



ASAMNews

Newsletter of The American Society of Addiction Medicine

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to ASAM's Med-Sci
Conference

www.asam.org



San Diego to Host ASAM's 37th Annual Med-Sci Conference

San Diego, California, is the site of ASAM's 37th Annual Medical-Scientific Conference, to be held May 4-7th at the Sheraton Hotel and Marina. The conference welcomes ASAM members as well as non-member physicians, nurses, psychologists, counselors, students and residents. It features three full days of clinical and scientific programming, as well as ASAM's annual Business Meeting at 7:00 a.m. Friday, 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 7th, 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 7)

New Educational Program Debuts at Med-Sci

A new ASAM medical education program on "Pharmacologic Therapies for Alcohol Dependence" will be offered for the first time during ASAM's Med-Sci Conference. Scheduled for Saturday evening, May 6th, the program will begin with dinner at 6:00 p.m., followed by the presentations from 7:00 to 9:00 p.m. Thanks to an unrestricted educational grant from Cephalon, Inc., there is no registration fee, but advance registration is required.

The program focuses on how to use ASAM's *Patient Placement Criteria* to successfully integrate new pharmacologic therapies with other components of addiction care. Faculty include noted addiction researcher and educator Charles P. O'Brien, M.D., Ph.D., of the University of Pennsylvania, a

recipient of ASAM's Distinguished Scientist Award. Dr. O'Brien will be joined by ASAM Criteria developers David Mee-Lee, M.D., and Gerald Shulman, M.A., FACATA, as well as other distinguished experts.

Chairman Marc Fishman, M.D., says the program — which is approved for 2 hours of Category 1 CME credit — is designed to be highly interactive and will include case vignettes and ample opportunity for audience-faculty interaction. In addition, each registrant will receive a program book that includes copies of the speakers' slides and other relevant material. For more information or to register, visit the ASAM website at www.asam.org or contact Angela Warner at awarner@asam.org.



ASAM Certification Is a Valuable Credential

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



Eileen McGrath, J.D.

As the recruitment advertisements in this newsletter and other publications testify, ASAM certification in addiction medicine has become a valuable credential. Certification signifies that an individual has mastered the scientific and clinical aspects of this emerging specialty, as demonstrated on a rigorous examination prepared by the National Board of Medical Examiners. 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 by ASAM.

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

which will be given on Saturday, December 9th, 2006, at three sites: Los Angeles, CA; New York, NY; and Atlanta, GA.

The fee for the examination is \$1,350 for ASAM members and \$1,600 for non-members. 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 website at

WWW.ASAM.ORG. The website contains a downloadable application and information about qualifications to sit for the examination.

Also, watch for the May-June **ASAM News** for details about the Review Course in Addiction Medicine, to be offered Thursday, October 26th through Saturday, October 28th, at Chicago's Westin O'Hare Hotel. For more information or to register for the course, visit the ASAM website at WWW.ASAM.ORG.

See the May-June issue of ASAM News for details about ASAM's Review Course in Addiction Medicine, to be offered Thursday, October 26th through Saturday, October 28th, at the Westin O'Hare Hotel in Chicago.



JACKSONVILLE, FLORIDA — Chemical Dependence Facility seeking Board Certified Internal Medicine or Family Practice physician to join our team. ASAM Certification preferred. Competitive salary and excellent benefits, including 401K match. **Email:** mprovines@lakeviewhealth.com, or fax 954/491-4193.

American Society of Addiction Medicine

4601 North Park Ave., Suite 101
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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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ASAM News

is an official publication of the American Society of Addiction Medicine. It is published six times a year.

Please direct all inquiries to the Editor at ASAMNEWSLETTER@AOL.COM or phone 410/770-4866.

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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).

DOD Study Finds MH, Substance Abuse Problems Among Returning Iraq Vets

Thirty-five percent of service members returning from the Iraq war have sought professional help for mental health issues, according to researchers at the Department of Defense. The 35 percent figure compares to 21 percent of veterans returning from Afghanistan and 24 percent of those who served elsewhere in the world. About 12 percent of the Iraq veterans were diagnosed with serious mental or emotional problems, said study author Col. Charles Hoge, M.D., of the Walter Reed Army Institute of Research.

In a separate study, released at a December 2005 Congressional hearing, Army researchers reported that 21 percent of soldiers returning from combat areas were misusing alcohol a year after their return home, although just 13 percent misused alcohol prior to deployment. The number of soldiers with anger and aggression problems increased from 11 percent pre-deployment to 22 percent post-deployment, while the divorce rate rose from 9 percent to 15 percent.

Military experts describe the Iraq war as especially stressful because it is a counterinsurgency operation with no defined front lines, meaning that soldiers rarely can relax and let down their guard.

"The most important finding is that a large number of soldiers and Marines are using mental health services very soon after they get home," Dr. Hoge noted. But some veterans' groups contend that Iraq war vets need more help than they are getting. "We've got 35 years of history from the Vietnam War that if they don't receive proper care, they turn to drugs and alcohol, they lose their homes. It's happening again," said Steve Robinson, director of the National Gulf War Resource Center.

Sources: Stars and Stripes, December 9, 2005; Hoge CW, Auchterlonie JL & Milliken CS (2006). Mental health problems, use of mental health services, and attrition from military service after returning from deployment to Iraq or Afghanistan. Journal of the American Medical Association 295:1023-1032.

Meth Bill Passes Despite White House Opposition

A bill calling for more spending on preventive advertising aimed at methamphetamine passed the House of Representatives in March on a 399-5 vote, despite a veto threat from the White House. The measure, sponsored by Rep. Mark Souder (R-IN), would require the Office of National Drug Control Policy (ONDCP) to spend at least 10 percent (\$12 million) of the funding for its national anti-drug media campaign on ads targeting methamphetamine, and to earmark another \$15 million to ads directed to "hot spots" around the country.

"The United States Congress wants some action out of this administration on meth," said Rep. Souder, who blasted the Bush administration's approach to methamphetamine as "appalling." His bill also calls for elevating the ONDCP director's post to that of a Cabinet secretary.

ONDCP spokesman Thomas Riley said the administration opposes the Souder bill because methamphetamine is "not a problem in big cities" and that young people's use of the drug is declining. "The campaign as it is right now is working, finally, and is stretched thin," he said. "Further constraining it and further limiting it at a time when it's already very vulnerable — I worry about the effect that might have on its success."

The White House also opposed making the ONDCP directorship a Cabinet-level office, on the grounds that the bill infringes on Presidential prerogatives. *Source: Join Together Online, March 12, 2006.*

Drug Smuggling by Mail on the Rise, Says INCB

Use of the mails to smuggle drugs into the U.S. and other countries poses a major threat to law enforcement, says the annual report of the International Narcotics Control Board (INCB). The Board is the independent and quasi-judicial control organ that monitors implementation of the United Nations drug control conventions.

In a message accompanying the report, released March 1st in Vienna, Board President Hamid Ghodse said that, over the past five years, almost every region of the world has experienced an increase in smuggling through the mail. For instance, in the United States, where 200 billion pieces of mail are handled every year, Professor Ghodse pointed to indications that traffickers are increasingly attempting to smuggle not just illicit drugs, but also chemical precursors and pharmaceutical products through the mail. In Thailand, government agents seized half a million diazepam tablets and capsules in 12 different cases in 2004. Other seizures involved alprazolam being shipped from Thailand to the United States and clonazepam shipped from Thailand to the United Kingdom. The large quantities involved indicate that traffickers intended to distribute the drugs to the illicit market, Professor Ghodse said,

with Internet pharmacies often acting as the dealers for such shipments.

While some portion of the seized tablets are illegally obtained from licit sources (as through theft, falsified trade authorizations and individual prescriptions, pharmacies not adhering to prescription requirements, etc.), the Board's report warned that significant quantities are provided by counterfeiters. It calls counterfeiting of narcotic drugs and psychotropic substances "an important element in supplying illicit markets through illegally operating Internet pharmacies."

To stem the tide, the Board urged governments to screen incoming and outgoing international mail for drug shipments. It also recommended limiting the number of entry points for parcels to allow for a more effective control of consignments and extending screening to include the premises of international mail courier companies. And, as in all counter-trafficking activities, it called close national and international cooperation "essential." *Source: International Narcotics Control Board, Annual Report, March 1, 2006; accessed at www.incb.org.*



Dr. Elizabeth F. Howell

ASAM HONORS SCIENTIFIC, EDUCATIONAL ACHIEVEMENTS

Elizabeth F. Howell, M.D., FASAM

Once again this year, ASAM will honor a distinguished group of individuals who have made outstanding contributions to the field of Addiction Medicine and to the Society itself. The awardees will be honored at a gala Awards Luncheon on Saturday,

May 6th, during ASAM's Med-Sci Conference. Our 2006 awards will be presented to the following outstanding leaders:

The 2006 R. Brinkley Smithers Distinguished Scientist Award goes to Rudolf H. Moos, Ph.D., Professor of Psychiatry and Behavioral Sciences at Stanford University and Senior Research Career Scientist with the Department of Veterans Affairs. The award will be presented at the Opening Plenary Session at 9:00 a.m. Friday, May 5th. At that time, Dr. Moos will deliver the award lecture, "Common Social Factors in the Development and Remission of Alcohol Use and Other Addictive Disorders."

The John P. McGovern Award on Addiction and Society goes to Carlo C. DiClemente, Ph.D., Professor and Chair of the Department of Psychology at the University of Maryland. The McGovern Award was established in 1997 to recognize and honor an individual who has made "highly meritorious contributions to public policy,

treatment, research, or prevention which has increased our understanding of the relationship of addiction and society." The award is sponsored by an endowment from the John P. McGovern Foundation.

The ASAM Annual Award for "outstanding contributions to the growth and vitality of our Society, for thoughtful leadership in the field, and for deep understanding of the art and science of addiction medicine" will be presented to James W. Smith, M.D., FASAM, and to Barry Stimmel, M.D., FASAM.

