



# ASAMNews

Newsletter of The American Society of Addiction Medicine

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*Plan to attend ASAM's  
State of the Art Course  
in Washington, DC,  
October 27-29, 2005*

[www.asam.org](http://www.asam.org)



## Hurricanes Devastate Treatment Programs, Patients

Among the estimated 1 million persons left homeless by Hurricanes Katrina and Rita are thousands of addicted individuals, many of whom have been torn away from their recovery programs. Even before Hurricane Katrina, Louisiana suffered a dearth of addiction treatment options. As many as 1,800 persons were on waiting lists, according to Samantha-Hope Atkins of Hope Networks, a recovery advocacy group in Baton Rouge. "Very few people realized that Louisiana had 32 medical detox beds for 4 million residents," she said. "Twenty of those were in (New Orleans') Charity Hospital, which is gone."

Katrina wiped out other recovery options as well. The New Orleans area hosted dozens of Twelve Step meetings every day, and the city's methadone clinics served about 1,300 patients.

While treatment centers in the Gulf States are trying to accommodate the surge in new clients, recovery programs and addiction specialists across the country have vowed to help out. Some of the nation's largest treatment centers have offered to provide free transportation and accommodations, while smaller groups have donated Big Books and supplies, and individual physicians have gone to the devastated areas to work as volunteers. Coverage of the latest developments and ways to help begins on page 5.

## ASAM's State of the Art Course to Meet in DC

Dr. Paul Greengard of The Rockefeller University, who received the Nobel Prize for Medicine in 2000 for his groundbreaking work on signal transduction in the nervous system, will deliver the opening lecture at ASAM's 2005 Course on the State of the Art in Addiction Medicine. The course, which focuses on cutting-edge scientific developments and their implications for clinical practice, has been scheduled for October 27-29, 2005, at the Hyatt Regency Capitol Hill Hotel in Washington, DC. The course is accompanied by a Buprenorphine Training Course on Sunday, October 30th at the same hotel.

Co-chaired by Shannon C. Miller, M.D., CMRO, FASAM, and Martha J. Wunsch, M.D., FAAP, the

course is designed to meet the needs of addiction specialists who seek an update on recent developments in addiction research and practice; researchers; educators who are tasked with translating science to services, and physicians, nurses, counselors and others who seek a succinct review of the latest knowledge about the causes, identification, and management of addictive disorders.

To register for the State of the Art Course, phone the ASAM Department of Conferences and Meetings at 301/656-3920 or consult the ASAM web site at [WWW.ASAM.ORG](http://WWW.ASAM.ORG). Questions about the course should be emailed to [SOACOURSE@AOL.COM](mailto:SOACOURSE@AOL.COM).

*(Coverage continues on page 14.)*

## "ASAM Is About Leadership"

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



*Eileen McGrath, J.D.*

I recently joined leaders from Federal agencies and other addiction organizations at a briefing by Stephen Pasierb, M.Ed., President & CEO of the Partnership For A Drug-Free America. Mr. Pasierb gave us an advance look at data from a recent Partnership study of young peoples' attitudes toward and use of prescription drugs for non-medical purposes. (The study is part of the Partnership's national education campaign on prescription and OTC drug abuse, which will be released in the Fall of 2005 as part of its "Partnering with Families" initiative.)

As you know, recent national surveys have reported dramatic increases in the non-medical use of prescription medications. In an effort to understand the reasons for the increased use, the Partnership for a Drug-Free America conducted a study to evaluate the awareness, knowledge, attitudes and behavior of young people toward prescription drugs with abuse potential.

The Partnership study focuses on adolescents' attitudes toward the availability of various prescription medicines and their perceptions of the risks involved in abusing those substances. Unfortunately, the data show that many young people view such misuse as a relatively benign activity, especially in comparison with their views of the risks involved in abusing illicit drugs like heroin and cocaine.

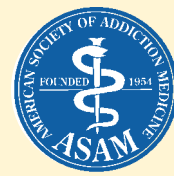
The study also provides insights into previously unrecognized reasons teens abuse drugs:

While the majority still say they did so for psychoactive effects, a growing number say they use such drugs to self-medicate for depression and stress, or to improve their performance in academic and athletic activities. The study also examined parents' awareness of and attitudes toward their children's prescription medicine abuse and found that many parents are shockingly ill-informed.

As I listened to the report, I realized that this is yet another area where ASAM has assumed a leadership role. Through our publications and conferences, your Society is reaching out to physicians and other health care professionals with fact-based advice on screening and counseling adolescents about their drug use. In fact, a session at the forthcoming ASAM Course on the State of the Art in Addiction Medicine will showcase the Partnership data and related research (see page 14 of this issue for the date and time). ASAM also has submitted an application to the Center for Substance Abuse Treatment for funds to develop a training course for physicians who prescribe drugs with abuse potential, modeled after our hugely successful Buprenorphine Training Courses.

This is another way in which ASAM works to serve its members, our professional colleagues, and the public. Please think about this the next time someone asks: "What is ASAM about?" You can answer with pride: "ASAM is about leadership."

***For more information about young peoples' use of prescription medications, visit the website of the Partnership For A Drug-Free America ([www.drug-free.org](http://www.drug-free.org)), or see the report by Richard Kadison in the September 15th issue of The New England Journal of Medicine ("Getting an Edge — Use of Stimulants and Depressants in College"), which can be viewed at [WWW.NEJM.ORG](http://WWW.NEJM.ORG).***



### **American Society of Addiction Medicine**

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

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

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is an official publication of the American Society of Addiction Medicine.

It is published six times a year.

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#### **Web Site**

For members visiting ASAM's web site ([WWW.ASAM.ORG](http://WWW.ASAM.ORG)), entrance to the on-line Membership Directory requires the Username "asam" and the password "asam" (in lower case letters).

## Lawsuit Prompts State to Investigate Patient Deaths

In the wake of a \$2.8 million jury award to the family of a Kentucky man who died while enrolled in an opioid treatment program, Kentucky regulators are taking the first steps toward monitoring the deaths of such patients. "There is no investigation process for the state with the death of a client," said Mac Bell, administrator for the Kentucky State Narcotic Authority, which oversees 11 methadone maintenance programs in the state. Bell said his office has no legal jurisdiction to investigate deaths reported to his agency.

Following an August trial in a wrongful-death lawsuit, a jury decided that the Hazard Professional Associates clinic — but not a physician and nurse named in the suit — was negligent in the 2002 death of Jason Caldwell, 21, of Leslie County, Kentucky. A former coal miner, Caldwell was injured in an auto crash and ultimately became addicted to OxyContin®, according to Gary C. Johnson, a Pikeville attorney who represented Caldwell's estate. Caldwell entered the Hazard clinic for treatment of his opioid addiction, but died five days later after receiving methadone, Johnson said.

Johnson and his co-counsel, Kenneth Hyden, argued that the clinic had administered too much methadone too fast. Defense attorneys countered that Caldwell supplemented the liquid methadone he received at the clinic with methadone tablets he bought from street dealers. While physician Ashok Jain of Pittsburgh and nurse Tammy Cornett were absolved of blame, the jury found for the plaintiffs, ordering the clinic to pay \$1.8 million to Caldwell's mother and \$1 million to his four-year-

old son. Attorneys, however, said they settled the case for lesser, undisclosed amounts before the jury announced its decision.

"We were certainly shocked by the jury's verdict, particularly since they found neither the doctor or the nurse to have been at fault," said H. Brent Brennenstuhl, a Bowling Green attorney who represented all of the defendants. "Had we not agreed to a settlement that was substantially less than the verdict, we would absolutely appeal it," Brennenstuhl added.

Narcotic Authority administrator Bell said his agency receives reports of about five deaths a year at opioid treatment programs in Kentucky. He added that the overall number of methadone patients is rising across the state, with as many as 1,800 patients currently undergoing methadone treatment. While state law doesn't allow his agency to conduct a criminal investigation in such cases, he said the agency plans to begin compiling data on the deaths. "Now, since we've gotten so large, we are in the process — and have been for the last year — of implementing a data collection system that will look at mortality and morbidity rates in our state," he added.

The Hazard clinic is one of several in Kentucky operated by Bowling Green Professional Associates PLC, which is owned by two licensed practical nurses. Administrator Bell said the clinics are among the nine privately-owned methadone clinics that have opened in the state since 1995, when Kentucky first began regulating them. There also are public clinics in Lexington and Louisville.

## CSAT Addresses Liability Risks

*In response to increasing reports of lawsuits and other actions against opioid treatment providers, the Center for Substance Abuse Treatment is offering a series of workshops on "Managing Individual and Program Liability Risk." There is no charge for the workshops, which are offered on a regional basis. See page 24 for more information.*

## Treatment Benefits for Military Personnel Urged

A pair of bills designed to improve addiction treatment services delivered by the Departments of Defense and Veterans' Affairs have been introduced in the U.S. House of Representatives, according to a report by the Legal Action Center.

Both H.R. 2131, the New GI Bill of Rights for the 21st Century Act, and H.R. 1588, the Comprehensive Assistance for Veterans Exposed to Traumatic Stressors Act of 2005, would require the development and use of appropriate addiction treatment protocols in combat zones and in the United States. The measures also call for screening for substance use disorders to be included in pre-deployment and post-deployment health assessments.

The bills also would require the Secretaries of Defense and Veterans Affairs to jointly establish a Council on Post-Deployment Mental Health to review the continuum of care between the two departments' health systems to identify any gaps in treatment capacity.

H.R. 2131, introduced by Representative Chet Edwards (D-TX) and 156 Democratic co-sponsors, has been referred to the Committees on House Veterans' Affairs, Ways and Means, and Armed Services for review.

H.R. 1588, introduced by Congressman Lane Evans (D-IL) with 60 Democratic co-sponsors, has been referred to the Veterans' Affairs Subcommittee on Health and the Armed Services Committee for review.

Source: Legal Action Center.

## SAMHSA to Expand National Registry of Evidence-Based Programs

The Substance Abuse and Mental Health Services Administration (SAMHSA) has announced its intention to expand the National Registry of Evidence-based Programs and Practices (NREPP). In the formal announcement, published August 26th in the *Federal Register*, SAMHSA Administrator Charles Curie noted that NREPP has become a nationally recognized tool for identifying and promoting effective interventions to prevent and treat substance abuse. He said that the proposed expansion "will create a national resource for the latest information on the scientific basis and practicality of interventions to prevent and/or treat mental and substance use disorders."

The *Federal Register* notice and supporting documents are available through the SAMHSA website at [www.samhsa.gov](http://www.samhsa.gov). Click on "National Registry of Evidence-based Programs and Practices FRN" under the "Quick Picks" section on the SAMHSA home page. Written comments in response to the *Federal Register* notice should be sent by regular mail to SAMHSA c/o NREPP Notice, 1 Choke Cherry Road, Rockville, MD 20857 or by email to [nrepp.comments@samhsa.hhs.gov](mailto:nrepp.comments@samhsa.hhs.gov).

## ASAM'S BOARD ACTS TO CLARIFY MEMBERSHIP CRITERIA

Louis E. Baxter, Sr., M.D., FASAM  
Chair, ASAM Constitution  
& Bylaws Council



Dr. Louis E. Baxter, Sr.

At their meetings in January, April, and July 2005, members of the ASAM Board of Directors adopted several important changes to the Society's Bylaws that affect eligibility for membership and the use of terms to describe a member's status.

**CRITERIA FOR ACTIVE MEMBERSHIP:** The Board approved several additions to the membership criteria with regard to medical licensure. First, the Board stipulated the following standards for a "valid medical license":

"Active members shall maintain a valid active allopathic or osteopathic medical license or certification of residency, fellowship, or student status. A valid active medical license shall be issued by the appropriate agency and shall certify that a physician is permitted to practice medicine within that country, province or state. The Society shall consider a medical license to be valid where stipulations and/or conditions have been placed on the license. The Society shall not consider a license to be valid if it has been revoked, suspended, surrendered, or made subject to a sanction similar or equivalent to revocation, suspension, or surrender, until such time as (1) the physician has notified ASAM that the sanction has expired or been removed, and (2) ASAM has confirmed the expiration or removal of the sanction with the state licensing board.

