January-February 2006
Volume 21, Number 1

ASAM News

Newsletter of The American Society of Addiction Medicine

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Register now for ASAM's 37th Annual Med-Sci Conference!

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ASAM's Annual Med-Sci Conference to Convene in California

Addiction medicine specialists from around the world will gather in San Diego, California, May 5-7th for ASAM's Annual Medical-Scientific Conference. The conference, now in its 37th year, welcomes ASAM members as well as non-member physicians, nurses, psychologists, counselors, students and residents. It features three full days of clinical and scientific offerings, as well as ASAM's annual Business Meeting, Friday morning, May 5th.

The Med-Sci Conference is preceded by the Ruth Fox Course for Physicians on Thursday, May 4th, also at the San Diego Sheraton Hotel and Marina. The educational activities conclude on Sunday, May 8th, with a Buprenorphine Training Course.

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. *(Conference coverage continues on page* **15***)*

ASAM's PPC-2R Web Portal Is Launched

CMHC Systems, Inc. has launched a web portal for the new assessment software to accompany the *ASAM Patient Placement Criteria, Second Edition-Revised* (*ASAM PPC-2R*). The PPC-2R Assessment System, as the software is called, has been in development for more than four years. The PPC-2R software takes the clinician through an hour-long interview with each patient. When the assessment is completed, the software produces a written and two graphical reports that suggest levels and types of care.

ASAM members who are interested in downloading and running the software must create a user account at the web portal, which can be accessed through ASAM's website (WWW.ASAM.ORG). "We have designed this portal to promote all aspects of the PPC-2R," said Paul Earley, M.D., Chief Science Officer of CMHC. Dr. Earley added, "As the portal evolves, we will make sure the site helps organizations and institutions that treat or manage addictive disease incorporate the PPC-2R" into their practices.

REGISTER NOW for ASAM's 2006 Certification Examination

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

Eileen McGrath, J.D.

Physicians who wish to register for ASAM's next Certification/Recertification Examination must complete and submit an application no later than April 30, 2006. After the applications are reviewed, candidates will notified by mail as to whether they qualify to sit for the examination.

The examination will be given on Saturday, December 9th, 2006, at three sites: Los Angeles, CA; New York, NY; and Atlanta, GA. Physicians who pass the examination become ASAM Certified or Recertified in Addiction Medicine. Since the exam first was offered in 1986, more than 4,000 physicians — including many of the nation's top addiction treatment professionals – have been certified. The fee for the examination is $1,350 for ASAM members and $1,600 for non-members.

The 2006 ASAM Certification/Recertification Examination will be given on Saturday, December 9th, 2006, at Los Angeles, CA; New York, NY; and Atlanta, GA.

For more information, contact ASAM Credentialing Director Christopher M. Weirs, M.P.A., by email at CWEIR@ASAM.ORG or by phone at 301/656-3920, or visit the ASAM web site at WWW.ASAM.ORG. The website contains a downloadable application and information about qualifications to sit for the examination, as well as suggested reading material, sample exam questions, and much more.

Also, watch **ASAM News** for details about the Review Course in Addiction Medicine, to be offered to examination candidates and other interested physicians October 26-28, 2006, in Chicago.

American Society of Addiction Medicine
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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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Web Site
For members visiting ASAM's web site (WWW.ASAM.ORG), entrance to the on-line Membership Directory requires the Username "asam" and the password "asam" (in lower case letters).

PRESIDENT BUSH SIGNS APPROPRIATIONS BILL

After weeks of deliberation and compromise, the House and Senate passed the final conference report for the FY 2006 Labor, Health and Human Services, and Education spending bill, which was signed into law by the President on Dec. 30, 2005. Most of the substance abuse prevention programs maintained level funding and the SDFSC program received an appropriation of $350 million, despite the fact that it was slated for elimination.

Although there were some decreases from FY 2005, the principal alcohol and drug agencies avoided severe funding cuts, as shown in the table below.

Appropriations in the Labor, HHS, Education Appropriations Bill	FY 2005[1] Appropriated	FY 2006 President's Budget Request	FY 2006 House Passed	FY 2006 Senate Passed	FY 2006[2] Appropriated
State Grants Portion of the Safe and Drug Free Schools and Communities Program	$437 million	0	$400 million	$300 million	$350 million
Substance Abuse Prevention and Treatment Block Grant	$1.776 billion	$1.776 billion	$1.776 billion	$1.776 billion	$1.776 billion
Center for Substance Abuse Prevention (CSAP)	$198.7 million	$184.3 million	$195.0 million	$202.3 million	$194.9 million
Center for Substance Abuse Treatment (CSAT)	$422.4 million[3]	$447.1 million[4]	$409.4 million[5]	$412.1 million[6]	$402.9 million[7]
National Institute on Drug Abuse (NIDA)	$1.006 billion	$1.010 billion	$1.010 billion	$1.035 billion	$1.010 billion
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	$438 million	$440 million	$440 million	$452 million	$440.3 million

[1] All FY 2005 numbers include an 0.83% across-the-board cut.
[2] All FY 2006 numbers are subject to a 1% across-the-board cut
[3] Includes $100 million for Access to Recovery
[4] Includes $150 million for Access to Recovery
[5] Includes $99.2 million for Access to Recovery
[6] Includes $100 million for Access to Recovery
[7] Includes $99.2 million for Access to Recovery

Methamphetamine Straining EDs, Treatment System

A pair of new surveys demonstrates the pernicious effect that methamphetamine abuse is having on hospital emergency rooms across the country, the *New York Times* reported Jan. 18th.

Hospitals nationally are reporting sharply higher numbers of people coming to emergency departments for problems related to methamphetamine use, especially in the Midwest, where 70 to 80 percent of hospitals reported that methamphetamine use was responsible for at least 10 percent of their patient loads. Of the 200 regional and county hospitals responding to the survey, 73 percent reported an increase in methamphetamine-related ED visits over the past five years. Forty-seven percent said methamphetamine caused more ED visits than any other illicit drug. Presenting problems range from chemical burns among meth lab workers to trauma and injuries linked to the paranoia and aggression associated with methamphetamine use.

The *National Association of Counties*, which prepared the reports, said the figures demonstrate how easily methamphetamine-related problems can overwhelm health care and social service providers. "These are labor-intensive cases, and the money that's put out is money that the hospitals won't recover," said Jeri Reese, an emergency room nurse manager in Greene County, Iowa. "They're so unpredictable and erratic that when someone comes in, you have to have separate staff just to watch them." More than half of the hospitals surveyed said their costs had risen as a direct result of methamphetamine use by patients.

Similarly, demand for treatment of methamphetamine addiction has risen by 69 percent, but 63 percent of the survey respondents said they did not have the capacity to meet the demand. "It has really rocked us," said Patrick Fleming, director of the Salt Lake County (Utah) Division of Substance Abuse Services. "People are staying in treatment slots longer, so I can't spin those beds to someone else. My waiting lists are mounting like crazy."

ASAM Joins Brief in Hawaii Infant Death Case

Dr. Elizabeth F. Howell

In June 2004, Tayshea Aiwohi pleaded no contest to manslaughter in the death of her two-day-old son. The child, born four weeks premature, died from methamphetamine toxicity. Ms. Aiwohi, a 31-year-old Native Hawaiian, testified that she had smoked the drug three days before and on the day of her son's birth. Her conviction marked the first time a Hawaiian woman was convicted of manslaughter based on the theory that pregnant women can be held criminally liable for the outcomes of their pregnancies. The case is now on appeal to the Hawaii Supreme Court, which heard oral arguments in October 2005.

ASAM joined 60 other national organizations and individuals in a friend-of-the court brief asking that the conviction be overturned on the grounds that Ms. Aiwohi's conviction is not authorized by state law and violates the well-established consensus in the medical community that such prosecution is irrational, ineffective, and counterproductive to maternal, fetal and newborn health. Other organizations joining the brief include the American College of Obstetrics and Gynecology, the American Psychiatric Association, National Advocates for Pregnant Women, and the Hawaii Chapter of the National Association of Social Workers.

The brief explained that, although the problems posed by drug use in pregnancy are serious public health issues, the arrest and prosecution of pregnant women is inappropriate because drug addiction is a disease, not a crime; because such prosecutions are likely to deter pregnant women from seeking prenatal care, as well as treatment for their drug or alcohol addiction; and because punitive approaches have no proven benefits to the health of the women, their children, or society at large.

> *...such prosecutions are likely to deter pregnant women from seeking prenatal care, as well as treatment for their drug or alcohol addiction...*

"Punishing women for failing to have healthy pregnancy outcomes undermines health care for both pregnant women and their future children by frightening women away from that health care," said Leslie Hartley Gise, M.D., Clinical Professor of Psychiatry at the John A. Burns School of Medicine, University of Hawaii. Dr. Gise added that the prosecution "reflects a terrible disregard for pregnant women and a profound misunderstanding of the nature of drug dependency." In addition to Dr. Gise, three other local experts joined the brief: Jennifer Frank, M.D., of the University of Hawaii; Kathleen Irwin, Ph.D., of the Department of Sociology at the University of Hawaii; and Mona Bomgaars, M.D., of the Hawaii Academy of Family Physicians.

SUPREME COURT'S DECISION IN "RIGHT-TO-DIE" CASE HAS BROAD IMPLICATIONS FOR MEDICAL PRACTICE, ADDICTION CARE

The Supreme Court's January 17th decision upholding Oregon's law on physician-assisted suicide, in which the Court ruled that the Justice Department may not punish doctors who help terminally ill patients end their lives, has significant implications for the governance of medical practice and for the addiction field.