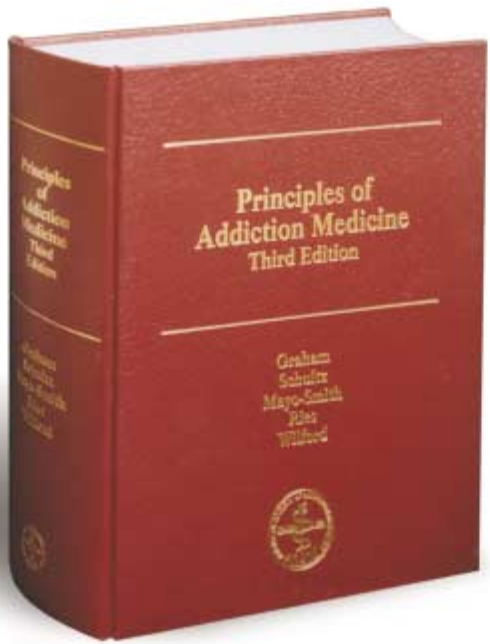
An ASAM Annual Award for "expanding the frontiers of the field of Addiction Medicine and broadening our understanding of the addiction process through research and innovation" will be presented to trauma surgeon Larry Gentilello, M.D., FACS, who has led the fight nationally to overcome statutory barriers to addiction care.

The Young Investigator Award for the best abstract submitted by an author who is within five years of receiving a doctoral degree goes to Janet Soeffing, M.D., and Hannah K. Knudsen, Ph.D.

The Medical-Scientific Program Committee Award for the abstract receiving the highest rating for scientific merit goes to Cindy Parks Thomas, Ph.D.

The Awards Luncheon is an extra-fee event. Visit the ASAM Registration Desk for tickets so that you can join us in recognizing the achievements of this distinguished group.

www.asam.org



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Third Edition

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Detailed, practical, and clearly written...truly comprehensive in its coverage... an essential resource...
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ASAM
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Legislators Asked to Repeal Alcohol Exclusions

Bills to repeal UPPL and other alcohol exclusions in insurance contracts have been introduced in five states in 2006: Colorado, Connecticut, Hawaii, Illinois, and Wyoming. The status of these measures as of March 2006 follows:

Colorado. Sponsored by Rep. Angela Paccione, repeal bill H.B.06-1106 was passed by the House, introduced in the Senate and, on March 7th, was recommended for approval by the Senate Business, Labor, and Technology Committee. The Senate passed the bill with amendments March 14th; the House has voted once to concur with the Senate.

Connecticut. Introduced in late-February, S.B.425 would prohibit insurance exclusions in a state that currently has no UPPL law but does have extensive judicial precedent allowing exclusions based on intoxication. The Insurance and Real Estate Committee held a public hearing March 7th and then approved the bill March 16th. The bill has been filed with the Legislative Commissioner and could be considered by the legislature as early as the week of March 19th.

Hawaii. H.B.2401/S.B.2364, which would prohibit insurance exclusions, were introduced as part of a coordinated effort to promote a comprehensive approach to alcohol problems. An op-ed in support of the measures by Lt. Governor James Aiona was published in the *Honolulu Star Bulletin* March 7th. The Senate version passed and was referred to the House, where the Health Committee approved the measure March 16th and referred it to the Consumer Protection and Commerce Committee.

Illinois. Sponsored by Sen. John Cullerton, S.B.2453 was referred to the Rules Committee, where it awaits consideration.

Wyoming. H.B.7 passed through the committee process, but was defeated in a vote of the House. No further action is expected during this legislative session. *Source: Ensuring Solutions to Alcohol Problems, March 17, 2006.*

STUDY: UPPL Laws Still a Barrier to Care

Insurance policies too often are barriers to the use of screening and brief intervention in emergency settings, because most state governments allow insurers to sell health and accident insurance policies that will not pay for injuries that occur while the insured person is under the influence of alcohol and certain other drugs. Specifically, 35 states and the District of Columbia have so-called UPPL laws (known generically as alcohol exclusion laws, or AELs) on the books.

UPPL and other AELs create a chilling effect in hospitals that interferes with effective treatment. When benefits are denied, injured patients often cannot pay for medical care. To avoid bankrupting their patients, many physicians and hospital managers decide to avoid any activity that might result in an alcohol-related diagnosis. As a result, one in every four U.S. trauma surgeons has had a case in which a health insurer denied coverage because a trauma victim had used alcohol or other drugs, according to a recent survey.

Study author Larry M. Gentilello, M.D., of the University of Texas Southwestern Medical School, writes that "This survey shows that the Uniform Accident and Sickness Policy Provision (UPPL) law is widely used to deny coverage across the nation...Although this law is terribly out of date, it continues to discourage surgeons

from doing what they believe is best for their patients."

Eighty-two percent of the emergency physicians interviewed for Dr. Gentilello's study said they would establish alcohol screening programs if no insurance barriers existed, but only eight states have repealed their UPPL laws.

An accompanying survey of state legislators found that 89 percent believed that alcoholism is treatable, and 80 percent said offering counseling in trauma centers was a good idea. Opposition to denying insurance coverage to patients injured while under the influence of alcohol or other drugs ran at about 2 to 1 among lawmakers. "Excessive alcohol use is the leading cause of injury that we see in trauma centers and ERs across the nation, and there is broad support among both physicians and legislators for eliminating a significant barrier to diagnosis and treatment," Dr. Gentilello concluded. *Sources: Gentilello LM (2005). Confronting the obstacles to screening and interventions for alcohol problems in trauma centers. Journal of Trauma, Injury Infection & Critical Care September;59(3):S137-S143, and Gentilello LM, Samuels PN, Henningfield JE et al. (2005). Alcohol screening and intervention in trauma centers: Confidentiality concerns and legal considerations. Journal of Trauma, Injury Infection & Critical Care November;59(5):1250-1255.*

ALCOHOL POLICY TOOLKIT AVAILABLE

To assist advocates for repeal of UPPL and other alcohol exclusion laws (AELs), Ensuring Solutions to Alcohol Problems — a policy study center at The George Washington University — has developed a toolkit filled with useful resources.

According to Eric Goplerud, Ph.D., Director of Ensuring Solutions, the toolkit (which can be downloaded from the Center's website at no charge) contains the following information:

- **A state policy database** contains state-specific information about alcohol exclusion laws, policies, and legislation.
- **Frequently asked questions** help advocates explain why an obscure insurance law gets in the way of solving alcohol problems.
- **AEL Update** reports on the latest developments in the effort to eliminate AELs.
- **A PowerPoint presentation and talking points** contain quotable information about alcohol exclusions and the benefits of AEL repeal.
- **Model legislation** provides legislative language to prohibit alcohol exclusions.
- **Sample testimony** is a powerful statement in support of AEL repeal.
- **An opinion piece** is an essay suitable for publication in journals, newsletters, and newspapers.

To access the Alcohol Exclusions Laws Toolkit, visit Ensuring Solutions' website at WWW.ENSURINGSOLUTIONS.ORG/RESOURCES.

Topiramate for Smoking Cessation

Alcohol misuse and smoking cause poor health, frequently co-occur, and can be difficult to treat simultaneously. A drug that can effectively treat both conditions would be of great clinical interest.

Accordingly, Bankole Johnson, M.D., Ph.D., and colleagues, who were studying whether oral topiramate improved outcomes in patients being treated for alcohol dependence, also examined whether the drug could promote smoking cessation. Using data from their previous randomized controlled trial, they compared smokers (that is, persons who smoked at least 1 cigarette a day) who had received topiramate for their alcohol use disorder (in an escalating dose of 25-300 mg per day for 12 weeks; n=45) with those who had received placebo (n=49).

Their findings suggested a clear advantage for the patients who received topiramate. At 12 weeks, 17 percent of the topiramate group and 7 percent of the placebo group reported abstinence from smoking. When the data were adjusted for potential confounders, individuals in the topiramate group were significantly more likely than those in the placebo group to report abstinence from smoking (odds ratio 4.5) and to have lower serum cotinine levels.

Although no serious adverse effects were observed, subjects in the topiramate group were significantly more likely than those in the placebo group to report paresthesias and weight loss.

Source: Johnson BA, Ait-Daoud N, Akhtar FZ et al. (2005). Use of oral topiramate to promote smoking abstinence among alcohol-dependent smokers: A randomized controlled trial. *Archives of Internal Medicine* 165(14):1600-1605.

SCREENING, BRIEF INTERVENTION IN THE SPOTLIGHT

Expanding health care providers' use of screening, brief intervention, referral and treatment (SBIRT) for alcohol and other drug problems has been designated a core strategy in the Bush administration's 2006 National Drug Control Strategy. "A key priority of this Administration has been to make drug screening and intervention programs part of the nation's existing network of health, education, law enforcement, and counseling providers," the National Drug Control Strategy declares, adding that "This effort will continue in partnership with the medical community."

Expansion of SBIRT also is the focus of a grant program recently announced by the Substance Abuse and Mental Health Services Administration (SAMHSA). To be administered by SAMHSA's Center for Substance Abuse Treatment, the SBIRT program allows only the immediate office of the Governor in each state or the highest tribal official to apply, although those offices may file a joint application with the state Substance Abuse Authority or other executive level organization.

Additional information on SBIRT and the grants program is available on SAMHSA's website (www.SAMHSA.GOV). The 2006 National Drug Control Strategy can be accessed at www.WHITEHOUSE.DRUGPOLICY.GOV.

AA Attendance Improves Outcomes

Alcoholics Anonymous (AA) is a preferred form of aftercare for patients discharged from formal treatment programs, but little is known about AA involvement and its effects on abstinence over time. In a study reported in the journal *Alcohol: Clinical & Experimental Research*, researchers assessed participation in AA, abstinence, and other alcohol outcomes over five years among 349 patients who entered treatment at baseline and attended AA at least once during the follow-up period.

The researchers described four patterns of AA attendance: "low" (mainly during the year following treatment entry); "medium" (about 60 meetings per year, with a slight increase by year 5); "high" (more than 200 meetings a year, with a slight decrease by year 5); and "declining" (almost 200 meetings the year following treatment entry and about 6 meetings in year 5).