*These provisions shall apply equally to all licenses held by a physician.* All active members shall submit the required dues and license certification at the time of joining, rejoining, or renewing, or shall forfeit membership."

Second, the Board addressed the use of the honorary designation "Fellow" by physicians whose license(s) have become invalid, as follows:

"In the event that any license held by the member is revoked, suspended, or surrendered, or made subject to a sanction similar or equivalent to revocation, suspension, or surrender, the Fellow designation may not be used until the member is reinstated by

the licensing board and applies for and regains active membership status in ASAM."

Third, the Board addressed the use of "Fellow" designation by Retired and Emeritus members, as follows:

"In the event of the member's change to inactive status as a result of conversion to Retired or Emeritus membership, the designations "Retired Fellow" or "Emeritus Fellow" may be used.

### **PUBLIC STATEMENTS AND REFERENCES TO ASAM MEMBERSHIP AND HONORS:**

Chapter IX of the Bylaws, among other things, addresses the important question of statements made by an individual member of ASAM who is either serving as ASAM's representative or has identified himself publicly (orally or in writing) as a member of ASAM. Chapter IX states that:

"No member or Chapter of the Society shall, except as outlined in Section 2, make public statements in the name of the Society without prior consent of the Board. Individual members may mention their membership in public statements or scientific

publications, but shall state that their views do not necessarily represent those of the Society."

In 2005, the Board confirmed the following additional policy to ensure that all members represent themselves and the Society accurately:

"References to the member's status in and association with ASAM in any format (e.g., public media, advertisements, CVs, citations) must be so worded as to convey accurately any honors or credits conferred by ASAM, such as Fellow status, awards, certification, or CME training."

### **REFERENCES TO "CERTIFICATION" OR "BOARD" STATUS:**

Since the time of ASAM's first Certification Examination in 1987, members occasionally have referred to themselves in public as "board certified" in Addiction Medicine. It is important to distinguish ASAM's certification from board certification. ASAM is not recognized as a board by the American Board of Medical Specialties. It is appropriate to state that the member is "certified in Addiction Medicine" by ASAM.

Further, a certificate which shows completion of an ASAM continuing medical education course does not constitute certification and does not "certify" the recipient in a particular subject. When these inaccuracies appear on websites, in CVs or in published articles, they can lead to false impressions.

The Constitution & Bylaws Council members thought it important to draw attention to these amendments and will from time to time present in these pages information related to specific events or policies.

Should you have questions about any of these changes to the Bylaws, please contact ASAM Executive Vice President Eileen McGrath by phone at 301/656-3920 or by email at [EMCGRATH@ASAM.ORG](mailto:EMCGRATH@ASAM.ORG).

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*Dr. Baxter is Senior Medical Director of the Physician Health Program of the Medical Society of New Jersey. He also is a member of the ASAM Board of Directors, representing Region III.*



## Survivors' Needs Strain Treatment System

At the Baton Rouge Treatment Center, people suffering a unique, hurricane-related misery have poured in by the hundreds, waiting as long as two hours each day to be seen. The center is one of the few places remaining in Louisiana where they can receive methadone. Without it, they face a harrowing withdrawal certain to compound their already considerable despair.

The suffering of addicts might not garner much public sympathy in the face of the overwhelming agony stirred by Hurricane Katrina, but some say it's a plight that should not be ignored. "They're people. Don't we care about the people?" said Kathleen Kane-Willis, a Roosevelt University researcher who has pushed for greater aid for displaced heroin addicts. "Why should we make a judgment that the people who use drugs aren't deserving of care?"

Help for these people and their caregivers is coming, and from multiple sources. SAMHSA Administrator Charles Curie has said the Federal government has released \$600,000 to help pay for treatment for displaced people. More money will be available as Congress passes additional disaster relief funds, he added.

Addiction medicine specialists, counselors and treatment centers across the country are trying to fill the void left by the disaster, bringing in supplies, volunteering their services, even offering free residential care to refugees. "We are admitting a 19-year-old girl who was in a treatment center in New Orleans and was displaced," said John Schwarzlose of the Betty Ford Center in California. "She went from there to a shelter. I don't know if she's been drinking and using. We'll find out when she gets here."

Administrator Curie said the hurricane could harm more than those who lost their treatment programs. History shows that trauma causes drug and alcohol problems for other people — including police, medics and other first responders — to increase. "We can anticipate...spikes in abuse after an event like this," he added.

**Status of OTPs in Louisiana.** The following list of opioid treatment programs affected by Hurricane Katrina is based on information provided by the Center for Substance Abuse Treatment (CSAT).

While this information was accurate at press time, the operational status of any program is subject to change. Addresses of the OTPs can be found at [WWW.DPT.SAMHSA.GOV](http://WWW.DPT.SAMHSA.GOV) under "Directory":

- DRD New Orleans Medical Clinic: All necessary identification and dosing information relative to patients of the DRD New Orleans Medical Clinic can be ascertained by phoning 800/447-8801 and asking for Janet or Laura.
- The Veterans Affairs Medical Center — New Orleans has an emergency agreement with the Houston Veterans Administration Hospital Out-patient Drug Treatment Program on Holcombe Blvd., Houston, Texas, and has all of the patient information needed to continue treatment. Phone 713/791-1414 x 3384 for treatment or patient information. (Although this clinic only treats veterans, staff will assist in the referral of evacuees to local programs in close proximity to the Houston location or elsewhere.
- Lake Charles Substance Abuse Clinic is currently open and treating patients (337/433-8281)
- Baton Rouge Treatment Center is currently open and treating patients (225/932-9867)
- Choices of Louisiana, LaPlace is currently open and treating patients (225/715-2961)
- Center for Behavioral Health, Shreveport is currently open and treating patients (318/425-3400)
- Choices of Louisiana, Alexandria is currently open and treating patients (318/792-6520)
- Opiate Replacement Therapy Center of America, Breaux Bridge, Louisiana, is open and treating patients (337/332-4878)
- Desire Narcotics Rehabilitation Center, New Orleans, is CLOSED (504/583-2428)
- Oscar E. Carter Jr. Memorial Rehabilitation Center, New Orleans, is CLOSED (504/949-2767)
- Metropolitan Treatment Center, New Orleans, is CLOSED (504/486-6277)
- New Orleans Narcotic Treatment Clinic at West Bank is CLOSED (504/347-1120)
- New Orleans Center for Addictive Disorders is CLOSED (504/568-7953)

### ATTCS OFFER SPECIAL TRAINING

*In response to Hurricane Katrina, addiction professionals and other health care providers have taken on the monumental task of helping survivors cope with acute stress and trauma while managing those same feelings themselves.*

*To support these efforts, the Addiction Technology Transfer Center (ATTC) Network is offering lecture-based conference calls and other information to help caregivers deal with traumatic stress in their patients and themselves. The calls are led by Dr. Mark Lerner, president of the American Academy of Experts in Traumatic Stress ([WWW.AAETS.ORG](http://WWW.AAETS.ORG)).*

*To access the information, visit the ATTC website at [WWW.ATTC.ORG](http://WWW.ATTC.ORG), or contact either Laurie Krom ([KROML@NATTC.ORG](mailto:KROML@NATTC.ORG)) or Mary Beth Johnson ([MBJ@NATTC.ORG](mailto:MBJ@NATTC.ORG)) at the ATTC National Office (816/482-1200).*

## Guidelines for Treating OTP Patients from the Hurricane-Affected Areas

*CSAT Director H. Westley Clark, M.D., J.D., M.P.H., FASAM, has issued the following guidelines to opioid treatment programs (OTPs) that accept patients dislocated by Hurricanes Katrina and Rita:*



**Evacuees Currently Enrolled in Opioid Treatment.** Every effort should be made to contact the person's home program. Information is available via the SAMHSA Substance Abuse Treatment Facility Locator at [HTTP://DASIS3.SAMHSA.GOV](http://DASIS3.SAMHSA.GOV). If the patient's home program cannot be reached, the following procedures should be used, in combination with any existing emergency plans:

1. The emergency guest patient should show a valid picture identification which includes an address in close proximity to the area affected by the hurricanes.
2. The patient should show some type of proof that he or she was receiving services from a clinic located in one of the affected areas, such as a medicine bottle, program identification card, receipt for payment of fees, etc. If the patient does not have such items, program staff should use their best judgment — combined with a stat drug test — to assess the presence of methadone.
3. An OTP may administer the amount of medication that the patient reports as his or her current dose; however, each patient should be reminded that the dose reported will be verified with the home program as soon as possible. Where the reported dose appears questionable, staff should use their own medical judgment in determining the dose level.
4. Emergency guest patients should be medicated daily, with take-home doses provided only for days that the program is closed (Sundays and holidays). If the patient's current take-home status can be verified, take-home doses may be provided in accordance with State and Federal regulations (42 CFR Part 8). If a patient is unable to travel to the program daily due to a medical problem or other hardship, take-home medication for unsupervised use may be considered via the SMA-168 Request for Exception process.
5. Documenting guest patient services should be a priority for OTPs. Each guest patient should be assigned a clinic identification number and issued a temporary chart. Reasonable efforts should be made to periodically contact the patient's home program to verify patient information before medication is dispensed. The results should be recorded in the temporary chart. The OTP should record the day, date and amount of medication administered to each patient, along with any observations made by the staff. As time passes, some patients may elect to remain in treatment at the host facility and change from guest to permanent status. Upon conclusion of the emergency treatment period, a summary of the total number of patients treated, services rendered, and disposition of patients seen should be submitted to CSAT and the State Methadone Authority. (Additional information may be forthcoming.)

**Availability of Methadone and Buprenorphine.** CSAT is in communication with the Drug Enforcement Administration (DEA) regarding the availability of methadone and has been assured that DEA will be flexible about program-to-program transfers of medication to address shortages. Mallinckrodt Inc., Ceberth Pharmaceuticals, Inc., and Vista Pharm have agreed to make methadone available to programs serving hurricane evacuees.

For additional information, contact Robert Lesnick at Mallinckrodt (847/ 247-6230), Royce Watkins at Ceberth (800/211-0589), and John Freeman at Vista Pharm (205/ 981-1387). For information about buprenorphine (Suboxone® and Subutex®), contact Reckitt-Benckiser (804/379-1090).

**Evacuees Not Currently In Treatment.** Persons who are dependent on opioids may seek help as a result of the disruption in supply of street drugs. OTPs may admit, treat and dose these patients under existing guidelines and regulations. Patients new to medication-assisted therapy may be appropriate for initiation on buprenorphine products. CSAT can facilitate the Drug Enforcement Administration (DEA) registration of the OTP to use buprenorphine and Reckitt-Benckiser can ship the medication directly to the program. Programs seeking such assistance should contact Nick Reuter, M.P.H., at CSAT (240/ 276-2716).

**Evacuees Being Treated for Pain.** OTPs have been contacted by evacuees who were being treated with methadone for pain and now out of medication. The first response should be to refer the patient to a local physician, particularly a pain management specialist. Additionally, the CSAT accreditation guidelines (available at [www.dpt.samhsa.gov](http://www.dpt.samhsa.gov)) provide the following guidance:

- Patients generally are not admitted to OTPs to receive opioids only for pain.
- Patients with a chronic pain disorder **and** physical dependence are managed by multidisciplinary teams that include pain and addiction medicine specialists. The site of such treatment may be either a medical clinic or an OTP, depending on patient needs and the best utilization of available resources.
- Similarly, addiction patients maintained on methadone/buprenorphine are not prohibited from receiving needed medications for pain, including adequate doses of opioid analgesics.
- Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving methadone or buprenorphine therapy for either maintenance or withdrawal in an OTP if such a setting provides expertise or is the only source of treatment.

