drug Testing Meets in Chicago

ASAM's fourth annual course on "Best Practices: Clinical Drug Testing in Addiction" meets in Chicago November 18th at the historic Palmer House Hilton Hotel in downtown Chicago. Course chair Louis E. Baxter, Sr., M.D., FASAM, explains that, as more addiction treatment is delivered in outpatient settings, it has become more important that providers become knowledgeable about clinical drug testing and the state-of-the-art technologies that are being developed for it.

Funding for the course was provided through an unrestricted educational grant from the federal Center for Substance Abuse Treatment (CSAT). For additional information or to register, visit the ASAM website at WWW.ASAM.ORG or contact ASAM's Department of Meetings and Conferences at 301/656-3920. (See pages 7, 16 and 20 for more information on this and other education and training opportunities offered by ASAM.)

ASAM Partners with Health Department to Offer Buprenorphine Training

ASAM leaders and Baltimore City officials have jointly announced a new initiative that will pay for any eligible physician in Baltimore City to receive the required training to obtain a waiver to prescribe buprenorphine. The initiative, approved by the city's Board of Estimates, is a first-ever collaboration between local government, the American Society of Addiction Medicine, and Clinical Tools, Inc. It will allow city physicians to receive free online training, a key step toward obtaining the federal waiver required to prescribe buprenorphine in office-based practice.

"I urge all primary care doctors and psychiatrists working in the city to learn to prescribe this effective treatment for the lethal illness of opiate addiction," said Baltimore Health Commissioner Joshua Sharfstein, M.D., noting: "The training is free, it's online, and it will help you save lives."

Baltimore's effort is drawing support from national leaders in substance abuse treatment. Nora Volkow, M.D., Director of the National Institute on Drug Abuse, praised the partnership, saying, "Buprenorphine represents a health services delivery innovation for opiate

addicted individuals because it can be administered in the privacy of a doctor's office.... Baltimore's commitment to widespread availability of physician training in treatment protocols will not only increase accessibility to buprenorphine, it is also likely to prompt earlier attempts to obtain treatment."

Judith Martin, M.D., co-chair of ASAM's Buprenorphine Training project, told the assembled press: "Baltimore's new initiative to increase the number of physicians able to prescribe buprenorphine is exciting. Buprenorphine allows treatment for addiction to be integrated with other medical care such as primary health care and mental health services."

ASAM Executive Vice President/CEO Eileen McGrath, J.D., added: "We see this as a model of best practice that can efficiently and cost effectively be replicated with Health Departments across the country to significantly address existing treatment gaps."

Additional information about the buprenorphine training initiative, including instructions for physicians, is online at <http://www.ci.baltimore.md.us/government/health/>.



Eileen McGrath, J.D.

ASAM Offers New Pharmacotherapy Webcast

Eileen McGrath, J.D., Executive Vice President/CEO

The presentation, "Advances in Pharmacotherapy for Alcohol Dependence and the Use of ASAM PPC-2R to Improve Patient Care," offered at ASAM's 2006 Medical-Scientific Conference, is now available as a Webcast. Course faculty discuss recent advances in the pharmacologic treatment of alcohol dependence and highlight effective strategies for improving patient outcomes, including overcoming treatment obstacles and matching patients to the most appropriate therapy.

Learning objectives for the program are to help learners:

- ✓ Understand strategies to overcome barriers to the effective use of pharmacotherapies.
- ✓ Discuss practical approaches to integrating pharmacotherapies into clinical practice including patient selection, dose, adherence issues, and patient management.
- ✓ Enhance their knowledge of ASAM PPC-2R and its application in order to augment patient assessment, treatment planning, and management to support sustainable recovery from addiction

The Webcast, which is made possible by an unrestricted educational grant from Cephalon, Inc., and Alkermes, Inc., has been approved for 2 Category 1 CME credits. For more information or to view the Webcast, go to: www.extendmed.com/alcoholdependence2.

ASAM Offers CME Training on ADHD

ASAM's program Development staff are working with leaders of State Chapter to plan two CME programs that address ADHD and Co-Occurring Substance Use Disorders. Funded through an unrestricted educational grant from Shire Pharmaceuticals, the courses will be delivered at two locations in early 2007.

PCSS Serves More Than 1000 Physicians

The Physician Clinical Support System (PCSS), SAMHSA's nationwide mentor network for clinicians providing buprenorphine for the treatment of opioid dependence is entering the third year of the grant and is continues to meet or exceed all project goals. There are

currently over 1100 active PCSS participants in the mentor network nationwide (and participants from Canada, Japan, and Ireland) and the number of new registrants increases exponentially each quarter.

The website (www.PCSSmentor.org) is receiving a large number of visits from interested individuals and is a well utilized resource that is updated continuously. The PCSS listserv provides an important source of information on clinical best practices and mentoring resources. The PCSS clinical guidances have been developed as self-study materials and are available free of charge on the site. They address the following topics:

- ✓ HIV/AIDS
- ✓ Transferring Patients from Methadone to Buprenorphine
- ✓ Physician Billing for Office-Based Treatment of Opioid Dependence
- ✓ Acute Pain
- ✓ Monitoring of Liver Function Tests and Hepatitis in Patients Receiving Buprenorphine/Naloxone

The PCSS warm-line provides a national system of telephone triage, registers participants and matches them with an appropriate mentor within 48 hours. The warm line fields approximately 25 inquiries a week from individuals seeking general information about buprenorphine, and provides a necessary referral service for individuals both by engaging them in the PCSS, and by directing them to the SAMHSA buprenorphine website and information service.

In addition to continued print promotion of the PCSS in various newsletters and print media, the PCSS is linking with many colleague organizations' websites to provide direct access and information to our services.

The PCSS is designed to increase access to buprenorphine treatment among the millions of untreated opioid dependent patients in the United States. It is supported by SAMHSA through ASAM, in consortium with other specialty addiction medicine, psychiatric, pain and general medicine societies. To access this free service, find a PCSS clinician in your locale or region, to become a PCSS mentor, or for more information, call 1-877-630-8812 or visit <http://www.PCSSmentor.org/>.



American Society of Addiction Medicine

4601 North Park Ave., Suite 101
Chevy Chase, MD 20815

ASAM is a specialty society of physicians concerned about alcoholism and other addictions and who care for persons affected by those illnesses.

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DEA ANNOUNCES PROPOSED RULE ON PRESCRIBING

The U.S. Drug Enforcement Administration has announced a proposal rule that will make it easier for patients with chronic pain and other chronic conditions to avoid multiple trips to a physician to obtain prescriptions.

Under the proposed rule, physicians acting in the usual course of professional practice would be permitted to issue multiple Schedule II prescriptions during a single office visit, allowing patients to receive up to a 90-day supply of controlled drugs.

A 60-day public comment period on the Notice of Proposed Rulemaking began September 6, 2006, the date of publication. We encourage all interested individuals and organizations to comment on the rule, which DEA Administrator Karen Tandy has said was drafted in response to multiple requests from health care professionals. In a press release announcing the proposed rule, Administrator Tandy expressed a hope that the proposed rule "reflects an awareness of patients' needs as well as the importance of preventing any illegal diversion of prescription drugs."

The proposed rule, an accompanying policy statement entitled "Dispensing Controlled Substances for the Treatment of Pain," and an updated version of the DEA's Practitioner's Manual can be accessed on the DEA's website (www.dea.gov).

Rumors Fly, But 30-Patient Limit Stands

The expectations of many addiction professionals were — if not dashed — at least dampened when recent rumors of Congressional action to lift the 30-patient limit on use of buprenorphine proved to be untrue. Although language that would make such a change was introduced in the Senate in April as part of a bill (S.2560) to reauthorize funding for the Office of National Drug Control Policy (ONDCP), the Senate went into recess in September without acting on the measure.

The proposed change would apply only to physicians who have held a waiver for at least one year. Specifically, the language (appearing in Sec. 1002) would amend the federal Controlled Substances Act by inserting the following exemption: "The total of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30 unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary [of HHS] of the need and intent of the practitioner to treat more than such applicable number of patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number."

Since buprenorphine was launched in 2003, a growing number of physicians have been trained and certified to use the drug in the office-based treatment of opioid addiction. However, many physicians say the 30-patient limit forces them to turn away individuals who want and need such treatment. At a recent press event, Senator Orrin Hatch (R-UT) called for removal of the limit, saying: "We must allow qualified doctors to treat more addicts than can be treated under current law.... [W]hy should we bind a healer's hands from helping as many as he or she could?"

Mark Kraus, M.D., co-chair of ASAM's Public Policy Committee, also has argued for overturning the limit on the grounds that the provision "is arbitrary and capricious." Dr. Kraus says: "As an internist, I am not restricted by an arbitrary number as to how many diabetic, cardiac, hypertensive, pulmonary, or GI patients I can treat. As an addiction medicine specialist working as a methadone treatment provider, I am not limited to an arbitrary number of opiate dependent patients I can treat with methadone. Yet there is an arbitrary number of opiate dependent patients I can treat with Suboxone. This is totally irrational.... No other FDA-approved medication has an arbitrary limit as to the number of patients a physician is allowed to treat. The 30 rule rationing of care/treatment ignores the evidence and hurts the patients it was designed to benefit."

The next opportunity for action to remove the limit occurs when the Congress reconvenes in November. Senator Hatch and Senator Carl Levin (D-MI) have promised to continue their efforts at that time.

Opioids a Growing Cause of Overdose Deaths

Since 1990, numerous jurisdictions in the United States have reported increases in mortality related to drug poisoning. During the same period, the use of opioid analgesics has increased markedly as part of more aggressive pain management. A new study from the CDC documents a dramatic increase in poisoning mortality rates and compares it to sales of opioid analgesics nationwide.

The abruptness of the increase is evident in data showing that unintentional drug poisoning mortality rates rose about 5 percent per year from 1979 to 1990, but jumped by 18 percent per year from 1990 to 2002. Between 1999 and 2002, the number of opioid analgesic poisonings listed on death certificates increased 91.2 percent, while heroin and cocaine poisonings increased 12.4 percent and 22.8 percent, respectively. By 2002, opioid analgesic poisoning was listed in 5,528 deaths — more than either heroin or cocaine. The increase in deaths generally matched the increase in sales for each type of opioid. The investigators noted that the increase in deaths involving methadone paralleled the increase in methadone used as an analgesic, rather than use of methadone in opioid treatment programs.

Source: Paulozzi LJ, Budnitz DS & Xi Y (2006). Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety Sep*;15(9):618-627.



ASAM Board Approves Public Policy Statement on Highway Safety

Elizabeth F. Howell, M.D., FASAM

At its May 2006 meeting in San Diego, ASAM's Board of Directors gave final approval to three revisions of previously adopted Public Policy Statements on "Buprenorphine," "Marijuana," and "Highway Safety." Each of these had been debated and scrutinized by members of the Public Policy Committee, by representatives of the State Chapters (eight of whom serve on the Committee), and by members of the Board over the course of many weeks of consideration and revision.

As is true of many topics, some basic disagreements emerged among various schools of thought regarding details of the first draft revisions. These were worked through carefully and with broad participation to achieve compromises which would retain the tradition and quality of meaningful statements by the Society, while incorporating the diverse views of its members.

The statement on "Highway Safety in Relation to Alcohol and Other Drug Use and Addiction," originally adopted in 1987, was revised for the first time to incorporate updated information on a number of public health aspects of alcohol and other drug use, including prevention measures, education, safety issues, and others.

ASAM's Public Policy Statements can be accessed on ASAM's



Dr. Elizabeth F. Howell

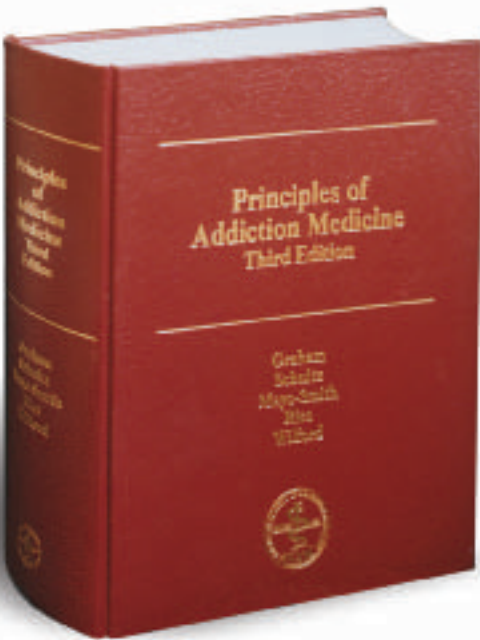
website (WWW.ASAM.ORG) by selecting "ASAM General" and "Public Policy" on the home page. The site also offers both a chronological and a topical listing of all ASAM Public Policy Statements, including the dates of revision, where applicable.