Although frequently described as a "right to die" case, *Gonzales v. Oregon* was not, strictly speaking, about the constitutional right to end one's own life. Instead, Justice Anthony M. Kennedy noted in the majority opinion that the question was whether Attorney General John Ashcroft acted in accordance with the federal Controlled Substances Act (CSA) when he issued an "interpretive rule" about what constitutes legitimate medical practice in 2001. Indeed, Justice Kennedy noted that the case "requires an inquiry familiar to the courts: interpreting a federal statute to determine whether Executive action is authorized by, or otherwise consistent with, the enactment."

The answer, he wrote, is No. Restating the issue as involving the states' right to regulate medical practice rather than a patient's right to die, he concluded that the Attorney General had made an overly broad interpretation of the 35-year-old CSA. That law, he wrote, was meant to stop drug abuse and drug trafficking, not to replace the states' traditional role in deciding what state-licensed doctors may and may not do within state borders: "The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the Congressional role in maintaining it." He wrote that the administration's position, if upheld, would "delegate to a single executive officer the power to effect a radical shift of authority from the states to the federal government to define general standards of medical practice in every locality."

The ruling is widely seen as a reprimand to Ashcroft. In his opinion, Justice Kennedy said the "authority claimed by the Attorney General is both beyond his expertise and incongruous with the [CSA's] statutory purposes and design." The ruling thus made clear the Justices' belief that the states — not federal authorities — have the power to regulate the practice of medicine and the licensing of physicians. Justice Kennedy was joined in the opinion by Justices John Paul Stevens, Sandra Day O'Connor, David H. Souter, Ruth Bader Ginsburg and Stephen G. Breyer. Justices Antonin Scalia and Clarence Thomas and Chief Justice John G. Roberts dissented.

HISTORY OF THE OREGON LAW

The Supreme Court already had ruled, in 1997, that there is no right to commit suicide, or to aid another in doing so, and it did not revisit that decision. In 1994, however, Oregon voters approved the Death With Dignity Act, which authorized physicians to prescribe — but not administer — a lethal dose of medication to dying individuals who request it and who meet certain criteria. According to the Oregon Department of Human Services, the act requires that the patient must be (1) an Oregon resident, (2) at least 18 years old, (3) capable of making and communicating health care decisions, and (4) diagnosed as having no more than six months to live. The patient also must give the physician a written request signed by two witnesses, and make two oral requests at least 15 days apart. Before issuing a prescription, two physicians must: (1) confirm the diagnosis, (2) determine that the patient is mentally competent to make the request, (3) inform the patient of alternatives, including pain control, and (4) ask, but not require, the patient to inform family members. The patient must take the drug by himself or herself, and the physician must notify the state. About 200 people have used the terms of the act to end their lives since the law took effect in late 1997.

State voters rejected a challenge to the law in 1997. Two efforts to override the measure in Congress, supported by John Ashcroft when he was a senator, failed. President Clinton's Attorney General, Janet Reno, declined to act against the law, saying she did not have the authority to "displace the states as the primary regulators of the medical profession." Shortly after taking office as Attorney General in 2001, Ashcroft reversed Reno's decision and declared that prescribing legal drugs to bring a life to an end did not serve a "legitimate medical purpose." Subsequently, a federal district court in Oregon upheld the law, as did the San Francisco-based U.S. Court of Appeals for the 9th Circuit. The Bush administration appealed to the Supreme Court, which agreed last year to take the case.

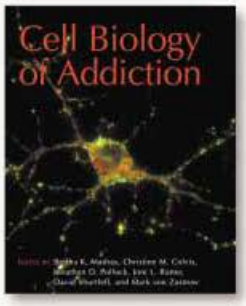
WIDE-RANGING IMPLICATIONS

While defenders of state authority hailed the ruling, the decision leaves open the possibility that the Congress could pass laws explicitly banning physician-assisted suicide, as it tried to do in 1999. It also could amend the CSA to assert federal authority. Such a move has the potential to profoundly change the system through which medical practice is governed, and opens the possibility that federal authority could be used to enforce or prohibit other medical procedures involving controlled drugs, such as medication-assisted addiction treatment or the management of certain medical conditions. Controversial areas of practice, such as pharmacotherapies for ADHD or pain, are thought to be particularly vulnerable.

On the other side, opponents of the decision argued that it would have the effect of undermining federal uniformity, as by allowing states to authorize uses of drugs that are not permitted under the CSA. Chief Justice John Roberts appeared particularly troubled by that prospect; during oral arguments in October 2005, he raised a hypothetical case involving morphine, noting that a state could allow physicians to prescribe it for any reason, "just to make people happy."

Sources: Washington Post and Los Angeles Times, January 18, 2006; Pew Forum on Religion and Public Life, January 18, 2006.

Cell Biology of Addiction



Edited by Bertha Madras, *Harvard Medical School*, Christine M. Colvis, *National Institute on Drug Abuse/NIH*, Jonathan D. Pollock, *National Institute on Drug Abuse/NIH*, Joni L. Rutter, *National Institute on Drug Abuse/NIH*, David Shurtleff, *National Institute on Drug Abuse/NIH*, and Mark von Zostrow, *University of California, San Francisco*

This monograph, written by experts in the field, is devoted to the molecular analysis of addiction pathways in the brain. It provides an intensive overview of the fundamentals, state-of-the-art advances, and major gaps in the cell and molecular biology of drug addiction within the broader context of neuroscience. Addiction research is a branch of neuroscience and psychology. The emphasis in this book is on hard science and the market for it will be found among research investigators and grad students within the field of neuroscience. The research presented is not only applicable to the study of drug abuse and addiction, but has clear implications for clarifying mechanisms of learning and memory, neuroadaptation, perception, volitional behavior, motivation, reward, and other disciplines of neuroscience.

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GENES THAT AFFECT DRINKING BEHAVIOR IN SMOKERS IDENTIFIED

A recent examination of families selected for their smoking behavior has identified the same region of chromosome four that was identified by earlier studies as being linked to the initiation of alcohol consumption. Results were published in the December issue of *Alcoholism: Clinical & Experimental Research*.

"It is commonly observed that people who drink also smoke and vice versa," explained Kirk C. Wilhelmsen, Ph.D., associate professor in the departments of genetics and neurology at the University of North Carolina, who served as corresponding author for the study. "This suggested to us that families selected for smoking behavior would also have an increased incidence of drinking behavior."

Using data collected in an ongoing interdisciplinary study of environmental and genetic determinants of tobacco use, conducted at the Oregon Research Institute under the direction of Dr. Hyman Hops, Dr. Wilhelmsen and colleagues examined 158 nuclear families who were determined to have at least two first-degree relatives who had smoked 100 or more cigarettes in their lifetimes. Genotypes were determined from blood DNA taken from each family participant and analyzed for linkages to selected phenotypes.

"We looked for chromosome regions that had genes that affect patterns of drinking behavior," said Dr. Wilhelmsen. "The locations with the strongest evidence were the same places that were previously found in other linkage studies looking for loci that affect alcoholism, although we found evidence that these loci affect drinking behavior less severely than for alcoholism" (the comment refers to one locus on chromosome two and two loci on chromosome four.) "When these genes are identified, and their normal function deduced, we will have a better understanding of the biology of drinking behavior. This may lead to new therapeutic approaches to treat alcoholism."

The researchers caution that, as with all studies of this sort, the findings need to be confirmed in other, nonclinical samples, particularly because the overall genetic signal observed in the study was modest, suggesting the presence of other genetic and environmental factors. However, the findings are significant because the families in the study were selected by virtue of their use of tobacco rather than for excessive drinking and alcoholism, which have been the selection traits in previous linkage studies. *Source: Addiction Technology Transfer Center, based on Amos C, Andrews J, Benowitz N et al. (2005). Support for previously identified alcoholism susceptibility loci in a cohort selected for smoking behavior. Alcoholism: Clinical & Experimental Research December;29(12).*

GENE THAT AFFECTS RESPONSE TO ALCOHOL IDENTIFIED

Researchers agree that how a person "feels" the effects of alcohol is, in part, genetically influenced and relates to their risk for developing alcoholism. A low level of response (LR) to alcohol, or the need for a higher number of drinks to feel intoxication the first few times a person drinks, is more likely to occur in children of alcoholics, and predicts a greater risk for alcohol problems. According to a study published in the November issue of *Alcoholism: Clinical & Experimental Research,* investigators have found that a gene on chromosome 10 — in particular, the KCNMA1 gene — is potentially linked to LR.

"The LR to alcohol is a genetically influenced phenotype, or measurable characteristic, that contributes toward the development of alcoholism," said Marc A. Schuckit, M.D., director of the Alcohol Research Center at the Veterans Affairs San Diego Healthcare System and first author of the study. "The earlier you study it, the better. We tested people with alcohol challenges to look at their LR at the youngest possible age they could give informed consent, as the picture is clearest when they're youngest." For the study, Dr. Schuckit and colleagues examined 238 18-to-29-year-old pairs of siblings (about 365 people) who had at least one alcohol-dependent parent. All of the pairs of siblings had some experience with alcohol use but were not yet alcohol-dependent. LR was established through use of the Subjective High Assessment Scale as well as measurements of body sway. "We looked at almost everything a person could feel after they drink alcohol — whether dizzy, nauseated, happy, intoxicated, whatever — and we asked the subjects to rate each one of these feelings from 0, meaning not at all, to 36, meaning the most they could imagine," Dr. Schuckit explained. In addition, all of the participants supplied blood samples that were used to look for linkages of their LR characteristic to selected chromosomal regions.