**Other Information.** Questions about issues not covered in the guidelines should be directed to Nick Reuter, M.P.H., or Todd Rosendale of CSAT's Division of Pharmacologic Therapies (240/276-2700).

*The website of the Substance Abuse and Mental Health Services Administration (SAMHSA) offers information and links to resources for clinicians and other personnel working with Hurricane Katrina and Hurricane Rita survivors. The information can be accessed at [WWW.SAMHSA.GOV](http://WWW.SAMHSA.GOV).*

## HOW YOU CAN HELP

Federal offices have asked those who wish to help hurricane survivors not to travel to the affected states, but instead to make cash donations to helping organizations. FEMA (the Federal Emergency Management Agency, at [WWW.FEMA.GOV](http://WWW.FEMA.GOV)) lists the following agencies as in need of cash to help hurricane victims:

- ✓ American Red Cross, 800/HELP NOW (435-7669) English, 800/257-7575 Spanish.
- ✓ Operation Blessing, 800/436-6348.
- ✓ America's Second Harvest, 800/344-8070.
- ✓ Adventist Community Services, 800/381-7171.
- ✓ Catholic Charities, USA, 703/549-1390.
- ✓ Christian Disaster Response, 941/956-5183 or 941/551-9554.
- ✓ Christian Reformed World Relief Committee, 800/848-5818.
- ✓ Church World Service, 800/297-1516.
- ✓ Convoy of Hope, 417/823-8998.
- ✓ Lutheran Disaster Response, 800/638-3522.
- ✓ Mennonite Disaster Service, 717/859-2210.
- ✓ Nazarene Disaster Response, 888/256-5886.
- ✓ Presbyterian Disaster Assistance, 800/872-3283.
- ✓ Salvation Army, 800/SAL-ARMY (725-2769).
- ✓ Southern Baptist Convention — Disaster Relief, 800/462-8657 x 6440.
- ✓ United Methodist Committee on Relief, 800/554-8583.

In addition, Steve Wyatt, D.O., has forwarded the following message from Samantha Hope-Atkins of Hope Networks, an advocacy organization: "People in recovery in New Orleans and the Gulf Coast need our help. Several local recovery advocates are working to respond to these needs, and they have issued a call for help in locating the following:

- A central point of contact (if possible, a toll-free hotline that actually has services readily available for those calling the number).
- Medical detoxification services for patients experiencing life-threatening withdrawal and those with co-occurring medical or psychiatric and addictive disorders.
- Post-detoxification treatment and recovery support placement.
- Transportation and case management services, including vital supports such as child care and elderly care.
- Public outreach and information and media support (PSAs, billboards, PR services).

Those interested in offering assistance may contact:

Samantha-Hope Atkins  
 Direct: 225-806-8552  
 Landline: 225-769-7867  
 Email: [SAM@HOPENETWORKS.ORG](mailto:SAM@HOPENETWORKS.ORG)

Ms. Hope-Atkins adds that "our servers are gone from the storm; however I am building a temp site at [www.hopenetworks.org](http://www.hopenetworks.org) to serve as a centralized clearinghouse for resources as they become available. At present, we are focused on primary detox, and securing donated transportation and beds for treating those with immediate needs.

"The void of services is enormous, we are doing what we can to

respond as waiting for government resources is not an option. For the medical detox needs we have urgent need for we have made some immediate progress. We will be providing the resources we are able to gather to the state agencies and ER's to provide support and relief for those with needs at this present time.

"Dr. Al Mooney has volunteered to come to Baton Rouge with others from North Carolina, and is will bring the basic medications needed for safe detoxification (donated by companies there). He is traveling in a motor home and we are coordinating with local folks for actual bed space to set up a triage medical detox unit, which is better than the present situation. The heart and soul of recovery is motion, and words can't express our gratitude for the help we have received.

"I have spoken to several folks who are working to link us with private treatment centers that wish to offer beds and transportation. The Betty Ford Center has opened that door for us, and we are so grateful for their quick response and willingness to help. Thank you so much!"

### *Letter from Louisiana*

*A. Kenison Roy III, M.D., FASAM*

Dear Colleagues:

Many people have asked me, "What can I do to help?" I have discussed this with people in my family and others and have decided to support a person-to-person "Adopt a family" approach to the need for help and the desire to help. The idea came when my wife described the plight of a former co-worker who lived in St. Bernard Parish and evacuated with her two children and the clothes on their backs. Her employment has moved to the same town to which she evacuated (Baton Rouge), but she has no housing, no clothes, no necessities of life. Pat has asked our son's fraternity to adopt this family so that the help she receives will be personalized and effective (their needs include an Internet connection for one of her children, who has a job that requires Internet access, clothes for school, and kitchenware.)

The idea is to ask a committee formed by my family and other community volunteers to identify working people and families in circumstances similar to the family described above, and to connect people who want to help directly with those families. Then the interaction would be between the recipient and the helper and can be personal and appropriate to the specific family devastated by Katrina.

If you are interested in this effort, please email Patricia Lilly Roy at [KATRINACONNECT@AOL.COM](mailto:KATRINACONNECT@AOL.COM). No funds will be solicited. Pat and her committee will give you contact information for one family and you can reach out to that family directly and assist as you are able and inclined.

Sincerely, Ken Roy

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*Dr. Roy is Medical Director of Addiction Recovery Resources of New Orleans (ARRNO) and Secretary of ASAM's Board of Directors. He can be reached at [WWW.ARRNO.ORG](http://WWW.ARRNO.ORG).*

# Treat the Condition

## Opioid Dependence Is a Chronic Medical Condition

Long-term, fundamental changes to structure and function of the brain occur.<sup>1,2</sup>



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

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

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

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

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

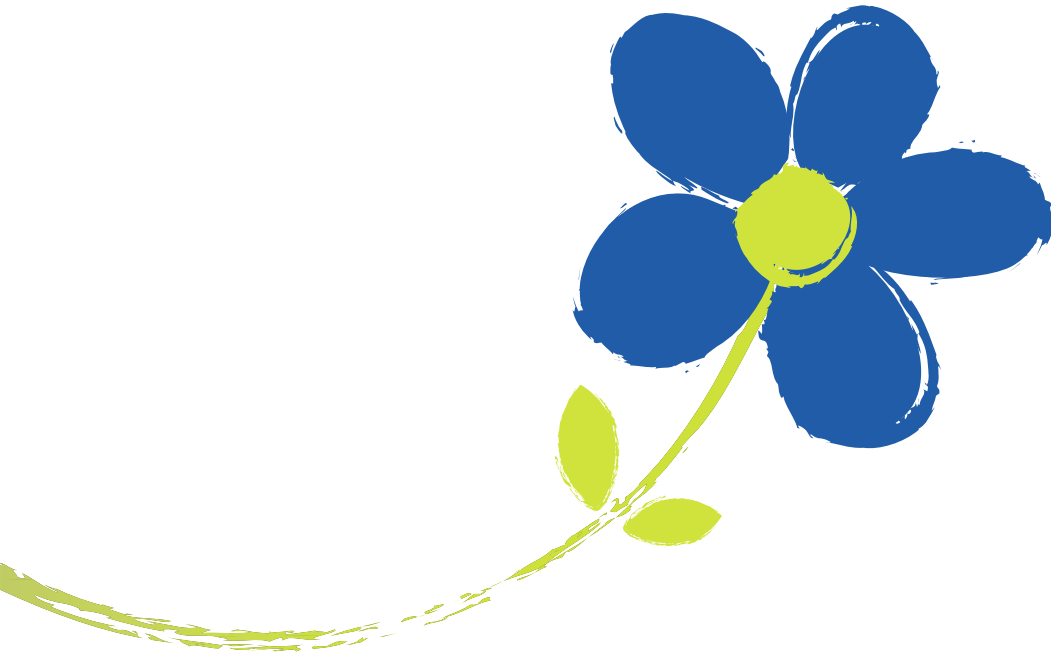
The most commonly reported adverse events with SUBOXONE include: headache (36%, placebo 22%), withdrawal syndrome (25%, placebo 37%), pain (22%, placebo 19%), nausea (15%, placebo 11%), insomnia (14%, placebo 16%), and sweating (14%, placebo 10%).

**Please see adjacent Brief Summary of Prescribing Information.**

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



# *Transform the Life*



## **In the Privacy and Convenience of Your Office**

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

## **Target the Biological Basis of Opioid Dependence**

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

**To learn more, call 1-877-SUBOXONE or visit [suboxone.com](http://suboxone.com)**

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

***Suboxone***<sup>®</sup>  
(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 parentally, 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 parentally 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/m<sup>2</sup> basis) for 27 months. Statistically significant dose-related increases in testicular interstitial (Leydig's) cell tumors occurred, according to the trend test adjusted for survival. Pair-wise comparison of the high dose against control failed to show statistical significance. In an 86-week study in CD-1 mice, buprenorphine was not carcinogenic at dietary doses up to 100 mg/kg/day (estimated exposure was approximately 30 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> 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 [<sup>3</sup>H]thymidine, and positive in unscheduled DNA synthesis (UDS) test using testicular cells from mice.

**Impairment of Fertility:** SUBOXONE: Dietary administration of SUBOXONE in the rat at dose levels of 500 ppm or greater (equivalent to approximately 47 mg/kg/day or greater; estimated exposure was approximately 28 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) produced a reduction in fertility demonstrated by reduced female conception rates. A dietary dose of 100 ppm (equivalent to approximately 10 mg/kg/day; estimated exposure was approximately 6 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) had no adverse effect on fertility.

SUBUTEX: Reproduction studies of buprenorphine in rats demonstrated no evidence of impaired fertility at daily oral doses up to 80 mg/kg/day (estimated exposure was approximately 50 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) or up to 5 mg/kg/day *im* or *sc* (estimated exposure was approximately 3 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis).

**Pregnancy: Pregnancy Category C:**

**Teratogenic effects:** SUBOXONE: Effects on embryo-fetal development were studied in Sprague-Dawley rats and Russian white rabbits following oral (1:1) and intramuscular (3:2) administration of mixtures of buprenorphine and naloxone. Following oral administration to rats and rabbits, no teratogenic effects were observed at doses up to 250 mg/kg/day and 40 mg/kg/day, respectively (estimated exposure was approximately 150 times and 50 times, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis). No definitive drug-related teratogenic effects were observed in rats and rabbits at intramuscular doses up to 30 mg/kg/day (estimated exposure was approximately 20 times and 35 times, respectively, the recommended human daily dose of 16 mg on a mg/m<sup>2</sup> 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/m<sup>2</sup> basis). In the rabbit, increased post-implantation losses occurred at an oral dose of 40 mg/kg/day. Following intramuscular administration in the rat and the rabbit, post-implantation losses, as evidenced by decreases in live fetuses and increases in resorptions, occurred at 30 mg/kg/day.

SUBUTEX: Buprenorphine was not teratogenic in rats or rabbits after *im* or *sc* doses up to 5 mg/kg/day (estimated exposure was approximately 3 and 6 times, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis), after *iv* doses up to 0.8 mg/kg/day (estimated exposure was approximately 0.5 times and equal to, respectively, the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis), or after oral doses up to 160 mg/kg/day in rats (estimated exposure was approximately 95 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) and 25 mg/kg/day in rabbits (estimated exposure was approximately 30 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis). Significant increases in skeletal abnormalities (e.g., extra thoracic vertebra or thoraco-lumbar ribs) were noted in rats after *sc* administration of 1 mg/kg/day and up (estimated exposure was approximately 0.6 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis), but were not observed at oral doses up to 160 mg/kg/day. Increases in skeletal abnormalities in rabbits after *im* administration of 5 mg/kg/day (estimated exposure was approximately 6 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) or oral administration of 1 mg/kg/day or greater (estimated exposure was approximately equal to the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis) were not statistically significant.