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ASAM Public Policy Statement on Highway Safety in Relation to Alcohol and Other Drug Use and Addiction

In view of the appalling toll of death, injury and damage caused by alcohol and other drug-related highway crashes, the American Society of Addiction Medicine makes the following recommendations:

Identification and Treatment

Even though crashes due to alcohol-or-other-drug-impaired driving occur in both alcoholic-and-other- drug-addicted drivers, and in drivers not diagnosable with an addictive disease, the identification and treatment of alcoholism and other drug dependencies should be an integral component of all policies, strategies and laws which address driving impaired by alcohol or other drugs. Without treatment of these diseases, there is no feasible means of reducing the number of repeat offenders.

Any legislation which imposes penalties for alcohol and/or other drug impaired driving should also include provisions for convicted drivers to undergo clinical assessment by a trained chemical dependency professional, and for convicted drivers diagnosed via assessment to have a substance use disorder to be required to complete appropriate treatment as a condition of a re-instatement of driving privileges. There should be evidence of successful rehabilitation, not merely attending sessions, before a suspended or revoked driver's license is reinstated.

Local jurisdictions should develop procedures for pre-sentence investigations, in conjunction with qualified professionals. The pre-sentence investigation process should include screening for identification of alcoholism and other drug dependencies, with referral to treatment as indicated.

The presence of alcohol, nicotine, other drugs, or their metabolites in an individual's breath or body fluids can provide evidence of substance use; but it must be emphasized that evidence of substance use by itself is insufficient to substantiate that any functional impairment related to substance use is present, or that a case of addiction is present. Nonetheless, when immediate post-crash toxicological testing identifies the presence of alcohol or other intoxicants, the crash victim should be referred to appropriate emergency medical services. Hospital emergency departments and trauma centers which receive intoxicated vehicular crash victims should provide evaluation and brief intervention to motivate the individual to accept referral to indicated chemical dependency services, consistent with the American College of Surgeons' guidelines for certified trauma centers.

ASAM recommends that state and specialty medical societies and public health associations initiate or increase their efforts to secure repeal of UPPL-related insurance codes at the state level. These alcohol exclusion laws allow for the denial of insurance payments for the treatment of injuries sustained as a consequence of the insured person having been an intoxicated driver. Laws deriving from such codes inadvertently compound problems with highway safety by discouraging emergency room staff from conducting blood or serum tests for alcohol concentration and by impeding screening for alcohol use among the population of vehicle crash victims — screening which would otherwise have the promise of identifying drivers with alcohol use disorders and reducing repeat offenses of driving while intoxicated (see ASAM Public Policy Statement on Repeal of the Uniform Accident and Sickness Policy Provision Law [UPPL]).

Governments should monitor compliance with the law and ensure the availability of high quality treatment and rehabilitation programs, in accordance with state-established standards, for intoxicated drivers referred by law to treatment.

State legislation or regulation should require health insurance providers to include coverage for comprehensive treatment of alcoholism and other drug dependencies in all health insurance policies, whenever such treatment is medically necessary, regardless of whether the referral to treatment was based on processes in place in the judicial system to identify and refer to addiction treatment intoxicated drivers identified as needing treatment.

Prevention

The American Society of Addiction Medicine has already adopted wide-ranging prevention policy recommendations. Their acceptance will reduce alcohol and other drug related highway deaths and injuries. Of special relevance to highway safety are the following:

States should cooperate in the retention of the national legal age of 21 for the purchase and public possession of all alcoholic beverages. The 21 year old minimum drinking age should apply in all US districts, territories and commonwealths as well as in the fifty states. Exceptions should not be made for military personnel under the age of 21 or any other groups.

State and local governments should prohibit consumption of alcoholic beverages in motorized vehicles and prohibit possession of open alcoholic beverage containers in passenger compartments of motor vehicles.

Each state should enact "Dram Shop" laws that establish liability against any person or establishment which sells or serves alcoholic beverages to an individual who appears to be intoxicated or who is under the legal purchase age. States should encourage such establishments to have devices for testing breath content of alcohol, and should set limits on levels at which sales of further alcohol to individuals is protected from prosecution under the "Dram Shop" laws.

Taxes on alcoholic beverages should be equalized across all types of alcoholic beverage and based on the percentage of alcohol content of the beverage. All tax revenues on alcoholic beverages should be dedicated to health-related treatment, research, education and prevention programs.

States should enact laws prohibiting the sale of alcoholic beverages at retail outlets where motor fuel is sold.

Programs for the treatment of alcoholism and other drug dependencies should contain an educational component about alcohol, other drugs and highway safety.

Law Enforcement

[ASAM's recommendations regarding highway safety, alcohol and other drug use and addiction, and law enforcement appear in ASAM's Public Policy Statement on "Law Enforcement issues Pertaining to the Unsafe Operation of Motor Vehicles."]

continued on page 6

PUBLIC POLICY STATEMENT *continued from page 6*

Public Education

Physicians, nurses, pharmacists and other health professionals should continue to take an active role in educating their patients and the public about the hazardous effects on highway safety of alcohol, other drugs—both legal (prescription and over-the-counter) and illicit—and various combinations of alcohol and other drugs.

Public information campaigns should continue to be developed on the state and national levels, in cooperation with the private sector, to focus on alcohol and other drug use, and their correlation with highway safety and other problems.

State and federal efforts should include information on alcoholism and other drug dependencies treatment in their public education campaigns related to enforcement of alcohol and other drug highway safety laws.

Editorial boards and trade associations should encourage their associates and members to communicate to the public regularly about alcohol and other drug use and their relationship to highway safety and other problems.

Broadcast and print media should portray alcohol and other drug use and their relationship to highway safety and other problems in a responsible manner and, when appropriate, use program content to communicate with the public about impaired driving and other social and health consequences of alcohol and other drug use.

Education should be provided for bartenders and other servers of alcoholic beverages (including social hosts and hostesses) about safe serving practices, prevention of harm to a person who is alcohol-impaired, and responsibilities under the law.

Professional Education

Professional education for all health and human service workers should include appropriate information about the health and public safety aspects of alcohol and other drug use and dependence.

Each state should have programs for training criminal justice personnel, including police officers, probation officers, judges, prosecutors, and defense attorneys, concerning the legal and public safety aspects of alcohol and other drug use and dependence.

Athletic coaches, trainers and teachers should be educated about the effects of alcohol and other drugs on health and behavior, and about their responsibilities toward team members, trainees and students in preventing alcoholism and other drug dependency.

Private Sector Organizations

Organizations should develop and disseminate policy statements regarding the use and misuse of alcohol and other drugs, in relationship to highway-related deaths and injuries and other social and health problems, including guidelines for the use of alcohol at organization-sponsored functions.

All employers should develop employee assistance programs, which serve family members as well as employees, to deal with alcoholism and other drug dependencies.

Organizations should become active advocates and participants in local, state and national endeavors to reduce the incidence of driving under the influence of alcohol and other drugs.

Youth Education

Schools should develop and teach age-appropriate curricula concerning the effects of alcohol and other drugs (including tobacco) on the brain and the rest of the body and their relationship to highway

safety and other health and social problems. Curricula should employ a lifestyle/risk reduction approach aimed at changing youthful behavior relative to impaired driving as well as other health and social problems related to alcohol and other drugs.

Athletic and other youth organizations should include information on the effects of alcohol and other drugs on the brain and the rest of the body with the aim of reducing risks associated with youthful impaired driving and other related problems.

Driver Education

Driver education programs should include information on alcohol and other drugs, their effects on the brain and the rest of the body, impact upon driving abilities and effects on attitudes, capabilities, coordination and judgment.

Driver licensing manuals should address the stress the relationship of alcohol and other drugs to highway safety and include information on penalties for arrest and conviction of alcohol and other drug driving offenses. These manuals should also include information on the nature of addictive disease, its manifestations and the availability of treatment for it, so that people may recognize and deal with these problems before they cause driving-related problems.

Drivers' license examinations should include questions to determine applicants' knowledge of the relationship of alcohol and other drugs to highway safety, and their understanding of laws governing alcohol and other drug purchasing, possession, use, and driving privileges.

Research

A broad range of basic and applied research on alcohol and other drug effects and related problems is a vital part of any effort to reduce alcohol and other drug related death and injury on the highway. ASAM specifically recommends:

Support for continuing research on the interactive effects of alcohol and other drugs on driving.

Support for research on the impact of various methods of alcohol and other drug dependency treatment on reducing the recidivism rate for alcohol-and-other-drug-related highway crashes and other offenses.

Support for research on the relative impacts of alcohol control measures on reducing alcohol-and-other-drug-impaired driving, including open container laws and increases in alcohol taxes.

Support for research on alcohol and other drug testing of blood, breath, saliva or other body fluids or tissues and their relationship to impaired driving. Specific target groups, including women, youth, elderly drivers and others should be considered as well as specific drug concentration thresholds and their relationship to impairment of driving abilities.

Support for research on alcohol media messages including public service announcements, alcohol and other drug-related program content and alcohol advertising, and their impact on attitudes and behavior related to impaired driving.

Support for research on the efficacy of drinking and driving-related warning labels on alcoholic beverages as a way to educate and influence decision-making regarding drinking and driving.

Support for development of improved methods for identifying impaired drivers, and for monitoring persons on probation because of an alcohol or other drug related driving offense.

Support for research into predictive and preventive factors in potential driver impairment.

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References: 1. CAMPRAL® (acamprosate calcium) Delayed-Release Tablets Prescribing Information, Forest Laboratories, Inc., St Louis, Mo, 2004. 2. Data on file, Forest Laboratories, Inc. 3. Pelc I, Verbanck P, Le Bon O, Gavrilovic M, Lion K, Leher P. Efficacy and safety of acamprosate in the treatment of detoxified alcohol-dependent patients: a 90-day placebo-controlled dose-finding study. *Br J Psychiatry*. 1997;171:73-77. 4. Sass H, Soyka M, Mann K, Zieglerberger W. Relapse prevention by acamprosate: results from a placebo-controlled study on alcohol dependence. *Arch Gen Psychiatry*. 1996;53:673-680. 5. Paille FM, Guelfi JD, Perkins AC, Royer RJ, Steru L, Parot P. Double-blind randomized multicentre trial of acamprosate in maintaining abstinence from alcohol. *Alcohol Alcohol*. 1995;30:239-247. 6. Pelc I, Ansoms C, Leher P, et al. The European NEAT Program: an integrated approach using acamprosate and psychosocial support for the prevention of relapse in alcohol-dependent patients with a statistical modeling of therapy success prediction. *Alcohol Clin Exp Res*. 2002;26:1529-1538. 7. Mason BJ. Acamprosate. *Recent Dev Alcohol*. 2003;16:203-215.

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CAMPRAL is contraindicated in patients who previously have exhibited hypersensitivity to acamprostate calcium or any of its components. CAMPRAL is contraindicated in patients with severe renal impairment (creatinine clearance ≤ 30 mL/min).

PRECAUTIONS

Use of CAMPRAL does not eliminate or diminish withdrawal symptoms. **General: Renal Impairment** Treatment with CAMPRAL in patients with moderate renal impairment (creatinine clearance of 30-50 mL/min) requires a dose reduction. Patients with severe renal impairment (creatinine clearance of ≤ 30 mL/min) should not be given CAMPRAL (see also CONTRAINDICATIONS). **Suicidality** In controlled clinical trials of CAMPRAL, adverse events of a suicidal nature (suicidal ideation, suicide attempts, completed suicides) were infrequent overall, but were more common in CAMPRAL-treated patients than in patients treated with placebo (1.4% vs. 0.5% in studies of 6 months or less; 2.4% vs. 0.8% in year-long studies). Completed suicides occurred in 3 of 2272 (0.13%) patients in the pooled acamprostate group from all controlled studies and 2 of 1962 patients (0.10%) in the placebo group. Adverse events coded as "depression" were reported at similar rates in CAMPRAL-treated and placebo-treated patients. Although many of these events occurred in the context of alcohol relapse, no consistent pattern of relationship between the clinical course of recovery from alcoholism and the emergence of suicidality was identified. The interrelationship between alcohol dependence, depression and suicidality is well-recognized and complex. Alcohol-dependent patients, including those patients being treated with CAMPRAL, should be monitored for the development of symptoms of depression or suicidal thinking. Families and caregivers of patients being treated with CAMPRAL should be alerted to the need to monitor patients for the emergence of symptoms of depression or suicidality, and to report such symptoms to the patient's health care provider. **Information for Patients** Physicians are advised to discuss the following issues with patients for whom they prescribe CAMPRAL. Any psychoactive drug may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that CAMPRAL therapy does not affect their ability to engage in such activities. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breast-feeding. Patients should be advised to continue CAMPRAL therapy as directed, even in the event of relapse and should be reminded to discuss any renewed drinking with their physician. Patients should be advised that CAMPRAL has been shown to help maintain abstinence only when used as a part of a treatment program that includes counseling and support. **Drug Interactions** The concomitant intake of alcohol and CAMPRAL does not affect the pharmacokinetics of either alcohol or acamprostate. Pharmacokinetic studies indicate that administration of disulfiram or diazepam does not affect the pharmacokinetics of acamprostate. Co-administration of naltrexone with CAMPRAL produced a 25% increase in AUC and a 33% increase in the C_{max} of acamprostate. No adjustment of dosage is recommended in such patients. The pharmacokinetics of naltrexone and its major metabolite 6-beta-naltrexone were unaffected following co-administration with CAMPRAL. Other concomitant therapies: In clinical trials, the safety profile in subjects treated with CAMPRAL concomitantly with anxiolytics, hypnotics and sedatives (including benzodiazepines), or non-opioid analgesics was similar to that of subjects taking placebo with these concomitant medications. Patients taking CAMPRAL concomitantly with antidepressants more commonly reported both weight gain and weight loss, compared with patients taking either medication alone.