They found that abstinence rates (past 30 days) differed significantly across the four groups. Specifically, 79 percent of patients with "high" attendance reported abstinence at year 5, followed by 73 percent with "medium" attendance, 61 percent with "declining" attendance, and 43 percent with "low" attendance. Source: Kaskutas LA, Ammon L, Delucchi K et al. (2005). *Alcoholics Anonymous careers: Patterns of AA involvement five years after treatment entry*. *Alcohol: Clinical & Experimental Research* 29(11):1983-1990.

St. Helena Hospital Center for Behavioral Health

Adventist Health

NAPA VALLEY, CALIFORNIA

Located in beautiful Napa Valley, California, St. Helena Hospital's Alcohol and Chemical Recovery Program has positions for BC, addiction medicine-certified physicians, one with Medical Director responsibilities.

This highly successful program offers 39 beds for patients who meet ASAM/DSM IV criteria. Responsibilities include pre-admission triage/assessment, direct patient care, case review and daily multi-modality team meetings. Call is after-hours weekdays and some weekends.

Competitive packages include salary, malpractice coverage, some benefits and relocation assistance.

CONTACT: Physician Recruitment, St. Helena Hospital
10 Woodland Rd., St. Helena, CA 94574

FAX: 707/963-6519

EMAIL: shhphysicianrecruiting@ah.org

WEBSITE: www.sthelenahospital.org

AMERICAN SOCIETY OF ADDICTION MEDICINE



37th Annual Medical-Scientific Conference

San Diego Sheraton ~ Hotel and Marina
May 4-7, 2006 ~ San Diego, CA

- Courses and Workshops
- Abstracts and Poster Presentations
- Up to 22 Continuing Medical Education Credits
- Scientific Exhibits
- Ruth Fox Course
- Distinguished Scientist Lecture
- Buprenorphine Training Course
- Public Policy Plenary Session

ASAM

Contact ASAM at www.asam.org or call 301.656.3920



Sunny San Diego is the site of ASAM's 37th Annual Medical-Scientific Conference, where addiction experts from around the world will gather for a program rich in scientific symposia, clinical courses and workshops, and research papers and poster sessions. The conference — which welcomes ASAM members as well as non-member researchers, educators, and clinicians — is preceded on May 4th by the Ruth Fox Course for Physicians, which marks its 50th anniversary this year. The conference concludes on Sunday, May 7th, with a Buprenorphine Training Course designed to qualify ASAM members and other physicians to prescribe buprenorphine in office-based practice.

Program chair Jeffrey Samet, M.D., M.A., M.P.H., has collaborated with co-chairs Lawrence S. Brown, Jr., M.D., M.P.H., FASAM, and Marc Galanter, M.D., FASAM, and the Program Committee to design a diverse program that affords participants an opportunity to interact with experts in the field. Major events include special day-long symposia organized by the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse, as well as a special session on methamphetamine organized by the Center for Substance Abuse Treatment.

The Annual Business Meeting and Breakfast will be gavelled to order at 7:00 a.m. Friday, May 5th, by ASAM President Elizabeth F. Howell, M.D., FASAM. Early risers will be rewarded with a delicious buffet breakfast, to be served from 6:45 a.m., courtesy of The Christopher D. Smithers Foundation. Dr. Howell promises a highly interactive meeting, with an emphasis on soliciting members' views as to their needs and priorities, and how ASAM can best meet those needs. The breakfast and business meeting, which are open only to ASAM members, are included in the conference registration fee.



37th Medical-Scientific Conference Convenes May 4th in San Diego

The official opening of the conference, which immediately follows the business meeting, features an address by Rudolf H. Moos, Ph.D., Professor of Psychiatry and Behavioral Sciences at Stanford University and Senior Research Career Scientist with the Department of Veterans Affairs. Dr. Moos is the recipient of the 2006 R. Brinkley Smithers Distinguished Scientist Award. He will deliver the award lecture on "Common Social Factors in the Development and Remission of Alcohol Use and Other Addictive Disorders." Other distinguished speakers scheduled for the opening plenary are H. Westley Clark, M.D., J.D., M.P.H., FASAM, Director of the Center for Substance Abuse Treatment; Ting Kai-Li, M.D., Director

of the National Institute on Alcohol Abuse and Alcoholism; and Nora Volkow, M.D., Director of the National Institute on Drug Abuse.

The ASAM Awards Luncheon, to begin at 12:15 p.m. Saturday, May 6th, honors outstanding contributions to the addiction field, as well as those who have made notable contributions to the Society. A traditional highlight of the luncheon is the John P. McGovern Award and Lecture on Addiction and Society, established in 1997 to honor an individual who has made highly meritorious contributions to public policy, treatment, research, or prevention and who has increased our understanding of the relationship of addiction and society. The award is sponsored by an endowment from the John P. McGovern Foundation. This year's recipient is Carlo C. DiClemente, Ph.D., Professor and Chair of the Department of Psychology at the University of Maryland. (The Awards Luncheon is an extra fee event.)

Details of conference activities are found on the following pages of **ASAM News** and on ASAM's web site at WWW.ASAM.ORG.

VISITORS TO THE ASAM CONFERENCE WILL FIND MUCH TO ENJOY IN SAN DIEGO

The conference will be held at the Sheraton San Diego Hotel and Marina, 1380 Harbor Island Drive, San Diego, CA 92101. Hotel features include outdoor pools, fitness and spa facilities, high-speed Internet access in all guest rooms, concierge service, and beaches nearby. The Sheraton also provides complimentary airport shuttle service, with vans operating every 20-25 minutes. Self-parking is available at the hotel for \$16 a night; valet parking is \$22 per day.

A limited number of guest rooms are available at the special conference rate of \$187 single or double. Rates are subject to state, local and occupancy taxes, currently 15% (subject to change). To make your reservation, contact the Sheraton San Diego Reservations Department directly at 619/291-2900 or use the Sheraton's central reservation line at 1-800/325-3535. All reservations must be accompanied by a deposit equal to one night's room and tax, or be

guaranteed with a major credit card number and expiration date. In order to receive the conference rate, tell the reservation agent that you are attending the "ASAM Medical Scientific Conference." The hotel cannot guarantee availability of rooms at the conference rate after April 10th, so make your reservations early!

Although the Med-Sci Conference offers more than enough activities to keep registrants busy, the conference hotel site offers great opportunities to explore San Diego, where the average year-round temperature is 72 degrees. The Sheraton is situated on Harbor Island in beautiful San Diego Bay, and offers panoramic views of the bay and the downtown city skyline. Unique attractions within a 10-minute drive of the hotel include Sea World, the San Diego Zoo, historic Old Town San Diego, Balboa Park, and Seaport Village. For more information, visit the hotel's website at WWW.SHERATON.COM/SANDIEGOMARINA.

CONFERENCE REGISTRATION AND FEES

Register on-site at the ASAM Conference Registration and Information Desk, which will be open during the following hours:

Wednesday, May 3rd 5:00 p.m. to 8:00 p.m.
 Thursday, May 4th 6:30 a.m. to 6:30 p.m.
 Friday, May 5th 7:00 a.m. to 6:00 p.m.
 Saturday, May 6th 7:00 a.m. to 6:00 p.m.
 Sunday, May 7th 7:00 a.m. to 1:00 p.m.

The following fees apply to on-site registrations only:

Ruth Fox Course for Physicians

(Thursday, May 4th)

| | |
|--|-------|
| ASAM member | \$200 |
| Non-member physician | \$250 |
| Non-physician professional (R.N., Ph.D., CAC, LCSW, etc.) | \$175 |
| Resident, Fellow, Intern (with proof of status) | \$150 |
| Student (with proof of status) | \$75 |

37th Annual Medical-Scientific Conference

(May 5-7th)

| | |
|--|-----------|
| ASAM member | \$475 |
| Non-member physician | \$585 |
| Non-physician professional (R.N., Ph.D., CAC, LCSW, etc.) | \$475 |
| Paper presenter | \$350 |
| Resident, Fellow, Intern (with proof of status) | No charge |
| Student (with proof of status) | No charge |

Daily Registration for the Medical-Scientific Conference

..... \$225 per day

ASAM Awards Luncheon

(Saturday, May 6th, 1:00 p.m.)

..... \$50
 for Medical-Scientific Conference registrants

Buprenorphine and Office-Based Treatment of Opioid Dependence

(Sunday, May 7th)

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|--|-------|
| ASAM member | \$100 |
| Non-member physician | \$125 |
| Non-physician professional (R.N., Ph.D., CAC, LCSW, etc.) | \$75 |

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MEET YOUR REGIONAL DIRECTOR

During the Dessert Reception on Friday, May 5th, from 9:00 to 11:00 pm, members will have an opportunity to meet informally with ASAM's Regional Directors and discuss issues of importance to their Chapters and Regions.

Ruth Fox Course for Physicians Marks Its 25th Anniversary

Join your colleagues as ASAM celebrates the 25th Anniversary of the Ruth Fox Course for Physicians on May 4th from 8:00 a.m. to 5:30 pm. The course is dedicated to providing practicing physicians with cutting-edge knowledge about current trends in the field of addiction medicine.

The first Ruth Fox course was organized by the late Maxwell N. Weisman, M.D., and held May 5, 1980, in Seattle, Washington, in conjunction with the National Alcoholism Forum. Over the ensuing 25 years, the Ruth Fox Course has educated thousands of physicians.