In rabbits, buprenorphine produced statistically significant pre-implantation losses at oral doses of 1 mg/kg/day or greater and post-implantation losses that were statistically significant at *iv* doses of 0.2 mg/kg/day or greater (estimated exposure was approximately 0.3 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis).

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

**Non-teratogenic effects:** Dystocia was noted in pregnant rats treated *im* with buprenorphine 5 mg/kg/day (approximately 3 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis). Both fertility and peri- and postnatal development studies with buprenorphine in rats indicated increases in neonatal mortality after oral doses of 0.8 mg/kg/day and up (approximately 0.5 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis), after *im* doses of 0.5 mg/kg/day and up (approximately 0.3 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis), and after *sc* doses of 0.1 mg/kg/day and up (approximately 0.06 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> basis). Delays in the occurrence of righting reflex and startle response were noted in rat pups at an oral dose of 80 mg/kg/day (approximately 50 times the recommended human daily sublingual dose of 16 mg on a mg/m<sup>2</sup> 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<br>N=107 | SUBUTEX 16 mg/day<br>N=103 | Placebo<br>N=107 |
|--|-----------------------------|----------------------------|------------------|
| <b>Body as a Whole</b>                           |                             |                            |                  |
| 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%)       |
| <b>Cardiovascular System</b>                     |                             |                            |                  |
| Vasodilation                                     | 10 (9.3%)                   | 4 (3.9%)                   | 7 (6.5%)         |
| <b>Digestive System</b>                          |                             |                            |                  |
| 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%)         |
| <b>Nervous System</b>                            |                             |                            |                  |
| Insomnia   | 15 (14.0%)                  | 22 (21.4%)                 | 17 (15.9%)       |
| <b>Respiratory System</b>                        |                             |                            |                  |
| Rhinitis   | 5 (4.7%)                    | 10 (9.7%)                  | 14 (13.1%)       |
| <b>Skin and Appendages</b>                       |                             |                            |                  |
| 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*<br>(N=184) | Low*<br>(N=180) | Moderate*<br>(N=186) | High*<br>(N=181) | Total*<br>(N=731) |
|   | N (%)                | N (%)           | N (%)                | N (%)            | N (%)             |
| <b>Body as a Whole</b>                          |                      |                 |                      |                  |                   |
| 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%)         |
| <b>Digestive System</b>                         |                      |                 |                      |                  |                   |
| 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%)           |
| <b>Nervous System</b>                           |                      |                 |                      |                  |                   |
| 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%)           |
| <b>Respiratory System</b>                       |                      |                 |                      |                  |                   |
| 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%)          |
| <b>Skin and Appendages</b>                      |                      |                 |                      |                  |                   |
| Sweat   | 23 (13%)             | 21 (12%)        | 20 (11%)             | 23 (13%)         | 87 (12%)          |
| <b>Special Senses</b>                           |                      |                 |                      |                  |                   |
| 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  
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#138274BS July 2005

## IOM Report Identifies Ethical Issues in Addiction Treatment



At the request of the National Institute on Drug Abuse, the National Research Council's Institute of Medicine (IOM) has completed a study of the ethical, legal, and behavioral issues that must be considered in the development and application of active and passive immunotherapies and sustained-release medications for the prevention and treatment of addiction. The IOM's conclusions underscore the need to balance therapeutic benefits and ethical considerations, particularly if the person receiving treatment — a minor child or a person involved in the criminal justice system, for example — is not the person who chooses it. The conclusions are presented in a 306-page report, accompanied by recommendations for a set of guiding principles for NIDA-supported research.

In its report, IOM says the development of immunotherapy and sustained-release medications highlights the need to understand addiction as a chronic medical condition that requires long-term management, a partnership between primary medical care and addiction treatment, and integration of psychosocial services into the treatment environment. The IOM report recommends that NIDA support models that integrate the new pharmacotherapies with psychosocial services in addiction treatment and primary care settings that reduce the stigma of substance abuse treatment.

The report recommends studies that can be used to establish clear guidelines for use of the new therapies in circumstances that are inherently coercive or nonconsensual, such as in the criminal justice system, child welfare cases, or the protective immunization of minor children. What, for example, are the possible legal consequences of administering immunotherapy medications to children or adolescents? Competent adults have the right to decline medical treatment, but the legal situation is more complicated when the patient is a minor and decisions made by others on his or her behalf may have a lifelong effect. Immunotherapies will leave long-lasting biological traces that can be detected in routine blood or urine tests. Such markers could label patients as drug abusers long after they have entered sustained recovery, which could discourage some from utilizing these treatments.

The full report, *New Treatments for Addiction: Behavioral, Ethical, Legal, and Social Questions*, is available online AT [WWW.NAP.EDU/CATALOG/10876.HTML](http://WWW.NAP.EDU/CATALOG/10876.HTML). Source: Patrick Zickler, "Institute of Medicine Report Recommends NIDA Research Agenda For New Addiction Therapies," *NIDA Notes*, August 2005.

## IDAA OFFERS HELP TO RECOVERING PHYSICIANS

Donald J. Kurth, M.D., FASAM

With more than 1,000 doctors and their families registered, the 56th annual meeting of International Doctors in Alcoholics Anonymous (IDAA), held in Palm Springs, California in August 2005, exceeded all previous attendance records.

CME and Dental CE, a separate and distinct aspect of the conference, was interspersed with full days of AA, Al-Anon, Ala-teen, and children recovery programs.

In addition to a sober 5K run and golf tournament, specific breakout sessions were available to address interests including Anesthesiology, Couples, CyberGroups, Doctors in Alanon, Dentists, Gay-Lesbian, Flying Docs, Marijuana Anon, NA, Nicotine Anon, OA, Psychiatrists, Psychologists, Re-entry issues, Retired Docs, SA/SAA/SLA, Veterinarians, and Workaholics.

International Doctors in Alcoholics Anonymous is a fellowship of physicians and their

families whose primary purpose is to support one another in recovery from alcoholism and other drug addictions. Membership in IDAA now numbers 4,800 women and men worldwide. Most IDAA members hold M.D. or D.O. degrees, but any individual who holds a doctoral degree in the health professions is eligible, including dentists, pharmacists, psychologists, and veterinarians.

The IDAA organization provides support and encouragement through the study and application of the steps and traditions of Alcoholics Anonymous, the annual IDAA meeting, and education and ongoing network development within the tradition of anonymity. The organization does not provide professional counseling, therapy or treatment.

IDAA strongly supports mainstream AA as the basis for recovery. The organization recognizes that health care professionals

confront special issues — such as patient confidentiality, practice and legal issues — that are difficult to address in open AA meetings. Caduceus groups often are monitored, making it difficult to discuss many issues of concern to the recovering physician, including professional shame and fear of failure, malpractice, financial difficulties and licensure problems. These issues can be addressed in IDAA.

Attending the annual IDAA meeting and interacting with hundreds of other physicians also helps the recovering physician deal with these issues and do whatever is necessary to achieve and maintain sobriety. A significant benefit is the help offered in working with families and getting them into recovery — often breaking the family cycle of addiction.

More information about IDAA is available at [www.IDAA.org](http://www.IDAA.org). The website provides information and resources for prospective and current members, as well as family members and friends, on the organization's mission and activities, the HelpLine, a directory of professional meetings, and links to other resources for recovery. Physicians interested in joining IDAA can register at the website. There are no dues or fees — IDAA is self-supporting through voluntary contributions. The only requirement for membership is a physician's desire to join.

Anonymity is carefully protected: IDAA has one list of members, which is maintained with total confidentiality in the IDAA Central Office. Any communication with individual members occurs only with the permission of both parties. All Internet communication is through IDAA's private server.

IDAA's 2006 annual meeting is scheduled for August in Minneapolis, Minnesota. The meeting promises support for recovery, fellowship, CME credits, and fun: IDAA has it all. Check it out on line, and if you qualify, we hope to see you there in 2006!

*Dr. Kurth is President of the California Society of Addiction Medicine as well as Treasurer of the American Society of Addiction Medicine. He is Chief of Addiction Medicine at the Loma Linda University Behavioral Medicine Center in Redlands, California and holds an appointment as Associate Professor in the Department of Psychiatry at Loma Linda University. He can be reached at [DONKURTH@AOL.COM](mailto:DONKURTH@AOL.COM).*



### Psychiatrist/Addiction Specialist

The Acadia Hospital, a free-standing, not-for-profit facility in Bangor, Maine is seeking a medical director of addiction services. This position involves medical direction of a large methadone maintenance clinic (500 and growing), a buprenorphine induction center, and a very active intensive outpatient substance abuse program.

As a lead agency in the Robert Wood Johnson "Pathways to Recovery" initiative, Acadia enjoys national recognition as a leader in substance abuse treatment. Acadia Hospital is the first free-standing psychiatric hospital in the nation to achieve Magnet status.

Applicants must, at a minimum, be board certified, or actively pursuing certification in general psychiatry as well have obtained or be pursuing ASAM certification or equivalent. Acadia offers a competitive salary and benefit package.



Interested applicants should send CV to:

Paul W. Tisher, MD  
Chief Medical Officer  
The Acadia Hospital  
PO Box 422  
Bangor, Maine  
04402-0422

or email CV to Dr. Tisher  
c/o Debbie Macaulay at  
[dmacaulay@emh.org](mailto:dmacaulay@emh.org)

207/973-6100  
FAX/973-6109

Other employment opportunities listed at:  
[www.acadiahospital.org](http://www.acadiahospital.org)

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## Light Smoking, Heavy Risks

So-called “light” smokers — individuals who smoke fewer than five cigarettes a day — still greatly increase their risk of dying from heart disease or lung cancer, according to Norwegian researchers. A report from the Norwegian Institute of Public Health examined the health and death records of 43,000 men and women who had been screened for heart disease at the beginning of a study that began in the 1970s.

“In both sexes, smoking 1 to 4 cigarettes per day was associated with a significantly higher risk of dying from ischemic heart disease and from all causes, and from lung cancer in women,” said Dr. Aage Tverdal of the Norwegian Institute of Public Health in Oslo.

Male light smokers were three times more likely to die of lung cancer than nonsmokers; female light smokers were five times more likely to die from the disease. *Source: Tobacco Control, September 2005.*

## Opiate Antagonists for Alcohol Dependence: Do They Work?

Many studies have examined the role of opiate antagonists in treating alcohol dependence. To summarize the findings, researchers from the Cochrane Collaboration systematically reviewed all relevant randomized controlled trials (RCTs) of opiate antagonists, including 27 trials involving naltrexone and two trials involving nalmefene. In most trials, subjects also received psychosocial treatment. The review found that:

- \* Most of the identified studies examined short-term (up to 12 weeks) treatment with naltrexone and short-term outcomes. The majority of these studies found that naltrexone, compared with placebo, decreased the risks of returning to heavy drinking (relative risk 0.6, a significant finding) and returning to any drinking (relative risk 0.9, a borderline significant finding).
- \* In the few studies of short-term treatment and medium-term (12 weeks to 52 weeks) outcomes, naltrexone significantly decreased the risk of returning to heavy drinking (relative risk 0.8) but not the risk of returning to any drinking.
- \* Studies that directly compared naltrexone with other drugs (e.g., acamprosate or disulfiram) were inconclusive but generally favored naltrexone.
- \* The few placebo-controlled studies of nalmefene found that short-term treatment with the drug significantly decreased the short-term risk of returning to any drinking (relative risk 0.6). Data on returning to heavy drinking, medium-term treatment, and medium-term outcomes were not reported.

*Source: Srisurapanont M & Jarusuraisin N (2005). Opioid antagonists for alcohol dependence. Cochrane Database System Reviews; Volume 1.*

## Fentanyl Patches Being Abused

Transdermal patches containing a time-released formulation of fentanyl are being diverted to non-medical use at an increasing rate, with a corresponding rise in overdoses, researchers say.