Carcinogenicity, Mutagenicity and Impairment of Fertility A carcinogenicity study was conducted in which Sprague-Dawley rats received acamprostate calcium in their diet at doses of 25, 100 or 400 mg/kg/day (0.2, 0.7, or 2.5-fold the maximum recommended human dose based on an AUC comparison). There was no evidence of an increased incidence of tumors in this carcinogenicity study in the rat. An adequate carcinogenicity study in the mouse has not been conducted. Acamprostate calcium was negative in all genetic toxicology studies conducted. Acamprostate calcium demonstrated no evidence of genotoxicity in an *in vitro* bacterial reverse point mutation assay (Ames assay) or an *in vitro* mammalian cell gene mutation test using Chinese Hamster Ovary V79 cells. No chromosomal damage was observed in an *in vitro* chromosomal aberration assay in human lymphocytes and no clastogenic damage detected in an *in vivo* mouse micronucleus assay. Acamprostate calcium had no effect on fertility after treatment for 70 days prior to mating in male rats and for 14 days prior to mating, throughout mating, gestation and lactation in female rats at doses up to 1000 mg/kg/day (approximately 4 times the maximum recommended human daily oral dose on a mg/m² basis). In mice, acamprostate calcium administered orally for 60 days prior to mating and throughout gestation in females at doses up to 2400 mg/kg/day (approximately 5 times the maximum recommended human daily oral dose on a mg/m² basis) had no effect on fertility.

Pregnancy Category C Teratogenic Effects Acamprostate calcium has been shown to be teratogenic in rats when given in doses that are approximately equal to the human dose (on a mg/m² basis) and in rabbits when given in doses that are approximately 3 times the human dose (on a mg/m² basis). Acamprostate calcium produced a dose-related increase in the number of fetuses with malformations in rats at oral doses of 300 mg/kg/day or greater (approximately equal to the maximum recommended human daily oral dose on a mg/m² basis). The malformations included hydronephrosis, malformed iris, retinal dysplasia, and retroesophageal subclavian artery. No findings were observed at an oral dose of 50 mg/kg/day (approximately one-fifth the maximum recommended human daily oral dose on a mg/m² basis). An increased incidence of hydronephrosis was also noted in Burgundy Tawny rabbits at oral doses of 400 mg/kg/day or greater (approximately 3 times the maximum recommended human daily oral dose on a mg/m² basis). No developmental effects were observed in New Zealand white rabbits at oral doses up to 1000 mg/kg/day (approximately 8 times the maximum recommended human daily oral dose on a mg/m² basis). The findings in animals should be considered in relation to known adverse developmental effects of ethyl alcohol, which include the characteristics of fetal alcohol syndrome (craniofacial dysmorphism, intrauterine and postnatal growth retardation, retarded psychomotor and intellectual development) and milder forms of neurological and behavioral disorders in humans. There are no adequate and well controlled studies in pregnant women. CAMPRAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects** A study conducted in pregnant mice that were administered acamprostate calcium by the oral route starting on Day 15 of gestation through the end of lactation on postnatal day 28 demonstrated an increased incidence of still-born fetuses at doses of 960 mg/kg/day or greater (approximately 2 times the maximum recommended human daily oral dose on a mg/m² basis). No effects were observed at a dose of 320 mg/kg/day (approximately one-half the maximum recommended human daily dose on a mg/m² basis).

Labor and Delivery The potential for CAMPRAL to affect the duration of labor and delivery is unknown. **Nursing Mothers** In animal studies, acamprostate was excreted in the milk of lactating rats dosed orally with acamprostate calcium. The concentration of acamprostate in milk compared to blood was 1.3:1. It is not known whether acamprostate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CAMPRAL is administered to a nursing woman. **Pediatric Use** The safety and efficacy of CAMPRAL have not been established in the pediatric population. **Geriatric Use** Forty-one of the 4234 patients in double-blind, placebo-controlled clinical trials of CAMPRAL were 65 years of age or older, while none were 75 years of age or over. There were too few patients in the ≥ 65 age group to evaluate any differences in safety or effectiveness for geriatric patients compared to younger patients. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (See CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS

The adverse event data described below reflect the safety experience in over 7000 patients exposed to CAMPRAL for up to one year, including over 2000 CAMPRAL-exposed patients who participated in placebo-controlled trials.

Adverse Events Leading to Discontinuation In placebo-controlled trials of 6 months or less, 8% of CAMPRAL-treated patients discontinued treatment due to an adverse event, as compared to 6% of patients treated with placebo. In studies longer than 6 months, the discontinuation rate due to adverse events was 7% in both the placebo-treated and the CAMPRAL-treated patients. Only diarrhea was associated with the discontinuation of more than 1% of patients (2% of CAMPRAL-treated vs. 0.7% of placebo-treated patients). Other events, including nausea, depression, and anxiety, while accounting for discontinuation in less than 1% of patients, were nevertheless more commonly cited in association with discontinuation in CAMPRAL-treated patients than in placebo-treated patients. **Common Adverse Events Reported in Controlled Trials** Common, non-serious adverse events were collected spontaneously in some controlled studies and using a checklist in other studies. The overall profile of adverse events was similar using either method. Table 1 shows those events that occurred in any CAMPRAL

treatment group at a rate of 3% or greater and greater than the placebo group in controlled clinical trials with spontaneously reported adverse events. The reported frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed, without regard to the causal relationship of the events to the drug.

Table 1. Events Occurring at a Rate of at Least 3% and Greater than Placebo in any CAMPRAL Treatment Group in Controlled Clinical Trials with Spontaneously Reported Adverse Events

Body System/ Preferred Term	CAMPRAL 1332 mg/day	CAMPRAL 1998 mg/day ¹	CAMPRAL Pooled ²	Placebo
Number of Patients in Treatment Group	397	1539	2019	1706
Number (%) of Patients with an AE	248(62%)	910(59%)	1231(61%)	955(56%)
Body as a Whole	121(30%)	513(33%)	685(34%)	517(30%)
Accidental Injury*	17 (4%)	44 (3%)	70 (3%)	52 (3%)
Asthenia	29 (7%)	79 (5%)	114(6%)	93 (5%)
Pain	6 (2%)	56 (4%)	65 (3%)	55 (3%)
Digestive System	85 (21%)	440(29%)	574(28%)	344(20%)
Anorexia	20 (5%)	35 (2%)	57 (3%)	44 (3%)
Diarrhea	39 (10%)	257(17%)	329(16%)	166(10%)
Flatulence	4 (1%)	55 (4%)	63 (3%)	28 (2%)
Nausea	11 (3%)	69 (4%)	87 (4%)	58 (3%)
Nervous System	150(38%)	417(27%)	598(30%)	500(29%)
Anxiety**	32 (8%)	80 (5%)	118(6%)	98 (6%)
Depression	33 (8%)	63 (4%)	102(5%)	87 (5%)
Dizziness	15 (4%)	49 (3%)	67 (3%)	44 (3%)
Dry mouth	13 (3%)	23 (1%)	36 (2%)	28 (2%)
Insomnia	34 (9%)	94 (6%)	137(7%)	121(7%)
Paresthesia	11 (3%)	29 (2%)	40 (2%)	34 (2%)
Skin and Appendages	26 (7%)	150(10%)	187(9%)	169(10%)
Furunculitis	12 (3%)	68 (4%)	82 (4%)	58 (3%)
Sweating	11 (3%)	27 (2%)	40 (2%)	39 (2%)

*Includes events coded as "fracture" by sponsor; **includes events coded as "nervousness" by sponsor
¹ includes 258 patients treated with acamprostate calcium 2000 mg/day, using a different dosage strength and regimen. ² includes all patients in the first two columns as well as 83 patients treated with acamprostate calcium 3000 mg/day, using a different dosage strength and regimen.

Other Events Observed During the Premarketing Evaluation of CAMPRAL

Following is a list of terms that reflect treatment-emergent adverse events reported by patients treated with CAMPRAL in 20 clinical trials (4461 patients treated with CAMPRAL, 3526 of whom received the maximum recommended dose of 1998 mg/day for up to one year in duration). This listing does not include those events already listed above; events for which a drug cause was considered remote; event terms which were so general as to be uninformative; and events reported only once which were not likely to be acutely life-threatening. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events in controlled trials appear in this listing; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. **Body as a Whole** – *Frequent:* headache, abdominal pain, back pain, infection, flu syndrome, chest pain, chills, suicide attempt; *Infrequent:* fever, intentional overdose, malaise, allergic reaction, abscess, neck pain, hernia, intentional injury; *Rare:* ascites, face edema, photosensitivity reaction, abdomen enlarged, sudden death.

Cardiovascular System – *Frequent:* palpitation, syncope; *Infrequent:* hypotension, tachycardia, hemorrhage, angina pectoris, migraine, varicose vein, myocardial infarct, plebitis, postural hypotension; *Rare:* heart failure, mesenteric arterial occlusion, cardiomyopathy, deep thrombophlebitis, shock. **Digestive System** – *Frequent:* vomiting, dyspepsia, constipation, increased appetite; *Infrequent:* liver function tests abnormal, gastroenteritis, gastritis, dysphagia, eructation, gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage, liver cirrhosis, esophagitis, hematemesis, nausea and vomiting, hepatitis; *Rare:* melena, stomach ulcer, cholecystitis, colitis, duodenal ulcer, mouth ulceration, carcinoma of liver. **Endocrine System** – *Rare:* goiter, hypothyroidism. **Hemic and Lymphatic System** – *Infrequent:* anemia, ecchymosis, eosinophilia, lymphocytosis, thrombocytopenia; *Rare:* leukopenia, lymphadenopathy, monocytosis. **Metabolic and Nutritional Disorders** – *Frequent:* peripheral edema, weight gain; *Infrequent:* weight loss, hyperglycemia, SGOT increased, SGPT increased, gout, thirst, hypercemia, diabetes mellitus, avitaminosis, bilirubinemia; *Rare:* alkaline phosphatase increased, creatinine increased, hyponatremia, lactic dehydrogenase increased. **Musculoskeletal System** – *Frequent:* myalgia, arthralgia; *Infrequent:* leg cramps; *Rare:* rheumatoid arthritis, myopathy. **Nervous System** – *Frequent:* somnolence, libido decreased, amnesia, thinking abnormal, tremor, vasodilatation, hypertension; *Infrequent:* convulsion, confusion, libido increased, vertigo, withdrawal syndrome, apathy, suicidal ideation, neuralgia, hostility, agitation, neurosis, abnormal dreams, hallucinations, hypesthesia; *Rare:* alcohol craving, psychosis, hyperkinesia, twitching, depersonalization, increased salivation, paranoid reaction, torticollis, encephalopathy, manic reaction.

Respiratory System – *Frequent:* rhinitis, cough increased, dyspnea, pharyngitis, bronchitis; *Infrequent:* asthma, epistaxis, pneumonia; *Rare:* laryngismus, pulmonary embolus. **Skin and Appendages** – *Frequent:* rash; *Infrequent:* acne, eczema, alopecia, maculopapular rash, dry skin, urticaria, exfoliative dermatitis, vesiculobullous rash; *Rare:* psoriasis. **Special Senses** – *Frequent:* abnormal vision, taste perversion, *Infrequent:* tinnitus, amblyopia, deafness; *Rare:* ophthalmitis, diplopia, photophobia. **Urogenital System** – *Frequent:* impotence; *Infrequent:* metrorrhagia, urinary frequency, urinary tract infection, sexual function abnormal, urinary incontinence, vaginitis; *Rare:* kidney calculus, abnormal ejaculation, hematuria, menorrhagia, nocturia, polyuria, urinary urgency. **Serious Adverse Events Observed During the Non-US Postmarketing Evaluation of CAMPRAL (acamprostate calcium)** Although no causal relationship to CAMPRAL has been found, the serious adverse event of acute kidney failure has been reported to be temporally associated with CAMPRAL treatment in at least 3 patients and is not described elsewhere in the labeling.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class Acamprostate calcium is not a controlled substance. **Physical and Psychological Dependence** CAMPRAL did not produce any evidence of withdrawal symptoms in patients in clinical trials at therapeutic doses. Post marketing data, collected retrospectively outside the U.S., have provided no evidence of CAMPRAL abuse or dependence.