This year's course, which is co-chaired by Doctors Margaret A.E. Jarvis, Louis E. Baxter, Sr., and John C. Tanner, features an address by John P. Walters, Director of the Office of National Drug Control Policy, as well as the following outstanding sessions:

- Remembering Dr. Ruth Fox — Looking Back/Looking Forward: *Stanley E. Gitlow, M.D., FACP, FASAM*
- Origins of ASAM/Addiction Medicine: *David C. Lewis, M.D.*
- Spirituality: A Tool for the Clinician's Armamentarium: *John N. Chappel, M.D., FASAM*
- Alcohol Screening & Interventions in Trauma & Emergency Departments: *Larry M. Gentilello, M.D., FACS*
- Professionalism: Boundaries, Principles & Ethics in Addiction Practice: *James C. Montgomery, M.D.*
- Impaired and Disruptive Physicians: *Peter A. Mansky, M.D.*
- What Influences the "Tipping Point" in the U.S. or International Tobacco Epidemic? *Lynda Hyder Ferry, M.D.*
- Recovery in the Middle East: *Keith Humphreys, Ph.D.*
- Treatment in the Criminal Justice System: *Jeffrey D. Baxter, M.D.*
- Literature Review: *David R. Gastfriend, M.D.*

QUICK GUIDE TO MED-SCI PROGRAM EVENTS

THURSDAY, MAY 4, 2006

6:00 – 8:00 pm

Welcome Reception and Opening of the ASAM Exhibit Hall

8:00 – 10:00 pm

COMPONENT SESSION I: Opioid Agonist Treatment 2005 — Training, Clinical Practice and Policy Initiatives

Sponsored by the ASAM Sub-Work Groups on Opioid Agonist Treatment and Buprenorphine Training

SPEAKERS: Daniel P. Alford, M.D., M.P.H., David A. Fiellin, M.D., Judith Martin, M.D., Edwin Salsitz, M.D., FASAM, Deb Stephenson, M.D., & Richard A. Yoast, Ph.D.

COMPONENT SESSION II: Why Not Private Practice? Practice Management: Coding and Billing Strategies

CHAIRS: A. Kenison Roy III, M.D., FASAM & John P. Femino, M.D., FASAM

COMPONENT SESSION III: Public Policy in Addiction Medicine: Past, Present, and Future

Sponsored by the ASAM Public Policy Committee

SPEAKERS: Mark L. Kraus, M.D., FASAM & Petros Levounis, M.D., M.A.

COMPONENT SESSION IV: Addiction Medicine and Primary Care

SPEAKERS: Bonnie B. Wilford, M.S. & Norman Wetterau, M.D., FAAFP

COMPONENT SESSION V: Chapters Council

Sponsored by the Chapters Council and the ASAM State Medical Specialty Society Program

FRIDAY, MAY 5, 2006

7:00 am

ASAM Annual Business Meeting & Breakfast

(ASAM Members only — breakfast service will start at 6:45 am)

7:30 am

Continental Breakfast for ASAM Guests and Non-Members

8:30 am

Opening Scientific Plenary and R. Brinkley Smithers Distinguished Scientist Lecture

“Common Social Factors in the Development and Remission of Alcohol Use and Other Addictive Disorders”

SPEAKER: Rudolph H. Moos, Ph.D., Senior Research Career Scientist, Department of Veterans Affairs, and Professor of Psychiatry and Behavioral Sciences, Stanford University, Menlo Park, CA

9:30 am

ASAM Exhibit Hall Opens

10:00 am

Refreshment Break — ASAM Exhibit Hall

10:30 am – 12:30 pm

and 2:30 pm – 6:00 pm

SYMPOSIUM 1: Clinical Approaches to HIV and Hepatitis C Infections in Drug Abuse

Sponsored by the National Institute on Drug Abuse (NIDA)

ORGANIZERS: Jag H. Khalsa, Ph.D. & Frank J. Vocci, Jr., Ph.D.

SPEAKERS: Andrea Cox, M.D., Ph.D., Brian Edlin, M.D., M.P.H., Richard Garfein, Ph.D., M.P.H., Ramesh Ganju, Ph.D., Kristy Marie Hendricks, Sc.D., Charles B. Hinkin, Ph.D., ABPP, Robert Horschburgh, M.D., Kenneth E. Sherman, M.D., Ph.D., Jack Stapleton, M.D., Ellen Tedaldi, M.D. & Terry Wright, M.D.

10:30 am – 12:30 pm

SYMPOSIUM 2: Crossing the Quality Chasm in Addiction Medicine

SPEAKERS: A. Thomas McLellan, M.D., Jeffrey Samet, M.D., M.A., M.P.H. & Constance Weisner, Dr.P.H., M.S.W.

COURSE 1: Criminal Justice System and the Therapeutic Community: Treatment Alternatives to Incarceration

SPEAKERS: George DeLeon, Ph.D., Terry Horton, M.D., Donald J. Kurth, M.D., FASAM, Richard Rosner, M.D. & Anne J. Swern

WORKSHOP A: Drug Seeking or Pain?

Teaching About Addiction and Chronic Pain

SPEAKERS: Karen Cropsey, Psy.D., Laura Morgan, Pharm.D. & Michael Weaver, M.D., FASAM

WORKSHOP B: Treatment of Methamphetamine Dependence in a Residential Drug Court Therapeutic Community: A Novel Pilot Project

SPEAKERS: John B. Averitt, Ph.D., Roland Gray, M.D., Seth Norman, J.D. & David K. Patzer, M.D.

10:30 am – 1:00 pm

PAPER SESSION 1

12:30 pm – 2:00 pm

Lunch break

1:00 – 2:00 pm

POSTER SESSION

2:00 pm – 4:00 pm

SYMPOSIUM 4: Integrated Treatment of the Dually Diagnosed

ORGANIZER: Marc Galanter, M.D., FASAM

SPEAKERS: Petros Levounis, M.D., Jaime Grodzicki, M.D. & Richard K. Ries, M.D., FASAM

2:00 pm – 4:30 pm

PAPER SESSION 2

2:00 pm – 6:00 pm

SYMPOSIUM 1 (continued): Clinical Approaches to HIV and Hepatitis C Infections in Drug Abusers

SYMPOSIUM 3: Treating the Physician – Engagement, Treatment Approaches and Outcomes

ORGANIZER: Peter A. Mansky, M.D.

SPEAKERS: Louis E. Baxter, Sr., M.D., FASAM, Lynn R. Hankes, M.D., FASAM & Margaret A E. Jarvis, M.D., FASAM

2:30 pm – 4:30 pm

COURSE 2: The Psychotherapy and Treatment of Methamphetamine Addiction

SPEAKERS: Steven J. Lee, M.D. & Petros Levounis, M.D., M.A.

WORKSHOP C: Addiction in Pregnancy: Motivational Enhancement Treatment

SPEAKER: James J. Nocon, M.D.

6:30 – 8:30 pm

Ruth Fox Endowment Reception (by invitation only)

8:00 – 10:00 pm

WORKSHOP D: Hospital Based Substance Abuse Consultation Services — Clinical and Administrative Experiences

SPEAKERS: Rita Azalos, M.D., Richard Blondell, M.D., Michael Weaver, M.D. & Christopher Welsh, M.D.

WORKSHOP E: Group Therapy of Substance Abuse

SPEAKERS: David W. Brook, M.D., FASAM & Marc Galanter, M.D., FASAM

WORKSHOP F: Narcotics Anonymous (NA) — A Vital Resource in the Treatment of Addiction

SPEAKERS: Bob MacFarlane, M.D., Donna Markus, Ph.D. & Bob Stewart

9:30 pm

ASAM Dessert and Coffee Reception (All registrants are invited)

SAVE MONEY!

Attend the Medical-Scientific Conference at the member rate by joining ASAM now!

SATURDAY, MAY 6, 2006

7:00 am – 8:00 am

Continental Breakfast —
ASAM Exhibit Hall

8:00 am – 9:30 am

PUBLIC POLICY PLENARY: The 30 Patient Rule — Rational, Irrational, or Both?

Sponsored by ASAM's Public Policy and Legislative Advocacy Committees
Invited Panel Members: CSAT Director H. Westley Clark, M.D., JD, M.P.H., FASAM, Mark L. Kraus, M.D., FASAM, Petros Levounis, M.D., M.A., and DEA Administrator Karen Tandy

9:30 am

Refreshment Break – ASAM Exhibit Hall

10:00 am – 12:00 Noon

and 2:30 pm – 5:30 pm

SYMPOSIUM 5: Medications Development for Alcoholism: From the Bench to the Patient

Sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA)
ORGANIZERS: Mark L. Willenbring, M.D. & Raye Z. Litten, Ph.D.

SPEAKERS: Raymond F. Anton, M.D., Jack R. Cornelius, M.D., M.P.H., Bankole A. Johnson, M.D., Ph.D., George F. Koob, Ph.D., Henry R. Kranzler, M.D., John M. Littleton, M.D., Ph.D., Barbara J. Mason, Ph.D. & Mark L. Willenbring, M.D.

SYMPOSIUM 6: Health Care Disparities, Quality of Care, and Pay for Performance: What Is An Addiction Medicine Specialist to Know and Do?

ORGANIZER: Lawrence S. Brown, Jr., M.D., M.P.H., FASAM

SPEAKERS: John C. Nelson, M.D., M.P.H., Randall W. Maxey, M.D., Ph.D., and Matthew Wynia, M.D.

COURSE 3: Teaching Addiction Medicine to Medical Students, Residents and Primary Care Providers

SPEAKERS: R. Jeffrey Goldsmith, M.D. & Edwin A. Salsitz, M.D.



Balboa Park in San Diego

WORKSHOP G: Al-Anon/Alateen Presents Recovery From The Family Disease of Addiction

ORGANIZER: Joseph A. Troncale, M.D.

SPEAKERS: Neil A. Capretto, D.O., FASAM, Claire Ricewasser & Jeffrey D. Roth, M.D., FASAM

WORKSHOP H: Crystal, Coke, Sex and the Net: Treating the Dangerous and Difficult Combinations

SPEAKERS: M. Deborah Corley, Ph.D. & James C. Montgomery, M.D.

WORKSHOP I: Monitoring Alcohol Abstinence: Using EtG and Other Markers and Devices

ORGANIZER: Gregory E. Skipper, M.D.

SPEAKERS: Michael Feldman, Ph.D., Michel Sucher, M.D., Douglas Stellato Kabat, L.C.S.W. & Friedrich Wurst, M.D.

12:15 pm

ASAM Awards Luncheon

2:30 – 4:30 pm

SYMPOSIUM 7: Lost in Translation: Breaking the Bottleneck of Research Adoption

ORGANIZER: Joan E. Zweben, Ph.D.