Results indicated that an area on chromosome 10 — the KCNMA1 gene — is potentially linked to LR. These results are particularly interesting, said Dr. Schuckit, because prior research has identified a potential link between this section of the chromosome and an individual's response to alcohol. Researchers in San Francisco had previously carried out some research on worms, he explained. They found that worms with a mutation in the KCNMA1 gene were fairly insensitive to alcohol. Dr. Schuckit said the investigators also knew that alcohol has an effect on what this gene controls, which is potassium flow, adding: "Our current results appear to show that the corollary of this gene in humans helps to control the intensity of the effects of alcohol on the flow of potassium in and out of cells." *Source: Addiction Technology Transfer Center, based on Feiler HS, Kalmijn J, Lange L et al. (2005). Autosomal linkage analysis for the level of response to alcohol. Alcoholism: Clinical & Experimental Research November 29(11):1976-1982.*

Treat the Condition

Opioid Dependence Is a Chronic Medical Condition

Long-term, fundamental changes to structure and function of the brain occur.[1,2]

Intravenous misuse of buprenorphine, usually in combination with benzodiazepines or other CNS depressants, has been associated with significant respiratory depression and death.

SUBOXONE has potential for abuse and produces dependence of the opioid type with a milder withdrawal syndrome than full agonists.

Cytolytic hepatitis and hepatitis with jaundice have been observed in the addicted population receiving buprenorphine.

There are no adequate and well-controlled studies of SUBOXONE (a category C medication) in pregnancy.

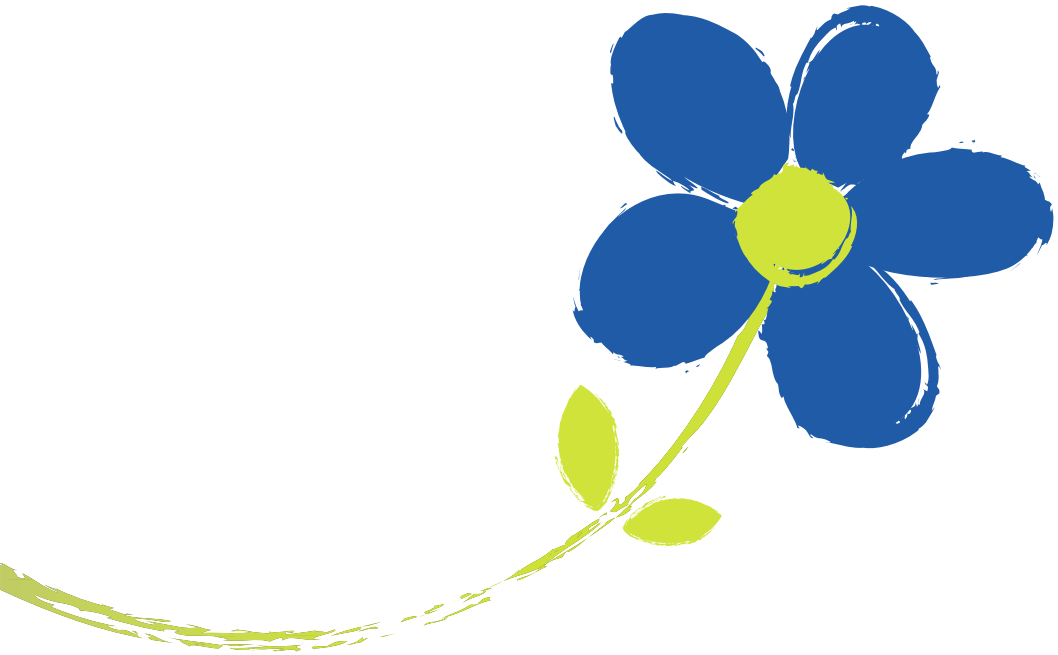
Due caution should be exercised when driving cars or operating machinery.

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.

Transform the Life



In the Privacy and Convenience of Your Office

SUBOXONE, combined with counseling, can be used to treat opioid-dependent patients with privacy,* as other chronic, medical conditions are treated.

Target the Biological Basis of Opioid Dependence

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.

To learn more, call 1-877-SUBOXONE or visit suboxone.com

*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) C III 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 addict 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 intracholedochal 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/m^2 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/m^2 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 [^{3}H]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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 basis). Acephalus was observed in one rabbit fetus from the low-dose group and omphacele 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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.

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) N (%)	Low* (N=180) N (%)	Moderate* (N=186) N (%)	High* (N=181) N (%)	Total* (N=731) 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

UPDATE: Medicare Drug Benefit

SAMHSA is collaborating with the Centers for Medicare & Medicaid Services (CMS) on efforts to help Medicare beneficiaries who have substance use and mental disorders make informed decisions about enrolling in the new Medicare prescription drug program. Efforts include distribution of printed materials and resources, informational fairs, presentations at regularly scheduled conferences, "train-the-trainer" sessions, and development of Internet referral and decision-making tools.

In addition, SAMHSA's website now features a special section on the Medicare Modernization Act. The site includes a description of the Medicare prescription drug coverage, an explanation of enrollment and significant enrollment dates, and links to other resources. For more information, visit www.samhsa.gov/MMA/index.aspx. A Drug Plan Finder tool is available on the CMS Web site at WWW.MEDICARE.GOV.

Managing Relapse Prevention in Older Adults

The Center for Substance Abuse Treatment recently released a 200-page manual, *Substance Abuse Relapse Prevention for Older Adults: A Group Treatment Approach*, to help providers working with older men and women who have substance use disorders. To order the free publication, contact SAMHSA's National Clearinghouse for Alcohol and Drug Information at P.O. Box 2345, Rockville, MD 20847-2345, or phone 1-800/729-6686 and ask for NCADI publication number BKD525.

ATTCs Publish Training Aid

A new publication from the ATTC National Office and the Research Society on Alcoholism, *Alcoholism: The Science Made Easy*, highlights current findings in the field of alcoholism and presents science-based information in a concise, easy-to-understand format. The result of a partnership between the ATTC National Office, the Research Society on Alcoholism and its journal *Alcoholism: Clinical and Experimental Research*, the new book compiles nearly 100 science-based articles for use in education and training activities. For example, information from the publication can be used to create handouts, presentations and trainings on topics related to alcohol for use in educating students, practitioners, patients and the public.

Alcoholism: The Science Made Easy can be downloaded as a PDF file at no charge from the ATTC's website at WWW.NATTC.ORG/PDF/ASME_BOOK.

Black, White Youth Show Differences in Nicotine Metabolism

New research by scientists with the National Institute on Drug Abuse (NIDA) suggests that some of the racial and ethnic differences underlying how adults' bodies metabolize nicotine also are at work during adolescence. The findings have implications for the way adolescents of different racial and ethnic backgrounds are provided smoking cessation treatments, commentators say.

"Previous research in adults showed that black smokers take in 30 percent more nicotine per cigarette and take longer to rid their bodies of the drug, compared to white smokers," said NIDA Director Nora D. Volkow, M.D. "The current findings, among the first on adolescent nicotine metabolism, reveal that these differences are in effect during the teen years, as well."

"Because nicotine plays an active role in smoking reinforcement, these variations may influence early onset addiction to tobacco," Dr. Volkow added. "Thus, these findings may constitute a strong warning to black youth to keep from smoking in the first place. They also may explain why certain smoking cessation therapies work better in some populations than in others, and therefore, which treatments should be offered to which teens."

A team of scientists led by Dr. Eric T. Moolchan, Director of NIDA's Teen Tobacco Addiction Research Clinic in Baltimore, Maryland, recruited 61 white and 30 black adolescent smokers to participate in the study. The scientists measured the ratio of one nicotine breakdown product to another to assess the rates at which the youths' bodies disposed of the drug. The ratio of the two metabolites was lower among black youth, indicating that nicotine/cotinine metabolism was occurring more slowly in this group.

The investigators also measured the ratio of one nicotine breakdown product (cotinine) to the number of cigarettes smoked per day (CPD). Although black youth smoked significantly fewer cigarettes per day — 15.1 cigarettes versus 19.6 cigarettes for white youth — white and black youth exhibited similar measures of nicotine dependence and blood cotinine concentrations. The significantly higher cotinine-to-CPD ratio among black youth confirmed the slower metabolism in that group.

The study results remained statistically significant after controlling for smoking menthol cigarettes (recent findings have suggested that menthol might increase the addictiveness of tobacco, and that menthol may play a role in inhibiting nicotine metabolism; other studies have indicated that blacks show a preference for menthol cigarettes compared to white smokers).

In commenting on the study, published in the January 2006 issue of *Ethnicity and Disease,* Dr. Moochan said, "Our findings support the hypothesis that racial and ethnic differences in nicotine metabolism exist among adolescent smokers, with black teens smoking less but being exposed to as much nicotine as white teens." The findings also suggest that smoking rates may be only one of a number of factors to consider when selecting appropriate treatments for smoking cessation, he added. "An important implication is that black youth may not be offered certain smoking cessation therapies if those treatments are selected largely on the number of cigarettes smoked per day," noted Dr. Volkow. "Thus, we need to look at aspects of nicotine dependence other than consumption to guide the selection of appropriate and effective therapies." *Source: NIH News, January 20, 2006.*

STUDY LINKS ALCOHOL ADS TO UNDERAGE DRINKING

According to a study funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), exposure to alcohol advertising directly increases the likelihood that young people will drink. Experts say the findings underscore the importance of reducing youth exposure to alcohol ads through environmental prevention strategies. The analysis was conducted by Leslie Snyder, Ph.D., and colleagues at the University of Connecticut and Colorado State University and was published in the January 2006 edition of the *Archives of Pediatrics & Adolescent Medicine*.