OVERDOSAGE

In all reported cases of acute overdose with CAMPRAL (total reported doses of up to 56 grams of acamprostate calcium), the only symptom that could be reasonably associated with CAMPRAL was diarrhea. Hypercalcemia has not been reported in cases of acute overdose. A risk of hypercalcemia should be considered in chronic overdose only. Treatment of overdose should be symptomatic and supportive.

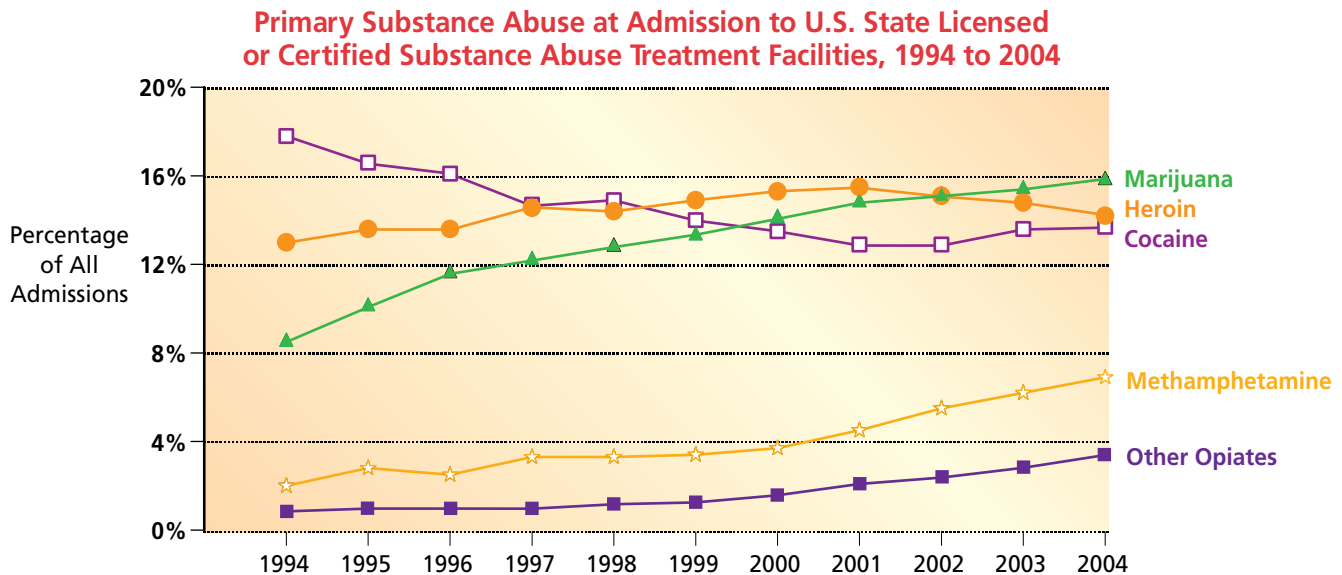
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 Subsidiary of Forest Laboratories, Inc.
 St. Louis, MO 63045
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TREATMENT ADMISSIONS Related to Marijuana, Methamphetamine, and Prescription Opiates Increase

The percentage of admissions to publicly funded treatment programs that were related to marijuana, methamphetamine and opiates continued a steady upward trend in 2004, according to recently released data from the national Treatment Episode Data Set (TEDS).

The percentage of individuals citing marijuana as their primary drug of abuse at the time of treatment admission has increased steadily over the past few years, reaching a high of 15.9% in 2004 (the most recent year for which data are available). Admissions related to abuse of methamphetamines and opiates other than heroin also increased.



Since 2000, treatment admissions for "other opiates" have doubled (from 1.6% to 3.4% in 2004). This category is composed primarily of oxycodone and nonprescription methadone, but also includes other synthetics such as codeine and hydrocodone. Similarly, treatment admissions related to methamphetamine have nearly doubled since 2000 (from 3.7% to 6.9%). In contrast, heroin-related treatment

admissions continued a steady decline, while admissions for primary abuse of cocaine have remained relatively steady.

Source: Adapted by CESAR from the Office of Applied Studies, SAMHSA, Treatment Episode Dataset (TEDS) 1994-2004, National Admissions to Substance Abuse Treatment Services, 2006. Available online at <http://www.dasis.samhsa.gov/teds04/tedsad2k4web.pdf>.

CORRECTION: Buprenorphine/Naloxone Treatment Called Effective

[ED: A research report published in the last issue of *ASAM News* incorrectly referred to once-weekly dosing with buprenorphine, rather than once-weekly dispensing. A corrected version of the report follows. *ASAM News* regrets the error.]

Once-weekly dispensing of buprenorphine/naloxone, combined with psychotherapy and delivered in a physician's office, were just as effective in treating opiate addiction as thrice-weekly dispensing and extensive counseling, researchers report. "We've demonstrated the safety and efficacy of providing this type of treatment in a primary-care setting, and that had never been done before," commented lead author David A. Fiellin, M.D. "We've also identified a moderate or minimum counseling therapy and medication dispensing that is safe and effective."

For the study, Dr. Fiellin and colleagues assigned 166 opiate-addicted patients to one of three treatment regimens: standard medical management (20 minutes of counseling once a week) with either once-weekly or three-times-a-week medication dispensing, or enhanced medical management (with 45 minutes of counseling)

and three-times-a-week medication dispensing. Patients in all three groups took the medication daily. At the end of the 24-week treatment period, the researchers found that the three treatments were equally effective in promoting abstinence and retaining clients in treatment, with each judged effective in about 4 of 10 patients.

Dr. Fiellin noted that the results could be attributed to the effectiveness of the medication, and said that less contact might actually be beneficial to recovery, adding: "For some of these patients, it may be a deterrent if you have them coming in too frequently or attending too much to issues around addiction, especially if they are doing well and are abstinent."

Source: Fiellin DA et al. (2006). *Counseling plus buprenorphine-naloxone maintenance therapy for opioid dependence*. *New England Journal of Medicine* 355(4):365-374.

★ ★ ★ ★ ★ Federal Officials Hail Declines ★ ★ ★ ★ ★ in Youth Drug Use

Using new estimates based on National Survey on Drug Use and Health (NSDUH), officials of the federal Substance Abuse and Mental Health Services Administration have reported that current illicit drug use among youth ages 12 to 17 continues to decline. The rate has been moving downward, from 11.6 percent of youth reporting that they had used drugs in the past month in 2002, to 11.2 percent in 2003, 10.6 percent in 2004, and 9.9 percent in 2005. NSDUH is an annual survey of approximately 67,500 persons in the U.S. The survey collects information from residents of households, residents of non-institutionalized group quarters, and civilians living on military bases.

SAMHSA also reports that the rate of current marijuana use among youth ages 12 to 17 declined significantly from 8.2 percent in 2002 to 6.8 percent in 2005, while the average age of first use of marijuana increased from younger than age 17 in 2003 to 17.4 years in 2005. Current alcohol use among teens also declined, with 16.5 percent of youth ages 12 to 17 reporting current alcohol use and 9.9 percent reporting binge drinking. (This compares with 17.6 percent of youth reporting drinking in 2004 and 11.1 percent reporting binge drinking in the past month in 2004.) The recently reported declines in alcohol use by youth follow years of relatively unchanged rates.

"The trends among young people are encouraging," said Health and Human Services Secretary Michael Leavitt. "We know prevention activities must start with our children. There is more to be done and we must build on our work to ensure that children and their parents understand that they must live free of drugs and alcohol to be healthy."

"Something important is happening with American teens," said John P. Walters, Director of National Drug Control Policy. "They are getting the message that using drugs limits their futures, and they are turning away from the destructive patterns and cruelly-misinformation perceptions about substance abuse that have so damaged previous generations."

"The news today is there is a fundamental shift in drug use among young people in America," added Assistant Surgeon General Eric B. Broderick, D.D.S., M.P.H., SAMHSA Acting Deputy Administrator. "We first saw this shift towards healthier decisions when rates of tobacco use among young people began to go down. Now, we see a sustained drop in rates of drug use. We will see if the decline in drinking among 12 to 17 years olds becomes a continued pattern as well."

For young adults, ages 18-25, the picture is mixed. While there were no significant changes in overall past month use of any illicit drugs in this age group between 2002 and 2005, cocaine use increased from 2.0 in 2002 to 2.6 percent in 2005. Past-month non-medical use of prescription drugs among young adults increased from 5.4 percent in 2002 to 6.3 percent in 2005, due largely to an increase in the non-medical use of opioid analgesics. The rate was placed at 4.1 percent in 2002 and 4.7 percent in 2003, 2004 and 2005.

Among adults aged 50 to 59, NSDUH data indicate that rates of current illicit drug use increased from 2.7 percent in 2002 to 4.4 percent in 2005.

RATES OF SUBSTANCE DEPENDENCE OR ABUSE

In 2005, an estimated 22.2 million persons (9.1 percent of the population ages 12 and older) were classified with substance dependence or abuse in the past year, based on criteria specified in the *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)*. Of these, 3.3 million were dependent on or abused both alcohol and illicit drugs; 3.6 million were dependent on or abused illicit drugs but not alcohol; and 15.4 million were dependent on or abused alcohol, but not illicit drugs. These numbers are basically unchanged since 2002.

There were 2.3 million people who received treatment at a specialty facility in 2005. There were 1.2 million persons who reported that they felt they needed treatment for an illicit drug or alcohol use problem, but of these 865,000 reported making no effort to get treatment. There were 296,000 who reported they had made an effort to get treatment. These numbers were not statistically different from the numbers in the 2004 survey.

ALCOHOL

More than one in five persons ages 12 and older (22.7 percent) participated in binge drinking in 2005. (Bingeing is defined as having five or more drinks on the same occasion on at least one day in the

continued on page 11



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EOE

DECLINES IN YOUTH DRUG USE *continued from page 10*

30 days prior to the survey.) This translates to about 55 million people, comparable to the 2004 estimate. The binge drinking rate among young adults ages 18-25 was 41.9 percent, and the heavy drinking rate was 15.3 percent.

In 2005, 6.6 percent of the population ages 12 and older (16 million people) engaged in heavy drinking. This rate is similar to the reported rate of 6.9 percent in 2004. Heavy drinking is defined as binge drinking on at least five days in the past 30 days.

About 10.8 million persons ages 12-20 (28.2 percent) reported past month use of alcohol in 2005. Nearly 7.2 million of these under-age drinkers (18.8 percent) were binge drinkers and 2.3 million (6.0 percent) were heavy drinkers. These figures have remained essentially the same since 2002. Most of the new initiates to alcohol use (88.9 percent) were younger than 21 at the time of initiation.

Adults ages 21 or older who had first used alcohol before age 21 were almost 5 times more likely than adults who had their first drink at age 21 or older to be classified with alcohol dependence or abuse (9.6 percent compared to 2.1 percent).

In 2005, an estimated 13.0 percent of persons ages 12 and older (31.7 million persons) drove under the influence of alcohol at least once in the past year. This percentage has dropped since 2002, when it was 14.2 percent.

TOBACCO

In 2005, SAMHSA epidemiologists estimate that 71.5 million Americans ages 12 and older were current users of a tobacco product. Of these, 60.5 million were current cigarette smokers; 13.6 million smoked cigars; 7.7 million used smokeless tobacco; and 2.2 million smoked tobacco in pipes. Between the years 2002 and 2005, past-month use of a tobacco product declined from 30.4 percent to 29.4 percent, and past-month cigarette use decreased from 26.0 percent to 24.9 percent.

The rate of past month cigarette use among youth ages 12-17 declined from 13.0 percent in 2002 to 10.8 percent in 2005. There also were declines in use of cigars in this age group.

PRESCRIPTION DRUGS

SAMHSA epidemiologists estimate that 6.4 million persons ages 12 or older, or 2.6 percent of the population, engaged in non-medical use of a prescription drug in 2005. Of this group, 4.7 million used opioid analgesics, about 500 used prescription stimulants, 1.8 million used tranquilizers, and 272,000 used other sedative-hypnotics. Each of these estimates is similar to the estimates for 2004.

Those who used prescription drugs nonmedically were asked how they obtained the drugs they used most recently. In 2005, the prevalent source for drugs used nonmedically was "from a friend or relative for free" (59.8 percent). Another 16.8 percent reported getting the drug from one doctor, while 4.3 percent reported getting narcotic pain relievers from a drug dealer or other stranger, and 0.8 percent reported buying the drug on the internet.

METHAMPHETAMINE

The number of recent new users of methamphetamine, aged 12 or older, was estimated at 192,000 in 2005. Between 2002 and 2004, the number of methamphetamine initiates remained steady at

around 300,000 per year, but there was a decline from 2004 (318,000 initiates) to 2005.

COCAINE

The rate of cocaine use was not statistically different in 2005 (with a change from 0.8 percent to 1.0 percent) and has remained unchanged since 2002.