SPEAKERS: Jeanne L. Obert, M.A., M.S.N., Jack B. Stein, Ph.D. & Mark L. Willenbring, M.D.

SYMPOSIUM 8: Rural Addiction Medicine: Real Need and Special Opportunity

ORGANIZER: Noman Wetterau, M.D., FAAFP, FASAM

SPEAKERS: Marcello A. Maviglia, M.D., M.P.H., Berton Toews, M.D. & Art Van Zee, M.D.

COURSE 4: Treatment Approaches for Persons in the Criminal Justice System Who Have Co-occurring Substance Use and Mental Disorders

SPEAKERS: Charlene Le Fauve, Ph.D., Fred C. Osher, M.D., & Roger H. Peters, Ph.D.

WORKSHOP J: Buprenorphine on the Cutting Edge: Advanced Issues in the Clinical Use of Buprenorphine

SPEAKERS: Eric D. Collins, M.D., Hendree Jones, Ph.D., Edwin A. Salsitz, M.D., FASAM & Michael Weaver, M.D., FASAM

4:30 pm

Refreshment Break – ASAM Exhibit Hall

6:00 – 9:00 pm

DINNER AND CME COURSE: Advances in Pharmacotherapy for Alcohol Dependence

SPEAKERS: Charles O'Brien, M.D., Ph.D., David Mee-Lee, M.D., Gerald Shulman, M.A., FACATA & Marc J. Fishman, M.D.

(There is no charge for dinner, but registration is required)

SUNDAY, MAY 7, 2006

8:00 am

Continental Breakfast

8:30 – 10:30 am

SYMPOSIUM 11: Pathological Gambling: A Non-Substance, Substance Use Disorder?

ORGANIZER: Edward Gottheil, M.D., Ph.D.

SPEAKERS: Nady el-Guebaly, M.D., Jon E. Grant, J.D., M.D., Clayton Neighbors, Ph.D. & Ken C. Winters, Ph.D.

COURSE 5: Six 12 Step-Oriented Principles in Addiction Treatment

SPEAKER: Daniel H. Angres, M.D.

WORKSHOP K: Addiction and Sleep Disorders

SPEAKERS: Jeff Daiter, M.D., CCFP, FCFP & Michael Varenbut, M.D., CCFP, FCFP

WORKSHOP L: Physician Health Programs — Effective Linking of Monitoring, 12-Step Fellowship Participation and Addiction Treatment — A Possible New Treatment Paradigm

ORGANIZER: Robert L. DuPont, M.D., FASAM

SPEAKERS: A. Thomas McLellan, Ph.D., Gregory E. Skipper, M.D. & William L. White, M.A.

WORKSHOP M: Addiction Treatment Using Spirituality Enhanced Twelve Step Facilitation (TSF) and Network Therapy in Residential Treatment for Physicians and Other Professionals

SPEAKER: John S. Sappington, M.D., FASAM

WORKSHOP N: Watching Over A Shoulder: Measurable Monitoring of Behavioral Addictions in the Workplace

SPEAKERS: M. Deborah Corley, Ph.D. & James C. Montgomery, M.D.

8:30 am - 12:30 pm

SYMPOSIUM 9: Treatment of Methamphetamine Use Disorders

Sponsored by the Center for Substance Abuse Treatment (CSAT)

ORGANIZER: Anton Ché Bizzell, M.D.

SPEAKERS: H. Westley Clark, M.D., J.D., M.P.H., FASAM, Rachel Gonzales, Ph.D., William Haning, M.D., Walter Ling, M.D., Jane C. Maxwell, Ph.D., Thomas F. Newton, M.D., Martin Paulus, M.D., Richard Rawson, Ph.D. & Matt Torrington, M.D.

10:30 am

Refreshment Break

11:00 am – 1:00 pm

WORKSHOP O: Addiction Treatment in Correctional Settings

SPEAKERS: Jeffrey Baxter, M.D. & Stacy Seikel, M.D.

End of Conference

Older Americans Misusing Alcohol, Opiates

More older Americans are entering addiction treatment, primarily because of problems with alcohol and prescription opiates, according to data released by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Data collected for the 2003 Treatment Episode Data Set (TEDS) show that treatment admissions among Americans ages 55 and older increased by 32 percent between 1995 and 2002. While alcohol remains the primary drug of abuse among older adults, a growing number cited prescription opiates: 12 percent in 2002, compared to 6.8 percent in 1995. Only 4 percent reported cocaine abuse, 3 percent reported marijuana abuse, and 1 percent reported abuse of stimulants. All of the rates were lower than those for the general population, except that the reports of alcohol abuse were higher among seniors than among patients of all ages.

Explaining that alcohol and other drug problems often are overlooked or misdiagnosed in older adults, SAMHSA Administrator Charles Curie said, "Too often, family members are ashamed of the problem and choose not to address it. Health care providers tend not to ask older patients about alcohol abuse.... Sometimes, the symptoms are mistaken for those of dementia, depression, or other problems common to older adults."

To counter the upward trend in abuse of opiates, SAMHSA and the Food and Drug Administration (FDA) have launched a public education campaign to encourage older adults to "Do The Right Dose" when using prescription pain relievers. The campaign will strive to educate older adults that prescription pain medications are safe and effective when used correctly, but if misused, could lead to addiction or other problems. The educational materials can be accessed online at [HTTP://ASYOUAGE.SAMHSA.GOV/DOThERIGHTDOSE/](http://ASYOUAGE.SAMHSA.GOV/DOThERIGHTDOSE/).

Surgeon General Issues Call to Action on Underage Drinking



**Surgeon General
Richard Carmona,
M.D., M.P.H.**

National attention to the problem of youth alcohol use picked up momentum last month as Surgeon General Richard Carmona, M.D., M.P.H., officially announced his intention to issue a Call to Action on underage drinking.

At a December 2005 meeting convened by the federal government's Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), Dr. Carmona promised that he would use his "bully pulpit" to address underage drinking. He followed through in February 2006, when his office issued a request for comments on the proposed Call to Action, with a deadline of March 15th for public input.

A 2003 report from the National Academy of Sciences, "Reducing Underage Drinking: A Collective Responsibility," is widely viewed as a model for the Surgeon General's initiative. The Congressionally mandated NAS report, issued by the National Research Council and the Institute of Medicine, advised the federal government to educate adults about existing laws and the consequences of underage drinking, urged parents to do a better job supervising their children, and called on the alcohol and entertainment industries to shield youth from unsuitable messages about alcohol consumption.

To fund the proposed activities, the report urged that Congress and state legislatures raise alcohol excise taxes — particularly on beer, which studies show is the alcoholic beverage that most young people prefer. Other NAS recommendations included increased compliance checks on retailers, backed by the threat of states losing federal funding if enforcement falls short.

Many observers doubt that the Bush administration will confront issues like alcohol taxes and advertising, and Dr. Carmona is barred from making specific policy recommendations as part of his Call to Action. On the other hand, Ohio First Lady Hope Taft notes that former Surgeon General Everett Koop's landmark report on tobacco didn't include policy recommendations, either, but still led to a paradigm shift in how the public viewed smoking. "We hope that this is the beginning of a shift on childhood drinking," she told *Join Together*.

The Surgeon General's report is expected to be released in April to correspond with Alcohol Awareness Month. *Source: Bob Curley, Join Together Online, March 13, 2006.*

Free Slideshow CD on Using the NIAAA Clinician's Guide

NIAAA presents a new instructional CD for using *Helping Patients Who Drink Too Much - A Clinician's Guide*. The CD features:

- A slideshow overview of the *Guide* with step-by-step instructions
- Slide templates and animated graphics - ideal for customizing presentations about the *Guide*

Download the *Guide* and related tools at www.niaaa.nih.gov



Pick up a
free CD at NIAAA's booth
at the annual **ASAM**
meeting in San Diego





An Effective Treatment for the Maintenance of Abstinence from Alcohol in Combination with Psychosocial Support¹

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- 2 to 3 times more patients maintained abstinence vs placebo in long- and short-term studies, respectively²
- Works well with a variety of psychosocial therapies³⁻⁶
- Excellent safety and tolerability profile¹⁻⁷
- Unique mechanism of action is thought to restore neurotransmitter balance^{*1}
- Used in over 1.5 million patients worldwide⁷

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

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

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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 C_{max} of acamprosate. No adjustment of dosage is recommended in such patients. The pharmacokinetics of naltrexone and its major metabolite 6- β -naltrexone were unaffected following co-administration with CAMPRAL. Other concomitant therapies: In clinical trials, the safety profile in subjects treated with CAMPRAL concomitantly with anxiolytics, hypnotics and sedatives (including benzodiazepines), or non-opioid analgesics was similar to that of subjects taking placebo with these concomitant medications. Patients taking CAMPRAL concomitantly with antidepressants more commonly reported both weight gain and weight loss, compared with patients taking either medication alone.

Carcinogenicity, Mutagenicity and Impairment of Fertility A carcinogenicity study was conducted in which Sprague-Dawley rats received 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 chromosomal damage 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/m² 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/m² 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/m² basis) and in rabbits when given in doses that are approximately 3 times the human dose (on a mg/m² 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/m² basis). The malformations included hydronephrosis, malformed iris, retinal dysplasia, and retroesophageal subclavian artery. No findings were observed at an oral dose of 50 mg/kg/day (approximately one-fifth the maximum recommended human daily oral dose on a mg/m² basis). An increased incidence of hydronephrosis was also noted in Burgundy Tawny rabbits at oral doses of 400 mg/kg/day or greater (approximately 3 times the maximum recommended human daily oral dose on a mg/m² basis). No developmental effects were observed in New Zealand white rabbits at oral doses up to 1000 mg/kg/day (approximately 8 times the maximum recommended human daily oral dose on a mg/m² basis). The findings in animals should be considered in relation to known adverse developmental effects of ethyl alcohol, which include the characteristics of fetal alcohol syndrome (craniofacial dysmorphism, intrauterine and postnatal growth retardation, retarded psychomotor and intellectual development) and milder forms of neurological and behavioral disorders in humans. There are no adequate and well controlled studies in pregnant women. CAMPRAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects** A study conducted in pregnant mice that were administered 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/m² basis). No effects were observed at a dose of 320 mg/kg/day (approximately one-half the maximum recommended human daily dose on a mg/m² basis).