The results of their research — the first national longitudinal study in the U.S. to demonstrate a link between youth exposure to alcohol advertising and alcohol consumption — are consistent with similar research in other countries. For the three-year study (1999 through 2001), telephone interviews were conducted with youth ages 15 to 26 who were randomly selected from 24 of the top 75 media markets in the United States. The investigators found that, for underage drinkers, exposure to even one advertisement more than the average for all youth correlated with a one percent increase in alcohol consumption. At the community level, each additional dollar per capita spent on alcohol advertising in a given market correlated with a three percent increase in underage alcohol consumption.

Previous research by the Center on Alcohol Marketing and Youth (CAMY) at Georgetown University has shown that, on a per capita basis, youth between the ages of 12 and 20 often see and hear more alcohol advertising in magazines and on television and radio than do adults of legal drinking age. David Jernigan, Ph.D., CAMY Executive Director, wrote in an editorial that accompanied the new report that "Excessive alcohol use kills over 4,000 kids under age 21 each year. Now we have long-term, peer-reviewed evidence that alcohol ads are contributing to this enormous public health problem."

CAMY and other organizations have recommended that alcohol marketers limit advertising to programs whose audiences contain less than 15 percent young people. A recent CAMY analysis showed that by adopting this policy change, youth exposure to alcohol advertising could be reduced by 20 percent without changing advertisers' ability to reach adults of legal drinking age. *Source: Archives of Pediatrics & Adolescent Medicine, January 2006.*

. . . For underage drinkers, exposure to even one advertisement more than the average for all youth correlated with a one percent increase in alcohol consumption.

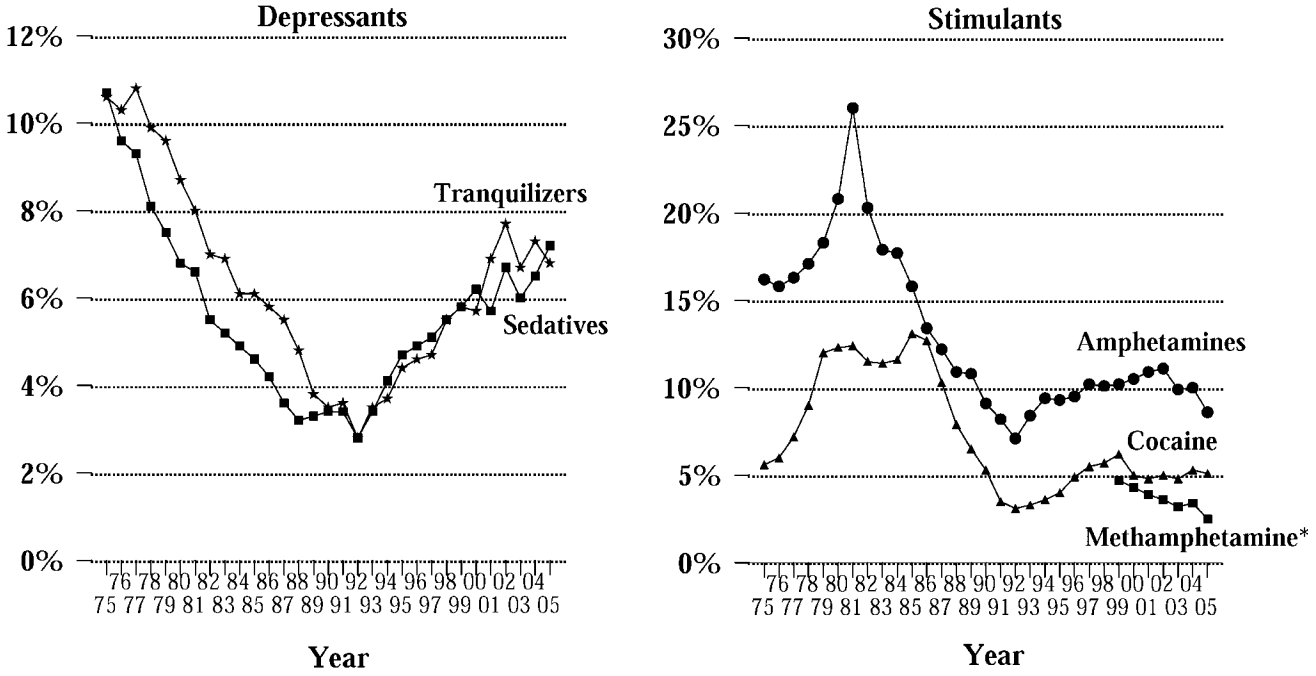
SEDATIVE USE UP, STIMULANT USE DOWN AMONG ADOLESCENTS

The use of prescription depressants among high school seniors in the U.S. continues to increase, according to data from the 2005 Monitoring the Future survey. The percentage of 12th graders reporting past year use of tranquilizers and sedatives increased from a low of 2.8% in 1992 to around 7% in 2005.

However, during the same period, use of cocaine stabilized and use of amphetamines declined. Methamphetamine use has decreased as well, reaching a low of 2.5% in 2005.

The study authors acknowledge that "the pattern of declining meth use among adolescents seems to be inconsistent with recent press reports of a growing meth epidemic" but note that "if use is spreading, it does not seem to be doing so in this segment of the population."

Percentage of Twelfth Graders Reporting Use of Depressants and Stimulants in the Past Year, 1975 to 2005



* Methamphetamine use is included in amphetamines in the table.

Additional data are available from "Teen Drug Use Down But Progress Halts Among Youngest Teens," Monitoring the Future, University of Michigan, December 19, 2005. Available online at HTTP://WWW.MONITORINGTHEFUTURE.ORG.

Adolescent Treatment Grants Available

Treatment grants totalling $5.2 million will be awarded to provide services to substance-abusing adolescents and their families, the Center for Substance Abuse Treatment (CSAT) announced January 19th. Applications for the awards, which will average $300,000 per year for up to three years, must be received by **March 29, 2006.**

CSAT expects to fund 17 awards in FY 2006. Eligible applicants include public and private not-for-profit organizations such as state and local governments; public or private universities and colleges; and community, faith-based and tribal organizations. Successful applicants will propose to use treatment protocols that have been shown to be effective in this population, including Assertive Community Reinforcement and Assertive Continuing Care.

Applications for No. TI-06-007 are available by calling SAMHSA's clearinghouse at 1-800-729-6686. They also can be downloaded from WWW.GRANTS.GOV or WWW.SAMHSA.GOV. Applicants are encouraged to apply on line using WWW.GRANTS.GOV.

Questions about program issues should be directed to Randolph Muck by phone at 240/276-1576 or by email TO RANDY.MUCK@SAMHSA.HHS.GOV. Questions on grants management issues should be addressed to Kimberly Pendleton at 240/276-1421 or by e-mail to KIMBERLY.PENDLETON@SAMHSA.HHS.GOV.

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Med-Sci Symposium to Focus on Methamphetamine

A symposium scheduled for ASAM's 2006 Medical-Scientific Conference will review multiple aspects of methamphetamine abuse and addiction and focus on strategies for treating the growing number of patients who have this devastating problem.

As ASAM members know, use of methamphetamine has been associated with severe medical, psychiatric and social consequences, including brain damage, cognitive impairment and memory loss, stroke, paranoia, anorexia, hyperthermia, hepatitis, HIV transmission, and violence.

Recent indicators suggest that such use, once confined largely to the Western states, has spread across the U.S. According to the 2004 National Survey on Drug Use and Health (NSDUH), an estimated 12 million persons — 4.9 percent of the population age 12 or older — had used methamphetamine at least once in their lifetime, 1.4 million (0.6 %) had used it in the past year, and 600,000 (0.2 %) had used it in the past month.[1] Moreover, an estimated 318,000 persons used methamphetamine for the first time in 2004. The average age at first use among new users was 18.9 years in 2002, 20.4 years in 2003, and 22.1 years in 2004.[1]

Treatment admissions for primary methamphetamine use problems increased from 21,000 in 1993 to 117,000 in 2003, according to the Treatment Episode Data Set.[2] Other indicators suggest that methamphetamine-related deaths and admissions to hospital emergency departments are increasing at a striking rate.

Although inpatient hospitalization may be indicated to treat severe cases of long-term methamphetamine dependence, optimal treatment for methamphetamine addicts employs an intensive outpatient setting. While there are no pharmacotherapies for methamphetamine addiction, cognitive behavioral interventions have proved effective.

In an effort to bring ASAM members the latest information on methamphetamine, the Center for Substance Abuse Treatment (CSAT) will bring together some of the nation's leading experts on the drug for a half-day symposium during the Med-Sci Conference in San Diego. To be chaired by CSAT Director H. Westley Clark, M.D., M.P.H., J.D., FASAM, the symposium has been organized by Anton C. Bizzell, M.D., Medical Director in CSAT's Division of Pharmacologic Therapies.

For additional information or to register for the symposium, visit the ASAM website at WWW.ASAM.ORG or contact ASAM's Department of Meetings and Conferences at 301/656-3920.

[1] Office of Applied Studies (2005). *Results from the 2004 National Survey on Drug Use and Health: National Findings* (DHHS Publication No. SMA 05-4062, NSDUH Series H-28). Rockville, MD: Substance Abuse and Mental Health Services Administration.

[2] Office of Applied Studies (2005). *Treatment Episode Data Set (TEDS) Highlights – 2003. National Admissions to Substance Abuse Treatment Services, DASIS Series: S-27* (DHHS Publication No. SMA 05-4043). Rockville, MD: Substance Abuse and Mental Health Services Administration.