In a report presented to the College on Problems of Drug Dependence, University of Florida researchers warned that such use of the fentanyl patches, usually prescribed to treat chronic or postoperative pain, can be deadly. “Because the patch is a sustained-release form of the drug, if one withdraws the 72 hours’ worth of drug and uses it in a form that it wasn’t designed to be used for, then it can rapidly result in death,” said lead researcher Bruce Goldberger, Ph.D.

Florida officials attributed 115 overdose deaths statewide to the fentanyl patch in 2004. Some victims removed the entire three-day supply of the drug from the patch and then injected, ingested, or smoked it, while others used multiple patches at one time.

“We have seen increased use and abuse of the patch form of fentanyl for the past five years or so,” Dr. Goldberger said. “Based on our study, we’re recommending that physicians better educate their patients on the use of the patch. As a result, we might see lower numbers of fentanyl-related deaths in the State of Florida.”

## Study Finds Beer, Liquor Raise Colon Cancer Risk

A new study shows that people who drink beer and hard liquor are more likely to develop colorectal cancer than non-drinkers, but those who drink wine in moderation appear to have a lower risk of getting the disease. “Alcohol is pernicious with regard to colorectal” tumors, said study author Joseph C. Anderson, M.D., of the State University of New York at Stony Brook. “Lifestyle plays a role, as genetics does, in the development” of tumors, he added.

Dr. Anderson and colleagues found that heavy beer or wine drinkers had more than twice the risk of developing significant colorectal tumors compared to non-drinkers or those who drank in moderation. Conversely, moderate wine drinkers saw their risk of colon cancer cut in half.

“Patients who regularly drink spirits have an increased risk for significant colorectal (tumors) and perhaps should be targeted for risk modification by their gastroenterologist in addition to their primary-care physician,” the researchers noted in their report, published in the *American Journal of Gastroenterology*. Dr. Anderson added: “I would target anyone who has more than one beer or drink per day.”

*Source: Anderson JC et al. (2005). Prevalence and risk of colorectal neoplasia in consumers of alcohol in a screening population. American Journal of Gastroenterology 100(9), 2049.*

## Counseling Can Reduce Young Adults’ Alcohol Use

Researchers have shown that use of brief counseling by primary care physicians can reduce drinking among young adults aged 18 to 30. The study of 226 young adults compared rates of alcohol consumption, traffic crashes, emergency department visits, and arrests for alcohol-related violations among young adults who received physician counseling and those who received no intervention.

Investigators found that — compared to study subjects who did not receive physician counseling — young adults who received counseling reduced their use of alcohol by 40 to 50 percent, had 42 percent fewer visits to the emergency department, and had 55 percent fewer motor vehicle crashes. Alcohol-related arrests also were significantly lower among the counseling group.

Based on these results, the study’s authors recommend that primary care physicians make it a priority to counsel young adults about the risks of drinking.

*Source: Grossberg P, Brown D & Fleming M (2004). Brief physician advice for high-risk drinking among young adults. Annals of Family Medicine 2(5): 474-480.*

## Nobel Laureate, Other Luminaries to Address ASAM's 2005 State of the Art Course

Co-chairs Shannon C. Miller, M.D., FASAM, CMRO, and Martha J. Wunsch, M.D., FAAP, invite all ASAM members and other interested professionals to attend ASAM's 2005 Course on the State of the Art in Addiction Medicine, to be held October 27th - 29th at the Hyatt Regency Capitol Hill Hotel in Washington, DC.

The program — whose theme is *"Addiction Across the Lifespan"* — has been organized in cooperation with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA) of the National Institutes of Health, as well as the Center for Substance Abuse Prevention (CSAP) and the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration. The co-sponsorship of these Federal agencies assures that the course is a centerpiece of addiction medicine education.

Led this year by Nobel Laureate Paul Greengard, Ph.D., of the Rockefeller University, the expert faculty who teach the course are asked to provide a concentrated review of recent scientific advances and how they will influence clinical care. The audience for past courses have been so enthusiastic that many faculty members return every two years for an update. Increasingly, faculty presenters choose to stay for the course beyond their own sessions, affording participants an unparalleled opportunity for networking with leaders in the field.

**COURSE GOALS.** ASAM's Course on the State of the Art in Addiction Medicine provides an important link between cutting-edge scientific research and clinical practice. The course showcases the most recent findings in addiction research, reported by the nation's leading addiction researchers. It is designed specifically for the physician or other professional who seeks an advanced level of understanding of the scientific underpinnings of addiction practice.

**WHO SHOULD ATTEND.** Physicians, medical students and residents, psychologists, nurses, social workers, researchers, educators, and others who need the most up-to-date information on the mechanisms, prevention and treatment of alcohol, tobacco and other drug addictions.

Co-chairs Dr. Wunsch and Dr. Miller invite ASAM members and colleagues to join in one of the few educational events where participants can listen, learn, and ask without distractions or demands, and enjoy the excitement of cutting-edge science, taught by the leaders most outstanding scientists.

## ASAM'S 2005 COURSE ON THE STATE OF THE ART IN ADDICTION MEDICINE

### "Addiction Across the Lifespan"

PROGRAM FOR THURSDAY, OCTOBER 27, 2005

#### SESSION 1 (MORNING).

##### BIOLOGICAL PLASTICITY: RISK AND PROTECTIVE FACTORS

- \* Mechanism of Action of Drugs of Abuse: Cellular and Molecular Studies (*Paul Greengard, Ph.D.*)
- \* Relapse Vulnerability: Neuronal Mechanisms and Clinical Implications (*Yavin Shaham, Ph.D.*)
- \* Biological Risk and Protective Factors: Perspectives from Functional Imaging (*Anna Rose Childress, Ph.D.*)
- \* Clinical Implications of Biological Plasticity: How Can Pharmacological or Behavioral Therapies Affect Synaptic Plasticity in Addiction? (*Peter Kalivas, Ph.D.*)

#### SESSION 2 (AFTERNOON).

##### DEVELOPMENTAL ASPECTS OF ADDICTION

- \* Methamphetamine and Cocaine: Fetal and Perinatal Effects (*Stephen Sheinkopf, Ph.D.*)
- \* Neuroimaging and Understanding Drug Effects in Infants, Children and Adolescents (*Mary Lou Behnke, M.D.*)
- \* Emerging Attitudes Toward and Patterns of Substance Abuse Among Adolescents and Young Adults: Results of a National Survey (*Stephen Pasierb, M.Ed.*)
- \* A Longitudinal Study of College Students: Risk and Resiliency Factors for Alcoholism and Drug Dependence (*Amelia Arria, Ph.D.*)
- \* Dopamine D2 Receptor Availability as a Marker of Cocaine Abuse in an Animal Model: Genetic and Environmental Influences in the Addiction Life Cycle (*Michael Nader, Ph.D.*)

#### SESSION 3 (EVENING).

##### AN UPDATE ON NEW AND PIPELINE ANTI-ADDICTION MEDICATIONS

- \* Acamprosate and Other Medications for Alcohol Addiction and Relapse Prevention (*Bankole Johnson, M.D.*)
- \* Rimonabant (*Robert Anthenelli, M.D.*)
- \* Depot Naltrexone: A First in Addiction Pharmacotherapy (*Helen Pettinati, Ph.D.*)
- \* New and Promising Medications for the Treatment of Cocaine Addiction (*Ahmed Elkashef, Ph.D.*)
- \* Emerging Medications: From the Bench to the Clinic (*Frank Vocci, Ph.D.*)



## PROGRAM FOR FRIDAY, OCTOBER 28, 2005

### SESSION 4 (MORNING).

#### PREDICTING COGENOMICS AND OTHER RECENT DEVELOPMENTS

- \* The Promise of Pharmacogenomics (*Bankole Johnson, M.D.*)
- \* Selecting the Right Medication for Alcoholism: A Clinically Significant Endophenotype (*Charles O'Brien, M.D., Ph.D.*)
- \* Vaccine Therapies (*Paul Pentel, M.D.*)
- \* General Anesthesia-Aided Rapid Opioid Detoxification: New Safety Data (*Eric Collins, Ph.D.*)

### SESSION 5 (AFTERNOON).

#### PREVENTION OF AND EARLY INTERVENTION FOR PROBLEM BEHAVIORS

- \* Brief Intervention in the Emergency Department (*Edward Bernstein, Ph.D. & Judith Bernstein, Ph.D.*)
- \* Neuropsychological Testing Data for Fetal Alcohol Syndrome (*Sandra Jacobsen, Ph.D. & Joseph Jacobsen, Ph.D.*)
- \* Late Life Drug and Alcohol Misuse: A Spectrum of Behaviors and Implications for Prevention (*David Oslin, M.D.*)
- \* Pain and Addiction: Recent Developments (*Scott Fishman, M.D.*)
- \* The New NIAAA Alcohol Guidelines: Clinical Implications for Patient Screening and Counseling (*Mark Willenbring, M.D.*)

## PROGRAM FOR SATURDAY, OCTOBER 29, 2005

### SESSION 6 (MORNING).

#### TERROR, TRAUMA AND ADDICTION

- \* PTSD and SUD in Military Personnel Returning from Operation Enduring Freedom and Operation Iraqi Freedom (*Charles Hoge, M.D.*)
- \* Brain Circuits Involved in Anxiety and Drug Abuse Anatomical and Functional Overlaps (*Gary Aston-Jones, Ph.D.*)
- \* Report from Front Lines 1: CSAT's Efforts to Organize Treatment Services for Refugees from Hurricane Katrina — Lessons for the Future (*Anton Bizzell, M.D.*)
- \* Report from Front Lines 2: A Physician Volunteer and Mobile Team Response — Lessons for the Future (*Sarz Maxwell, M.D.*)
- \* Report from Front Lines 3: The Effect of Hurricane Katrina on Opioid Treatment Programs and Patients — The Perspective of AATOD (*Martha Wunsch, M.D.*)
- \* Dealing With Natural and Man-Made Disasters and the Resulting Trauma and Risk for SUD (*Panel Discussion*)

### SESSION 7 (AFTERNOON).

#### CHALLENGES IN TRANSLATING SCIENCE TO SERVICES

- \* Undergraduate Medical Education: Changing the Curriculum to Reflect Emerging Scientific Knowledge (*Laura McNicholas, M.D., Ph.D.*)
- \* Residency Training: Integrating the Needed Skills into Clinical Teaching (*Paul Seale, M.D.*)
- \* Continuing Medical Education: What Have We Learned from the Buprenorphine Training and Mentoring Model? (*David Fiellin, M.D.*)
- \* Can Clinical Trials Be Made More Relevant to Clinical Practice? (*Susan Silva, Ph.D.*)

### GENERAL INFORMATION

**HOTEL.** The State of the Art Course will be held at the Hyatt Regency Capitol Hill Hotel, 400 New Jersey Avenue, N.W., Washington, DC 20001. A limited number of rooms are being held at the special conference rate of \$189 single or double. Rates are subject to state and local taxes, currently 14.5% (subject to change).

To receive the conference rate, phone the hotel's Reservation Department at 1-800/233-1234 or 202/737-1234 no later than September 28, 2005. Identify yourself as attending the ASAM State of the Art Course. All reservations require a deposit for the first night's room by check or major credit card. Deposits are refundable only if the reservation is cancelled in advance.

**CONTINUING EDUCATION. ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME):** The American Society of Addiction Medicine is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

**AMERICAN MEDICAL ASSOCIATION (AMA):** The American Society of Addiction Medicine designates this continuing medical education activity for a maximum of 21 credit hours in Category 1 toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the activity.

**PSYCHOLOGISTS:** The American Society of Addiction Medicine's Continuing Medical Education (CME) has been approved for renewal of certification by the APA Practice Organization's College of Professional Psychology. ASAM CME credits may be applied toward the APA Practice Organization's "Certificate of Proficiency in the Treatment of Alcohol and Other Psychoactive Substance Use Disorders."