Labor and Delivery The potential for CAMPRAL to affect the duration of labor and delivery is unknown. **Nursing Mothers** In animal studies, 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%) |
| Furritus | 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, postural hypotension; Rare: heart failure, mesenteric arterial occlusion, cardiomyopathy, deep thrombophlebitis, shock. **Digestive System** – Frequent: vomiting, dyspepsia, constipation, increased appetite; Infrequent: liver function tests abnormal, gastroenteritis, gastritis, dysphagia, eructation, gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage, liver cirrhosis, esophagitis, hematemesis, nausea and vomiting, hepatitis; Rare: melena, stomach ulcer, cholecystitis, colitis, duodenal ulcer, mouth ulceration, carcinoma of liver. **Endocrine System** – Rare: goiter, hypothyroidism. **Hemic and Lymphatic System** – Infrequent: anemia, ecchymosis, eosinophilia, lymphocytosis, thrombocytopenia; Rare: leukopenia, lymphadenopathy, monocytosis. **Metabolic and Nutritional Disorders** – Frequent: peripheral edema, weight gain; Infrequent: weight loss, hyperglycemia, SGOT increased, SGPT increased, gout, thirst, hypercemia, diabetes mellitus, avitaminosis, bilirubinemia; Rare: alkaline phosphatase increased, creatinine increased, hyponatremia, lactic dehydrogenase increased. **Musculoskeletal System** – Frequent: myalgia, arthralgia; Infrequent: leg cramps; Rare: rheumatoid arthritis, myopathy. **Nervous System** – Frequent: somnolence, libido decreased, amnesia, thinking abnormal, tremor, vasodilatation, hypertension; Infrequent: convulsion, confusion, libido increased, vertigo, withdrawal syndrome, apathy, suicidal ideation, neuralgia, hostility, agitation, neurosis, abnormal dreams, hallucinations, hypesthesia; Rare: alcohol craving, psychosis, hyperkinesia, twitching, depersonalization, increased salivation, paranoid reaction, torticollis, encephalopathy, manic reaction.

Respiratory System – Frequent: rhinitis, cough increased, dyspnea, pharyngitis, bronchitis; Infrequent: asthma, epistaxis, pneumonia; Rare: laryngismus, pulmonary embolus. **Skin and Appendages** – Frequent: rash; Infrequent: acne, eczema, alopecia, maculopapular rash, dry skin, urticaria, exfoliative dermatitis, vesiculobullous rash; Rare: psoriasis. **Special Senses** – Infrequent: 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 overdose 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 overdose only. Treatment of overdose should be symptomatic and supportive.

Manufactured by: Merck Santé s.a.s.

Subsidiary of Merck KGaA, Darmstadt, Germany
 37 rue Saint-Romain
 69008 LYON FRANCE

Manufactured for FOREST PHARMACEUTICALS, Inc.
 Subsidiary of Forest Laboratories, Inc.
 St. Louis, MO 63045

07/04

Legislators Swarm CSAM's Leg Day IV

Donald J. Kurth, M.D., FASAM

California legislators have found the value of speaking to addiction doctors and proved it by making a strong showing at the Fourth Annual Legislative Day sponsored by the California Society of Addiction Medicine. All told, CSAM members met with 32 Assembly members or their aides, as well as representatives of the Governor's office. "The exciting part," explained CSAM President David Pating, "is that the legislators are beginning to compete for our attention. Each one wants to outdo colleagues."

This year's Leg Day was co-sponsored by the California Association of Alcohol and Drug Abuse Counselors. CSAM members welcomed the counselors' involvement in shaping the public policies that affect all of us.

The day began with a meeting of legislative advocates and representatives of CSAM's public policy allies, led by CSAM Public Policy Chair Denise Greene, M.D. Following the opening remarks, ASAM President Elizabeth Howell, M.D., FASAM, addressed the group of 70 attendees and thanked everyone for the inspiration California has provided for all ASAM members in the area of legislative advocacy and public policy. Peter Banyas, M.D., then spoke about Proposition 36; Christy Waters, M.D., and Timmen Cermak, M.D., discussed methamphetamine; CSAM Immediate Past President Donald J. Kurth, M.D., FASAM, addressed the human rights of patients with addictive disorders; Diane Sylvestre, M.D., discussed hepatitis C; Gary Jaeger, M.D., FASAM, provided an update on parity; and Warren Daniels, CAADAC, described addiction counselor certification.

After a quick box lunch, the group divided into teams and headed for the Capitol. In addition to the four legislators who addressed the group in the morning, CSAM members met with 28 legislators and/or their aides.

Some legislative districts are affected more than others by the spread of addictive disease and the acute need for increased treatment services. For example, the Fresno area, represented by Assembly Member Bill Maze, has the highest density of intravenous drug use in the Nation. The good news is that Assembly Member Maze is willing to roll up his sleeves and tackle the problem.

Assembly member Jackie Goldberg has

fought for humane detoxification in correctional institutions for years and has carried bills for CSAM in the past. Assembly member Gloria Negrete McCleod is a long-time friend of CSAM and has worked hard to ensure adequate testing and treatment of hepatitis C in incarcerated persons. Assembly member Mark Leno has been a strong advocate for equal protection under the law for all Californians.

The take-home message is that CSAM is making a difference! We are having an impact on public policy and legislation in the State of California and we want you to join

us. Come with us to Sacramento for CSAM Legislative Day V. Watch the CSAM website (www.CSAM-ASAM.org) for details. Better yet, start a Legislative Day in your own home state and help us make a difference for all Americans suffering from addictive disease. Together, we can change the world!

DR. KURTH is Immediate Past President of the California Society of Addiction Medicine and currently serves as Treasurer of the American Society of Addiction Medicine. He also Chairs ASAM's Legislative Advocacy Committee.

TENNESSEE SOCIETY REACTIVATED



Roland Gray, M.D. (center), Director of the Tennessee Medical Foundation physician health program, recently accepted a \$5,000 donation from the Tennessee Society of Addiction Medicine. Making the presentation are TNSAM President Richard G. Soper, M.D., J.D. (at right), and Secretary Jon Butler, M.D. The donation was the first action taken by the Tennessee Society at the chapter's reactivation meeting in December 2005.

Chapter Development Tied to Specialty Recognition

Kevin Kunz, M.D., FASAM

ASAM's mission includes the promotion of high quality scientific and compassionate care to our patients, their families, and our communities. Another essential, yet unfulfilled element of our officially stated mission has been to ensure that our specialty takes a formal seat at the table of mainstream medicine — by gaining recognition from the American Board of Medical Specialties. Addiction medicine needs a presence in every community and state, and as we strive towards national recognition and inclusion the participation of a vibrant and well-organized network of local addiction physicians is necessary. ASAM has two arms, a strong national leadership and local involvement at the state level. The latter must become fully integrated and administratively mature within ASAM if we are to fulfill our mission.

To achieve this, ASAM must transform its state chapters into functioning state medical specialty societies that operate on an equal footing with the state affiliates of other medical specialty groups. This has been the primary goal of the State Medical Specialty Society (SMSS) Program, organized in 2002 under the chairmanship of Richard Beach, M.D. The objectives of the SMSS program are: (1) to create an administrative office within each participating state or ASAM Region, (2) to obtain that state's medical society's formal recognition as a medical specialty society in addiction medicine, and (3) to offer an annual continuing medical education conferences.

We have learned from this project that to achieve these objectives, a state society must take action in six areas: corporate identity, fiscal resources, administration, member activity, communication, and medical society inclusion. The first three are the infrastructure, while the next three are how the members become engaged in carrying out the mission. These are start-up tasks, which many physicians find onerous, but with assistance and guidance, as has been provided via the SMSS program, are achievable. The model each chapter seeks to emulate is that of the California Society of Addiction Medicine (CSAM), the first and most active of ASAM's chapters. CSAM has 350 members and an elected Executive Council, is administered by an association management firm, offers an annual CME conference attended by more than 300, publishes a bi-monthly newsletter and an annual directory, is active

in the California Medical Association, and provides education and consultation to the health care community and policymakers. While few states have the capacity to replicate the scale of CSAM's successes, the SMSS pilot program has proven that any state, even those with just a small team of ASAM physicians, can organize successfully and positively impact addiction care at every level, from the bedside to the legislature. Our experience indicates that a quiescent chapter, with a few dedicated leaders, can complete the basic objectives in as little as 18 months.

ACHIEVEMENTS TO DATE

Under the leadership of former ASAM Executive Vice President and current program consultant James F. Callahan, DPA., an impressive list of successes have already been achieved. ASAM physicians are promoting treatment for their patients just as internists, psychiatrists and other specialists form specialty societies to represent their patients' needs within the state. Twenty-seven states now take part in this program, up from 23 in 2004, and 12 in 2002. Our goal is to increase this number to 32 participating states by December 2006, when the current



Members of the SMSS program and the Chapters Council met with ASAM's elected leadership January 20-21st in Bethesda, Maryland. Pictured are:

Front Row, left to right: Michael M. Miller, M.D. (ASAM President-Elect), Richard Soper, M.D. (Tennessee), Elizabeth F. Howell, M.D. (ASAM President), Martha Wunsch, M.D. (Region V Director), Merrill Herman, M.D. (New York), Berton Toews, M.D. (Northwest Chapter), and John Femino, M.D. (Region III Director).

Second Row, left to right: Helen Huff and Nancy Brighindi (ASAM staff), Robert Jones, M.D. (Texas), J. Ramsay Farah, M.D. (Maryland), Donald J. Kurth, M.D. (California and ASAM Treasurer), George D. Hall, M.D. (North Carolina), and Ronald J. Schwerzler, M.D. (Oregon).