TREATMENT OF METHAMPHETAMINE USE DISORDERS: A CSAT SYMPOSIUM

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TREATMENT OF METHAMPHETAMINE USE DISORDERS

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Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

OBJECTIVES:

At the conclusion of the symposium, participants will be able to:

- Identify evidence-based treatment approaches for methamphetamine use or dependence such as the Matrix Model and other behavioral approaches
- Describe methamphetamine's mechanism of action, physical and behavioral effects, treatments, and potential predictors of treatment success
- Identify and manage the medical and psychological problems and complications of methamphetamine use and abuse including methamphetamine withdrawal

PROGRAM

Welcome and Overview
H. Westley Clark, M.D., J.D., M.P.H., C.A.S., FASAM
Director, Center for Substance Abuse Treatment

Epidemiology of Methamphetamine Abuse
Jane Maxwell, Ph.D., Addiction Research Institute, Austin, Texas

Methamphetamine and Its Effect on the Brain and Behavior
Edyth London, Ph.D., University of California-Los Angeles

APPROACHES TO TREATMENT

Medical Aspects of Methamphetamine Use Disorders

- Assessment and Diagnosis
- Clinical Manifestations and Medical Management
- Identification and Management of Medical Complications
  Matt Torrington, M.D., University of California – Los Angeles

Medical Aspects of Methamphetamine Use Disorders *(Continued)*

- Methamphetamine Withdrawal & Management
  William Haning, M.D., University of Hawaii
- Identification and Management of Psychological Complications
  Walter Ling, M.D., University of California – Los Angeles

Psychosocial and Behavioral Treatments

- Matrix Model
  Richard Rawson, Ph.D., University of California – Los Angeles

Treatment Issues for Special Groups and Settings

- Female Methamphetamine Users
  Shirley Semple, Ph.D. , University of California – San Diego
- Behavioral Treatment Approaches for Methamphetamine Dependence and HIV-related Sexual Risk Behaviors
  Steve Shoptaw, Ph.D., University of California – Los Angeles
- Adolescents
  Rachel Gonzales, University of California – Los Angeles

Closing Remarks: *Dr. Clark*

UK: "Hangover Hospitals" Established

As Great Britain changes its licensing laws to allow for 24-hour alcohol service, some communities are establishing temporary health care facilities to deal with the anticipated increase in alcohol-related injuries. About 80 percent of emergency services delivered in the U.K. on Friday and Saturday nights are alcohol-related, officials say.

The first such "hangover hospital" opened in Newcastle, on Britain's northeast coast, and more are being contemplated by the National Health Service. Officials hope the clinics will help deal with an expected rise in demand for emergency treatment as the nation allows pubs to remain open around-the-clock. Located near a major social district, the Newcastle facility is open on Fridays and Saturdays from 8:00 p.m. to 8:00 a.m. On the opening night, staff treated 11 patients, including five who had passed out from drinking too much. "Normally, all of these patients would have been taken to Newcastle General (emergency room), which puts pressure on ambulances and hospital staff and causes long waiting times," said Simon Swallow, emergency planning officer with North-East Ambulance Service. "The five unconscious patients each needed treatment for more than two hours. They would have taken up five beds overnight at the hospital."

WHO Launches Alcohol Study

Citing growing problems with binge drinking and increased consumption in developing countries, the *World Health Organization (WHO)* has launched a worldwide study of alcohol use.

Adopting a resolution proposed by the European Union and others, the board of the *World Health Organization (WHO)* agreed to launch the study after issuing a report noting that alcohol killed 1.8 million people worldwide in 2000. Alcohol use and overuse appear to be rising worldwide even as consumption falls in some industrialized nations, the WHO noted. "Alcohol is now a global problem," said Catherine Le Gales-Camus, WHO's assistant director-general for non-communicable diseases and mental health. "Member states are more and more concerned by the use of alcohol among the younger part of the population. New patterns of consumption, binge drinking, are major issues."

The last major WHO study of alcohol was conducted more than 20 years ago. WHO has undertaken similar studies on tobacco and obesity in recent years. The new research project could lead to a global campaign against alcohol misuse similar to WHO's efforts on smoking and obesity. The resolution sets a two-year deadline for the report and calls for discussions with the alcohol industry.

Treatment Savings Outweigh Costs, U.K. Study Says

The cost savings realized from treating people with alcohol problems are five times greater than the cost of providing treatment, according to British researchers. The UK Alcohol Treatment Trial examined 600 patients enrolled in one of two treatment programs that allowed participants to go on with their daily lives rather than checking into a residential facility. The programs offered network or motivational therapy. Both programs were found to be successful in doubling participants' alcohol-free days and cutting daily drinking by about a third.

At one-year follow up, investigators found that drinking was still reduced and patients were 50 percent less likely to be experiencing alcohol-related problems.

When a cost-benefit analysis was performed, researchers said that while the cost of treating one person was about $321, treatment reaped about $1,656 in reduced health care and criminal justice costs. The research was published in the Sept. 10, 2005, issue of the *British Medical Journal.*

List of Drug-Producing Countries Contains Familiar Names

The same nations that produced most of the drugs coming into the U.S. two decades ago still top the *State Department's* annual list of drug-producing countries. Despite Federal laws penalizing such nations, and outlays of $1 billion annually to fight drug production overseas, Colombia, Peru, and Jamaica have remained on the list throughout its history. In 1985, for example, the report praised the Peruvian government for eradicating coca plants but noted that trafficking still flourished in the Andean nation; the 2005 report says essentially the same thing. Colombia remains the source for 90 percent of the cocaine and half of the heroin coming into the U.S.

Colombia remains the source for 90 percent of the cocaine and half of the heroin coming into the U.S.

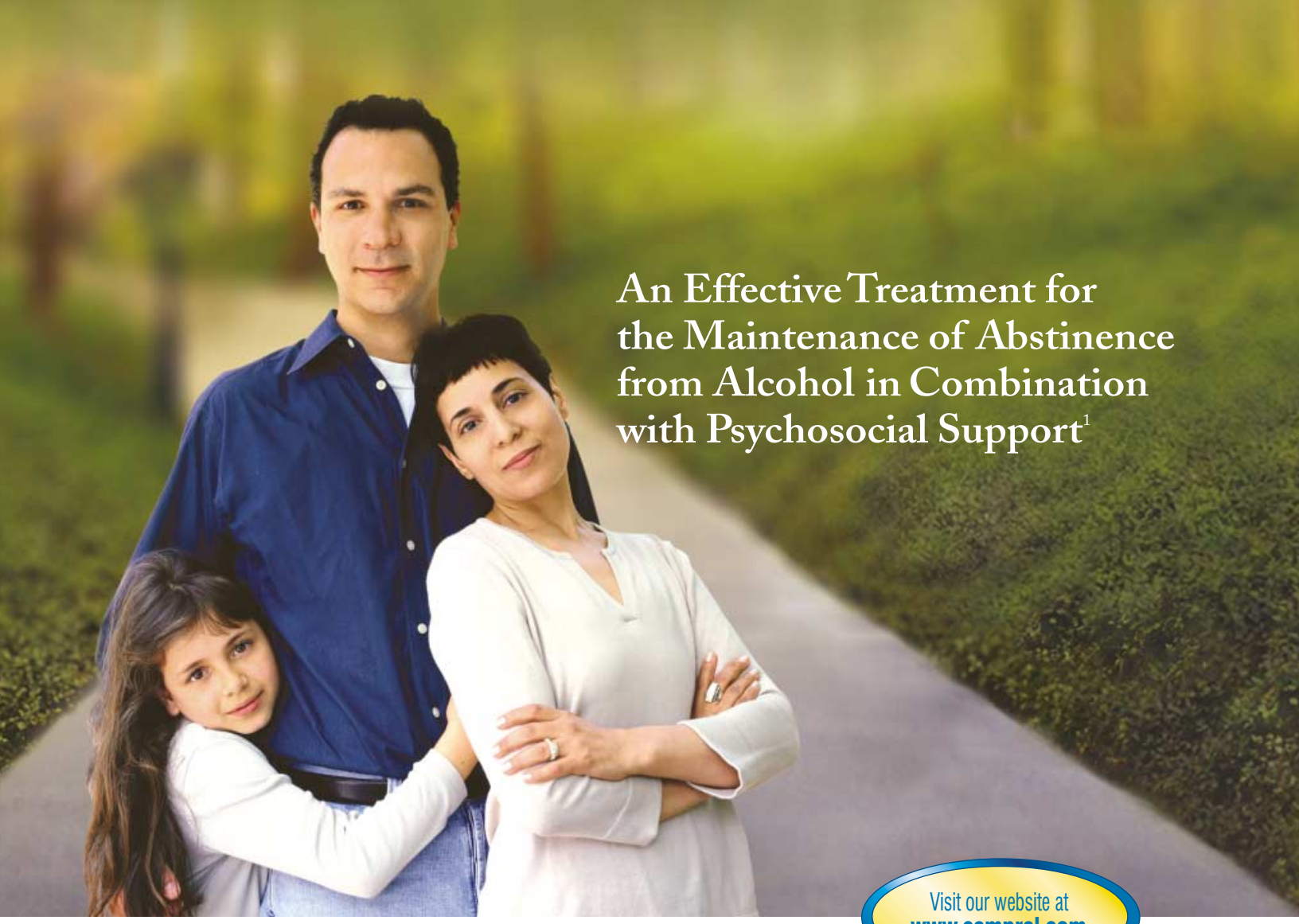
The list was intended to put offending countries on notice and punish those that did not cooperate in the drug war. But aid has only been cut to an allied nation once (Colombia in 1994). Two years ago, the Bush administration de-linked the report from decisions about which countries receive U.S. anti-drug aid.

Twenty-two nations were listed in this year's report. The most striking change is that, for the first time in more than 20 years, Thailand is not listed.