**COUNSELORS:** ASAM has been approved as an Education Provider (#152) by the National Association of Alcoholism and Drug Abuse Counselors. Individuals who are applying for NAADAC credit should report their hours directly to NAADAC.

**CONFERENCE FEES/REGISTRATION.** Please register by phone or mail before Friday, October 7, 2005. For more information, see the ASAM website ([www.asam.org](http://www.asam.org)) or phone ASAM's Department of Meetings and Conferences at 301/656-3920.

Payment must accompany all registrations. Registrations received after October 7, 2005, will be processed as on-site registrations and a late fee of \$50 will be added.

*The ASAM Registration Desk will be open for on-site registration at the following hours:*

- \* Wednesday, October 26, 5:00 pm - 8:00 pm
- \* Thursday, October 27, 7:00 am - 5:00pm
- \* Friday, October 28, 7:30 am - 5:00pm
- \* Saturday, October 29, 7:30 am - 5:00pm

Continental breakfast will be offered in the Registration Area on Thursday, Friday, and Saturday mornings before the program begins.

## NOMINEES SOUGHT FOR ASAM OFFICER, DIRECTOR-AT-LARGE POSTS

*ASAM members are invited to submit names of potential candidates for Officer and Director-at-Large to the Nominating & Awards Council, which will select two candidates for each position. Such nominations are to be submitted by October 15, 2005, to the Nominating & Awards Council C/O ASAM, 350 Third Avenue – #352, New York, NY 10010.*

### NOMINEES FOR OFFICER POSITIONS

Nominees for Officer positions must be current members of the ASAM Board of Directors, or have served on the Board within the past four years. An exception may be made in the case of a nominee for the office of Treasurer, who may be a member of the general membership who has qualifications for the position and has been a member of the Finance Council within the past four years. (On this basis, James W. Smith, M.D., FASAM, and Max A. Schneider, M.D., FASAM, are eligible to be nominated as Treasurer in addition to the individuals listed below.)

The term of office for ASAM Officers is two years (2007-2009). No member may hold the office of President or President-Elect for more than one term, successively. A Secretary or Treasurer may succeed himself/herself once without hiatus, and may subsequently be re-elected after a hiatus of two years.

The Nominating & Awards Council has determined that the following individuals are eligible for nomination to Officer positions:

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

Peter Banys, M.D.

Richard E. Beach, M.D., FASAM

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

Anthony H. Dekker, D.O., FASAM

Paul H. Earley, M.D., FASAM

John P. Femino, M.D., FASAM

Timothy L. Fischer, D.O.

Marc Galanter, M.D., FASAM

David R. Gastfriend, M.D.

Stuart Gitlow, M.D., M.P.H.

R. Jeffrey Goldsmith, M.D.

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

Raju Hajela, M.D., M.P.H., FASAM

James A. Halikas, M.D., FASAM

Thomas L. Haynes, M.D., FASAM

Lori D. Karan, M.D., FACP, FASAM

Kevin B. Kunz, M.D., M.P.H., FASAM

Donald J. Kurth, M.D., FASAM  
(Treasurer — eligible for re-election)

David C. Lewis, M.D.

Peter A. Mansky, M.D.

Ronald F. Pike, M.D., FASAM

A. Kenison Roy III, M.D., FASAM  
(Secretary — eligible for re-election)

Marvin Seppala, M.D.

C. Chapman Sledge, M.D., FASAM

Barry Stimmel, M.D., FASAM

Trusandra E. Taylor, M.D.

Berton E. Toews, M.D., FASAM

Howard Wetsman, M.D.

Martha J. Wunsch, M.D., FAAP

Penelope P. Ziegler, M.D., FASAM

### NOMINEES FOR DIRECTOR-AT-LARGE:

In accordance with the ASAM Bylaws, there shall be twice the number of nominees as available positions for Director-at-Large, which currently number six. In addition, at least two doctors of osteopathy must be nominated for the Director-at-Large seat reserved for a D.O. The membership will vote for 5 of the 10 candidates and for one of the two D.O.'s nominated for the reserved seat, so that six Directors-at-Large will be elected.

Directors-at-Large are elected to four-year terms. A Director-at-Large may succeed himself/herself only once, and may subsequently be re-elected after a hiatus of four years away from the Board. On this basis, the Nominating & Awards Council has determined that following incumbents are eligible for re-election as Directors-at-Large (current Director-at-Large David R. Gastfriend, M.D., is not eligible because he will have served two consecutive four-year terms at the time of the next election):

Anthony H. Dekker, D.O., FASAM

Stuart Gitlow, M.D., M.P.H.

R. Jeffrey Goldsmith, M.D.

Trusandra E. Taylor, M.D.

Penelope P. Ziegler, M.D., FASAM

All candidates must disclose any potential conflicts of interest and candidates with actual conflicts of interest should not consider service to ASAM in these offices.

### NOMINATION AND ELECTION SCHEDULE

Profiles of the candidates nominated for election as Officers and Directors-at-Large posts will appear in the September-October 2006 issue of ASAM News. Ballots will be mailed to members in good standing by November 1, 2006, and must be completed and returned by December 1, 2006. In addition to a ballot, the election packages will contain campaign statements, biographical sketches and photos of the candidates. ASAM's campaign guidelines prohibit the use of "restricted or unrestricted written or electronic communication" by candidates or their advocates. Election results will be announced in the January-February 2007 issue of ASAM News, and the newly elected Officers and Director-at-Large will assume their posts during the 2007 Medical-Scientific Conference.

***If you have not already done so, be sure to renew your ASAM membership so that you are eligible to vote!***



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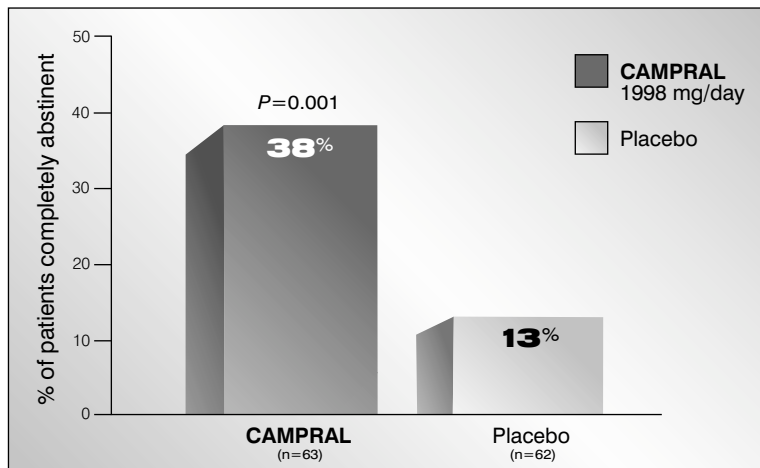
**References:** 1. CAMPRAL® (acamprosate calcium) Delayed-Release Tablets Prescribing Information, Forest Pharmaceuticals, Inc., St. Louis, Mo, 2004. 2. Data on file, Forest Laboratories, Inc. 3. Pelc I, Verbanck P, Le Bon O, Gavrilovic M, Lion K, Lebert P. Efficacy and safety of acamprosate in the treatment of detoxified alcohol-dependent patients: a 90-day placebo-controlled dose-finding study. *Br J Psychiatry*. 1997;171:73-77. 4. Sass H, Soyka M, Mann K, Zieglgansberger W. Relapse prevention by acamprosate: results from a placebo-controlled study on alcohol dependence. *Arch Gen Psychiatry*. 1996;53:673-680. 5. Paille FM, Guelfi JD, Perkins AC, Royer RJ, Steru L, Parot P. Double-blind randomized multicentre trial of acamprosate in maintaining abstinence from alcohol. *Alcohol Alcohol*. 1995;30:239-247. 6. Mason BJ. Acamprosate. *Recent Dev Alcohol*. 2003;16:203-215.

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# Maintenance of Abstinence with Psychosocial Support<sup>1</sup>

In a 13-week study<sup>\*†‡</sup>

**CAMPRAL helps 3 times more patients maintain complete abstinence<sup>‡</sup> vs placebo, in combination with psychosocial support**



**Study design:** Multicenter, randomized, double-blind, placebo-controlled study of CAMPRAL in alcohol-dependent patients. 188 patients were randomized at study start to receive acamprosate 1332 mg/day (63 patients), CAMPRAL 1998 mg/day (63 patients), or placebo (62 patients). Patients were 18 to 65 years old, met DSM-III-R criteria for alcohol dependence, and had undergone a 14-day detoxification program prior to treatment start. All patients in this study received counseling based on the routine practices of the individual participating study sites.<sup>2,3</sup>

In separate 48- and 52-week studies<sup>\*†‡</sup>

**2 times as many CAMPRAL patients maintained abstinence vs placebo**

**CAMPRAL provides excellent safety and tolerability<sup>1-6</sup>**

- Favorable side-effect profile with discontinuation rates due to adverse events similar to placebo (8% for CAMPRAL-treated patients vs 6% for placebo)<sup>1</sup>
- Minimal potential for drug interactions; not metabolized by the liver<sup>1</sup>
- Can be taken with antidepressants,<sup>§</sup> anxiolytics, hypnotics, sedatives (including benzodiazepines), nonopioid analgesics, disulfiram, and naltrexone<sup>1</sup>
- Used for more than a decade; over 1.5 million patients treated worldwide<sup>6</sup>

**Unique mechanism of action<sup>||</sup>**

- Thought to restore neurotransmitter balance

\*All efficacy studies included psychosocial support.

†Results are for the intent-to-treat population over the study treatment phase.

‡Complete abstinence was defined as no alcohol consumption. Assessment included patient and/or family reports, laboratory tests, and either urine alcohol levels, blood alcohol levels, or breathalyzer tests.<sup>3-5</sup>

§Patients taking CAMPRAL concomitantly with antidepressants more commonly experienced weight gain or weight loss than patients taking either agent alone.

||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.

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(acamprosate calcium)  
Delayed-Release Tablets

Strengthens the will to say no

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(acamprosate calcium)  
Delayed-Release Tablets

Rx only

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

**Carcinogenicity, Mutagenicity and Impairment of Fertility** A carcinogenicity study was conducted in which Sprague-Dawley rats received acamprosate calcium in their diet at doses of 25, 100 or 400 mg/kg/day (0.2, 0.7 or 2.5-fold the maximum recommended human dose based on an AUC comparison). There was no evidence of an increased incidence of tumors in this carcinogenicity study in the rat. An adequate carcinogenicity study in the mouse has not been conducted. Acamprosate calcium was negative in all genetic toxicology studies conducted. Acamprosate calcium demonstrated no evidence of genotoxicity in an *in vitro* bacterial reverse point mutation assay (Ames assay) or an *in vitro* mammalian cell gene mutation test using Chinese Hamster Lung V79 cells. No clastogenicity was observed in an *in vitro* chromosomal aberration assay in human lymphocytes and no chromosomal damage detected in an *in vivo* mouse micronucleus assay. Acamprosate calcium had no effect on gestation after treatment for 70 days prior to mating in male rats and for 14 days prior to mating, throughout mating, fertilization and lactation in female rats at doses up to 1000 mg/kg/day (approximately 4 times the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). In mice, acamprosate calcium administered orally for 60 days prior to mating and throughout gestation in females at doses up to 2400 mg/kg/day (approximately 5 times the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis) had no effect on fertility.