Third Row, left to right: Allan M. Ebert, M.D. (Michigan), Valerie Foote (ASAM staff), Kevin Kunz, M.D. (Hawaii and Council Chair), Eileen McGrath, J.D. (ASAM EVP), Gary D. Helmbrecht, M.D. (Virginia), Tim Fischer, D.O. (South Carolina), James F. Callahan, Ph.D. (SMSS Consultant), and C. Chapman Sledge, M.D. (Region X Director).

Back Row, left to right: Wayne E. Pasanen, M.D. (Massachusetts), James M. Miner, M.D. (Virginia), Thomas L. Haynes, M.D. (Region VI Director), George L. Carlson, M.D. (Hawaii), K. L. Hallman, M.D. (Virginia), and Stephen A. Wyatt, D.O. (Connecticut).

Not pictured are Jeffrey C. Craddock, M.D. (South Carolina), Miriam H. Komaromy, M.D. (New Mexico), Sarz Maxwell, M.D. (Illinois), David Pating, M.D. (California), John D. Patz, M.D. (Washington State), Mark Publicker, M.D. (Maine), Marvin Seppala, M.D. (Region VIII Director) and Howard Wetsman, M.D. (Region VII Director).

funding ends, and a new budgeting strategy will be needed.

Most patients with addictive disorders are unlikely to receive adequate medical care until addiction medicine is part of our country's health and medical education systems. The ultimate goal for assuring this is to have an American Board of Addiction Medicine as a member board of the American Board of Medical Specialties. Formal recognition of addiction medicine by the AMA and the state medical societies is an essential step toward this goal. Through the efforts of the SMSS and its state affiliates, 10 state medical societies now recognize their state society of addiction medicine and have given addiction medicine a seat in the state society's house of delegates or governing body. This is up from 7 in 2004, and 3 in 2003. Our goal for 2006 is to increase the number to 15. We have demonstrated that addiction medicine can be a welcome and functional member of the family of medical specialties.

In participating states, the number of medical education conferences has increased significantly each year. In Texas, attendance at the Region VII 2005 annual conference tripled over 2004, despite the difficulties posed by hurricane Katrina. In 2006, a 1.5 day physician education track will be added to the Cape Cod Symposium (Massachusetts), an annual conference that draws 500 registrants. Several states are routinely incorporating addiction medicine sessions with their state societies annual meeting.

Public policy achievements have been equally remarkable, including successes in battling against state bills to legalize marijuana (under the euphemism of "medical marijuana") and in working for the repeal of harmful legislation such as the Uniform Accident and Sickness Policy Provision Law [UPPL]. The UPPL is a major barrier to screening and referral for alcohol and other drug problems because it expressly states that "the (health) insurer shall not be liable for any loss sustained or contracted in consequence of the insured's being intoxicated or under the influence of any narcotic, unless administered on the advice of a physician." Parity for addiction medicine has also been addressed at the state level.

GOALS FOR THE FUTURE

Among our goals for 2006, two are essential to assure the continuation of the program. The first is to help each state society secure sufficient income and administrative staff to support medical education and public policy. The second goal is to integrate the SMSS program into the ASAM operating budget under the ASAM Chapters Council, which is charged with chapter development and growth. It is clear that the Chapters Council must continue to encourage and support the objectives of the SMSS program for the current momentum to continue.

Robert L. DuPont, M.D., FASAM, continues to offer his wisdom and has kept us focused on what we are trying to achieve. As he does so well, he summarized our purpose when he said, "Our work...is not for the glory of ASAM. Our work is aimed at helping the thousands of addicted people, in communities large and small all over the country, find their ways out of addiction into recovery through the use of modern, scientific addiction medicine. ASAM member physicians in those communities are the ones who can best help their patients find their ways to recovery. They are the dedicated physicians who are best able to give their patients the advantages of the evidence-based medicine that is newly available to facilitate lasting recovery, including wholehearted support of lifelong participation in Alcoholics Anonymous and Narcotics Anonymous as the best way to prevent relapses into the quicksand of addiction."

In summary, the strength of ASAM is found in our two arms: a strong national leadership and involvement at the state level. Both are required to fulfill our mission. Indeed, it is the hands-on efforts of our members in their hometowns and home states that ultimately increase our patients' access to high quality care. It is at the local level where we directly interface with, assist and educate our peers and the public. If addiction medicine is to reach full specialty status, the input and enthusiasm of a diverse and included membership will be essential.

ASAM is grateful to John P. McGovern, M.D., FASAM (Honorary) and the John P. McGovern Foundation, as well as to the Scaife Family Foundation, for their steadfast support of this vital initiative. In addition, the ASAM Board, which initially approved the program in 2002, has been unwavering in its support of the initiative, as has Executive Vice President/CEO Eileen McGrath, J.D.

Dr. Kunz chairs the SMSS program and the ASAM Chapters Council. He is Past-President of the Hawaii Society of Addiction Medicine.

CTSAM Works for Better Care of Physicians

Stephen A. Wyatt, D.O.

Douglas Gibson, M.D., Medical Director of the Connecticut Physician Health Program, has made tremendous strides in establishing a more science-based, equitable, and confidential program to assist impaired health care professionals in Connecticut. The vehicle is Raised Bill No. 5718 [LCO 2532], An Act Concerning a Professional Assistance Program for Health Care Professionals. The language of the bill can be accessed online at [HTTP://WWW.CGA.CT.GOV/2006/TOB/H/2006HB-05718-R00-HB.HTM](http://www.cga.ct.gov/2006/TOB/H/2006HB-05718-R00-HB.HTM)

This important measure currently is before the Committee on Public Health of the state legislature. Please review the bill, discuss it with your colleagues, and contact your legislators and friends to advocate for its enactment.

Dr. Gibson's work is an example of the progress we are making in Connecticut. The Connecticut Society of Addiction Medicine is at the table in the state medical society. CTSAM is the organization the public and the legislature turn to most frequently for expertise in our field. And we have very active representation nationally through ASAM — the most active voice in the field of addiction medicine. There has never been a time when addiction medicine has had such an opportunity to lead; indeed, with the advent of new therapeutic options and the growth of Fellowship training, physicians are now the lynchpins of the therapeutic team.

I'm also pleased to announce that our state society has a new website, WWW.CTSAM.ORG. Please consider the importance of supporting this strong and active voice by joining or renewing your membership in the Connecticut Society and ASAM. *Together* we can fight for appropriate care for our patients and educate the public and policymakers. Treat addiction, save lives!

DR. WYATT is President of the Connecticut Society of Addiction Medicine and Medical Director of the Stonington Institute, North Stonington, CT.

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.

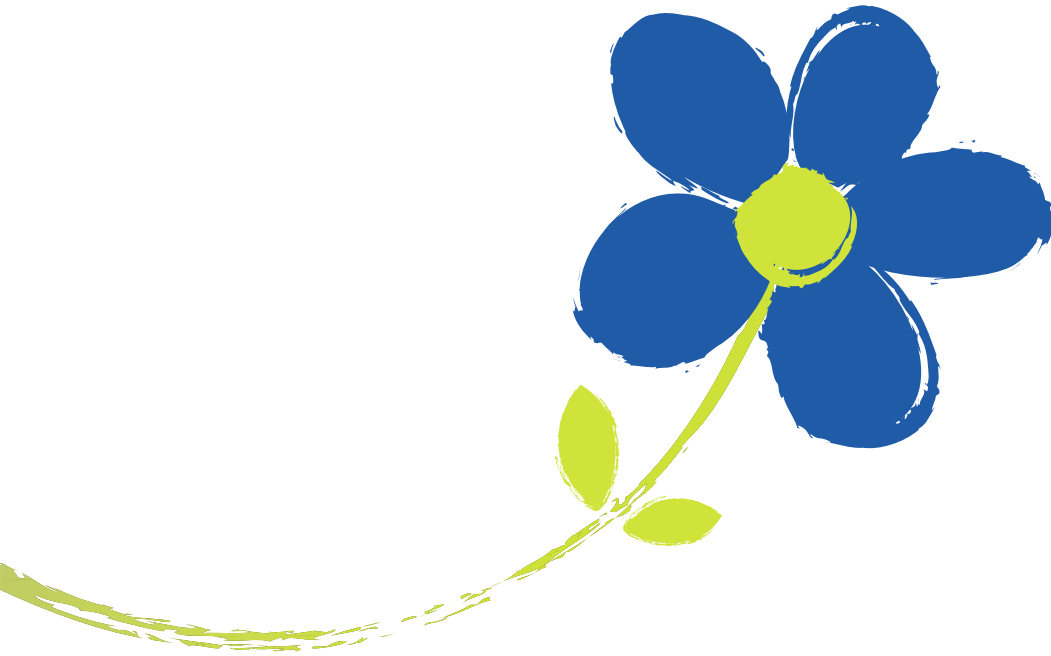
Due caution should be exercised when driving cars or operating machinery.

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.

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

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

Because Treatment Transforms Lives

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

Rx only

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

PRECAUTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pregnancy: Pregnancy Category C:

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

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

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

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

OVERDOSAGE

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

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

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

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

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

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

#138274BS

July 2005

ASAM's Member-Get-A-Member Campaign Continues

ASAM's Member-Get-A-Member Campaign, which began October 1, 2005, continues through April 15th, so there still is time to take part! Share your ASAM experience when you are meeting with colleagues and ask them to consider joining ASAM. Not only will you be doing yourself a favor by strengthening your Society, but your colleagues will thank you for inviting them.

Each new member you recruit moves you closer to receiving one of the following*:

1st prize: One free registration to the 2007 Med-Sci Conference (value up to \$585)

2nd prize: One free membership renewal for 2007 (value up to \$485)

3rd prize: One free copy of ASAM's textbook, *Principles of Addiction Medicine, 3rd Edition* (value up to \$175).

As of February 2006, each of the following members has recruited at least one new member:

RECRUITED 3 NEW MEMBERS

Richard G. Soper, M.D.

RECRUITED 2 NEW MEMBERS

Sanjay Chandragiri, M.D.

RECRUITED 1 NEW MEMBER

Mihran N. Ask, M.D.