HEROIN

There was no significant change in the number of current heroin users in 2005 (136,000), nor in the rate of heroin use (0.1 percent), compared with estimates from 2004, 2003, and 2002.

CO-OCCURRING DISORDERS

Serious psychological distress, as measured by the survey administered to adults ages 18 and older, was associated with past year substance dependence or abuse in 2005. Among the 24.6 million adults with serious psychological distress in 2005, 21.3 percent (5.2 million) were dependent on or abused illicit drugs or alcohol. The rate of substance dependence or abuse among adults without serious psychological distress was 7.7 percent (14.9 million people).

Among the 5.2 million adults with both serious psychological distress and substance dependence or abuse in 2005, 47 percent received mental health treatment or substance use treatment at a specialty facility: 8.5 percent received both treatment for mental health and substance use disorder, 34.3 percent received only treatment for mental health problems, and 4.1 percent received only specialty substance use treatment.

Data from the National Survey on Drug Use and Health are available on the Web at <http://oas.samhsa.gov/NSDUH/latest.htm>. Electronic versions of Recovery Month materials are available at <http://www.recoverymonth.gov/>.

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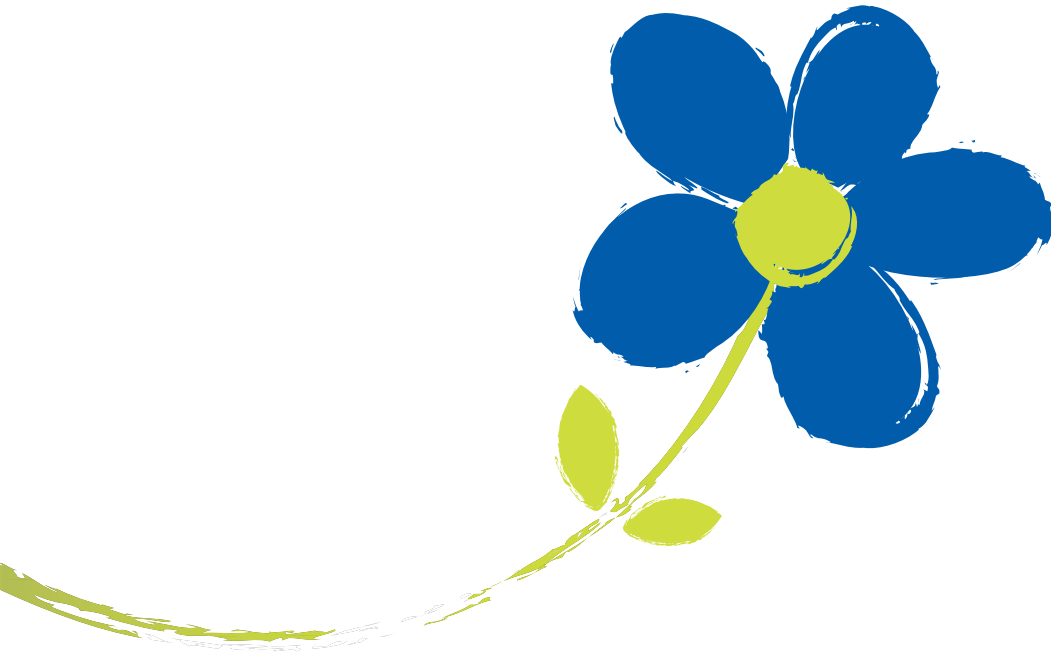
Due caution should be exercised when driving cars or operating machinery.

The most commonly reported adverse events with SUBOXONE include: headache (36%, placebo 22%), withdrawal syndrome (25%, placebo 37%), pain (22%, placebo 19%), nausea (15%, placebo 11%), insomnia (14%, placebo 16%), and sweating (14%, placebo 10%).

Please see adjacent Brief Summary of Prescribing Information.

References: 1. Leshner AI, Koob GF. Drugs of abuse and the brain. *Proc Assoc Am Physicians*. 1999;111(2):99-108. 2. Leshner AI. Addiction is a brain disease, and it matters. *Science*. 1997;278:45-47.

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SUBOXONE suppresses withdrawal symptoms, decreases cravings, and improves treatment retention. With the support of pharmacotherapy and counseling, patients may gain control over opioid dependence and be able to address other aspects of their lives.

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*Under the Drug Addiction and Treatment Act of 2000 (DATA 2000), physicians who meet certain qualifying requirements may prescribe SUBOXONE. Visit OpioidDependence.com for information about qualifying.

Suboxone[®]
(buprenorphine HCl/naloxone HCl dihydrate)  sublingual
tablets

Because Treatment Transforms Lives

SUBOXONE (CIII)
(buprenorphine HCl and naloxone HCl dihydrate sublingual tablets)
SUBUTEX (CIII)
(buprenorphine HCl sublingual tablets)

Rx only

Brief Summary: Consult the SUBOXONE package insert for complete prescribing information.

Under the Drug Addiction Treatment Act of 2000 (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence.

INDICATIONS AND USAGE

SUBOXONE and SUBUTEX are indicated for the treatment of opioid dependence.

CONTRAINDICATIONS

SUBOXONE and SUBUTEX should not be administered to patients who have been shown to be hypersensitive to buprenorphine, and SUBOXONE should not be administered to patients who have been shown to be hypersensitive to naloxone.

WARNINGS

Respiratory Depression: Significant respiratory depression has been associated with buprenorphine, particularly by the intravenous route. A number of deaths have occurred when addicts have intravenously misused buprenorphine, usually with benzodiazepines concomitantly. Deaths have also been reported in association with concomitant administration of buprenorphine with other depressants such as alcohol or other opioids. Patients should be warned of the potential danger of the self-administration of benzodiazepines or other depressants while under treatment with SUBUTEX or SUBOXONE.

IN THE CASE OF OVERDOSE, THE PRIMARY MANAGEMENT SHOULD BE THE RE-ESTABLISHMENT OF ADEQUATE VENTILATION WITH MECHANICAL ASSISTANCE OF RESPIRATION, IF REQUIRED. NALOXONE MAY NOT BE EFFECTIVE IN REVERSING ANY RESPIRATORY DEPRESSION PRODUCED BY BUPRENORPHINE.

SUBOXONE and SUBUTEX should be used with caution in patients with compromised respiratory function (e.g., chronic obstructive pulmonary disease, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression).

CNS Depression: Patients receiving buprenorphine in the presence of other narcotic analgesics, general anesthetics, benzodiazepines, phenothiazines, other tranquilizers, sedative/hypnotics or other CNS depressants (including alcohol) may exhibit increased CNS depression. When such combined therapy is contemplated, reduction of the dose of one or both agents should be considered.

Drug Abuse and Dependence: SUBOXONE and SUBUTEX are controlled as Schedule III narcotics under the Controlled Substances Act.

Buprenorphine is a partial agonist at the mu-opioid receptor and chronic administration produces dependence of the opioid type, characterized by moderate withdrawal upon abrupt discontinuation or rapid taper. The withdrawal syndrome is milder than seen with full agonists, and may be delayed in onset.

Neonatal withdrawal has been reported in the infants of women treated with SUBUTEX during pregnancy (See PRECAUTIONS).

SUBOXONE contains naloxone and if misused parenterally, is highly likely to produce marked and intense withdrawal symptoms in subjects dependent on other opioid agonists.

Hepatitis, Hepatic Events: Cases of cytolytic hepatitis and hepatitis with jaundice have been observed in the addit population receiving buprenorphine both in clinical trials and in post-marketing adverse event reports. The spectrum of abnormalities ranges from transient asymptomatic elevations in hepatic transaminases to case reports of hepatic failure, hepatic necrosis, hepatorenal syndrome, and hepatic encephalopathy. In many cases, the presence of pre-existing liver enzyme abnormalities, infection with hepatitis B or hepatitis C virus, concomitant usage of other potentially hepatotoxic drugs, and ongoing injecting drug use may have played a causative or contributory role. In other cases, insufficient data were available to determine the etiology of the abnormality. The possibility exists that buprenorphine had a causative or contributory role in the development of the hepatic abnormality in some cases. Measurements of liver function tests prior to initiation of treatment is recommended to establish a baseline. Periodic monitoring of liver function tests during treatment is also recommended. A biological and etiological evaluation is recommended when a hepatic event is suspected. Depending on the case, the drug should be carefully discontinued to prevent withdrawal symptoms and a return to illicit drug use, and strict monitoring of the patient should be initiated.

Allergic Reactions: Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the post-marketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported. A history of hypersensitivity to buprenorphine is a contraindication to SUBUTEX or SUBOXONE use. A history of hypersensitivity to naloxone is a contraindication to SUBOXONE use.

Use in Ambulatory Patients: SUBOXONE and SUBUTEX may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery, especially during drug induction and dose adjustment. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that buprenorphine therapy does not adversely affect their ability to engage in such activities. Like other opioids, SUBOXONE and SUBUTEX may produce orthostatic hypotension in ambulatory patients.

Head Injury and Increased Intracranial Pressure: SUBOXONE and SUBUTEX, like other potent opioids, may elevate cerebrospinal fluid pressure and should be used with caution in patients with head injury, intracranial lesions and other circumstances where cerebrospinal pressure may be increased. SUBOXONE and SUBUTEX can produce miosis and changes in the level of consciousness that may interfere with patient evaluation.

Opioid Withdrawal Effects: Because it contains naloxone, SUBOXONE is highly likely to produce marked and intense withdrawal symptoms if misused parenterally by individuals dependent on opioid agonists such as heroin, morphine, or methadone. Sublingually, SUBOXONE may cause opioid withdrawal symptoms in such persons if administered before the agonist effects of the opioid have subsided.

PRECAUTIONS

General: SUBOXONE and SUBUTEX should be administered with caution in elderly or debilitated patients and those with severe impairment of hepatic, pulmonary, or renal function; myxedema or hypothyroidism, adrenal cortical insufficiency (e.g., Addison's disease); CNS depression or coma; toxic psychoses; prostatic hypertrophy or urethral stricture; acute alcoholism; delirium tremens; or kyphoscoliosis.

The effect of hepatic impairment on the pharmacokinetics of buprenorphine and naloxone is unknown. Since both drugs are extensively metabolized, the plasma levels will be expected to be higher in patients with moderate and severe hepatic impairment. However, it is not known whether both drugs are affected to the same degree. Therefore, dosage should be adjusted and patients should be watched for symptoms of precipitated opioid withdrawal.

Buprenorphine has been shown to increase intracholelithal pressure, as do other opioids, and thus should be administered with caution to patients with dysfunction of the biliary tract.

As with other mu-opioid receptor agonists, the administration of SUBOXONE or SUBUTEX may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Drug Interactions: Buprenorphine is metabolized to norbuprenorphine by cytochrome CYP 3A4. Because CYP 3A4 inhibitors may increase plasma concentrations of buprenorphine, patients already on CYP 3A4 inhibitors such as azole antifungals (e.g., ketoconazole), macrolide antibiotics (e.g., erythromycin), and HIV protease inhibitors (e.g., ritonavir, indinavir and saquinavir) should have their dose of SUBUTEX or SUBOXONE adjusted.

Based on anecdotal reports, there may be an interaction between buprenorphine and benzodiazepines. There have been a number of reports in the post-marketing experience of coma and death associated with the concomitant intravenous misuse of buprenorphine and benzodiazepines by addicts. In many of these cases, buprenorphine was misused by self-injection of crushed SUBUTEX tablets. SUBUTEX and SUBOXONE should be prescribed with caution to patients on benzodiazepines or other drugs that act on the central nervous system, regardless of whether these drugs are taken on the advice of a physician or are taken as drugs of abuse. Patients should be warned of the potential danger of the intravenous self-administration of benzodiazepines while under treatment with SUBOXONE or SUBUTEX.

Information for Patients: Patients should inform their family members that, in the event of emergency, the treating physician or emergency room staff should be informed that the patient is physically dependent on narcotics and that the patient is being treated with SUBOXONE or SUBUTEX.

Patients should be cautioned that a serious overdose and death may occur if benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol are taken at the same time as SUBOXONE or SUBUTEX.

SUBOXONE and SUBUTEX may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery, especially during drug induction and dose adjustment. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that buprenorphine therapy does not adversely affect their ability to engage in such activities. Like other opioids, SUBOXONE and SUBUTEX may produce orthostatic hypotension in ambulatory patients.

Patients should consult their physician if other prescription medications are currently being used or are prescribed for future use.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Carcinogenicity: Carcinogenicity data on SUBOXONE are not available. Carcinogenicity studies of buprenorphine were conducted in Sprague-Dawley rats and CD-1 mice. Buprenorphine was administered in the diet to rats at doses of 0.6, 5.5, and 56 mg/kg/day (estimated exposure was approximately 0.4, 3 and 35 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) for 27 months. Statistically significant dose-related increases in testicular interstitial (Leydig's) cell tumors occurred, according to the trend test adjusted for survival. Pair-wise comparison of the high dose against control failed to show statistical significance. In an 86-week study in CD-1 mice, buprenorphine was not carcinogenic at dietary doses up to 100 mg/kg/day (estimated exposure was approximately 30 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis).