Asian Traffickers Shift to Amphetamines, U.N. Says

As Asian heroin production drops, drug traffickers in the region are switching to dealing a variety of amphetamine-type drugs, including ecstasy and methamphetamine, U.N. experts say. "There's an increasingly serious problem in amphetamines in Southeast Asia because they do not require any agricultural production," said Akira Fujino, who heads the United Nations Office on Drugs and Crime in Bangkok, Thailand. "All you need to do is get the starting materials and then any urban laboratory can be established anywhere in the world."

While opium production in Southeast Asia declined 78 percent since 1996, the U.N. says that China and Myanmar have become the world's largest producers of amphetamine-type drugs. Illicit production also is increasing in the Philippines and Fiji. Mr. Fujino reports that methamphetamine labs destroyed in 2003 in the Philippines accounted for 10 percent of the drug seized worldwide in that year.



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- **2 to 3 times more patients maintained abstinence vs placebo in long- and short-term studies, respectively**[2]
- **Works well with a variety of psychosocial therapies**[3–6]
- **Excellent safety and tolerability profile**[1–7]
- **Unique mechanism of action is thought to restore neurotransmitter balance***[1]
- **Used in over 1.5 million patients worldwide**[7]

CAMPRAL® (acamprosate calcium) is contraindicated in patients with severe renal impairment (creatinine clearance ≤30 mL/min). CAMPRAL is contraindicated in patients with known hypersensitivity to acamprosate calcium or any excipients used in the formulation. CAMPRAL does not eliminate or diminish withdrawal symptoms. Alcohol-dependent patients, including those patients being treated with CAMPRAL, should be monitored for the development of symptoms of depression or suicidal thinking. The most common adverse events reported with CAMPRAL vs placebo (≥3% and higher than placebo) were asthenia, diarrhea, flatulence, nausea, and pruritus.

*The mechanism of action of acamprosate in the maintenance of abstinence is not completely understood. Chronic alcohol exposure is hypothesized to alter the normal balance between neuronal excitation and inhibition. *In vitro* and *in vivo* studies in animals have provided evidence to suggest acamprosate may interact with neurotransmitter systems centrally, and has led to the hypothesis that acamprosate restores this balance. The clinical significance in humans is unknown.

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, Lehert 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, Zieglgansberger 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, Lehert 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.

Please see Brief Summary of Prescribing Information on the following page.

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Campral®
(acamprosate calcium)
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Brief Summary:
For complete details, please see full Prescribing Information for CAMPRAL

INDICATIONS AND USAGE
CAMPRAL (acamprosate calcium) is indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Treatment with CAMPRAL should be part of a comprehensive management program that includes psychosocial support. The efficacy of CAMPRAL in promoting abstinence has not been demonstrated in subjects who have not undergone detoxification and not achieved alcohol abstinence prior to beginning CAMPRAL treatment. The efficacy of CAMPRAL in promoting abstinence from alcohol in polysubstance abusers has not been adequately assessed.

CONTRAINDICATIONS
CAMPRAL is contraindicated in patients who previously have exhibited hypersensitivity to acamprosate 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 acamprosate 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 acamprosate. Pharmacokinetic studies indicate that administration of disulfiram or diazepam does not affect the pharmacokinetics of acamprosate. Co-administration of naltrexone with CAMPRAL produced a 25% increase in AUC and a 33% increase in the Cmax of acamprosate. No adjustment of dosage is recommended in such patients. The pharmacokinetics of naltrexone and its major metabolite 6-beta-naltrexol 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 acamprosate 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. Acamprosate calcium was negative in all genetic toxicology studies conducted. Acamprosate 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 Lung V79 cells. No clastogenicity was observed in an *in vitro* chromosomal aberration assay in human lymphocytes and no chromosomal damage detected in an *in vivo* mouse micronucleus assay. Acamprosate 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/m^2 basis). In mice, acamprosate 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/m^2 basis) had no effect on fertility. **Pregnancy Category C Teratogenic Effects** Acamprosate calcium has been shown to be teratogenic in rats when given in doses that are approximately equal to the human dose (on a mg/m^2 basis) and in rabbits when given in doses that are approximately 3 times the human dose (on a mg/m^2 basis). Acamprosate 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/m^2 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/m^2 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/m^2 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/m^2 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 acamprosate 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/m^2 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/m^2 basis). **Labor and Delivery** The potential for CAMPRAL to affect the duration of labor and delivery is unknown. **Nursing Mothers** In animal studies, acamprosate was excreted in the milk of lactating rats dosed orally with acamprosate calcium. The concentration of acamprosate in milk compared to blood was 1.3:1. It is not known whether acamprosate 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%)**
Pruritus	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 acamprosate 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 acamprosate 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 are those occurring in at least 1/100 patients (only those not already listed in the summary of 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, phlebitis, 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, hyperuricemia, 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 (acamprosate 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 Acamprosate 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 overdosage with CAMPRAL (total reported doses of up to 56 grams of acamprosate 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 overdosage only. Treatment of overdose should be symptomatic and supportive.

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CSAT ADDRESSING POST-KATRINA NEEDS

Dr. Westley Clark, Director, CSAT

In the wake of Hurricane Katrina, patients in Opioid Treatment Programs (OTPs) in the Gulf Coast region found themselves unable to access to their daily medications, particularly methadone and buprenorphine. All seven OTPs in the New Orleans area were closed by the storms. Six OTPs remained open in other parts of the state.

The situation was made more challenging by the fact that more than 5,000 physicians were forced to evacuate the New Orleans area, including 34 physicians who were registered with the Center for Substance Abuse Treatment (CSAT) to prescribe buprenorphine. In addition, an unknown number of medical practitioners had been using opioids to manage patients with severe and chronic pain, leaving those patients without a way to continue their treatment.

In the days and weeks that followed, hurricane evacuees appeared at clinics in Baton Rouge, Houston, and elsewhere in desperate need of medication. In many cases, they lacked identification papers, medical records, or documentation to show that they had been enrolled in a methadone or buprenorphine treatment program. Notes Robert Lubran, M.S., M.P.A., Director of CSAT's Division of Pharmacologic Therapies, "The big challenge is when somebody shows up at your door and says 'Hi, I'm a methadone patient from New Orleans.' Verifying that information is next to impossible, as is verifying dosage."

The task of helping clinic staff respond to these challenges fell to local service providers and CSAT volunteers — including Medical Officers Anton C. Bizzell, M.D., and Kenneth Hoffman, M.D., M.P.H., and Senior Public Health Analyst Ray Hylton, R.N., M.S.N. — who deployed to Baton Rouge and the surrounding area. The group assisted Louisiana's Department of Health and Hospitals' Office of Addictive Disorders and, in the early days, also provided direct patient care. They faced many hurdles, struggling with questions such as: How do you know if an individual really is registered in a program? How do you find physicians who might be willing to prescribe medications? How do you establish a registry so you can have some continuity of care?

To provide overall guidance, SAMHSA issued guidelines on emergency medications (see the July-August 2005 issue of **ASAM News**), which outlined procedures for short- and long-term emergency methadone and buprenorphine treatment services. But more often than not, solutions had to be created on the spot. "You just take someone as a new patient," Dr. Hoffman recalls. "You do a physical assessment and look at their mental status. Then you can start them on a protocol."

Dr. Bizzell, who was assigned to work with Louisiana's Assistant Secretary for Addictive Disorders and Assistant Secretary for Mental Health in Baton Rouge, says: "We helped develop plans to make sure we had substance abuse and mental health professionals on the ground." In some cases, CSAT staff helped grantees adapt to special needs arising from the hurricanes. For example, Dr. Bizzell received a request from a SAMHSA grantee to reorganize funding so as to sustain services in the storm's wake. After assessing the request, Dr. Bizzell was able to help the grantee make the needed adjustments.

Mr. Lubran says, "A lot of outreach was done by SAMHSA's Screening, Brief Intervention, Referral, and Treatment (SBIRT) program. SBIRT staff went into the [Houston] Astrodome and screened people for substance abuse. And the state provided transportation to get these people into treatment programs."

All four states in the disaster area — Louisiana, Mississippi, Alabama, and Texas — received SAMHSA Emergency Response Grants. Those funds are exhausted now, but the grant-funded work done after the hurricanes has paved the way for improvements in the organization of the region's OTPs. For example, Mr. Lubran reports that SAMHSA is piloting an innovative, Internet-based system to assure continuity of care in future disasters. When the system is fully operational, information on buprenorphine and methadone patients enrolled in OTPs will be available to staff at treatment programs anywhere in the U.S. "Once the system is up," said Arlene Stanton, Ph.D., the CSAT official in charge of the project, "if a patient from New Orleans walked into a clinic in Houston, the Texas staff could meet that person's critical treatment needs with minimal delay."

CSAT's Office of Applied Studies also has compiled baseline data on pre-hurricane treatment needs in Alabama, Florida, Louisiana, Mississippi, and Texas. Each state's information includes substance use prevalence data, substate data and maps. For more information on *Katrina/Rita Areas: Baseline State and Sub-State Estimates of Substance Use from the 2002-2004 National Surveys on Drug Use and Health*, visit SAMHSA's Web site at HTTP://OAS.SAMHSA.GOV/KATRINA/TOC.CFM. The website will be updated as more information becomes available. *Source: Jon Bowen, SAMHSA News, November-December 2005.*

CSAM Schedules Annual Legislative Day

The California Society of Addiction Medicine (CSAM) held its annual Legislative Day in Sacramento on February 1st. The event included a morning devoted to presentations on key issues, followed by afternoon meetings between CSAM members and legislators to discuss reimbursement and funding issues, the effectiveness of addiction treatment, public health concerns such as HIV and hepatitis C, and pending legislation. Co-sponsored this year by the California Association of Alcoholism and Drug Abuse Counselors (CAADAC), the goal of CSAM's Legislative Days are to educate policymakers about the disease of addiction and the effectiveness of treatment, so as to improve the quality of future policymaking.