**Pregnancy Category C Teratogenic Effects** Acamprosate calcium has been shown to be teratogenic in rats when given in doses that are approximately equal to the human dose (on a mg/m<sup>2</sup> basis) and in rabbits when given in doses that are approximately 3 times the human dose (on a mg/m<sup>2</sup> basis). Acamprosate calcium produced a dose-related increase in the number of fetuses with malformations in rats at oral doses of 300 mg/kg/day or greater (approximately equal to the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). The malformations included hydronephrosis, malformed iris, retinal dysplasia, and retroesophageal subclavian artery. No findings were observed at an oral dose of 50 mg/kg/day (approximately one-fifth the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). An increased incidence of hydronephrosis was also noted in Burgundy Tawny rabbits at oral doses of 400 mg/kg/day or greater (approximately 3 times the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). No developmental effects were observed in New Zealand white rabbits at oral doses up to 1000 mg/kg/day (approximately 8 times the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). The findings in animals should be considered in relation to known adverse developmental effects of ethyl alcohol, which include the characteristics of fetal alcohol syndrome (craniofacial dysmorphism, intrauterine and postnatal growth retardation, retarded psychomotor and intellectual development) and milder forms of neurological and behavioral disorders in humans. There are no adequate and well controlled studies in pregnant women. CAMPRAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects** A study conducted in pregnant mice that were administered acamprosate calcium by the oral route starting on Day 15 of gestation through the end of lactation on postnatal day 28 demonstrated an increased incidence of still-born fetuses at doses of 960 mg/kg/day or greater (approximately 2 times the maximum recommended human daily oral dose on a mg/m<sup>2</sup> basis). No effects were observed at a dose of 320 mg/kg/day (approximately one-half the maximum recommended human daily dose on a mg/m<sup>2</sup> 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  $\geq$  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/<br>Preferred Term               | CAMPRAL<br>1332 mg/day | CAMPRAL<br>1998 mg/day <sup>1</sup> | CAMPRAL <sup>2</sup><br>2019 | Placebo<br>1706  |
|--|------------------------|-------------------------------------|------------------------------|------------------|
| <b>Number of Patients in Treatment Group</b> | <b>397</b>             | <b>1539</b>                         | <b>2019</b>                  | <b>1706</b>      |
| <b>Number (%) of Patients with an AE</b>     | <b>248 (62%)</b>       | <b>910 (59%)</b>                    | <b>1231 (61%)</b>            | <b>955 (56%)</b> |
| <b>Body as a Whole</b>                       | <b>121 (30%)</b>       | <b>513 (33%)</b>                    | <b>685 (34%)</b>             | <b>517 (30%)</b> |
| 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%)          |
| <b>Digestive System</b>                      | <b>85 (21%)</b>        | <b>440 (29%)</b>                    | <b>574 (28%)</b>             | <b>344 (20%)</b> |
| 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%)          |
| <b>Nervous System</b>                        | <b>150 (38%)</b>       | <b>417 (27%)</b>                    | <b>598 (30%)</b>             | <b>500 (29%)</b> |
| 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%)          |
| <b>Skin and Appendages</b>                   | <b>26 (7%)</b>         | <b>150 (10%)</b>                    | <b>187 (9%)</b>              | <b>169 (10%)</b> |
| Pruritus                                     | 12 (3%)                | 68 (4%)                             | 82 (4%)                      | 58 (3%)          |
| Sweating                                     | 11 (3%)                | 27 (2%)                             | 40 (2%)                      | 39 (2%)          |

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

## Other Events Observed During the Premarketing Evaluation of CAMPRAL

Following is a list of terms that reflect treatment-emergent adverse events reported by patients treated with CAMPRAL in 20 clinical trials (4461 patients treated with CAMPRAL, 3526 of whom received the maximum recommended dose of 1998 mg/day for up to one year in duration). This listing does not include those events already listed above; events for which a drug cause was considered remote; event terms which were so general as to be uninformative; and events reported only once which were not likely to be acutely life-threatening. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring in at least 1/100 patients (only those not already listed in the summary of adverse events in controlled trials appear in this listing); infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. **Body as a Whole** - *Frequent:* headache, abdominal pain, back pain, infection, flu syndrome, chest pain, chills, suicide attempt; *Infrequent:* fever, intentional overdose, malaise, allergic reaction, abscess, neck pain, hernia, intentional injury; *Rare:* ascites, face edema, photosensitivity reaction, abdomen enlarged, sudden death. **Cardiovascular System** - *Frequent:* palpitation, syncope; *Infrequent:* hypotension, tachycardia, hemorrhage, angina pectoris, migraine, varicose vein, myocardial infarct, phlebitis, postural hypotension; *Rare:* heart failure, mesenteric arterial occlusion, cardiomyopathy, deep thrombophlebitis, shock. **Digestive System** - *Frequent:* vomiting, dyspepsia, constipation, increased appetite; *Infrequent:* liver function tests abnormal, gastroenteritis, gastritis, dysphagia, eructation, gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage, liver cirrhosis, esophagitis, hematemesis, nausea and vomiting, hepatitis; *Rare:* melena, stomach ulcer, cholecystitis, colitis, duodenal ulcer, mouth ulceration, carcinoma of liver. **Endocrine System** - *Rare:* goiter, hypothyroidism. **Hemic and Lymphatic System** - *Infrequent:* anemia, ecchymosis, eosinophilia, lymphocytosis, thrombocytopenia; *Rare:* leukopenia, lymphadenopathy, monocytosis. **Metabolic and Nutritional Disorders** - *Frequent:* peripheral edema, weight gain; *Infrequent:* weight loss, hyperglycemia, SGOT increased, SGPT increased, gout, thirst, hyperuricemia, diabetes mellitus, avitaminosis, bilirubinemia; *Rare:* alkaline phosphatase increased, creatinine increased, hyponatremia, lactic dehydrogenase increased. **Musculoskeletal System** - *Frequent:* myalgia, arthralgia; *Infrequent:* leg cramps; *Rare:* rheumatoid arthritis, myopathy. **Nervous System** - *Frequent:* somnolence, libido decreased, amnesia, thinking abnormal, tremor, vasodilatation, hypertension; *Infrequent:* convulsion, confusion, libido increased, vertigo, withdrawal syndrome, apathy, suicidal ideation, neuralgia, hostility, agitation, neurosis, abnormal dreams, hallucinations, hypesthesia; *Rare:* alcohol craving, psychosis, hyperkinesia, twitching, depersonalization, increased salivation, paranoid reaction, torticollis, encephalopathy, manic reaction. **Respiratory System** - *Frequent:* rhinitis, cough increased, dyspnea, pharyngitis, bronchitis; *Infrequent:* asthma, epistaxis, pneumonia; *Rare:* laryngismus, pulmonary embolus. **Skin and Appendages** - *Frequent:* rash; *Infrequent:* acne, eczema, alopecia, maculopapular rash, dry skin, urticaria, exfoliative dermatitis, vesiculobullous rash; *Rare:* psoriasis. **Special Senses** - *Frequent:* abnormal vision, taste perversion; *Infrequent:* tinnitus, amblyopia, deafness; *Rare:* ophthalmitis, diplopia, photophobia. **Urogenital System** - *Frequent:* impotence; *Infrequent:* metrorrhagia, urinary frequency, urinary tract infection, sexual function abnormal, urinary incontinence, vaginitis; *Rare:* kidney calculus, abnormal ejaculation, hematuria, menorrhagia, nocturia, polyuria, urinary urgency. **Serious Adverse Events Observed During the Non-US Postmarketing Evaluation of CAMPRAL (acamprosate calcium)** Although no causal relationship to CAMPRAL has been found, the serious adverse event of acute kidney failure has been reported to be temporally associated with CAMPRAL treatment in at least 3 patients and is not described elsewhere in the labeling.

## DRUG ABUSE AND DEPENDENCE

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

## OVERDOSAGE

In all reported cases of acute 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.

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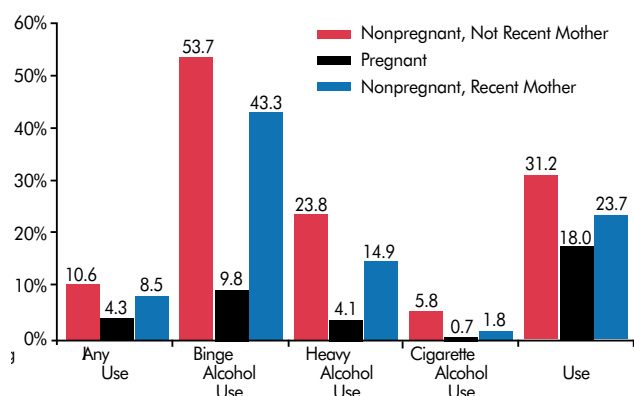
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## New Report Focuses on Substance Use by Pregnant Women

A new report from the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that, despite many warnings, over 4 percent of pregnant women age 15 to 44 reported illicit drug use during the past month, 4 percent engaged in binge drinking, and 18 percent smoked cigarettes. The report also shows a distinct age discrepancy in this substance use: Pregnant women age 15 to 25 were more likely to use illicit drugs than pregnant women age 26 to 44. The report, based on combined 2002 and 2003 data from SAMHSA's National Survey on Drug Use and Health (NSDUH), shows that 4.3 percent of pregnant women age 15 to 44 reported using an illicit drug during the past month, compared with 10.4 percent of non-pregnant women in that age group. NSDUH defines illicit drug use as the use of marijuana/hashish, cocaine (including crack), inhalants, hallucinogens, heroin, or prescription-type drugs used non-medically. Among pregnant women in the 15 to 44 age group, 9.8 percent reported drinking alcohol during the past month, 4.1 percent reported binge alcohol use, and less than 1 percent reported heavy alcohol use. NSDUH defines binge alcohol use as drinking five or more drinks on the same occasion on at least 1 day in the past 30 days. Heavy alcohol use is defined as drinking five or more drinks on the same occasion on each of 5 or more days in the past 30 days. In the 15 to 44 age group, the rates of past-month illicit drug, alcohol, and cigarette use were lower among pregnant women than among non-pregnant women. Among non-pregnant women, substance use rates were lower for recent mothers than for women who were not recent mothers. This suggests that women in this age group increased their substance use during the year after giving birth, although not to the level of non-pregnant women who were not recent mothers. For a copy of the report, *Substance Use During Pregnancy: 2002 and 2003 Update*, contact SAMHSA's National Clearinghouse for Alcohol and Drug Information at P.O. Box 2345, Rockville, MD 20847-2345, or phone 800/729-6686. The report is also available on the SAMHSA website at [WWW.OAS.SAMHSA.GOV](http://WWW.OAS.SAMHSA.GOV).

### PERCENTAGES OF WOMEN AGE 15 TO 44 WHO REPORTED PAST-MONTH SUBSTANCE USE, BY PREGNANCY AND RECENT MOTHERHOOD STATUS\*\*: 2002 AND 2003



Source: SAMHSA National Survey on Drug Use and Health, Office of Applied Studies, 2002 and 2003.

\*\*"Pregnant women" were those women age 15 to 44 who were currently pregnant at the time of the survey. "Non-pregnant recent mothers" were defined as women age 15 to 44 who were not currently pregnant and who gave birth during the prior year. "Non-pregnant, not recent mothers" were defined as women age 15 to 44 who were not currently pregnant and who did not have a biological child under age 1 in the household.

## SAMHSA Releases New Data on Drug-Related Deaths

For the first time, the Substance Abuse and Mental Health Services Administration (SAMHSA) has released state-specific data on drug-related mortality. The data, from the 2003 Drug Abuse Warning Network (DAWN), provide a picture of deaths involving recent drug use in 6 states and 32 metropolitan areas.

States reporting data on drug-related deaths were Maine, Maryland, New Hampshire, New Mexico, Utah, and Vermont. The data show substantial variations in drug-related deaths across jurisdictions. For example, rates of drug-related deaths in the reporting states ranged from 88 to 162 deaths per 1 million population.

Among the reporting metropolitan areas, Baltimore and Albuquerque had the highest rates of drug-related deaths, exceeding 200 deaths per 1 million population. Another 14 areas had drug-related death rates that exceeded 100 deaths per 1 million population.