Mutagenicity: SUBOXONE: The 4:1 combination of buprenorphine and naloxone was not mutagenic in a bacterial mutation assay (Ames test) using four strains of *S. typhimurium* and two strains of *E. coli*. The combination was not clastogenic in an *in vitro* cytogenetic assay in human lymphocytes, or in an intravenous micronucleus test in the rat. SUBUTEX: Buprenorphine was studied in a series of tests utilizing gene, chromosome, and DNA interactions in both prokaryotic and eukaryotic systems. Results were negative in yeast (*Saccharomyces cerevisiae*) for recombinant, gene convertant, or forward mutations; negative in *Bacillus subtilis* "rec" assay, negative for clastogenicity in CHO cells, Chinese hamster bone marrow and spermatogonia cells, and negative in the mouse lymphoma L5178Y assay. Results were equivocal in the Ames test: negative in studies in two laboratories, but positive for frame shift mutation at a high dose (5 mg/plate) in a third study. Results were positive in the Green-Tweets (*E. coli*) survival test, positive in a DNA synthesis inhibition (DSI) test with testicular tissue from mice, for both *in vivo* and *in vitro* incorporation of [³H]thymidine, and positive in unscheduled DNA synthesis (UDS) test using testicular cells from mice.

Impairment of Fertility: SUBOXONE: Dietary administration of SUBOXONE in the rat at dose levels of 500 ppm or greater (equivalent to approximately 47 mg/kg/day or greater; estimated exposure was approximately 28 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) produced a reduction in fertility demonstrated by reduced female conception rates. A dietary dose of 100 ppm (equivalent to approximately 10 mg/kg/day; estimated exposure was approximately 6 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) had no adverse effect on fertility.

SUBUTEX: Reproduction studies of buprenorphine in rats demonstrated no evidence of impaired fertility at daily oral doses up to 80 mg/kg/day (estimated exposure was approximately 50 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) or up to 5 mg/kg/day *im* or *sc* (estimated exposure was approximately 3 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis).

Pregnancy: Pregnancy Category C:

Teratogenic effects: SUBOXONE: Effects on embryo-fetal development were studied in Sprague-Dawley rats and Russian white rabbits following oral (1:1) and intramuscular (3:2) administration of mixtures of buprenorphine and naloxone. Following oral administration to rats and rabbits, no teratogenic effects were observed at doses up to 250 mg/kg/day and 40 mg/kg/day, respectively (estimated exposure was approximately 150 times and 50 times, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m² basis). No definitive drug-related teratogenic effects were observed in rats and rabbits at intramuscular doses up to 30 mg/kg/day (estimated exposure was approximately 20 times and 35 times, respectively, the recommended human daily dose of 16 mg on a mg/m² basis). Acephalus was observed in one rabbit fetus from the low-dose group and omphalocele was observed in two rabbit fetuses from the same litter in the mid-dose group; no findings were observed in fetuses from the high-dose group. Following oral administration to the rat, dose-related post-implantation losses, evidenced by increases in the numbers of early resorptions with consequent reductions in the numbers of fetuses, were observed at doses of 10 mg/kg/day or greater (estimated exposure was approximately 6 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis). In the rabbit, increased post-implantation losses occurred at an oral dose of 40 mg/kg/day. Following intramuscular administration in the rat and the rabbit, post-implantation losses, as evidenced by decreases in live fetuses and increases in resorptions, occurred at 30 mg/kg/day.

SUBUTEX: Buprenorphine was not teratogenic in rats or rabbits after *im* or *sc* doses up to 5 mg/kg/day (estimated exposure was approximately 3 and 6 times, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m² basis), after *iv* doses up to 0.8 mg/kg/day (estimated exposure was approximately 0.5 times and equal to, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m² basis), or after oral doses up to 160 mg/kg/day in rats (estimated exposure was approximately 95 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) and 25 mg/kg/day in rabbits (estimated exposure was approximately 30 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis). Significant increases in skeletal abnormalities (e.g., extra thoracic vertebra or thoraco-lumbar ribs) were noted in rats after *sc* administration of 1 mg/kg/day and up (estimated exposure was approximately 0.6 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis), but were not observed at oral doses up to 160 mg/kg/day. Increases in skeletal abnormalities in rabbits after *im* administration of 5 mg/kg/day (estimated exposure was approximately 6 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis) or oral administration of 1 mg/kg/day or greater (estimated exposure was approximately equal to the recommended human daily sublingual dose of 16 mg on a mg/m² basis) were not statistically significant.

In rabbits, buprenorphine produced statistically significant pre-implantation losses at oral doses of 1 mg/kg/day or greater and post-implantation losses that were statistically significant at *iv* doses of 0.2 mg/kg/day or greater (estimated exposure was approximately 0.3 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis).

There are no adequate and well-controlled studies of SUBOXONE or SUBUTEX in pregnant women. SUBOXONE or SUBUTEX should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic effects: Dystocia was noted in pregnant rats treated *im* with buprenorphine 5 mg/kg/day (approximately 3 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis). Both fertility and peri- and postnatal development studies with buprenorphine in rats indicated increases in neonatal mortality after oral doses of 0.8 mg/kg/day and up (approximately 0.5 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis), after *im* doses of 0.5 mg/kg/day and up (approximately 0.3 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis), and after *sc* doses of 0.1 mg/kg/day and up (approximately 0.06 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis). Delays in the occurrence of righting reflex and startle response were noted in rat pups at an oral dose of 80 mg/kg/day (approximately 50 times the recommended human daily sublingual dose of 16 mg on a mg/m² basis).

Neonatal Withdrawal: Neonatal withdrawal has been reported in the infants of women treated with SUBUTEX during pregnancy. From post-marketing reports, the time to onset of neonatal withdrawal symptoms ranged from Day 1 to Day 8 of life with most occurring on Day 1. Adverse events associated with neonatal withdrawal syndrome included hypertonia, neonatal tremor, neonatal agitation, and myoclonus. There have been rare reports of convulsions and in one case, apnea and bradycardia were also reported.

Nursing Mothers: An apparent lack of milk production during general reproduction studies with buprenorphine in rats caused decreased viability and lactation indices. Use of high doses of sublingual buprenorphine in pregnant women showed that buprenorphine passes into the mother's milk. Breast-feeding is therefore not advised in mothers treated with SUBUTEX or SUBOXONE.

Pediatric Use: SUBOXONE and SUBUTEX are not recommended for use in pediatric patients. The safety and effectiveness of SUBOXONE and SUBUTEX in patients below the age of 16 have not been established.

ADVERSE REACTIONS

The safety of SUBOXONE has been evaluated in 497 opioid-dependent subjects. The prospective evaluation of SUBOXONE was supported by clinical trials using SUBUTEX (buprenorphine tablets without naloxone) and other trials using buprenorphine sublingual solutions. In total, safety data are available from 3214 opioid-dependent subjects exposed to buprenorphine at doses in the range used in treatment of opioid addiction.

Few differences in adverse event profile were noted between SUBOXONE and SUBUTEX or buprenorphine administered as a sublingual solution.

New Reports Offer Insights Into Addiction Treatment System

The Office of Applied Studies (OAS) of the Substance Abuse and Mental Health Services Administration has released two reports based on recent studies of the Nation's addiction treatment system.

The DASIS Report: Facilities Offering Special Programs or Groups for Women, a three-page report, is based on SAMHSA's Drug and Alcohol Services Information System (DASIS). The report compares the characteristics of substance abuse treatment facilities that offer special services for women with facilities that do not.

Of the 13,317 treatment facilities that responded to SAMHSA's 2005 National Survey of Substance Abuse Treatment Services (N-SSATS), 13 percent did not accept women as clients. Of the 11,578 facilities that do accept women as clients, 41 percent provided special programs or groups for women: 24 percent of these were for adult women only, 3 percent were for pregnant or postpartum women only, and 14 percent were for adult women and/or pregnant or postpartum women.

Facilities that offered special programs or groups for women also were more likely to provide a variety of additional treatment services, such as relapse prevention groups (91 percent vs. 74 percent), aftercare counseling (84 percent vs. 78 percent), and family counseling (81 percent vs. 74 percent). The report can be accessed at <http://oas.samhsa.gov/2k6/womenTx/womenTX.cfm>.

National Survey of Substance Abuse Treatment Services (N-SSATS): Data on Substance Abuse Treatment Facilities, 2005. This annual report provides a portrait of the current national substance abuse treatment system, with data on the location, characteristics, and use of alcohol and drug treatment facilities and services available throughout the 50 States, the District of Columbia, and other U.S. jurisdictions.

- ★ The report shows that the number of facilities remained relatively constant between 2000 and 2005: 13,428 reporting facilities in 2000 versus 13,371 facilities in 2005. However, the number of clients in treatment increased by 8 percent over the same period, from 1,000,896 in 2000 to 1,081,049 in 2005.
- ★ The survey found that most treatment facilities are operated by private non-profit organizations. In 2005, 61 percent were private nonprofit organizations and 27 percent were private for-profit organizations. In addition, 8 percent were operated by local governments, 3 percent by State governments, 2 percent by the Federal government, and 1 percent by tribal governments.
- ★ As of March 31, 2005, 89 percent of all clients were in outpatient treatment, 10 percent in non-hospital residential treatment, and 1 percent in hospital inpatient facilities.

The report can be accessed at <http://oas.samhsa.gov/DASIS/2k5nssats.cfm>, or a free copy can be obtained from SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI), either on the web or by phone. Request #BK-OAS-32 at <http://ncadi.samhsa.gov/> or by phone at 1-800/729-6686.

In a comparative study, adverse event profiles were similar for subjects treated with 16 mg SUBOXONE or 16 mg SUBUTEX. The following adverse events were reported to occur by at least 5% of patients in a 4-week study (Table 1).

Table 1. Adverse Events (≥5%) by Body System and Treatment Group in a 4-week Study

Body System /Adverse Event (COSTART Terminology)	N (%) SUBOXONE 16 mg/day N=107	N (%) SUBUTEX 16 mg/day N=103	N (%) Placebo N=107
Body as a Whole			
Asthenia	7 (6.5%)	5 (4.9%)	7 (6.5%)
Chills	8 (7.5%)	8 (7.8%)	8 (7.5%)
Headache	39 (36.4%)	30 (29.1%)	24 (22.4%)
Infection	6 (5.6%)	12 (11.7%)	7 (6.5%)
Pain	24 (22.4%)	19 (18.4%)	20 (18.7%)
Pain Abdomen	12 (11.2%)	12 (11.7%)	7 (6.5%)
Pain Back	4 (3.7%)	8 (7.8%)	12 (11.2%)
Withdrawal Syndrome	27 (25.2%)	19 (18.4%)	40 (37.4%)
Cardiovascular System			
Vasodilation	10 (9.3%)	4 (3.9%)	7 (6.5%)
Digestive System			
Constipation	13 (12.1%)	8 (7.8%)	3 (2.8%)
Diarrhea	4 (3.7%)	5 (4.9%)	16 (15.0%)
Nausea	16 (15.0%)	14 (13.6%)	12 (11.2%)
Vomiting	8 (7.5%)	8 (7.8%)	5 (4.7%)
Nervous System			
Insomnia	15 (14.0%)	22 (21.4%)	17 (15.9%)
Respiratory System			
Rhinitis	5 (4.7%)	10 (9.7%)	14 (13.1%)
Skin and Appendages			
Sweating	15 (14.0%)	13 (12.6%)	11 (10.3%)

The adverse event profile of buprenorphine was also characterized in the dose-controlled study of buprenorphine solution, over a range of doses in four months of treatment. Table 2 shows adverse events reported by at least 5% of subjects in any dose group in the dose-controlled study.