Methamphetamine Conference. CSAM also recently sponsored a conference, "Meeting the Methamphetamine Challenge," to focus on methamphetamine addiction as a medical disease. The program, chaired by Monika Koch, M.D., included state-of-the-science reports on patterns of methamphetamine use, mechanisms of its protracted impact on the brain, methamphetamine's effects on physical and mental health, and successful treatment approaches. The conference concluded with a discussion of the public policy implications of methamphetamine for communities and legislative action.

In addition to Dr. Koch, members of the conference planning committee included CSAM members Timmen Cermak, M.D., Denise Greene, M.D., David Pating, M.D., and Christy Waters, M.D.

Contact CSAM Administrator Kerry Parker at or visit the CSAM website at WWW.CSAM.ORG.

FSAM Hosts Annual Conference on Addictions

The Florida Society of Addiction Medicine (FSAM) has scheduled its Annual Conference on Addictions for March 24-26th at the Marriott Orlando Lake Mary Hotel. Featured speakers include Andrea Barthwell, M.D., on "The World of Addiction Medicine Today"; Mark Gold, M.D., on "Overeating and Obesity: A Substance Abuse Disorder"; Bernd Wollschlaeger, M.D., on "Application of Opioid Treatment Modalities in Primary Care Practice: A Family Physician's Perspective"; G. Douglas Talbott, M.D., on "Utilization of Recovering Physicians as Members of the Treatment Team"; Joseph Monastero, M.D., on "Addictions in Corrections — New Pathways"; William Jacobs, M.D., on "Prevention of Pain Medication Abuse and Dependence"; Scott Teitelbaum, M.D., on "Evaluation and Treatment of Marijuana Abuse"; Steven Kahn, M.D., on "Holistic Approach to Addiction Treatment"; Deborah Mash, Ph.D., on "Update on Ibogaine Therapy for Addiction"; Bruce Goldberger, Ph.D., on "An Epidemic of Opioid-Related Deaths in The State Florida"; Todd Jaffe, M.D., on "Pain Management Issues for the Addictionologist"; Michael Wilkerson, M.D., on "Return to Work Issues for the Chemically Dependent Professional"; Stacy Seikel, M.D. and Barry Blumenthal, D.O., on "Medication Errors Update — Educational Requirements for Florida Health Care Professionals"; Raymond Pomm, M.D., on "New Trends in Monitoring Health Care Professionals," and Jeffrey Kamlet, M.D., on "Practice Issues in Addiction Medicine." The conference is approved for 18 hours of Category 1 CME credit.

In addition, a special pre-conference workshop on March 23rd will address "Pharmacological and Non-Pharmacological Treatment of Alcohol Dependence." Approved for 4 CME credits, the workshop is organized by ASAM and underwritten by an unrestricted educational grant from Forest Laboratories.

For more information or to register for the conference, contact the FSAM office at 890 Lexington Road, Pensacola, Florida 32514 or email REGISTRATIONINFO@EXCITE.COM.

Texas Society Hosts Training Course

The Texas Society of Addiction Medicine (TSAM) hosted ASAM's newest educational course – Pharmacological Non-Pharmacological Treatment of Alcohol Dependence — February 4th in San Antonio. The is designed to review clinically relevant developments in the use of pharmacological therapies for alcohol use disorder; to identify and discuss clinical issues relative to the use of pharmacotherapies; to review current and emerging treatments and management options for alcohol dependence; and to describe evidence-based behavioral interventions, including the integration of psychosocial support services with pharmacotherapies. Participants also will review relevant clinical information on co-occurring conditions.

Contact TSAM President Robert Jones, M.D., at DOCJONES1@SBCGLOBAL.NET, *or TSAM Administrator Dolores Capo Reynoso at 210/222-0196 or by email at* TSAMSATEX@SBCGLOBAL.NET.

HSAM Helps Educate Family Physicians

The Hawaii Society of Addiction Medicine (HSAM) is providing 2 hours of addiction medicine continuing education at the annual meeting of the Hawaii Academy of Family Physicians. Scheduled for February 17-19th in Waikiki, the conference features a group of three lectures on addiction issues commonly encountered in family practice: "The History of Opiates in Medicine and Society" (by Christopher Linden, M.D.), "State of the Art Addiction Therapies" (by William Haning, M.D.), and "The Epidemic of Prescription Drug Abuse — Strategies for Family Physicians" (Kevin Kunz, M.D.).

ADVOCATE FOR RECOVERY AWARD. HSAM has presented its first annual " Advocate for Recovery Award" to Honolulu Mayor Harry Kim, in recognition of his leadership in bring attention and resources to combat Hawaii's ice epidemic. Mayor Kim worked with community-based organizations and a bipartisan political coalition to create a three-pronged initiative incorporating prevention, treatment and enforcement. He also organized the first Ice Summit in the state and secured millions of dollars in new treatment funds.

PHYSICIAN HEALTH CONFERENCE. Gerald McKenna, M.D., chair of HSAM's Public Policy Committee, recently co-chaired the Western Regional Conference of State Physician Health Programs at the Turtle Bay Hotel in Kahuku, Oahu. The conference was cosponsored by the Hawaii Medical Association, HSAM, and the Montana Physicians Health Program. In addition to the Hawaiian delegation, approximately 40 mainland physicians attended the event. Dr. McKenna reports that all the participants seemed to enjoy the venue, which fortunately had its usual perfect weather.

Contact HSAM Administrative Assistant Liza Lee at 808/536-7702 x 105 or visit the Society's website at WWW.HSAM.INFO

More Dates for New Alcohol Course Announced

ASAM has announced additional sites and dates for its new CME course on the treatment of alcohol use disorders. The popular course, which is free to participants, is underwritten by an unrestricted educational grant from Forest Laboratories, manufacturer of acamprosate, and is co-sponsored by ASAM's state affiliates.

The course is designed to meet the needs of addiction specialists who seek a succinct review and update on the latest strategies for identifying and managing alcohol use disorders. The course is approved for 4 Category 1 CME credits. The newly scheduled sites are:

- Los Angeles, California, Four Points Sheraton Hotel (February 25, 2006)
- Valley Forge, Pennsylvania, Crowne Plaza Hotel (March 18, 2006)
- Lake Mary, Florida, Marriott Orlando Lake Mary Hotel (FSAM preconference opportunity; March 23, 2006)

The course already has been offered in Illinois, Maryland, Michigan, New Jersey, New York, and Wisconsin, in collaboration with the following state societies:

California Society of Addiction Medicine
Florida Society of Addiction Medicine
Illinois Society of Addiction Medicine
Maryland Society of Addiction Medicine
Michigan Society of Addiction Medicine
New Jersey Society of Addiction Medicine
New York Society of Addiction Medicine
Pennsylvania Society of Addiction Medicine
Wisconsin Society of Addiction Medicine

ASAM is collaborating with NAADAC (The Association for Addiction Professionals) to convene a plenary panel of physicians and addiction counselors at the course who can discuss strategies to strengthen physician/counselor relationships so as to improve patient outcomes.

Other supporting organizations include the Central East Addiction Technology Transfer Center, the Florida Addiction Technology Transfer Center, the Great Lakes Addiction Technology Transfer Center, the Gulf Coast Addiction Technology Transfer Center, the Northeast Addiction Technology Transfer Center, and the Pacific Southwest Addiction Technology Transfer Center.

For more information or to register, visit the ASAM website at WWW.ASAM.ORG, or contact project manager Angela Warner by phone at 301/656-3920, ext. 6010, or by email at AWARNER@ASAM.ORG.

REGION VII OFFICE RETURNS TO LOUISIANA

In a welcome sign of progress, the Region VII office is about to reopen in New Orleans. In the wake of Hurricane Katrina, the office was moved to Texas, through the generous support of the Texas Society of Addiction Medicine. During the transition, Regional Director Howard Wetsman, M.D., and Regional Administrator Lisa Stolier can be reached by email at LISASTOLIER@EARTHLINK.NET.

Ruth Fox Memorial Endowment Fund

Dr. Ruth Fox

RUTH FOX DONOR RECEPTION

The 2006 Ruth Fox Donor Reception is scheduled for Friday evening, May 5th, in San Diego, during ASAM's 2006 Medical-Scientific Conference.

As in years past, Dr. and Mrs. Joseph Dorsey have graciously agreed to underwrite the cost of this by-invitation-only event. Another generous gift from Dr. Dorsey enabled the Fund to reach its $4 million goal in 2005.

Dear Colleague:

The Ruth Fox Scholarship Program has become a great success since its 2002 launch. Through the program, interest income from the Endowment Fund is used to sponsor scholarships for physicians-in-training to attend ASAM's Medical-Scientific Conference and Ruth Fox Course. To date, 24 such scholarships have been awarded. Scholarships cover travel, hotel and registration expenses for recipients to attend ASAM's Annual Medical-Scientific Conference and Ruth Fox Course, as well as one year's free membership in ASAM. The Fund is pleased to announce that four scholarship recipients have been selected for 2006:

- Kathleen Ang-Lee, M.D., Seattle, Washington
- Katrina Ball, D.O., Loma Linda, California
- Norana Irene Caivano, M.D., West Hollywood, California
- Mark Hrymoc, M.D., Harbor UCLA Medical Center, Los Angeles

The 2006 Ruth Fox Donor Reception is scheduled for Friday evening, May 5th, in San Diego. It is by invitation only, so if you have not already contributed or pledged to the Endowment, please do so now and help us reach our goal. Pledges can be paid over five years. Thanks to a generous gift from Joseph Dorsey, M.D., FASAM, the fund has reached its 2005 goal of $4 million.