Jeffrey Baxter, M.D.

Louis E. Baxter, Sr., M.D., FASAM

E. Coffman, D.O.

Barry E. Cole, M.D.

Jeff Daiter, M.D.

Christina Delos-Reyes, M.D.

Allan Ebert, M.D.

J. Ramsay Farah, M.D.

Marc Galanter, M.D., FASAM

Samuel Ganz, M.D.

Frederick C. Goggans, M.D.

Lloyd J. Gordon III, M.D., FASAM

Susan T. Howard, M.D., FASAM

Ebenezer Kolade, M.D.

Vijaya Kotha, M.D.

Kevin B. Kunz, M.D., FASAM

David R. McDuff, M.D.

Anthony Miller, M.D.

Michael M. Miller, M.D., FASAM

Tania Nordli, M.D.

David Pating, M.D.

Mark R. Publicker, M.D.

Nader Sharifi, M.D.

Paul Tisher, M.D.

Scott Treworgy, M.D.

Michael Varenbut, M.D.

Lawrence Westreich, M.D.

Melanie Willows, M.D.

Jack Woodside, M.D.

William Wooten, M.D.

Add your name to the growing list and increase your chances of receiving a prize by recruiting a new member today! Visit the ASAM website at www.asam.org for details and membership application forms.

* In the event of a tie, the winner will be determined by a drawing.

RUTH FOX MEMORIAL ENDOWMENT FUND

Associate Medical Director

THE NORTH CAROLINA PHYSICIANS HEALTH PROGRAM (www.ncphp.org) seeks a physician in recovery for the Associate Medical Director position. The AMD helps to facilitate treatment of health care professionals with medical conditions that could compromise patient care.

Qualifications include a medical degree from an AMA-accredited school and public speaking skills. Successful completion of AMA-recognized medical residency and certification by ASAM or ABPN are highly desirable. Must qualify for NC medical licensure. Send CV, bio, two letters of reference, and salary requirements to:

Kim McCallie
NC Physicians Health Program
220 Horizon Drive, Suite 218
Raleigh, NC 27615
Email: kim@ncphp.org



Dr. Ruth Fox

Dear Colleague:

The 2006 Ruth Fox Donor Reception is scheduled for 6:30 to 8:30 p.m. on Friday evening, May 5th, during ASAM's Medical-Scientific Conference in San Diego. The reception honors the generosity of those who have made donations to the Fund. As in years past, the cost of the reception has been underwritten by a generous gift from ASAM member Joseph E. Dorsey, M.D., and Mrs. Dorsey.

The Reception also provides an opportunity to celebrate the achievements of this year's recipients of the Ruth Fox Scholarships, given to an outstanding group of physicians-in-training. 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 four scholarship recipients for 2006 are Kathleen Ang-Lee, M.D. (Seattle, Washington), Katrina Ball, D.O. (Loma Linda, California), Norana Irene Caivano, M.D. (West Hollywood, California), and Mark Hrymoc, M.D. (Harbor UCLA Medical Center, Los Angeles).

The Endowment was established to create a fiscally sound base so as to assure ASAM's continued ability to realize its mission: to provide ongoing leadership in newly emerging areas affecting the field of addiction medicine, to continue its commitment to educating physicians, to increasing access to care and to improving the quality of care. With the professional and financial support of ASAM's members and friends, the Fund will achieve its mission.

Invitations to the Ruth Fox Donor Reception are extended only to donors, so if you have not already contributed or pledged to the Endowment Fund, please do so now. For information about making a pledge, contribution, bequest, memorial tribute, or to discuss other types of gifts in confidence, please contact Claire Osman by phone at 1-800/257-6776 or 1-718/275-7766, or email Claire at ASAMCLAIRE@AOL.COM. She welcomes your calls. All contributions to the Endowment Fund are tax-deductible to the full extent allowed by law.

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Chair, Ruth Fox Memorial Endowment Subcommittee

Claire Osman
Director of Development

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Today's source for tomorrow's pain management!

Visit us at the ASAM 37th Annual Medical-Scientific Conference, May 4-7, 2006

The screenshot shows the website's layout with a navigation bar (Home, Mission Statement, Log In, Contact Us, Tell A Colleague), a main content area with a welcome message and a quiz, and a sidebar with various resource links. A 'Breakthrough News' section is highlighted with a yellow box.

ESP Tool Kit
A multimedia collection of practical, educational resources and tools, focusing on patient assessment of pain and of risk for abuse, misuse or addiction; patient monitoring to evaluate treatment efficacy; and best practices for clinicians in the field of pain management

Calendar of Live Meetings and Events
A series of accredited regional meetings for pain management clinicians, focusing on balancing effective opioid therapy with appropriate assessment and monitoring for potential risk of abuse, misuse and addiction

- ESP Tool Kit
- Case Study Library
- CE Links
- Meetings & Events
- Slide Library
- Resource Library

Clinical Experts
Jeffrey Gudin, MD
Howard Heil, MD
Steven Passik, PhD
Richard Payne, MD

Test Your Knowledge

What percent of patients with advanced cancer experience severe pain?

50%

70%

80%

90%

What percent of cancer pain patients receive inadequate analgesic treatment?

10-14%

15-41%

42-65%

66-100%

Welcome To EmergingSolutionsinPain.com

... a comprehensive initiative that is designed to meet the needs of physicians, pharmacists, nurses and other health care professionals who are actively involved in pain management, and in working with patients who are prescribed opioids.

The Emerging Solutions in Pain initiatives are a diverse collection of practical tools, resources and programs, reflecting the diversity of challenges and issues that pain management clinicians face on a daily basis. The Emerging Solutions in Pain tools and techniques, when implemented, are designed to contribute to:

- Improving patient care
- Protecting public health by addressing the risks of opioid abuse, misuse and addiction
- Protecting the practices of those clinicians actively involved in pain management

Registration is fast, easy, and convenient, and provides users with access to assessment and monitoring tools, references, and other resources.

Thank you for your interest!

Breakthrough News

The Current State of Pain Management: An Expert Interview With Scott M. Fishman, MD

All NSAIDs May Be Linked to MI Risk, Study Indicates

MDs Should Be Able to Dispense Drugs if Pharmacists Won't: AMA



Clinical Expert Commentary

The "Chilling Effect"

The phrase "chilling effect" refers to the intimidating influence of regulatory oversight by agencies of the law that are charged with deterring the diversion of controlled substances from legitimate medical use to non-medical use. These agencies are constantly telling...

[More...](#)

In The News

Ethical Challenges in the Management of Chronic Nonmalignant Pain: Negotiating Through the Cloud of Doubt

Untreated pain has received increased attention over the past two decades, though the bulk of this has been given to the treatment of cancer-related pain.

[More...](#)

Breakthrough News
A rotating series of headlines and daily news articles highlighting breaking news in the field of pain management

Clinical Expert Commentary
Leading experts provide their interpretation of hot topics in the field of pain management

In the News
Summaries of the latest clinical journal articles relevant to the field of pain management

A nonbranded educational website



Supported by an educational grant from



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

April 22-26, 2006

2006 AATOD National Conference:
"Treating People With Dignity —
Working With Criminal Justice
and Health Care Systems"
American Association for the
Treatment of Opioid Dependence
Hyatt Regency Atlanta, Georgia
[Visit: WWW.AATOD.ORG or email
AATOD@TALLEY.COM]

April 28-29, 2006

Second Annual National
Aging and Addiction Conference
Marriott West Palm Beach Hotel, West
Palm Beach, Florida
Sponsored by the Hanley Center
[Visit: WWW.HANLEYCENTER.ORG/NAAC]

*Except where otherwise indicated,
additional information is available
on the ASAM web site (WWW.ASAM.ORG)
or from the ASAM Department of
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Chevy Chase, MD 20815-4520;
phone 301/656-3920;
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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.

April 22, 2006

Atlanta, Georgia
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

September 7, 2006

San Francisco, CA
Sponsored by ASAM &
the California Medical Association

COMPONENT SESSIONS

The following Component Sessions, organized by ASAM councils and committees, are scheduled for 8:00 to 10:00 p.m. Thursday, May 4th during ASAM's Med-Sci Conference (see the final program for locations).

- ★ "Opioid Agonist Treatment 2005 — Training, Clinical Practice and Policy Initiatives"
- ★ "Why Not Private Practice? Practice Management: Coding and Billing Strategies"
- ★ "Public Policy in Addiction Medicine: Past, Present, and Future"
- ★ "Addiction Medicine and Primary Care"
- ★ "Chapters Council / SMSS Program"

BUPRENORPHINE AND OFFICE-BASED TREATMENT OF OPIOID DEPENDENCE

Sunday, May 7, 2006 • 8:00 am – 5:30 pm • San Diego Sheraton Hotel & Marina • San Diego, California

Course Director: David Fiellin, M.D., Yale University Medical School

This course is designed for physicians who have an interest in or experience with treating opioid-dependent patients, and who wish to qualify to use buprenorphine in office-based treatment of opioid dependence.

Topics to be addressed by an expert faculty include:

- Overview of opioid dependence and rationale for opioid agonist treatment
- Legislative changes allowing office-based treatment
- General pharmacology of the opioids
- Pharmacology, efficacy and safety of buprenorphine and buprenorphine/naloxone
- Clinical uses of buprenorphine and buprenorphine/naloxone, including induction, maintenance, and pharmacologic withdrawal
- Patient assessment and selection
- Office procedures and logistics
- Medical comorbidities in opioid-dependent patients
- Psychiatric comorbidities in opioid-dependent patients
- The role of psychosocial counseling in the treatment of opioid dependence
- Special treatment populations, including adolescents, pregnant women, and pain patients

The course is approved for up to 8 credit hours of Category 1 continuing education credit. (Only those who attend the full 8-hour program are eligible for a certificate of attendance.)

A separate registration fee is required for this course.

**ATTENDANCE IS LIMITED,
SO BE SURE TO REGISTER EARLY!**

Visit ASAM's web site at
WWW.ASAM.ORG, or register on-site
(registration opens at 7:15 a.m.).