Table 2. Adverse Events (≥5%) by Body System and Treatment Group in a 16-week Study

Body System/Adverse Event (COSTART Terminology)	Buprenorphine Dose*				
	Very Low* (N=184)	Low* (N=180)	Moderate* (N=186)	High* (N=181)	Total* (N=731)
	N (%)	N (%)	N (%)	N (%)	N (%)
Body as a Whole					
Abscess	9 (5%)	2 (1%)	3 (2%)	2 (1%)	16 (2%)
Asthenia	26 (14%)	28 (16%)	26 (14%)	24 (13%)	104 (14%)
Chills	11 (6%)	12 (7%)	9 (5%)	10 (6%)	42 (6%)
Fever	7 (4%)	2 (1%)	2 (1%)	10 (6%)	21 (3%)
Flu Syndrome	4 (2%)	13 (7%)	19 (10%)	8 (4%)	44 (6%)
Headache	51 (28%)	62 (34%)	54 (29%)	53 (29%)	220 (30%)
Infection	32 (17%)	39 (22%)	38 (20%)	40 (22%)	149 (20%)
Injury Accidental	5 (3%)	10 (6%)	5 (3%)	5 (3%)	25 (3%)
Pain	47 (26%)	37 (21%)	49 (26%)	44 (24%)	177 (24%)
Pain Back	18 (10%)	29 (16%)	28 (15%)	27 (15%)	102 (14%)
Withdrawal Syndrome	45 (24%)	40 (22%)	41 (22%)	36 (20%)	162 (22%)
Digestive System					
Constipation	10 (5%)	23 (13%)	23 (12%)	26 (14%)	82 (11%)
Diarrhea	19 (10%)	8 (4%)	9 (5%)	4 (2%)	40 (5%)
Dyspepsia	6 (3%)	10 (6%)	4 (2%)	4 (2%)	24 (3%)
Nausea	12 (7%)	22 (12%)	23 (12%)	18 (10%)	75 (10%)
Vomiting	8 (4%)	6 (3%)	10 (5%)	14 (8%)	38 (5%)
Nervous System					
Anxiety	22 (12%)	24 (13%)	20 (11%)	25 (14%)	91 (12%)
Depression	24 (13%)	16 (9%)	25 (13%)	18 (10%)	83 (11%)
Dizziness	4 (2%)	9 (5%)	7 (4%)	11 (6%)	31 (4%)
Insomnia	42 (23%)	50 (28%)	43 (23%)	51 (28%)	186 (25%)
Nervousness	12 (7%)	11 (6%)	10 (5%)	13 (7%)	46 (6%)
Somnolence	5 (3%)	13 (7%)	9 (5%)	11 (6%)	38 (5%)
Respiratory System					
Cough Increase	5 (3%)	11 (6%)	6 (3%)	4 (2%)	26 (4%)
Pharyngitis	6 (3%)	7 (4%)	6 (3%)	9 (5%)	28 (4%)
Rhinitis	27 (15%)	16 (9%)	15 (8%)	21 (12%)	79 (11%)
Skin and Appendages					
Sweat	23 (13%)	21 (12%)	20 (11%)	23 (13%)	87 (12%)
Special Senses					
Runny Eyes	13 (7%)	9 (5%)	6 (3%)	6 (3%)	34 (5%)

*Sublingual solution. Doses in this table cannot necessarily be delivered in tablet form, but for comparison purposes:

"Very low" dose (1 mg solution) would be less than a tablet dose of 2 mg

"Low" dose (4 mg solution) approximates a 6 mg tablet dose

"Moderate" dose (8 mg solution) approximates a 12 mg tablet dose

"High" dose (16 mg solution) approximates a 24 mg tablet dose

OVERDOSAGE

Manifestations: Manifestations of acute overdose include pinpoint pupils, sedation, hypotension, respiratory depression and death.

Treatment: The respiratory and cardiac status of the patient should be monitored carefully. In the event of depression of respiratory or cardiac function, primary attention should be given to the re-establishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated.

IN THE CASE OF OVERDOSE, THE PRIMARY MANAGEMENT SHOULD BE THE RE-ESTABLISHMENT OF ADEQUATE VENTILATION WITH MECHANICAL ASSISTANCE OF RESPIRATION, IF REQUIRED. NALOXONE MAY NOT BE EFFECTIVE IN REVERSING ANY RESPIRATORY DEPRESSION PRODUCED BY BUPRENORPHINE.

High doses of naloxone hydrochloride, 10-35 mg/70 kg may be of limited value in the management of buprenorphine overdose. Doxapram (a respiratory stimulant) also has been used.

Manufactured by: Reckitt Benckiser Healthcare (UK) Ltd, Hull, UK, HU8 7DS

Distributed by: Reckitt Benckiser Pharmaceuticals, Inc., Richmond, VA 23235

#138274BS July 2005

New York Society Leads on Addiction Parity, Member Education

PARITY LEGISLATION: Merrill Herman, M.D., President of the New York Society of Addiction Medicine (NYSAM), reports that the New York State Assembly passed "Timothy's Law" (A.2912-A), which would require parity in insurance benefits for addiction and mental health treatment. The bill, sponsored by Assemblyman Paul Tonko, is aimed at ending discrimination by insurance companies against persons in need of care for mental health and substance use disorders.

At a news conference announcing passage of Timothy's Law, Assemblyman Tonko was joined by Assembly Insurance Committee Chair Alexander (Pete) Grannis, and Assemblyman Peter Rivera, who chairs the Assembly's Mental Health, Mental Retardation and Developmental Disabilities Committee, as well as advocates for mental health and addiction treatment, all of whom urged the State Senate to pass the measure this year. The legislators hailed the bill's goal of expanding the limited mental health care and addiction treatment benefits currently available to New York residents.

However, Dr. Herman cautions that enactment of Timothy's Law will be an "uphill fight" because the bill did not receive Republican majority sponsorship in the Senate. He added that Democratic Senator Tom Duane, who has spoken passionately on behalf of the bill in the past, introduced Timothy's Law in the Senate.

NYSAM has distributed a "Memo in Support of Timothy's Law" to state legislators, and Dr. Herman has encouraged all NYSAM members to contact their Senators to ask for passage of Timothy's Law, adding: "Our voices are needed to help move this issue to a successful conclusion."



NYSAM Membership Chair Jun David, M.D. (left), John Coppola of the NYSAM Albany Staff, and Society President Merrill Herman, M.D., compare notes during a NYSAM Conference.

EDUCATION AND TRAINING OFFERINGS: NYSAM has dedicated itself to developing excellent CME opportunities for our members and other interested health care and addiction treatment and prevention professionals. Gregory Bunt, MD, a NYSAM Board member, has provided leadership in this area and has spearheaded a number of very successful CME events. For example, NYSAM engaged in a very successful partnership with the New York State Academy of Family Physicians (NYSAFP) to sponsor the Fourth Regional Family Medicine Conference, held in Saratoga Springs in September. (For more on collaboration with family physicians, see the report by Dr. Norman Wetterau on page 17.)

On the day preceding the NYSAFP conference, NYSAM arranged for an ASAM-sponsored buprenorphine training course at the conference site, ensuring that a number of "addiction-interested" family physicians would be able to attend. An evening reception hosted by Bruce Maslack, M.D., provided NYSAM and NYSAFP members an opportunity to network and share common interests.

The addiction medicine component of the NYSAFP conference began with a "Buprenorphine 201" presentation by David Fiellin, M.D. During his highly interactive presentation, Dr. Fiellin invited audience members to share their clinical experiences as a stimulus for discussion. The highly informative, interactive, and practical tone set by Dr. Fiellin was continued in the rest of the day's sessions. Topics addressed included management of co-occurring psychiatric disorders in primary care settings (Merrill Herman, M.D.), prescription
continued on page 17

ATTN: ASAM MEMBERS!

Member-Get-A-Member Campaign (October 1, 2006 – April 15, 2007)



Share your ASAM experience with a peer and invite him or her to join ASAM today! When you are meeting or on the phone with colleagues, ask them to consider joining ASAM. Not only will you be doing a big favor for yourself by strengthening your Society, but also your contemporaries will be thanking you for inviting them. Each new member you recruit moves you closer to receiving one of the following:

Visit the ASAM website at www.asam.org for details and membership application forms.

ASAM

Earn One Free Registration to ASAM's Med-Sci Conference and Other Valued Rewards.

- 1. One free registration to the 2008 Med-Sci Conference** (valued up to \$585)
- 2. One free membership renewal for 2008** (valued up to \$495)
- 3. One free copy of Principles of Addiction Medicine, 3rd Edition** (valued up to \$175)

ASAM and Family Medicine: A Promising Partnership

Norman Wetterau, M.D., FASAM, ASAM Liaison to Family Medicine

More than 500 ASAM members are family physicians. As a result, ASAM has designated a liaison to the American Academy of Family Physicians (AAFP). In addition, a group of ASAM members who are family physicians have formed an informal family practice work group. Members of the work group are involved in giving presentations at local, state and national family practice meetings, writing articles, teaching, and working on multiple projects, some of which are described below.

Any ASAM member who wishes to join the work group is welcome — we usually meet during a component session at the annual Med-Sci Conference. Those who cannot attend but want to be kept informed are welcome to contact me at NormWetterau@aol.com.

Screening and Brief Intervention

The 2004 ONDCP Leadership Conference on Medical Education in Substance Abuse made screening and brief intervention a priority. If we do not screen, then we do not even know who in our practice has a problem with alcohol, tobacco or other drugs.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) recently released a new monograph, *Helping Patients Who Drink Too Much, A Clinicians Guide*, which was distributed through ASAM, the AMA and other medical organizations. NIAAA is planning to release the information in a DVD format, with examples of primary care interventions.

The AAFP has developed a tool kit that includes information for physicians and patients, and thousands of the kits have been distributed to date. Join Together has given several grants to help support screening and brief interventions in local communities (see www.JoinTogether.org). In Rochester, New York, family physicians used the grant funds to develop training materials and handouts, and to engage several family practice groups in performing screening and brief interventions during office visits.

One of the great unmet needs is to train family medicine residents in screening, and to encourage them to use this training in their model practice. ASAM member Paul Seale, M.D., of Mercer Medical College, has received a grant to introduce screening and brief intervention into several family practice residency programs. Sam Jones, M.D., who chairs the Association of Family Medicine Residency Directors, is spearheading a movement to train more family medicine residency faculty and residents in screening and brief intervention techniques. Such training would involve one or two faculty members, a practice administrator, and several residents from each residency group. The goal would

be to screen every patient in the model practice.

Federal agencies have awarded several very large grants to support the introduction of screening and brief interventions in hospitals, clinics, and medical groups, but to date none of the funds have reached medical organizations such as ASAM or AAFP. A large grant for training in primary care residencies could be very helpful.

Despite these very positive efforts, it continues to be a challenge to persuade family physicians to incorporate screening and brief intervention into their office practices. This kind of change requires more than information — it demands new skills and changes in practice organization. Use of the electronic medical record could be helpful if the right questions are asked. Daniel Vinson, M.D., of the Department of Family Medicine at the University of Missouri — Columbia, has a special interest in practice organization and has been working with NIAAA and the AAFP in this area.

Pain Management and Addiction

Proper prescribing of opioids for chronic pain remains a difficult problem in primary care. No matter what the prescribing physician does, some patients sell their medications, while others misuse them. Last year, the Center on Alcohol and Substance Abuse at Columbia University (CASA) issued a report on prescription drug abuse, *Under the Counter* (which can be accessed at www.casacolumbia.org.) The New York Society of Family Physicians assisted CASA with the research for the report through a series of focus groups.

Buprenorphine

As more primary care physicians begin to use buprenorphine to treat opioid addiction in office-based practice, an evolving support system is proving useful. Various state chapters of AAFP have sponsored buprenorphine training courses.

2007 Component Session

At the next component session, members of the work group will discuss ideas for communicating through a listserv or on the Web. There is a lot happening in state chapters and through residency programs which others might want to know about. Most of the members of the work group are listed in the ASAM membership directory, or I can provide contact information by email — just let me know. (*Dr. Wetterau can be reached at NormWetterau@aol.com.*)

NEW YORK SOCIETY LEADS *continued from page 16*

drug abuse in primary care settings (Norman Wetterau, M.D. and Richard Blondell, M.D.), substance abuse emergency consultations in hospital settings (Rita Aszalos, M.D.); and pharmacotherapies for alcoholism (Petros Levounis, M.D.).

Earlier in the year, NYSAM partnered with ASAM to host a CME conference in New York City devoted to the treatment of alcohol use disorders. The program, presented by Dr. Petros Levounis of the Addiction Institute of New York and Dr. Eric Gunderson of Columbia University, reviewed the most current findings on the effectiveness

of various pharmacologic and behavioral therapies for alcohol dependence. There was also discussion of co-occurring medical and psychiatric illnesses, and of the newest NIAAA screening recommendations.

More recently, NYSAM sponsored its annual Scientific Conference in October in New York City. Each of these courses reflects NYSAM's commitment to collaboration in sponsoring events that meet the needs of both addiction medicine "veterans" and newcomers to the field.

RUTH FOX MEMORIAL ENDOWMENT FUND

MEDICAL DIRECTOR

THE NEW YORK CENTER FOR LIVING is a new, nonprofit organization that is scheduled to open an adolescent/family outpatient treatment program in midtown New York by mid-January 2007. We seek a psychiatrist to serve as Medical Director (*approximately 20 hours per week*).

The Medical Director will provide clinical oversight of all program functions, training of other clinical staff, and will perform psychiatric evaluations and medication management, as needed for admitted adolescents.

The candidate must be an M.D., licensed to practice medicine in New York State, and have fulfilled ASAM certification requirements. He or she must have extensive clinical experience with adolescents with CD and MICA diagnoses.