We want to take this opportunity to thank those whose generosity and continued support have helped toward this goal which we are sure will be reached before the end of this year. Please let us know if you have included the Endowment in your estate plans so that we can acknowledge your generosity now. Also, now may be an opportune time to examine the amount and timing of your gifts in order to maximize your tax savings this year. All contributions to the Endowment Fund are completely tax-deductible to the full extend provided by law.

For information about making a contribution or pledge, or to discuss other types of gifts in confidence, contact Claire Osman by phone at 1-800/257-6776 or 718/275-7766, or by e-mail at ASAMCLAIRE@AOL.COM.

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

Claire Osman
Director of Development

ASAM Staff & Consultants

Except where indicated, all staff can be reached at ASAM's Headquarters Office, 4601 North Park Ave., Suite 101 Upper, Chevy Chase, MD 20814; phone 301/656-3920; EMAIL@ASAM.ORG.

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Dr. Donald Kurth

ASAM Public Policy Is Ignored, Resulting in Three Deaths

Donald J. Kurth, M.D., FASAM

The government of Sacramento County, California, has repeatedly refused to allow detainees suffering from opiate dependence access to medical care. As a result, three incarcerated human beings are dead due to suicide. News sources report that the county now faces a Federal lawsuit brought by the families of the deceased.

These individuals might or might not have even been convicted of a crime — typically, detainees in county jails are awaiting arraignment prior to trial, so there is no way to know if they would have been convicted. Even if they ***had*** been convicted, forcing a human being to withdraw from addiction to opiates without medical care is cruel and should not be allowed by any civilized society. However, in Sacramento County, prison guards are taught that opiate withdrawal (even from severe, chronic addiction to heroin or methadone) is no more uncomfortable than a case of the flu. This policy in inhumane and illegal.

Four years ago, ASAM approved a Public Policy Statement recommending that all detainees who have a current addictive disorder should be evaluated by a qualified physician prior to incarceration (excerpts follow). Two years ago, prompted by another wave of prison deaths, the California Society of Addiction Medicine drafted legislation to require that all California detainees who show signs of an addictive disorder be evaluated by an ASAM-certified physician prior to incarceration. However, the California union of prison guards blocked the legislation, arguing that it was not necessary because detainees already received adequate care.

I can only hope that these human beings have not died in vain and that their families' legal action will result in humanitarian changes that will save future lives. It is up to us to fight for humane treatment for those who cannot fight for themselves. We ***can*** make a difference!

DR. KURTH *is Chief of Addiction Medicine at Loma Linda University Behavioral Medicine Center; Immediate Past President of the California Society of Addiction Medicine; ASAM Treasurer; and Chair of ASAM's Legislative Advocacy Committee.*

ASAM Public Policy Statement onAccess to Appropriate Detoxification Services for Persons Incarcerated in Prisons and Jails

...The use of alcohol, nicotine, and illicit drugs is forbidden in jails and prisons, and appropriately so. But beyond prohibitions against possession and use of contraband, many correctional facilities have policies and procedures that prohibit the use of opiate medications by inmates, even if these have been prescribed by a physician prior to the moment of incarceration.

It is not uncommon for jails, prisons, and correctional half-way houses to forbid residents to continue methadone maintenance once the individual has been placed in such a facility. When methadone maintenance treatment is abruptly discontinued, acute opiate withdrawal will ensue. Other correctional facilities have inadequate policies and procedures or inadequately trained personnel to appropriately recognize signs or symptoms of alcohol, sedative, or opiate withdrawal in individuals they serve. Thus, through neglect or through administrative rules, individuals suffering from chemical dependency may not receive appropriate evaluation and management of an acute withdrawal condition....

The U.S. Supreme Court has held that the proscription of cruel and unusual punishment by the Eighth Amendment of the United States Constitution requires that proper medical care be rendered, when indicated, to individuals who are incarcerated. In accordance with such rulings, correctional facilities assure that qualified medical personnel are routinely available to treat people in custody for medical conditions such as diabetes mellitus, cardiac disease, and surgical emergencies such as appendicitis. Patients with treatable medical conditions are not required to suffer or die while in custody — except, tragically, in the case of addictive disease....

In light of these circumstances, ASAM recommends the following:

1. Individuals brought into custody by criminal justice authorities should receive appropriate general medical screening to assure that their medical needs will not go unaddressed during their incarceration. The circumstance of being under arrest, detained, jailed, or imprisoned should not preclude access to and provision of medically necessary treatment for alcohol and other drug withdrawal.
2. Individuals with addiction who are placed in jails or prisons, should not be discriminated against because of their diagnosis. Prisoners and other detainees with addiction should receive the medical care necessary to manage withdrawal syndromes, just as they receive the medical care necessary to manage any other acute illnesses or injuries.
3. Given the high prevalence of substance use and addiction among individuals who are arrested or detained in jails or other correctional facilities, individuals should be screened for the presence of, or risk of, addiction and withdrawal at the point of entry into a criminal detention facility. Appropriately trained personnel should conduct the screening. When screening identifies a condition of withdrawal, or a significant likelihood that withdrawal is present or could develop, affected individuals should be seen by a licensed health care professional who can make a definitive diagnosis. When medically necessary, such health care professionals should render appropriate detoxification services for the withdrawing individual, or arrange for transfer to a health care facility where services will be provided.
4. Jails and prisons should revise any policies and procedures that preclude ill detainees from receiving necessary and appropriate health care services, including withdrawal management services, appropriate to their condition.... *(Adopted by the ASAM Board of Directors, July 2002)*

ASAM Conference Calendar

ASAM

May 4, 2006
Ruth Fox Course for Physicians
San Diego Sheraton Hotel & Marina
San Diego, California
[8 Category 1 CME Credits]

May 5-7, 2006
37th Annual
Medical-Scientific Conference
San Diego Sheraton Hotel & Marina
San Diego, California
[21 Category 1 CME Credits]

July 21-23, 2006
Medical Review Officer (MRO)
Training Course (Basic)
Ritz Carlton Phoenix Hotel
Phoenix, Arizona
[8 Category 1 CME Credits]

October 26-28, 2006
ASAM Review Course in
Addiction Medicine
Westin O'Hare Hotel
Chicago, Illinois
[21 Category 1 CME Credits]

October 29, 2006
Course on Pain & Addiction
Westin O'Hare Hotel
Chicago, Illinois
[8 Category 1 CME Credits]

December 8-10, 2006
Medical Review Officer (MRO)
Training Course (Basic & Advanced)
Marriott Metro Center Hotel
Washington, DC
[8 Category 1 CME Credits]

OTHER EVENTS OF NOTE

February 26-28, 2006
New York Academy of Sciences
Conference on Resilience in Children
Arlington, Virginia
[Visit: WWW.NYAS.ORG/RESILIENCE
or contact RWILKERSON@NYAS.ORG]

March 23-26, 2006
Society for Research on Adolescence
& National Institute on Drug Abuse:
Violence and Prenatal Drug Exposure
—Impact on Adolescent Behavior
San Francisco, California
[Contact SWANSONB@UMICH.EDU]

March 24-26, 2006
Florida Society of Addiction Medicine
Annual Conference on Addictions
plus free Pre-Conference Workshop
on March 23rd
Marriott Orlando Lake Mary Hotel
Lake Mary, Florida
[Contact: FSAM at
REGISTRATIONINFO@EXCITE.COM]

March 28-29, 2006
Center for Substance Abuse Treatment
Managing Individual and
Program Liability Risk
Wilshire Grand Hotel
Los Angeles, California
(No registration fee; 12.5 Category 1
CME Credits)
[Contact: JBS at 240/645-4517
or email LBRITTON@JBS.BIZ]

Except where otherwise indicated, additional information is available on the ASAM web site (WWW.ASAM.ORG) or from the ASAM Department of Meetings and Conferences at 4601 No. Park Ave., Suite 101, Chevy Chase, MD 20815-4520; phone 301/656-3920; fax 301/656-3815; email EMAIL@ASAM.ORG.

BUPRENORPHINE TRAINING

For information or to register for a Buprenorphine Training Course, contact 1-888/362-6784 or visit the website: WWW.DOCOPTIN.COM. All courses are approved for 8 Category 1 CME credits.

March 4, 2006
Seattle, Washington
Sponsored by ASAM & the
Washington Society of Addiction
Medicine

March 11, 2006
Grand Rapids, Michigan
Sponsored by ASAM & the
Michigan Society of Addiction Medicine

March 18, 2006
Cleveland, Ohio
Sponsored by ASAM & the
Ohio Society of Addiction Medicine

April 22, 2006
Atlanta, George
Sponsored by ASAM & the
Georgia Society of Addiction Medicine

May 6, 2006
Augusta, Maine
Sponsored by ASAM & the
Maine Society of Addiction Medicine

May 7, 2006
San Diego, California
Sponsored by ASAM & the
California Society of Addiction
Medicine

May 10, 2006
Madison, Wisconsin
Sponsored by ASAM & the
Wisconsin Society of Addiction
Medicine

June 3, 2006
Columbia, Maryland
Sponsored by ASAM & the
Maryland Society of Addiction Medicine

ASAM MEMBERS:

Congratulations to Miriam Adelson, M.D., of Las Vegas, Nevada, who is the winner of ASAM's drawing for a free 2007 Med-Sci Registration or a one-year ASAM Membership Renewal, for renewing her membership by January 1, 2006.

You too could receive a free 2007 Med-Sci Registration or other awards for recruiting new members between now and April 15, 2006.
Find out more at WWW.ASAM.ORG or by phoning the ASAM Membership Department at **301/656-3920**.