DAWN mortality data indicate that the typical drug-related death involves multiple drugs (an average of 2.7 drugs per case). Opiates, including prescription analgesics and illicit drugs like heroin, were found more often than any other type of drug in 29 of the 32 reporting metropolitan areas and all of the 6 reporting states. Cocaine was the most frequently reported drug in 3 metropolitan areas and was ranked in the top five drugs in 28 metropolitan areas and all 6 states. Alcohol was one of the five most common drugs in 30 of the 32 metropolitan areas and 5 of 6 states.

The report indicates that stimulants — reported as either methamphetamine or amphetamines — appeared in the top five drugs in 5 metropolitan areas: Minneapolis-St. Paul; Ogden-Clearfield, Utah; Phoenix; San Diego; and San Francisco. Other frequently reported drugs involved in drug-related deaths were prescription antidepressants and anti-anxiety medications.

While interesting, the DAWN data also have significant limitations. First, participation in DAWN is voluntary, so not all jurisdictions provide data. Therefore, DAWN counts of drug-related deaths cannot be projected to the Nation as a whole. Second, this year's report, *Drug Abuse Warning Network, 2003: Area Profiles of Drug-Related Mortality*, is the result of a major redesign, so the data cannot be compared with data from prior years.

Third, DAWN now captures any death related to recent drug use: Findings are presented for deaths involving drug misuse and abuse, as well as drug-related suicides. Thus, caution must be used in interpreting changes in rates of drug-related deaths when the new data are set against those from other sources or for other years.

For more information, visit SAMHSA's DAWN website at [WWW.DAWNINFO.SAMHSA.GOV](http://WWW.DAWNINFO.SAMHSA.GOV).

## ADDICTION PSYCHIATRY FELLOWSHIP

The Albert Einstein College of Medicine Addiction Psychiatry Fellowship is seeking PGY-5 level psychiatry residents for July 2006. This is a 1-2 year program with ACGME accreditation and is under the auspices of the Division of Substance Abuse of the Albert Einstein College of Medicine. The Division of Substance Abuse is the largest medical school affiliated addiction treatment program in the United States and currently treats over 4200 patients in its various sites throughout the Bronx. The Fellowship provides clinical experience in all aspects of addiction treatment, including opioid treatment, outpatient rehabilitation, inpatient alcohol and drug detoxification, and consultation-liaison psychiatry leading to eligibility for the added qualifications in Addiction Psychiatry ABPN certification.

Clinical and basic research is encouraged, with particular focus on strength in the neurobiology of drug addiction, as well as research in enhancing the care of drug abusers with HIV disease. Trainees will have the opportunity to participate in one of the ongoing research projects of their choice.

The Fellowship includes a mentoring program for those interested in academic careers. Competitive salary with full benefits package. Please send letter of interest, curriculum vitae and 3 letters of reference to: **Merrill Herman, M.D., Department of Psychiatry and Behavioral Sciences, Albert Einstein College of Medicine, Jack and Pearl Resnick Campus, 1300 Morris Park Ave, Belfer Hall 403, Bronx, New York 10461; TEL: (718) 430-3080; FAX: (718) 430-8987. EOE.**



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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.

For information about making a pledge, contribution, bequest, memorial tribute, or to discuss other types of gifts in confidence, please contact Claire Osman by phone at 1-800/257-6776 or 1-718/275-7766, or email Claire at ASAMCLAIRE@AOL.COM. She welcomes your calls. All contributions to the Endowment Fund are tax-deductible to the full extent allowed by law.

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

*Claire Osman*  
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## State Leaders to Meet in October

The next meeting of ASAM's State Society and Chapter leaders is scheduled for October 29-30, 2005, in Washington, DC. The meeting will feature special sessions for the State Membership Chairs, as well as for chapter and society Presidents and Staff Directors, as well as ASAM's Regional Directors.

Working in break-out groups, representatives of the State Societies and ASAM Chapters will make plans for their 2006 membership programs, while in the plenary sessions, state leaders will report on their plans and exchange ideas on how states can help one another achieve their 2006 goals.

At the lunch break, there will be a separate working lunch for SMSS Managers, so that they can meet one another and make plans for their monthly calls.

For more information, contact SMSS Project Director James F. Callahan, D.P.A., by email at JCALL2@COMCAST.NET.

## REGION VII

REPORTER: *Howard Wetsman, M.D.*

Texas has become the new home of ASAM Region VII, whose offices in Louisiana were destroyed by Hurricane Katrina. Region VII incorporates State Societies in Louisiana, Texas, Arkansas, and Oklahoma, as well as the Midwest Chapter (Kansas, Nebraska, and Missouri). Region VII administrator Lisa Stolier has relocated to Texas as well. Her new contact information is: Lisa Stolier, Executive Director, ASAM Region VII  
4310 Appalachian Trail  
Kingwood, TX 77345  
Tel: 281/548-7775  
LISASTOLIER@EARTHLINK.NET

Despite Hurricane Katrina, Region VII successfully held its Third Annual Region VII Symposium in San Antonio, September 10-11th. A Buprenorphine Training Course, presented by the American Osteopathic Academy of Addiction Medicine and directed by Anthony Dekker, D.O., FASAM, was held in connection with the conference.

## ALASKA

REPORTER: *Charles Michael Herndon, M.D., M.A., FACP*

A two-day Addiction Medicine Symposium is scheduled for October 13-14, 2005, in Anchorage. Notable members of the symposium faculty include David Fiellin, M.D., who chairs ASAM's Buprenorphine Training and Mentoring Projects, and Richard K. Ries, M.D., co-editor of ASAM's textbook, *Principles of Addiction Medicine*. For information or to register, contact Charles Michael Herndon, M.D., at Providence Breakthrough in Anchorage, by phone at 907/562-7325; by fax at 907/562-6193; or by email at CHERNDON@PROVAK.ORG.

## HBO Film Paints Negative Portrait of Methadone Treatment

Field leaders report that the HBO cable network is planning to air an extremely negative depiction of methadone treatment of addiction. Titled "Methadonia," the film is to premiere at the New York Film Festival at Lincoln Center on September 24th and will air on the HBO network beginning October 6th. Mark Parrino, M.P.A., President of the American Association for the Treatment of Opioid Dependence (AATOD), reports that his organization has been receiving dozens of anxious calls from treatment programs, patients and state officials since news of the production's negative bias has begun to circulate. They are concerned, Mr. Parrino says, that the film will "add gasoline to a number of brushfires in different states" by providing opponents of methadone treatment with a new weapon to support their perspectives. He adds that a number of active methadone patients are extremely worried about how their families, friends and employers will react to the presentation.

AATOD is working to coordinate a multilevel response, involving treatment funders, providers, patient advocates and families. Mr. Parrino says that through coordinated action, it may be possible to use an extremely negative event to help bring greater understanding of addiction treatment — and particularly methadone treatment — to the media and the public. For additional information or to offer assistance, contact:

Mark W. Parrino, M.P.A., President, AATOD  
217 Broadway, Suite 304  
New York, NY 10007  
Tel: 212/566-5555 • Fax: 212/349-2944  
Email: MARK.PARRINO@AATOD.ORG

## Physicians' Health Programs Full Time Medical Director

The Foundation of the Pennsylvania Medical Society, a 501(c)(3) charitable organization, seeks a physician to serve as full-time Medical Director for the Physicians' Health Programs (PHP) in Harrisburg, PA. The PHP provides confidential non-disciplinary assistance, primarily to Pennsylvania physicians and dentists, with a focus on chemical dependency.

The Medical Director will facilitate interventions, make referrals for evaluation and treatment, serve as Medical Review Officer, review and approve treatment plans and monitoring arrangements, and make recommendations concerning interruption of and re-entry to medical/dental practice.

The position requires clinical experience in addiction, board certification in a medical specialty, and additional qualifications in addiction medicine or addiction psychiatry. The ideal candidate is comfortable working in a state medical society setting, using a multidisciplinary team approach.

A full-time salaried position with comprehensive benefits package is provided. Please send curriculum vitae with salary requirements to:

### The Foundation of the Pennsylvania Medical Society

Attention: Human Resources Department  
777 East Park Drive  
PO Box 8820  
Harrisburg, PA 17105-8820

# ASAM CONFERENCE CALENDAR

## ASAM

**October 27-29, 2005**

ASAM Course on the State of the Art in Addiction Medicine  
Hyatt Regency  
Capitol Hill Hotel  
Washington, DC  
[Approved for 21 Category 1 CME Credits]

**December 8, 2005**

Best Practices: Clinical Drug Testing in Addiction Medicine  
Westin Embassy Row Hotel  
Washington, DC  
[7.5 Category 1 CME Credits]

**December 9-11, 2005**

ASAM Medical Review Officer (MRO) Training Course  
Westin Embassy Row Hotel  
Washington, DC

**May 4, 2006**

Ruth Fox Course  
San Diego Sheraton  
Hotel & Marina  
San Diego, California

**May 4-7, 2006**

ASAM 37th Annual Meeting and Medical-Scientific Conference  
San Diego Sheraton  
Hotel & Marina  
San Diego, California

**May 7, 2006**

Buprenorphine Training Course  
San Diego Sheraton  
Hotel & Marina  
San Diego, California

## OTHER EVENTS OF NOTE

**September 26-27, 2005**

"Managing Individual and Program Liability Risk"  
Sponsored by the Center for Substance Abuse Treatment  
Radisson Hotel, St. Louis, Missouri  
(also to be offered in California early in 2006)  
[Approved for 12.5 Category 1 CME Credits]  
[For information or to register, phone 240/645-4136]

**September 29-30, 2005**

American Society for Clinical Pharmacology and Therapeutics  
"Adverse Drug Events and Medication Errors: Impact on Medical Care in the 21st Century"  
Loews Philadelphia Hotel,  
Philadelphia, PA  
[For information, phone Bethany Oser at 703/836-6981 or email INFO@ASCPT.ORG]

**October 27-29, 2005**

Association for Medical Education and Research in Substance Abuse  
29th Annual National Conference  
"Substances, Services and Systems Change"  
Hyatt Regency Hotel, Bethesda, Maryland  
[For information or to register, visit WWW.AMERSA.ORG]  
[13.25 Category 1 CME credits]

**April 22-26, 2006**

American Association for the Treatment of Opioid Dependence (AATOD)  
National Conference: "Working with Criminal Justice and Health Care Systems"  
Hyatt Regency Hotel, Atlanta, GA  
[For information, phone 856/423-7222 x 360, or visit WWW.AATOD.ORG]

## BUPRENORPHINE TRAINING

(The following courses are approved for 8 Category 1 CME credits)

**September 3, 2005**

ASAM — Hawaii Society of Addiction Medicine  
Honolulu, Hawaii  
Contact: WWW.DOCOPTIN.COM or phone 888/362-6784

**September 9, 2005**

AOAAM — ASAM Region VII  
San Antonio, Texas  
Contact: WWW.DOCOPTIN.COM or phone 888/362-6784

**September 9, 2005**

NYSAM — ASAM  
Saratoga Springs, New York  
Contact: WWW.DOCOPTIN.COM or phone 888/362-6784

**September 11, 2005**

CSAM — ASAM  
San Francisco, California  
Contact: WWW.DOCOPTIN.COM or phone 888/362-6784

**October 30, 2005**

ASAM (follows the State of the Art Course)  
Hyatt Regency Capitol Hill Hotel  
Washington, DC  
Contact: WWW.DOCOPTIN.COM or phone 888/362-6784

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

### September is National Alcohol and Drug Addiction Recovery Month.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Substance Abuse and Mental Health Services Administration  
Center for Mental Health Services  
Center for Substance Abuse Prevention  
Center for Substance Abuse Treatment

National Alcohol & Drug Addiction Recovery Month

## BUPRENORPHINE AND OFFICE-BASED TREATMENT OF OPIOID DEPENDENCE

Sunday, October 30, 2005 • 8:00 am – 5:30 pm • Hyatt Regency Capitol Hotel • Washington, DC

**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](http://WWW.ASAM.ORG), or register on-site (registration opens at 7:15 am on Sunday, October 30th).