Interested applicants should fax their CV in confidence to:

PAUL RUCHAMES
Executive Director
FAX 212-248-3008



Dr. Ruth Fox

Dear Colleague:

The Ruth Fox Memorial Endowment Fund was established to assure ASAM's continued ability to provide ongoing leadership in newly emerging areas affecting the field of addiction medicine, to continue its commitment to educating physicians, to increasing access to care and to improving the quality of care. An important component of this mission is fulfilled each year when the recipients of the Ruth Fox Scholarships — an outstanding group of physicians-in-training — join us at ASAM's Annual Medical-Scientific Conference. The scholarships cover travel, hotel and registration expenses for recipients to attend the Med-Sci Conference and Ruth Fox Course, as well as one year's free membership in ASAM.

The four scholarship recipients for 2006 are Kathleen Ang-Lee, M.D. (Seattle, Washington), Katrina Ball, D.O. (Loma Linda, California), Norana Irene Caivano, M.D. (West Hollywood, California), and Mark Hrymoc, M.D. (Harbor UCLA Medical Center, Los Angeles). All told, 24 such scholarships have been awarded.

With your participation, and the professional and financial support of ASAM's members and friends, the Fund will continue to fulfill its mission. If you have not already pledged or donated to the Endowment Fund, please do so now. For information about making a pledge, contribution, bequest, memorial tribute, or to discuss other types of gifts in confidence, please contact Claire Osman by phone at 1-800/257-6776 or 1-718/275-7766, or email Claire at ASAMCLAIRE@AOL.COM. She welcomes your calls. All contributions to the Endowment Fund are tax-deductible to the full extent allowed by law.

Max A. Schneider, M.D., FASAM
Chair, Ruth Fox Memorial Endowment Subcommittee

Claire Osman
Director of Development

ASAM STAFF & CONSULTANTS

Eileen McGrath, J.D.
Executive Vice President/CEO
EMCGRATH@ASAM.ORG

Berit Boegli
Conferences &
Meetings Consultant
BBOEG@ASAM.ORG

Nancy Brighindi
Director of Membership
& Chapter Development
NBRIG@ASAM.ORG

Janet Brownell
Program Development
Consultant
JBROWNELL@ASAM.ORG

Ruby Bailey Edmondson
Office Manager/Receptionist
RBAIL@ASAM.ORG

Valerie Foote
Data Entry Operator
VFOOT@ASAM.ORG

Joanne Gartenmann
Consultant
JGART@ASAM.ORG

Tracy Gartenmann
Director of Program Development
TGART@ASAM.ORG

Alexis Geier-Horan
Director, Government Relations
AGEIER@ASAM.ORG

Maria Glanz
Exec. Assistant to the EVP
MGLANZ@ASAM.ORG

Gionne Graetz
Program Development Manager
GGRAETZ@ASAM.ORG

Amy Hotaling
Member & Chapter
Development Manager
AHOTA@ASAM.ORG

Except where indicated, all staff can be reached at ASAM's Headquarters Office, 4601 North Park Ave., Suite 101 Upper, Chevy Chase, MD 20815; phone 301/656-3920; EMAIL@ASAM.ORG.

Lynda Jones
Director of Finance
LJONE@ASAM.ORG

Sandra Metcalfe
Acting Director,
Conferences & Meetings
SMETC@ASAM.ORG

Claire Osman
Director of Development
Phone: 1-800/257-6776
Fax: 718/275-7666
ASAMCLAIRE@AOL.COM

Noushin Shariate
Accounts Payable
NSHAR@ASAM.ORG

Angela Warner
Program Development
Senior Consultant
AWARNER@ASAM.ORG

Christopher Weirs
Director of Credentialing/
IT Manager
CWEIR@ASAM.ORG

Vanetta Whitfield
Program Development Assistant
VWHITFIELD@ASAM.ORG

Darlene Williams
Program Development Assistant
DWILLIAMS@ASAM.ORG

Bonnie B. Wilford
Managing Editor,
ASAM Publications
29261 Pin Oak Way
Easton, MD 21601-4631
Phone: 410/770-4866
Fax: 410/770-4711
BBWILFORD@AOL.COM

Preparing for the Certification Exam, Keeping Up to Date in Addiction Medicine — ADVICE FROM THE EXPERTS

More than 500 physicians gathered in Chicago recently for ASAM's biennial *REVIEW COURSE IN ADDICTION MEDICINE*. Many participants used the course to prepare for the 2006 Certification/Recertification Examination, to be given December 9, 2006, in Los Angeles, New York City, and Atlanta. Others sought a comprehensive review of addiction medicine and an update on the many recent developments in the field. Under the guidance of course co-chairs Edwin A. Salsitz, M.D., and Karen Drexler, M.D., and through outstanding presentations by an expert faculty, conferees agreed that both goals were met.

Preparing for the Certification Exam

Faculty members advised that there is no substitute for thorough preparation, and most recommended careful review of ASAM's textbook, *Principles of Addiction Medicine, Third Edition*, as the cornerstone of a study plan. During a special session on "Preparing for the Certification Examination and Beyond — The Challenge of Staying Up to Date in Addiction Medicine," moderator Louis E. Baxter, Sr., M.D., FASAM, offered the following insights and assurances:

- The exam tests core knowledge in addiction medicine. Questions are based on established, objective data. There are no "trick" questions.
- Although the exam is clinically focused, it is easiest to test basic science and pharmacologic principles.
- All questions that appear on the examination are field-tested, with careful psychometric analyses, so that only questions that discriminate between better and worse performance on the exam are used. Because this is a time-consuming process, one could surmise that advances in addiction medicine would need to be at least a year old to have been field-tested in time to appear on the 2006 exam.
- The exam is moving toward the use of clinical vignettes as the basis for test questions. Single-best-answer type questions predominate, with some matching items. However, some older question types may still be in the question pool.

By way of example, *REVIEW COURSE* participants were given some practice questions from past Certification Exams. The questions have been "retired" and will not be used again, but are representative of the types and relative complexity of the questions to be found on the exam. Three examples follow:

1. Clinically, hallucinogens are most closely associated with

(A) acute anxiety reactions	(D) life-threatening withdrawal symptoms
(B) chronic medical complications	(E) physical dependence
(C) life-threatening overdoses	
2. A 24-year-old man uses the transdermal nicotine patch to quit smoking. Two weeks after quitting, he no longer has cravings for cigarettes, but notices that by the end of the day he is anxious and tremulous and has difficulty falling asleep. He drinks five cups of coffee throughout the day and has one glass of wine every evening. Which of the following is the most appropriate intervention to ameliorate his nervousness and sleep disturbance?

(A) Administration of nicotine nasal spray (Nicotrol)
(B) Administration of sustained-release bupropion (Zyban)
(C) Administration of zolpidem (Ambien) nightly at bedtime
(D) Complete abstinence from alcohol
(E) Reduction in caffeine intake
3. A patient who has taken diazepam (Valium) 50 mg daily for two years abruptly stops taking the medication. In how many days will symptoms of psychomotor agitation peak?

(A) 1 to 2	(B) 3 to 4	(C) 5 to 8	(D) 9 to 12	(E) 14 to 16
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ANSWERS: Question 1 (A) acute anxiety reactions; Question 2 (B) reduction in caffeine intake; Question 3 (C) 5 to 8 days.

Finally, analyses of exam results show that examinees appear to have the most difficulty with questions in the following areas: (a) the epidemiology, neurobiology and neurophysiology of addiction; (b) the pharmacology of alcohol, opioids, stimulants, and benzodiazepines; (c) concepts of specificity and sensitivity as applied to laboratory testing and diagnostic interpretation; and (d) the principles and processes of Alcoholics Anonymous and other Twelve Step programs. Therefore, faculty members advised that these be made a major focus of exam preparation.

Keeping Up With Advances in Addiction Medicine

Examinations aside, keeping one's personal fund of knowledge current is one of the most formidable challenges physicians face. Strategies recommended by *REVIEW COURSE* faculty include: (a) developing personal goals for staying current, (b) systematically and periodically searching the literature for high-quality material relevant to those topics, (c) developing skills to critically appraise the literature, and (d) scheduling a regular time for reading. Other advice included giving priority to original articles and quickly scanning the methods section of articles to select studies that have used sufficiently high standards to warrant clinical action based on study results.

The following list of recently published articles is compiled from recommendations offered at the REVIEW COURSE. Articles can be accessed through the website of the National Library of Medicine (www.pubmed.gov).

- Babor TF, Higgins-Biddle JC, Dauser D et al. (2006). Brief interventions for at-risk drinking: Patient outcomes and cost-effectiveness in managed care organizations. *Alcohol and Alcoholism* Oct.10 (epub ahead of print).
- Dackis C & O'Brien CE (2005). Neurobiology of addiction: Treatment and public policy ramifications. *Nature Neuroscience* Nov;8(11):14321-14326.
- Doggrell SA (2006). Which treatment for alcohol dependence: Naltrexone, acamprostate and/or behavioural intervention? *Expert Opinions in Pharmacotherapy* Oct. 7(15):2169-2173.
- Draper JC & McCance-Katz EF (2005). Medical illness and comorbidities in drug users: Implications for addiction pharmacotherapy treatment. *Substance Use and Misuse* 40 (13-14):1899-1921, 2043-2048.
- Fournier ME & Levy S (2006). Recent trends in adolescent substance use, primary care screening, and updates in treatment options. *Current Opinions in Pediatrics* Aug;18(4):352-358.
- Huang B, Dawson DA, Stinson FS et al. (2006). Prevalence, correlates, and comorbidity of nonmedical prescription drug use and drug use disorders in the United States: Results of the National Epidemiologic Survey on Alcohol and Related Conditions. *Journal of Clinical Psychiatry* Jul;67(7):1062-1073.
- Hyman SE, Malenka RC & Nestler EJ (2006). Neural mechanisms of addiction: The role of reward-related learning and memory. *Annual Review of Neuroscience* April 20 (epub ahead of print).
- Krystal JH, Staley J, Mason G et al. (2006). Gamma-aminobutyric acid type A receptors and alcoholism: Intoxication, dependence, vulnerability, and treatment (Review). *Archives of General Psychiatry* Sep;63(9):957-968.
- Loftis JM, Matthews AM & Hauser P (2006). Psychiatric and substance use disorders in individuals with hepatitis C: Epidemiology and management (Review). *Drugs* 66(2):155-174.
- O'Brien CP (2005). Benzodiazepine use, abuse, and dependence (Review). *Journal of Clinical Psychiatry*. 66 Suppl 2:28-33.
- Stein MD, Weinstock MC, Herman DS et al. (2006). A smoking cessation intervention for the methadone-maintained. *Addiction* Apr;101(4):599-607.
- Van den Brink W & Haasen C (2006). Evidenced-based treatment of opioid-dependent patients. *Canadian Journal of Psychiatry* Sep;51(10):635-646.
- Vocci FJ, Acri J & Elkashef A (2005). Medication development for addictive disorders: The state of the science (Review). *American Journal of Psychiatry* Aug;162(8):1432-1440.

ASAM CONFERENCE CALENDAR

ASAM



December 8-10, 2006
Medical Review Officer (MRO)
Training Course
(Level I and Level II)
Marriott Metro Center Hotel
Washington, DC
[12 Category 1 CME Credits]

April 26, 2007
Ruth Fox Course in
Addiction Medicine
Marriott Doral Resort & Spa
Miami, Florida
[8 Category 1 CME Credits]

April 27-29, 2007
ASAM's 38th Annual
Medical-Scientific Conference
Marriott Doral Resort & Spa
Miami, Florida
[21 Category 1 CME Credits]

April 29, 2007
Buprenorphine
Training Course
Marriott Doral Resort & Spa
Miami, Florida
[8 Category 1 CME Credits]

October 25-27, 2007
ASAM's Course on the
State of the Art in
Addiction Medicine
Hyatt Regency Capitol Hill
Washington, DC
[21 Category 1 CME Credits]

November 18, 2006

Best Practices:
Clinical Drug Testing in
Addiction Treatment IV
Hilton Palmer House Hotel
Chicago, Illinois
[7.5 Category 1 CME
Credits]

December 9, 2006

Certification and
Recertification
Examination in
Addiction Medicine
[5 Category 1 CME Credits]
Los Angeles, New York,
and Atlanta

OTHER EVENTS OF NOTE



November 2-4, 2006

Association for Medical Education
and Research in Substance Abuse
30th Annual National Conference
Washington, DC

[Note: NIAAA has funded 20
scholarships for individuals who
would be attending an AMERSA
conference for the first time.
Applicants must be health profes-
sional educators or researchers
who are conducted alcohol-related
research or are interested in the
field. They must be providing
training or research to underserved
populations such as Latinos, African-
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information, email Isabel@amersa.org
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December 9, 2006

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December 15-16, 2006

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To register for any of the buprenorphine courses,
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For information regarding the December 2nd Atlanta
course only, please go to www.naatp.org/secad
or phone 1-866/293-5510.

Except where otherwise indicated, additional information is available on the ASAM
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